DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 414, and 494

[CMS–1651–F]

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: Final rule.

SUMMARY: This rule updates and makes revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year 2017. It also finalizes policies for coverage and payment for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. This rule also sets forth requirements for the ESRD Quality Incentive Program, including the inclusion of new quality measures beginning with payment year (PY) 2020 and provides updates to programmatic policies for the PY 2018 and PY 2019 ESRD QIP.

This rule also implements 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 expands suppliers' appeal rights in the event of a breach of contract action taken by CMS, by revising the appeals regulation to extend the appeals process to all types of actions taken by CMS for a supplier's breach of contract, rather than limit an appeal for the termination of a competitive bidding contract. The rule also finalizes changes to the methodologies for adjusting fee schedule amounts for DMEPOS using information from CBPs and for submitting bids and establishing single payment amounts under the CBPs for certain groupings of similar items with different features to address price inversions. Final changes also are made to the method for establishing bid limits for items under the DMEPOS CBPs. In addition, this rule summarizes comments on the impacts of coordinating Medicare and Medicaid Durable Medical Equipment for dually eligible beneficiaries. Finally, this rule also summarizes comments received in response to a request for information related to the Comprehensive ESRD Care Model and future payment models affecting renal care.

DATES: These regulations are effective January 1, 2017.

FOR FURTHER INFORMATION CONTACT: *ESRDPayment@cms.hhs.gov,* for issues related to the ESRD PPS and coverage and payment for renal dialysis services furnished to individuals with AKI.

Stephanie Frilling, (410) 786–4597, 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 email *tom.duvall@cms.hhs.gov*, for issues related to the Comprehensive ESRD Care Model.

SUPPLEMENTARY INFORMATION:

Addenda Are Only Available Through the Internet on the CMS Web Site

In the past, a majority of the Addenda referred to throughout the preamble of our proposed and final rules were available in the **Federal Register**. However, the Addenda of the annual proposed and final rules will no longer be available in the **Federal Register**. Instead, these Addenda to the annual proposed and final rules will be available only through the Internet on the CMS Web site. The Addenda to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) rules are available at: *http://www.cms.gov/ESRDPayment/PAY/list.asp.* Readers who experience any problems accessing any of the Addenda to the proposed and final rules of the ESRD PPS that are posted on the CMS Web site identified above should contact *ESRDPayment@cms.hhs.gov.*

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Acronyms

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

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
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
EOD Every Other Day
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
LCD Local Coverage Determination
LDO Large Dialysis Organization
MAC Medicare Administrative Contractor
MAP Medicare Allowable Payment
MCP Monthly Capitation Payment
MDO Medium Dialysis Organization
MFP Multifactor Productivity
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
MLR Minimum Lifetime Requirement
MMA Medicare Prescription Drug, Improvement and Modernization Act of 2003
MMEA Medicare and Medicaid Extenders Act of 2010 Public Law 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
REMIS Renal Management Information System
RFA Regulatory Flexibility Act
RN Registered Nurse
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 (PPS) system for renal dialysis services furnished by ESRD facilities. This rule updates and makes revisions to the End-Stage Renal Disease (ESRD) (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) (Pub. L. 110–275), and section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act (Pub. L. 111–148), established that beginning CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

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. 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 sets 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 Action

This rule implements statutory requirements for Bid Surety Bonds and State Licensure. We are revising the appeals regulation 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.

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

This rule adjusts the method 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:* For CY 2017, the ESRD PPS base rate is $231.55. This amount reflects a final market basket increase (0.55 percent), and application of the wage index budget-neutrality adjustment factor (0.999781) as well as the application of the training budget-neutrality adjustment factor (0.999737).
- *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 did not propose any changes to the application of the wage index floor and we will 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 policy to annually update the outlier policy using the most current data, we are updating 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 will increase from $62.19 to $68.49 and the MAP amount will decrease from $39.20 to $38.29, as compared to CY 2016 values. For adult beneficiaries, the fixed-dollar loss amount will decrease from $86.97 to $82.92 and the MAP amount will decrease from $50.81 to $45.00. 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 not finalizing 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). In response to comments received from stakeholders, we have determined that the burden placed on providers would be substantial and we are exploring alternate avenues for collecting these data.
- *The home and self-dialysis training add-on payment adjustment:* We are finalizing an increase in the total number of hours of training by an RN (registered nurse) 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 calculated the increase based on the average treatment times and weights based on utilization for each modality. We used treatment times as proxies for the total time spent by nurses training beneficiaries for home or self-dialysis in calculating the increase to the home dialysis training add-on. Based on these proxies, for CY 2017, we have increased 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. We also updated the national hourly wage for a nurse providing dialysis training for 2017 to $35.94, resulting in a home and self-dialysis training add-on payment adjustment amount of $95.60.

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 finalizing coverage of renal dialysis services furnished by renal dialysis facilities paid under section 1881(b)(14) of the Act to individuals with AKI. We will pay ESRD facilities for renal dialysis services furnished to individuals with AKI 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 and practitioners may continue to bill Medicare for services in the same manner as they did before the payment rate for renal dialysis services furnished by dialysis facilities to individuals with AKI was adopted.

3. ESRD QIP

This rule sets forth requirements for the ESRD QIP for payment years (PYs) 2018, 2019 and 2020.

Hypercalcemia Clinical Measure: We proposed to make two substantive updates to the technical specifications for the Hypercalcemia clinical measure beginning with PY 2018, as recommended during the measure maintenance process at the National Quality Forum (NQF). In response to comments received, we are finalizing these changes but are delaying their implementation until PY 2019. First, we are adding plasma as an acceptable substrate in addition to serum calcium. Second, we are amending the denominator definition to include patients regardless of whether any serum calcium values were reported at the facility during the 3-month study period. These changes will ensure that, beginning in PY 2019, the measure aligns with the NQF-endorsed measure and will continue to satisfy the requirements of the Protecting Access to Medicare Act of 2014 (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.

New Requirements for PY 2019: Beginning with PY 2019, we are reintroducing the National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure back into the ESRD QIP measure set. Additionally, beginning with PY 2019, we are creating a new NHSN Bloodstream Infection (BSI) Measure Topic which will consist of the proposed NHSN Dialysis Event Reporting Measure and the existing NHSN BSI Clinical Measure. We are also establishing 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 Safety Measure Domain will initially consist of the proposed NHSN BSI Measure Topic.

PY 2020 Measure Set: Beginning with PY 2020, we are replacing the Mineral Metabolism Reporting Measure with the newly finalized 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 adopting two new measures: (1) The Standardized Hospitalization Ratio (SHR) Clinical Measure and (2) the Ultrafiltration Rate Reporting Measure.

Weighting for the Clinical Measure Domain, the Reporting Measure Domain and the Safety Measure Domain: With the addition of the Safety Measure Domain into the ESRD QIP, we are making changes to the weighting of the Clinical Measure Domain and the Reporting Measure Domain, and we are establishing weights for the Safety Measure Domain for PY 2019 and for PY 2020.

Specifically, for PY 2019, we are assigning 15 percent of a facility's total performance score (TPS) to the 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 adjusting individual measure weights for the measures that remain in the Clinical Measure Domain. In response to comments received, for PY 2020, we are maintaining the weight of the Safety Measure Domain at 15 percent of a facility's TPS rather than at 10 percent as proposed.

Data Validation: In section IV.C.9 of this final rule, we set forth the updates to the data validation program in the ESRD QIP. For PY 2019, we are continuing the pilot validation study for validation of CROWNWeb data. Under this continued validation study, we are continuing to use 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 increasing the size of the NHSN BSI Data Validation study. Specifically, we will 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

This final rule implements statutory requirements for the DMEPOS CBP for bid surety bonds and state licensure. In addition, we are finalizing a definition for the term ''bidding entity'' for purposes of the DMEPOS CBP. We also are finalizing revisions to the appeals regulations 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. The final rule establishes the following:

• 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 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 are conforming 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 that requires suppliers to meet applicable State licensure requirements.

• We are finalizing changes to § 414.423 to extend the appeals process to all breach of contract actions taken by CMS specified in § 414.422(g)(2). We are finalizing revisions to § 414.422(g)(2) to eliminate certain breach of contract actions. We also are finalizing revisions to § 414.423(l) to describe the effects of certain breach of contract actions that CMS takes.

5. DMEPOS Competitive Bidding Program and Fee Schedule Adjustments

This final rule sets 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 program vulnerability by shifting beneficiaries from products with features to less appropriate products without the features because the product without the features receives higher payment under competitive bidding. We are finalizing provisions of § 414.210 to limit SPAs for certain 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 to adjust the fee schedule amounts for certain groupings of similar items specified below. The item weights will 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 rule 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 finalizing provisions of § 414.412 to add a lead item bidding method where all of the HCPCS codes for similar items with different features will be grouped together and will be priced relative to the bid for the lead item in order to prevent price inversions under the DMEPOS CBPs. We are applying this as an alternative to the current bidding method so that CMS will be able to apply this method to situations where groupings of similar items have resulted in price inversions based on past experience. This alternative method will 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, as required by section 1847(b)(2)A)(iii) 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 finalizing revisions to the regulations to limit bids for future competitions to the fee schedule amounts that would otherwise apply if CBPs had not been implemented, prior to making adjustments to the fee schedule amounts using information from CBPs. This will 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 XV.A of this final rule, we set forth a detailed analysis of the impacts of the finalized changes for affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact chart in section XV.B.1 of this final 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 0.73 percent increase in payments. Hospital-based ESRD facilities have an estimated 0.9 percent increase in payments compared with freestanding facilities with an estimated 0.7 percent increase.

We estimate that the aggregate ESRD PPS expenditures will increase by approximately $80 million from CY 2016 to CY 2017. This reflects a $60 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 0.73 percent overall payment increase, we estimate that there will be an increase in beneficiary co-insurance payments of 4.2 percent in CY 2017, which translates to approximately $10 million.

2. Impact of the Final Coverage and Payment for Renal Dialysis Services Furnished to Individuals With AKI

We anticipate an estimated $2 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 Final ESRD QIP

The impact chart in section XVI.B.3.a of this final rule displays estimated QIP impacts for payment year (PY) 2020. The overall impact is an expected reduction in payment to all facilities of $31 million, with an estimated total facility burden for the collection of data of $91 million.

4. Impacts of the Final DMEPOS Competitive Bidding Bid Surety Bonds, State Licensure and Appeals Process for a Breach of DMEPOS Competitive Bidding Program Contract Actions

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 actions 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 final state licensure and appeals process for breach of DMEPOS CBP contract actions regulations will have minimal administrative costs.

We do not anticipate that the final 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 Final DMEPOS Competitive Bidding Program and Fee Schedule Adjustments

The overall economic impact for the final changes to the DMEPOS CBPs and Fee Schedule Adjustments would be about $20 million dollars in savings to the Part B Trust Fund over 5 years beginning January 1, 2017. The savings are a result of avoiding price inversions. This final rule 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 final rule.

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. 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 to 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 comorbidity 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. For a summary of the provisions in that final rule, we refer readers to the CY 2017 ESRD PPS proposed rule (81 FR 42809 through 42810).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the Calendar Year (CY) 2017 ESRD PPS

The proposed rule, titled ''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'' (81 FR 42802 through 42880), hereinafter referred to as the CY 2017 ESRD PPS proposed rule, was published in the **Federal Register** on June 30, 2016, with a comment period that ended on August 23, 2016. In that proposed rule, for the ESRD PPS, we proposed to (1) make a number of annual updates for CY 2017, (2) increase the home and self-dialysis training add-on payment adjustment, (3) implement the statutory provisions set forth in the Trade Preferences Extension Act of 2015 (TPEA) amendments to the Act, and (4) utilize a payment equivalency for hemodialysis furnished more than 3 times per week. We received approximately 340 public comments on our proposals, including comments from ESRD facilities; national renal groups, nephrologists and patient organizations; patients and care partners; manufacturers; health care systems; and nurses.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the CY 2017 ESRD PPS. Comments related to the paperwork burden are addressed in the ''Collection of Information Requirements'' section in this final rule. Comments related to the impact analysis are addressed in the ''Economic Analyses'' section in this final rule.

1. 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 (c) 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 Medicare Administrative Contractors (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 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 (LCDs) 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, in some cases, 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 3 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 (c) 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 proposed 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. While the policy would be effective January 1, 2017, we proposed not to implement the HD equivalency payments until July 1, 2017, to allow time to make operational changes to accommodate this new payment mechanism.

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

For CY 2017, for adult patients, we proposed 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). 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, 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 proposed 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 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. The comments and our responses to the comments for these proposals are set forth in section II.B.1.d below.

c. 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.

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 is to provide a payment mechanism for patients with more than 3 HD treatments per week that do not have medical justification. 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. The comments and our responses to the comments for these proposals are set forth in section II.B.1.d below.

d. 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 discussed in section II.B.2 of the proposed rule (81 FR 42812) and in section II.B.2 below, 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 total sessions, in accordance with our policy for training for conventional HD.

Because the home dialysis training add-on under the ESRD PPS 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.

In the CY 2017 ESRD PPS proposed rule (81 FR 42812), we explained that we believe this payment mechanism 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.

The comments and our responses to the comments for the proposals related to payment for HD when more than 3 treatments are furnished per week are set forth below.

Comment: The majority of comments were from individual patients and their care partners describing their dialysis

experience from onset, through PD, transplant, return to in-center 3 times weekly and finally to more frequent home HD. The commenters describe significant improvement in their health status, including better blood pressure, cardiac status, and phosphorus levels, fewer dietary restrictions, less fatigue after dialysis, and the ability to schedule dialysis around work and family activities. Many commenters strongly encouraged CMS to review the clinical literature related to dialysis frequency because based on the literature and their own clinical experience, more frequent dialysis has many benefits. They believe CMS payment policy should be modified to more closely align with evidence-based research. They urged CMS to take steps to facilitate access to home HD, such as routinely paying for more than 3 treatments per week for any patient who agrees to have more, so that more patients can receive the same benefits.

Other commenters indicated that their more frequent home dialysis resulted in more hours of dialysis treatment than is typically furnished in-center. One commenter pointed out that typically patients on more frequent dialysis generally treat 30–40 percent longer than patients receiving 3 times per week therapy in-center. Commenters also described the health advantages of nocturnal dialysis and other dialysis schedules that provide a similar level of toxin and fluid removal to in-center dialysis, but spread out the treatments over 4 or more days. Another commenter pointed out that with the same weekly volume of fluid to be removed it is clearly demonstrable that removal in five treatments is safer, protects vital organs and is far more stable for patients. This does not mean that all patients must be treated 5 times per week or that all patients receiving that frequency are necessarily fully dialyzed. Therefore, some flexibility in approach is necessary. The commenter concluded that dialysis patients are in general intolerant of fluid removal. Elderly nursing home patients are at greater risk of problems that can be alleviated substantially by more frequent dialysis.

Many other commenters urged CMS to provide payment for customizing the dialysis treatment to the patient. One commenter indicated that unlike in-center dialysis, which is one size fits all, they are able to tailor each treatment to their physical needs; for example, if the beneficiary has too much fluid after travelling, then a few extra, longer, slower treatments could be done to gently remove the fluid. The commenter stated that a diabetic controls their treatment by regulating their blood sugar, and a patient on dialysis should be allowed the same freedom to treat accordingly. More frequent treatments, as needed, are a must for maintaining maximum health. There must not be a one size fits all dialysis treatment mentality.

Several commenters objected to the proposed update to home HD payment policies because they believed that it locks in the 3-times-per-week schedule. The comments indicated that there is no research that supports capping the dialysis dose in such an unsafe way. A 3-day a week schedule requires a nearly 3-day ''dialysis weekend'' every week, which is a risky choice. Another commenter stated that 3-times-per-week dialysis (Monday, Wednesday, Friday and Tuesday, Thursday, Saturday schedules) was not based on clinical research, but rather was a way to dialyze two groups of patients and allow the nurses to have Sunday off. Another commenter believes the 3-times-per-week scheduling reflects the shortage of dialysis machines and supplies in the 1960s when HD began. Other commenters pointed out that alternative schedules are unavailable in-center, other than in very narrow circumstance where there is medical justification, and thus are generally furnished at home.

Response: We believe that the choice of modality and frequency of treatments for a patient are decisions that are made by the physician and the patient. We continue to believe that patients should have access to various treatment options and schedules and facilities should offer various treatment options to meet the needs of its patients. Comments recommending that we facilitate access to home HD by routinely paying for more than 3 treatments per week are beyond the scope of the proposed rule. However, we believe that routinely paying ESRD facilities the full ESRD PPS payment for up to 6 or even 7 treatments per week for home HD patients would overpay facilities relative to their resources and cost. Patients on more frequent schedules have indicated in public comments that they no longer need to take many of the medications routinely provided to in-center patients and have limited involvement with their ESRD facility, two significant components of the ESRD PPS base rate.

We acknowledge that the proposed HD equivalency would have maintained the current policy which limits monthly payment to 13 or 14 treatments, which reflects the number of treatments received by the vast majority of ESRD patients; but our intention was to provide more flexibility for patients, not to increase the overall amount of payment. Patients with certain medical conditions reportedly benefit from shorter and/or longer and more frequent HD and, as a result, MACs can approve additional treatments. While we have reviewed the studies regarding more frequent HD that have been conducted, many of the studies are too small in scope and do not provide a sufficient basis for a national payment policy change of this magnitude. In particular, in a literature review reported November 2015 in the American Journal of Kidney Diseases, titled ''Timing of Dialysis Initiation, Duration and Frequency of Hemodialysis Sessions, and Membrane Flux: A Systematic Review for a KDOQI Clinical Practice Guideline'', *Slinin et al,* reported that more than thrice-weekly hemodialysis and extended-length hemodialysis did not improve clinical outcomes compared to conventional hemodialysis and resulted in a greater number of vascular access procedures. The authors concluded that the limited data available indicate that more frequent and longer hemodialysis did not improve clinical outcomes compared to conventional hemodialysis. As a result, we believe that payment for additional treatments should remain individualized to the patient as medically necessary and that the determination continue to be made on a case-by-case basis by the MACs.

Comment: While many commenters expressed support for CMS' efforts to obtain a reliable source of data for the number of HD treatments patients receive each week, most of the comments from individual facilities and dialysis organizations of all sizes, physicians, and patient advocacy organizations strongly objected to the HD equivalency proposal because they believe it is unnecessary, would increase providers' burden, would be administratively complex, and would discourage growth of home HD. Although we developed the proposal based on provider feedback about their inability to report all dialysis treatments on a monthly claim, many commenters indicated that this concern is unfounded because current claims processes allow providers to report all dialysis treatments delivered either in-center or at home. They suggested that modifiers could be used to distinguish medically justified additional treatments from those that do not meet their MAC's LCD for medically justified treatments.

Dialysis organizations pointed out that use of the prescribed number of treatments as the basis of payment increases the burden. An LDO pointed

out that the number of prescribed treatments can change weekly based on a patient's condition. For other various reasons (for example, hospitalization), a patient may not receive a prescribed treatment, making the proposal administratively challenging for facilities and providers. In addition, the HD equivalency proposal only achieves CMS' goal of allocating the total amount of payment based on three HD sessions per week in accordance with the number of treatments actually furnished when the actual and prescribed treatments are equal.

An MDO agreed and expressed serious reservations about substituting prescribed treatments for delivered treatments in the calculation of payments, as the proposal contemplates. The commenter indicated the proposed HD equivalency policy would increase the reporting burden in order to correct claims for patients who do not attend the prescribed number of treatments. The line item billing requirements would impose further burden in billing for patients treated on schedules, such as every other day treatments. Moreover, months ending in the middle of a week would pose additional complexity, since it would be necessary to use 2 monthly claims to determine whether there had been more than three treatments during the week.

The commenters stated these additional burdens would represent additional administrative cost for every dialysis provider, for every vendor supplying dialysis billing software, for every MAC receiving these claims, and for CMS itself. They stated that this will be particularly burdensome for smaller organizations and independent providers which are not highly automated and tightly integrated with clinical systems. Another organization representing nonprofit facilities pointed out that with all the other requirements being placed on providers, particularly smaller providers, they do not see how CMS' need for better data outweighs the additional burden at this time and strongly opposed CMS finalizing the proposal.

Many other commenters objected to the proposal to pay for shorter, more frequent HD in a similar manner as PD, pointing out that PD and home HD are vastly different therapies and should not be compared to one another clinically or paid as if they are equivalent therapies. The comments indicated that PD is currently paid as the equivalent to 3 treatments per week HD because it requires multiple exchanges per day to achieve the same basic outcomes for patients.

Many commenters recommended that CMS issue simple billing clarifications to ESRD facilities to encourage reporting of all treatments and remind the MACs that their LCD or similar policies should include criteria for additional, medically justified dialysis treatments. Otherwise, the commenters indicated that CMS' current policies are sufficient to meet the needs of beneficiaries, providers, and Medicare, and the HD equivalency is not necessary.

Response: After careful consideration of the public comments, we agree with commenters and believe that implementing HD-equivalent payment for shorter, more frequent HD could be burdensome. Following publication of the proposed rule, we learned that ESRD facilities in certain MAC areas have the ability to report all treatments furnished, whether paid or not. We are exploring claim reporting mechanisms, such as modifiers, to meet our data needs and reflect patient treatments provided while minimizing burden on facilities. Once we decide on the mechanism for reporting treatments that are medically justified and those that do not meet the MAC's LCD for medically justified additional treatments, we will issue billing clarifications to MACs and ESRD facilities.

Comment: Although many commenters requested that CMS withdraw the equivalency proposal, a few commenters believe that the status quo should not remain in place and that CMS is on the right track with the HD equivalency proposal. One commenter expressed concern that the proposal could produce a perverse unintended consequence of rewarding facilities that provide more frequent dialysis but less in the aggregate than is necessary to give patients high-quality care. We are unsure exactly what the commenter meant by this comment and the commenter did not elaborate on this point.

Another commenter pointed out that current reimbursement for more frequent home HD creates for this one particular therapy a reimbursement level that can be double that of conventional 3-times-per-week HD if all the HD treatments are paid as medically justified treatments. The commenter stated that the cost to the provider for additional treatments (beyond 3 per week) delivered at home with more frequent home HD should be a relatively small incremental cost as compared to the first 3 treatments per week. Within the reimbursement of the first 3 treatments (the conventional schedule) the cost of the machine, the patient training, the nursing support, etc., would already have been covered and the incremental cost for additional home HD treatments is strictly the treatment supplies.

The commenter stated that reimbursing for the additional treatments beyond 3 treatments per week at the full bundled base rate does not seem appropriate and creates at least the appearance of a profit incentive for providers (and their physician partners) to utilize this therapy. Patients should have access to more frequent home HD as a therapy option, but the reimbursement for this therapy should be more straightforward and transparent, and on a level playing field with other dialysis therapy options, such as conventional 3 times weekly HD or PD. The commenter believes the CMS equivalency proposal would do that.

The commenter suggested that CMS consider adding a new lower incremental treatment rate for home HD treatments beyond 3 treatments per week to cover the additional incremental supply cost beyond the first 3 treatments per week, if CMS feels that is appropriate and is interested in promoting more frequent home HD therapy. However, another commenter stated that dialysis centers not only incur the cost of supplies for the additional treatments, but also incur the cost for staff to manage the treatments. It makes sense they should be paid accordingly and therefore avoid costly emergency rooms visits for episodes of fluid overload or hyperkalemia.

Response: We agree with the commenter that paying the full base rate amount for treatments over 3 per week without documented medical justification would have created risks for patients but we note that this is not the policy that we proposed. We also note that we aggressively monitor ESRD facility claims so that we are aware of changes in practice, and they may prompt us to engage in future rulemaking in this area. As we explained previously, we are not finalizing the HD equivalency proposal. As an alternative, we will be making changes in reporting treatments that will allow us to monitor changes in treatment patterns more effectively.

Comment: Several commenters, while disagreeing with the equivalency payment proposal as discussed above, supported CMS in paying the full ESRD PPS base rate for each home HD training treatments, even when those treatments are furnished more than 3 times per week. The commenters agreed that this frequency of payment would assist CMS in the investigation for payments and costs related to training for future refinement. The commenters indicated that the proposal is appropriate because

training treatments are an essential process to transitioning patients home safely. In addition, they agreed it would permit facilities to bill for training treatments that are furnished to beneficiaries receiving more than 3 HD treatments per week and allow these facilities to receive payment for training more consistently with how they are furnishing these treatments.

Response: We appreciate the commenters' support for the proposal regarding allowing the payment of the full base rate for all home dialysis training treatments, even when they are furnished more than 3 times per week, subject to our payment limit of 25 HD training sessions. While we are not finalizing the equivalency payment for maintenance HD (discussed above) when it is furnished more than 3 times per week, we continue to believe that it is important for our payment for home HD training to be consistent with how we pay for home PD training. In addition, we do not believe that this will change the amount of total dollars paid out for home HD training because facilities will receive the training add-on for only 25 treatments, which has been a longstanding policy. The difference is that facilities can receive the full base rate for more than 3 HD training treatments in a single week. Therefore, for this rule we are finalizing our proposal to pay the full ESRD PPS base rate for all training treatments even when they exceed 3 times per week with a limit of 25 sessions as proposed.

Comment: A commenter suggested what they believe is a much simpler solution under which CMS would instruct the MACs to 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, the commenter believes payment should be limited to 13 treatments and for a 31-day month the commenter believes payment should be limited to 14 treatments. The commenter indicates this approach enforces the 3 times a week rule effectively. In addition, it permits flexibility, allowing payment for a 4 treatment week followed by a 2 treatment week for those few cases having logistical but no medical justification, such as Christmas and New Year's, weather or water system failures causing unexpected facility closure, as well as major events in patients' lives such as out of town family weddings and funerals.

Several commenters stated that Medicare reimbursement should signal its willingness to support safe schedules, especially every other day (EOD) HD schedules. The commenter recommended that the PPS should base home HD reimbursement on 7 treatments every 2 weeks, that is, reimburse home HD fully, equivalent to EOD schedules, and to reimburse a partial bundle amount for treatments in excess of EOD.

Other commenters implored CMS to explore paying for HD by the hour rather than by the treatment, or, minimally, to pay for up to 15 standard in-center HD treatments per month without medical justification to allow dialysis every other day and eliminate the 3-day dialysis weekend.

Response: Since ESRD facilities submit bills on a monthly basis, we currently enforce the 3-treatments–per-week payment policy through established treatment limits by month, that is, 13 treatments for 30-day months and 14 treatments for 31-day months and we will continue to do so. We appreciate the suggestions to increase the monthly limits, however, these suggestions are beyond the scope of the proposed rule. As we mentioned above, payment for additional treatments should remain individualized to the patient as medically necessary and that the determination will continue to be made on a case-by-case basis by the MACs.

Comment: We received many comments objecting to the notion expressed in the proposed rule that extra sessions would be prescribed based on patient preference or convenience. One commenter stated that the idea that they took on the responsibility for their treatments, coordinating and storage of medical supplies, cannulating themselves, drawing blood, completing and filing flow sheets, troubleshooting medical and mechanical emergencies, and then having to clean up and sanitize the equipment as a matter of convenience is ludicrous. Another commenter pointed out that patients receiving additional treatments only consent to them because they experience a real and sustained clinical benefit.

Another commenter objected to statements in the proposed rule stating that more frequent HD is the result of evolving or new technology. The commenter believes it is more accurate to say that the option to furnish more than 3 HD treatments per week is an existing option that is increasingly utilized because of evolving technology that facilitates treatment in the home setting, where more frequent HD is more feasible, as well as increasing awareness of the unsolved clinical problems that more frequent HD can positively address. The commenter also pointed out evidence that more frequent HD is not new and referred to a systematic review of clinical outcomes in patients on more frequent HD that studied patients who initiated more frequent hemodialysis in Asia, Europe, North America, and South America as early as 1972. In other words, more frequent hemodialysis was an internationally-recognized prescription long before the advent of the currently dominant home HD technology in the US.

One commenter expressed concern about the implication that a significant number of prescribed extra HD sessions are not predicated upon medical necessity. The commenter pointed out that more frequent HD requires a greater investment of time on therapy than thrice-weekly therapy, no matter how it is prescribed. This therapy is not prescribed for convenience. The commenter pointed out that CMS has noted that no HD session is without risks, and more frequent therapy would not be prescribed unless it is clinically necessary to address a particular patient's needs. The commenter believed suggesting otherwise is inconsistent with the responsible practice of medicine. Another commenter explained that the hemodynamic benefits are a major reason why doctors prescribe, and patients embrace, this form of therapy. As such, the hemodynamic benefits are at the very core of the basis for the medical necessity for more frequent HD therapy.

Response: We appreciate these clarifications. Our intent was merely to pay appropriately for shorter, more frequent dialysis prescriptions that are equivalent to in-center treatments. We did not mean to imply that physicians order treatments that are not medically necessary, or that patients receive shorter, but more frequent dialysis solely for their convenience. However, when a home dialysis machine supplier met with us and was asked if their machine could perform in the same way as an in-center machine performs, that is, whether patients could dialyze 3 times per week, we were told the patients could do so, but that it would take longer. Consequently, the patients using this home modality choose shorter, more frequent dialysis treatments at home 5 times per week. We agree with the commenter that it is more accurate to say that the option to furnish more than 3 HD treatments per week has been increasingly chosen as a treatment option. This may be due to the evolving technology facilitating more frequent HD treatment in the home setting.

Comment: An LDO, a national dialysis industry organization, a patient advocacy organization and many patients, caregivers, physicians, and nurses supported the proposal to continue current payment policy for treatments determined medically justified based on MAC consideration of medical evidence as required under a LCD. The commenters stated this is an important existing policy that allows patients who have a medical need to be able to obtain extra treatments and for the facilities to be reimbursed for them. They also noted that this policy preserves the physician's medical decision-making to meet the individual needs of patients.

A dialysis nursing association expressed concern that despite the promulgation of LCDs for additional dialysis treatments, there are substantial differences in the MAC's assessment of medical justification for these treatments. They urged CMS to continue to educate the MACs on what constitutes medical justification and ensure the MACs are thoroughly examining each medical record in its entirety when assessing whether there is medical justification for additional treatments. They pointed out that differences in documentation requirements necessitate additional work for their members, and it is imperative that the MACs exhibit greater consistency when determining the appropriateness of payment based upon the medical documentation.

However, many other commenters, primarily physicians, implored Medicare not to interfere with the physician's clinical judgment in determining the best treatment regimen that meets the needs of their patients. Physicians indicated that all the treatments they prescribe are medically necessary. Several commenters expressed concern the proposal may limit the physician's freedom to prescribe additional HD sessions for patients who could benefit. Commenters pointed out that currently there is no national policy that restricts a physician's ability to prescribe medically appropriate extra HD sessions for their patients and that the decision about whether the therapy prescribed is medically appropriate is made locally, between the physician and the local MAC. The commenter expressed concern that the HD equivalency proposal may take away some of that freedom if certain language in the rule is not changed. One commenter stated they are not asking CMS to specify what the MACs should or should not pay for, but rather that CMS should leave that decision to physicians.

A clinical association stated that while they are generally supportive of the current medical justification approach, they noted that it can create administrative burdens and, in some cases, interfere with the patient-physician relationship. Due to the heterogeneity with which various MACs interpret what is medically justified, clinicians in some areas have less latitude to provide what they believe is medically justified care. For example, it may be appropriate for certain patients who have benefitted from a fourth dialysis session in 1 week to receive a fourth dialysis session in the following week as a prophylactic measure to prevent an adverse outcome from occurring again. The commenter believes CMS should urge all MACs to approach medical justification with a consistent, broad view and a respect for physicians' responsibility in determining, in consultation with their patients, what constitutes medically necessary additional dialysis sessions.

Another commenter agreed, stating that absence of documentation on some claims forms requesting payment for extra prescribed sessions does not indicate absence of medical necessity. Instead, it may be due to variations in the documentation particular MACs are seeking, or a misunderstanding of how to properly submit a claim for a type of therapy that is rarely prescribed. In these instances, documentation of medical necessity likely is to be found in the prescribing physician's patient records. The commenter stated that it is rational to assume that a reiteration of clear instructions on this point, from CMS and the MACs, would address the discrepancies in claims submissions that CMS has noted.

An advocacy organization asked that CMS reiterate again in final rulemaking that there is no national coverage decision for additional hemodialysis sessions, that the determination of medical justification for both acute and chronic prescriptions involving more than three sessions per week is left entirely to the discretion of the MACs and that if a MAC wishes to restrict coverage to any certain conditions or require any unique documentation, it must execute a formal LCD process with public comment.

Other commenters stated that the overwhelming clinical evidence shows that the closer HD treatment approximates the functioning of the healthy human kidney (24 hours/per day, 7 days/per week), the better the patient outcomes. Therefore, they believe Medicare should presume that longer, more frequent dialysis is medically justifiable in all cases, and that the actual treatment regimen should be determined by the patient, in consultation with their physician, taking into account both anticipated clinical outcomes and the patient's overall life goals.

Another commenter suggested that a conversation should be opened with Medicare contractors to permit a full understanding for the reasons for more frequent HD therapy. Justifications for on-going more frequent HD therapy are not necessarily the same as that for a one-time only justification for an extra treatment for a conventionally treated patient. The justifications for the two groups should be separated. The commenter stated that Medicare should unequivocally signal support for the concept of more frequent HD and should also clearly signal that more frequent HD treatments, when justified, will be funded. Lastly, the commenter stated that should more frequent HD be prescribed without justification, then treatments in excess of 3-per-week should not be reimbursed. Another commenter agreed, stating that all home HD treatments provided should be reported and, through use of a modifier, be indicated as medically supported or not medically supported with all supported treatments being paid at the designated HD facility rate.

Response: We thank the commenters for their comments. However, we did not propose to change the process for MAC approval of additional dialysis treatments. We believe the current process has been effective in approving additional treatments based on the medical evidence for individual patients. We agree with the commenter who stated that there is no national coverage decision for additional HD sessions and that the determination of medical justification for prescriptions involving more than three sessions per week is left entirely to the discretion of the MACs and related administrative processes. We support more frequent HD for those patients who can benefit from it and agree that if more frequent HD is prescribed without medical justification, the treatments in excess of 3-per-week should not be paid. We thank the commenters for their suggestions and will consider them if we make changes to this policy.

Comment: Several commenters stated they appreciate that CMS listed heart failure, a chronic disease, as a potential medical justification for the delivery of more than 3 HD treatments per week. They noted that the medical directors of at least one MAC have asserted that CMS has guided that only acute diseases can constitute medical justification for additional treatments. They encouraged

CMS to reiterate in the final rule that both acute and chronic diseases can constitute medical justification. The commenter indicated that heart failure is a good example of a chronic disease that may constitute medical justification for more frequent HD because of its leading role in morbidity, mortality, and medical spending among dialysis patients, but it is certainly not the only example of a chronic disease. Persistent hypertension, persistent hyperphosphatemia, sleep disturbances, pain attributable to dialysis-related amyloidosis, and symptomatic intradialytic hypotension are all examples of chronic comorbid conditions that may be positively addressed by ongoing treatment with more frequent HD.

However, another commenter pointed out that the need for more than 3 HD treatments per week occurs in less than 1 percent of the ESRD population and the need for additional treatments is very brief in duration. This commenter indicated that after receiving perhaps a few extra treatments, the patient should be able to be managed with 3 treatments a week. The commenter indicated that if facilities report a diagnostic code such as congestive heart failure (CHF), the extra treatments are automatically paid by the MAC without pre-payment review and, moreover, the MAC will continue to pay for these treatments as long as the diagnosis is included on the claim. The commenter believes that this payment procedure is an invitation to serious Medicare abuse and recommended that CMS demand pre-payment review of every patient requiring more than 3 treatments a week for a period of more than 1 week. Specifically, the facility should be required to provide monthly physician progress notes, chest x-ray reports, and other confirmatory testing and medical justification for the ongoing need for extra treatments and the patient's inability to return to 3 times a week treatments.

Response: In the proposed rule (81 FR 42810), we mentioned that additional conventional HD treatments are reimbursed at the full ESRD PPS payment if the facility's MAC determines the treatments are medically justified based on a patient condition, such as CHF or pregnancy. We did not mean to imply that the MACs should view the presence of a CHF diagnosis on a claim as medical justification for additional treatments, nor did we mean to imply that chronic disease diagnoses should confer medical justification. We agree with the commenter that automatically paying for additional treatments for patients with chronic medical conditions every month for as long as bills with the diagnosis code for CHF appear does not seem appropriate. However, all decisions regarding medical justification for additional dialysis treatments are paid at the discretion of the MAC. We will continue to monitor claims that include additional treatments and will consider whether additional guidance or other prepayment review as suggested by the commenter is needed.

Final Rule Action: After considering the comments we received, we are not finalizing our proposal for payment for HD when more than 3 treatments are furnished per week. Based on the feedback from commenters regarding the administrative burden associated with this policy, we have determined that the best course is not to finalize this policy and, instead, to evaluate other billing mechanisms to collect data on the treatments provided to beneficiaries. We are reiterating that facilities are expected to report all dialysis treatments provided, whether they are separately paid or not paid.

However, we reiterate that we are finalizing our proposal to pay the full ESRD PPS base rate for all training treatments even when they exceed 3 times per week with a limit of 25 sessions as proposed.

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 (75 FR 49062), 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 Registered Nurses (RN), from the Bureau of Labor Statistics (BLS) data updated to 2011 (75 FR 49063), and reflects 1 hour of training time by a 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 RNs as published in the Occupational Employment Statistics (OES) data compiled by 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.

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 care partners have stated that the RN training time per session spanned from 2 to 6 hours per training treatment, that the number of training sessions ranged from 6 to 25 sessions, and that the training they received took place in a group setting. The range of hours per training treatment may indicate that the amount of 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.

We are 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. We indicated in the proposed rule that 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) (81 FR 42813). We also noted that 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, we are unable to identify in the data when the maximum number of training treatments have been completed, 25 for HD and 15 for PD, however, administrative guidance will be forthcoming on this issue. 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. 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 stated our intention to issue sub-regulatory guidance to provide a method for facilities to report retraining treatments. We solicited input from stakeholders on retraining, how often retraining occurs, how much RN time is involved, and the most common reason for retraining.

A summary of these comments and our responses are provided below. In addition, historically 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 the proposed rule (81 FR 42813), there are claims processing edits in place that may 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. 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 proposed 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.

As we explain in section II.B.1 of this final rule, we are not finalizing the HD payment equivalency proposal due to the burden it would have on facilities, however, we are pursuing other methods for identifying medically justified treatments and treatments that do not meet the MAC's LCD for additional dialysis treatments, such as through the use of modifiers. We are also finalizing that we would not limit the number of home HD training treatments per week for which we would pay the full ESRD PPS base rate to be consistent with how we pay for PD training and to better align Medicare payments for training to when facilities are incurring the cost for training. We believe these changes will greatly improve the accuracy of the reporting of training treatments.

We solicited comments on implementing the HD payment equivalency and sought information on the use of retraining and the establishment of coding on the ESRD

facility claim for retraining. The comments and our responses to the comments regarding retraining are set forth below. The comments and our responses regarding the HD payment equivalency proposal are located in section II.B.1.d of this final rule.

Comment: A dialysis industry organization appreciates that CMS will begin working with the kidney care community as it seeks to better understand retraining, how often it occurs, the amount of nursing time involved, and the most common reasons for it. They and many other commenters stated their support for the definition of retraining found in the Medicare Claims Processing Manual, described above. They believe that retraining does not occur often, but when it does, each retraining can vary depending on the specific circumstances. In some instances, it would be the same as training, but designated as retraining only because the patient had received home dialysis training previously. For example, when a patient changes modality, there may be consistency in partner support, but the same amount of RN training time and number of training sessions may be required to ensure that the patient understands how to operate the new device safely. The same could be true if a patient experienced a temporary memory loss. In some instances, it might be possible to reduce the number of training sessions, such as when there is a minor modification to the device, something changes in the patient's home, or the patient's dialysis partner changes. As discussed in the Medicare Claims Processing Manual, Chapter 8, Section 50.8, retraining may also be necessary when there is evidence that a patient needs a refresher in how to properly use the device because they have developed an infection or other problems. They and other organizations expressed support for CMS' efforts to improve data collection that would give CMS and providers a clearer sense of the incidence of training and retraining in the aggregate to inform policy decisions.

A physician organization agreed, stating that some research has shown that individuals starting PD commonly develop complications like peritonitis, need hospitalization, and are transferred to catheter-based HD within the first 90 days of dialysis initiation. The organization noted that adapting to home dialysis is challenging and may indicate a need for improved initial training and a targeted increase in early retraining interventions.

Based on an informal survey of their members, the organization suggests that retraining is warranted in the following circumstances: After any episode of peritonitis, bacteremia, or infection in which root-cause analyses suggests that the condition resulted from a break in sterility of technique; after prolonged period of hospitalization or skilled nursing facility care, when the patient or caregiver may be out of practice; after changes in HD access (catheter to fistula or graft, new fistula or graft, especially if on the opposite side, or difficulty with cannulation at a particular part of a fistula or graft); training for use of a heparin pump; change in dialysis machine or equipment; when there is a change in who is going to perform or assist with home PD or HD (for example, if a patient has had a stroke and now their spouse will do PD or if one caregiver is replaced by another); when home dialysis patients move or transfer to another program (whether permanently or temporarily), reflecting that protocols, equipment and care practices may differ among programs.

An LDO indicated that in its experience retraining typically occurs at six-month intervals and following a hospitalization, infection, or return to therapy. The commenter agreed that in some circumstances, it can be difficult to differentiate training from retraining treatments. A patient advocacy organization urged CMS to allow flexibility for facilities to deliver retraining, when it is necessary, to ensure patients continue to dialyze safely at home. They also noted that training currently is and should continue to be individualized and tailored to the patients' needs and learning aptitude, and policies should remain flexible to ensure a patient-centered approach is attainable. A manufacturer stated that the first step will be to establish nomenclature and definitions. The commenter indicated that they plan to send a communication on this point separately, not as part of this comment process.

Response: We appreciate the valuable information submitted and will address retraining once we are able to analyze claims data that identifies retraining treatments. We are pleased to announce that we have been approved to establish a condition code to identify retraining treatments. Change Request 9609 (*https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9609.pdf*), titled ''Updates to the 72X Type of Bill for Home and Self-Dialysis Training, Retraining, and Nocturnal Hemodialysis'' and issued on September 16, , which establishes a condition code for retraining treatments effective July 1, 2017.

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

In the CY 2016 ESRD PPS 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.

We did not receive any comments on this technical correction.

d. Analysis of ESRD Cost Report Data

CMS 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, and as we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42814), we are 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 also 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.

The comments and our responses to the comments for this 3-pronged strategy to improve the ESRD cost report data are set forth below.

Comment: Several industry organizations and clinical associations agreed that the current cost report data do not provide an accurate view of home dialysis training costs. They noted that there is significant variation between ESRD facilities' cost report data, and it is likely that CMS is collecting data that inaccurately assesses the adequacy of the home and self-dialysis training add-on. They believe CMS should update the cost reports and insert new fields with clear instructions on how to report training costs and labor. They and many other commenters strongly encouraged CMS to work with dialysis facilities to provide clear and accurate instructions as to how to report training costs and labor to address this problem. One organization emphasized the importance of CMS working with the provider community to identify possible changes to cost reports and other data collection mechanisms and expressed their interest in working with CMS on any proposals while in development and under consideration.

One commenter indicated that new fields on the cost report can provide additional information on patient training resource allocation (among other issues), however, they strongly recommended that the new fields be designed to have clear and concise micro specifications (that is, specific description of definitions, criteria, and contents) to avoid ambiguity and multiple interpretations among dialysis facility personnel and vendors. They further recommended that these micro specifications be released for public comment in order for CMS to appreciate how the different stakeholders interpret them and to allow for feedback and questions, thereby allowing for clarification and modifications prior to implementation. They also urged CMS to implement changes in a manner that recognizes that providers have different cost reporting periods, requiring longer—at least 6 months—lead time to implement. As CMS begins this data collection and analysis initiative, they recommended inclusion of industry stakeholders to provide input on appropriate changes.

Another commenter indicated that the proposed approach to improving the quality of cost report data, and to improve the estimate of the cost of home training, is very reasonable, as long as the locking mechanism is implemented cautiously. New fields on cost reports will probably require new fields in electronic health records and bookkeeping systems. Users should receive warnings and notifications when they skip mandatory fields, to avoid last-minute crises when they discover that they have omitted required data. If not prepared by such warnings, commenters fear that the requirement to meet a filing deadline might lead some users to submit less precise data.

Another commenter strongly supports CMS' multi-pronged effort to improve the data associated with the cost of home dialysis training treatments. In their analysis of resources necessary to deliver home training, they found similar data variances, especially between those programs with a higher volume of home patients and those who were training only a few individuals. The commenters believe that the analysis and audits proposed will result in a greater understanding of common errors, and lead to agency clarification and guidance around the reporting elements that will greatly improve data quality.

MedPAC supports CMS' effort to collect more reliable data on the cost of providing home dialysis training. Once CMS collects sufficiently reliable data about the duration and composition of training treatments, MedPAC believes the agency should assess the need to adjust the training add-on payment amount from the current rate.

A dialysis industry organization had thoughtful suggestions on how the current cost report might be used in a way that avoids issues with data variability. They proposed using an alternative weighting scheme based on an analysis of total HD treatments versus PD treatments that yielded a training add-on payment of $229.83 for 2017. Using cost report data, the analysis established 4.65 hours of additional staff time per training treatment and RN hourly compensation of $49.43. As a result, the organization urged CMS to increase the proposed training add-on adjustment to $229.83 per treatment for 2017.

Response and Final Rule Action: While we appreciate the efforts made by an organization to establish a training add-on amount using the current cost report, we note that the organization's analysis addressed the variability in costs by removing facilities with extreme values and estimated the add-on based on 70 percent of facility cost reports. Although we usually apply edits to remove outlier costs from our analyses to ensure that our results are not skewed by extreme values, we did not feel comfortable removing 30 percent of the data in order to set the training add-on payment amount. Rather, we believe our proposed approach to revise the cost report will allow us to use more facility cost report data to set the training add-on payment amount.

We appreciate the views expressed by commenters and are proceeding with changes to the ESRD facility cost report as proposed. As we work to improve the data reporting ability on claims and cost reports, we will keep in mind the various helpful suggestions made by commenters on this topic. We are considering various options for obtaining assistance from stakeholders, such as obtaining feedback via the ESRD Payment mailbox at *ESRDPayment@cms.hhs.gov*.

e. Final 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 dialysis 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 proposed 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 as described below, until such time as we have data that concretely indicates what an adequate payment should be.

For wages, we proposed to 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 proposed 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 used the average treatment times for PD and HD as 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. We noted that 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 proposed to base the payment for home dialysis training on 2.66 hours of treatment time ((.67 × 2 hours) + (.33 × 4 hours) = 2.66 hours) resulting in a training add-on payment of $95.57 (2.66 hours × $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.

As we did in CY 2014 when we last increased the training add-on payment, we proposed that the 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 resulted in a budget neutrality adjustment of 0.999729.

The comments and our responses to the comments for the proposed increase to the home dialysis training add-on are set forth below.

Comment: Many commenters, including patients and their care partners, nurses, and physicians described the benefits of home dialysis overall and the importance of training, and requested CMS' continued support of the modality. Commenters indicated that home dialysis is more convenient, particularly in rural settings, and stressed that training makes dialyzing at home feel safer.

One LDO noted that dialysis modality selection is a complex decision for any individual and believes that too much attention has been paid to the training an individual receives (and the cost of such training) and too little has been paid to the myriad other factors that influence this decision. The commenter pointed out that numerous comment letters from the community and a recent report from the General Accounting Office (GAO) have identified factors that influence decisions regarding home dialysis, including everything from an individual's home life to their familial support structure to their clinical status, as well as their physician's familiarity with home therapies.

One commenter urged CMS to set separate payment rates for home HD and for PD training to eliminate any payment incentive for a center to favor PD training over the more-costly home HD training. The commenter indicated that the only incentive for choosing one mode of home dialysis over the other should be how closely each modality comes to making it possible for patient to meet his or her treatment and lifestyle goals, after being fully informed about the clinical and lifestyle implications of each type of dialysis modality. Another commenter expressed support for CMS' proposals to obtain better data, and noted that separately evaluating the adequacy of the payment for each unique modality may be warranted.

A physician stated that home HD is ultimately a better treatment option medically for many patients and would like to see improved access to home training. This commenter went on to explain that in order to accomplish this dialysis centers would need to invest additional resources into home training, and the physician is hopeful that the proposed increased training payment would allow for this. The commenter noted that in their experience most dialysis centers do not offer home HD training and those that do offer training usually have a long waitlist for patients to receive the training, resulting in delays in training for patients. The commenter indicated that applying the same training payment for PD and home HD seems to benefit PD because they have not experienced delays in training PD patients due to lack of staff resources. Finally, the commenter indicated that training treatments are an essential process to transitioning patients home safely and agrees that these treatments should all be paid.

Response: We appreciate the comments emphasizing the importance of home dialysis training and we share the commenter's hope that the increased home dialysis training add-on will lead to greater investment by ESRD facilities into home modalities and home dialysis training. We believe that dialysis modality selection and whether dialysis will occur in-center or at home is a decision made by the patient and their physician. We continue to make an effort to provide proper payment for home dialysis training because that is something we can do through the ESRD PPS to encourage more ESRD facilities to offer home modalities and home dialysis training.

With respect to the comments requesting that we establish separate training rates for PD and HD, we will take these views into account as we contemplate revisions to the cost report to better capture training costs. However, we note that historically, we have paid the same base rate and per treatment training add-on to both PD and HD to encourage use of PD for those patients who can benefit from that modality. As we explained in the CY 2011 ESRD PPS proposed rule (74 FR 49115), composite rate costs and separately billable payments are lower for PD, and as a result, the use of a modality payment variable would result in substantially lower payments for PD patients. We stated that we believed the substantially lower payments for PD patients that would result if modality were used as a payment adjuster in the ESRD PPS would discourage the increased use of PD for patients able to use that modality (74 FR 49967). Because we want to encourage home dialysis, in which PD is currently the prevailing mode of treatment, we adopted an ESRD PPS base rate that did not rely on separate payment rates based on modality.

With regard to the comment about the proposal to pay for all treatments during training, we will no longer apply weekly training limits during HD training. However, we continue to believe that the limit of 25 home HD training treatments is appropriate. In response to the CY 2011 ESRD PPS proposed rule, we received numerous comments requesting that CMS retain the existing policy that limits coverage of the total number of training treatments at the current levels of 15 for PD (CAPD and CCPD) and 25 for HD. In the CY 2011 ESRD PPS final rule (75 FR 49063, we agreed with the commenters and stated that under the ESRD PPS, we will continue the current cap on training treatments at 15 for PD (CAPD and CCPD) and 25 for HD training because most commenters indicated that they can complete training within these training treatment parameters. Based on an analysis of claims data, it appears that patients are still able to be trained for home dialysis within the existing limits and we are finalizing the proposal to pay the full base rate for all treatments furnished during home dialysis training, up to the current limits of 15 for PD and 25 for HD.

Comment: Several industry organizations, a manufacturer and a clinical association supported the training add-on increase but only if CMS implements the increase without applying the budget neutrality reduction to the base rate. Commenters stated that there is no requirement for CMS to make such a change in a budget neutral manner. The commenter noted that the budget neutrality requirements associated with the ESRD PPS, as set forth in section 1881(b)(14)(A) of the Act, are plainly limited to the first year of the ESRD PPS. As we are many years into the functioning of the ESRD PPS, the commenters believe that CMS has no statutory obligation to continue to apply a budget neutrality adjustment. Another commenter indicated that the budget-neutral approach is inappropriate because the increased training add-on payments represent new costs outside of the ESRD PPS that facilities incur for a specific group of patients.

Many commenters argued that the training add-on is different than other adjusters. For example, case-mix adjusters seek to tailor the more general base rate to ensure that facilities are not penalized for caring for patients who require more resources than those who do not. So, while the rate goes up slightly for the more expensive patients, it is reduced for the less expensive patients. This approach seeks to even out the resources being provided.

However, due to the fact that the training rate is an add-on and not an adjuster, the commenter contends that the training add-on is not redistributing existing resources according to patient need. Rather, it is meant to reimburse facilities for additional costs that otherwise would not be necessary for the typical in-center patient. These costs are outside of the base rate and, as such, the commenter believes there is no rationale for making the adjustment budget-neutral.

The commenter acknowledged that CMS has historically made modifications to the home dialysis training add-on in a budget-neutral manner. However, given the ongoing concerns related to the integrity of the ESRD PPS bundle, underpayments, and the growing instability of the economics of the ESRD system overall, the commenter believes there is a solid rationale for changing this policy. The commenter indicated that the ESRD PPS bundle continues to erode each year and creating further erosion by imposing budget neutrality in the context of the training add-on is inappropriate. While it may be true that a 6-cents-per-treatment reduction is small, the problem is that the ongoing systemic reduction of the base rate places in-center patients, as well as those receiving home dialysis, at risk.

MedPAC, however, believes that CMS should make a change to the training add-on payment in a budget-neutral manner. They stated that it is unclear whether the proposed budget-neutrality adjustment factor accounts for any increase in the number of home HD training treatments eligible for Medicare payment that may result from the proposed claims adjudication process change and recommended that CMS clearly explain the methods used to calculate the budget-neutrality adjustment factor and identify the total number of training treatments accounted for by the factor.

Response: In responding to these comments, we believe it may be helpful to first recount the significant history of the home dialysis training add-on adjustment. In the CY 2011 ESRD PPS proposed rule, we proposed that the cost for all home dialysis services would be included in the bundled payment (74 FR 49930). We noted that because we were proposing that training costs under the ESRD PPS would be treated no differently than any other overhead expense, an explicit adjustment to the bundled payment amount for HD and PD training expenditures would not be necessary (74 FR 49931). We also explained in the proposed rule that we were proposing modality-neutral payments, because PD, the predominant modality for home dialysis at that time, is less costly than HD, and we believed that estimating a prospective rate that is higher for PD than it would otherwise be would encourage home dialysis for PD patients (74 FR 49967).

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

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

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

Then in the CY 2014 ESRD PPS final rule (78 FR 72183), we concluded in response to public comments that the training add-on, which represented 1 hour of nursing time, did not adequately represent the staff time required to ensure that a patient is able to perform home dialysis safely. We had received numerous comments on the home dialysis training add-on payment adjustment raising concerns about access to home dialysis and identifying training elements that were not contemplated in 2011, such as self-cannulation and certain aspects of operating an HHD machine. As a result, we recomputed the add-on based upon 1.5 hours of nursing time per training treatment, which amounted to a 50 percent payment increase of $16.72 per training treatment in addition to the training treatment costs included in the base rate. Therefore, the add-on payment rose from $33.44 to $50.16. In calculating the budget neutrality factor, the historical number of home HD training treatments was used. We did not attempt to guess how much that number would change in the future under the new reporting principles. This is consistent with the approach taken for other issues in the past such as the number of patients with comorbidity adjusters or outlier thresholds. Historic data, not speculation about future behavior, were used to set the payment parameters. We have the flexibility to make adjustments budget neutral and have chosen to do so with past adjustments. Our decision to make the training add-on adjustment budget neutral is consistent with other past adjustments.

We believe increasing the training adjustment in a budget-neutral manner is appropriate. As noted above, we consider this increase to be a temporary accommodation while we collect cost and claims data to determine a more accurate training add-on payment adjustment in the future. We are increasing the training adjustment before we are able to collect that data to ensure continued access to this important modality. However, we do not believe it is appropriate to increase overall expenditures under the ESRD PPS during this interim period. As we note above, home dialysis training is also accounted for in the base rate and not just paid for through the home dialysis training adjustment. Because of this, we view moving dollars from the base rate to the home dialysis training adjustment as a way to effectively target this modality. When we have collected sufficient data to examine the cost and utilization of home dialysis training, we will be in a better position to evaluate whether it may be more appropriate to not make the adjustment budget neutral.

Finally, in terms of how we calculated the budget neutrality adjustment factor, we first evaluated the impact of increasing the home and self-dialysis training add-on from $50.16 (as of CY 2016) to $95.60 (which is being finalized for CY 2017). This was done by comparing the Medicare Allowable Payments (MAP) that were estimated under a PPS with the existing training add-on of $50.16 with those that were estimated under a PPS with the revised training add-on of $95.60. This comparison was made while holding other aspects of the ESRD PPS policy constant, and before determining estimated outlier payments. The number of training treatments estimated to be eligible for the adjustment was based on the most recent year of claims data. Training treatments were identified on 2015 claims containing pricer return codes that indicated the training adjustment was applied, which included 72,364 training treatments during 2015 based on the claims data used for the final rule. In estimating payments, the existing training-add on for CY 2016 and the revised training add-on for CY 2017 were applied to the eligible training treatments identified on the 2015 claims. The training budget neutrality adjustment factor was calculated as the ratio of the estimated MAP when applying the CY 2016 training add-on to the total estimated MAP when applying the CY 2017 training add-on. This calculation resulted in a training budget neutrality adjustment factor of 0.999737 for CY 2017.

Comment: Many home dialysis advocates requested that the training add-on be increased to recognize the full cost of training and include a factor to reflect the value of employee benefits and taxes. They believe that CMS intended to reimburse the full cost of the incremental labor necessary to deliver home training treatments. Commenters pointed out that the Office of Management and Budget (OMB) suggests a benefit rate of 36.2 percent. As OMB Circular 76–A states, in calculating direct labor, agencies should not only include salaries and wages, but also other ''entitlements'' such as fringe benefits. CMS uses the fringe benefits assumptions from OMB Circular 76–A in calculations in other sections of the proposed rule, but neglected to apply it in the calculation of the training adjustment. The factor defined in OMB 76–A for civilians is 36.25 percent. The commenters recommended that we apply the fringe benefit percentage to the reference wage rate which would increase the wage rate from the proposed $35.93/hour to $48.95/hour ($35.93 × 1.3625) and result in a home dialysis training add-on payment of $130.21 ($48.95/hour × 2.66 hours = $130.21.

Many other commenters pointed out that the proposed payment is a move in the right direction; however, the training add-on falls short of covering training costs. One commenter stated that while they appreciate CMS' proposal to increase the training add-on payment adjustment in 2017, they strongly urged CMS to raise the amount to $229.83 per treatment to better account for facility training costs. The commenters contend that the proposed amount simply does not adequately cover facility training costs to sufficiently promote and facilitate greater use of home and self-dialysis, particularly for small and medium dialysis facilities.

Response: We did not propose the increase to the home dialysis training

add-on payment amount to reflect the full cost for the RN. Instead, as we explained in the proposed rule, 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 $95.60 (as finalized below) to account for RN time devoted to training. As such, we did not apply the fringe benefit factor described in OMB Circular 76–A to the training add-on proxy, similar to the original add-on methodology, as it was not intended to cover all costs. We further note that most of the training treatment payment is derived from the ESRD PPS payment amount which is updated annually by the ESRD bundled market basket and includes a fringe benefits weighting factor. The home dialysis training add-on payment provides ESRD facilities with payment in addition to the ESRD PPS payment amount, which accounts for the costs associated with the actual treatment, that is, the equipment, supplies, and staffing. Therefore, the ESRD PPS payment amount plus the $95.60 (as finalized below) 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.

In order to 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, we looked for a reasonable proxy for the home dialysis training add-on. We believe the interim rate, which is not intended to reflect the full cost of the RN, and almost doubles the current training add-on payment amount, is sufficient. Once reliable data is available, we will consider whether the adjustment needs to be increased or decreased.

Comment: Several individual commenters indicated that nursing care during training is vital to the success of the training period and that the proposed increase to 2.6 hours is good, but more is needed as 3 to 3.5 hours of training better represents the typical amount of time needed. Other commenters pointed out that their training was 4 hours per day for four weeks, others said eight weeks, some commenters recommended 4.5 hours and others said 4 to 5 hours, and one commenter recommended 6 hours.

However, another commenter pointed out that increasing the training add-on from 1.5 to 2.66 hours of RN labor is a move in the right direction. Providing training for patients and care partners is a critical element of facilitating and maintaining a home treatment regimen for the highest number of patients who are candidates for home dialysis. The commenter stated that as CMS works to improve their own data related to costs, this is an appropriate interim step.

Response: We have learned through public comments that training appears to vary widely from patient to patient. As we stated above, the ESRD PPS base rate reflects the costs for the staff time involved with treatment and the training add-on serves as a supplemental payment. Furthermore, we pay based on averages. While home HD training may take 4 hours, PD takes considerably less time. As the training add-on is meant to address the training for both modalities, 2.66 hours represents the average time for both modalities, weighted by their frequency. Lastly, we believe that the updated training add-on payment rate is sufficient as an interim rate until we are able to develop a rate based on our data.

Comment: A patient advocacy organization expressed concern that when outlining the formula CMS used for determining the increased training adjuster, CMS references that there are KDOQI guidelines on the nursing hours recommended to train patients. However, none of the KDOQI guidelines include recommendations related to the number of hours a nurse is involved in training patients for PD or home HD and the commenter is unaware of any conclusive evidence that would point to such a recommendation.

Another commenter agreed indicating that the KDOQI guidelines are clinical practice guidelines which are not based on time studies of actual training sessions. While guidelines may provide an outline of the expected time for training sessions, they do not accurately represent the time spent training home dialysis patients. The commenter encouraged CMS to continue to research and evaluate this issue to align payments with the true cost of training services.

Response: We did not mean to imply that the KDOQI guidelines were used as a source for establishing the number of hours of RN training time. We used the KDOQI guidelines strictly for the average number of hours for HD, which is 3 to 4 hours. We intend to maintain the current amount of the training add-on, which is based on treatment times, until we are able to analyze reliable cost report data after the cost report refinements are complete in order to align payments with the true cost of training services.

Comment: One commenter stated that CMS allows dialysis providers 90 days to stabilize a patient on therapy and create a plan of care and questioned why that approach was not the same for training patients on a new therapy. The commenter pointed out that dialysis providers take months to train employees who already have medical backgrounds and throughout employee training, there is a mentor who continues to educate and ensure the new employee's work is thorough and reflects knowledge of the therapy and the job. The commenter questioned why we do not ensure that home dialysis patients receive the same level of intensive training.

Response: ESRD facilities that are certified to provide home dialysis training are responsible for providing support services to patients dialyzing at home. The support services required are specified in 42 CFR 494.100(c) and include periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care, coordination of the home patient's care by a member of the dialysis facility's interdisciplinary team, and development and periodic review of the patient's individualized comprehensive plan of care that specifies the services necessary to address the patient's needs and expected outcomes.

We thank the commenter for their suggestion. Our policy is to pay for 25 training treatments for home hemodialysis patients and 15 training treatments for peritoneal dialysis patients, which remains unchanged at this time. The goal of training is to ensure that beneficiaries are able to safely dialyze independently at home once complete. We do allow for additional retraining treatments under specific reasons detailed in the Medicare Claims Processing Manual (Pub 100–4, Chapter 8, section 50.8). We will consider this comment as we evaluate our training and retraining policies as we collect data.

Comment: An LDO indicated that CMS needs to ensure that it does not create a perverse incentive for physicians to start patients on a modality that is unlikely to succeed for them. The commenter does not observe an access barrier to home HD, and they noted that they do not turn away eligible patients from this modality. However, they are mindful of the long-term viability of this modality for many of their patients given the burdens it

places on them and their care partners. Rather than view home HD myopically as a stand-alone therapy as some in the dialysis community seek to do, they agree with CMS that home HD must be viewed in the broader context of the overall performance of the ESRD PPS.

Response: As we have previously stated, the decision about modality selection and location is determined by the patient and their physician. We rely on the physician to recommend home HD only for those patients who have the ability to learn the dialysis process and dialyze themselves at home, with the support of their ESRD facility.

Comment: One commenter pointed out that the 67 percent/33 percent weighting used in the calculation appears to assume that the dialysis training add-on payment is paid for in all PD training treatments, when, in fact, most are paid under the new patient adjustment, or more specifically, the onset of dialysis payment adjustment. The commenter urged CMS to recalculate the proxy to take into account only those PD training sessions that actually receive the training add-on payment rather than those that are paid under the new patient adjustment (onset of dialysis adjustment).

Response: When patients are in the onset of dialysis period (the first 4 months of dialysis), the ESRD facility receives the onset of dialysis adjustment and does not receive the training add-on payment adjustment. As a result, the calculation for the weighting ratio of PD included only PD treatments with the home dialysis training add-on payment applied which is what we understand the commenter to suggest. We believe that ESRD facilities correctly accounted for all PD treatments during training because they receive the full ESRD PPS base rate for training treatments rather than the HD-equivalent rate they receive for treatments after training is completed.

Comment: One commenter recommended that CMS provide for an annual inflation adjustment to the training add-on payment.

Response: In consideration of industry concerns about applying the training add-on in a budget neutral manner, we are not implementing an annual inflation update to the training add-on. Instead, we intend to monitor changes in the BLS data to determine if an update to the national average RN hourly wage is warranted. If we determine an update is necessary, we would propose a change to the training add-on and solicit public comments.

Comment: One organization commented that it would have been more appropriate for CMS to use the BLS RN salary for Outpatient Care Centers (Industry Group 621400) in the BLS Occupational Employment Statistics. Thus, the more appropriate wage proxy for renal nurses is the national mean hourly wage for RN (Occupation 29–1141) in the Outpatient Care Centers industry group. The commenter pointed out that the data collected by BLS are gross pay wages, excluding overtime, shift differentials, and employer cost of supplemental benefits.

Response: We agree that the BLS data provides various wages for RNs that we could have proposed to use for establishing an interim increase for the home dialysis training add-on and we are aware that the BLS data are gross wages, without supplemental benefits. We looked at many sources of wage data and selected the BLS because their Occupational Employment Statistics (OES) program provides comprehensive data on wages which is updated annually and identifies wages by setting. In CY 2011 when we first established the training add-on, we based the training add-on on the national RN average hourly wage because we believed that the training activities we were paying for were best reflected in that wage rather than any of the other categories BLS data includes.

We do not believe that use of the Outpatient Care Center group wage is a better reflection of the training performed by these RNs, and, for this reason, we are utilizing the BLS wage rate we proposed.

Final Rule Action: We are finalizing the proposal to base the payment for home dialysis training on 2.66 hours of treatment time ((.67 × 2 hours) + (.33 × 4 hours) = 2.66 hours) resulting in a training add-on payment of $95.60 (2.66 hours × $35.94 = $95.60). This provides an increase of $45.44 per training treatment (that is, $95.60 − $50.16 = $45.44). This approach provides a significant increase in payment for home dialysis training for CY 2017 while maintaining consistent payment for both PD and HD modalities. We intend to apply the above referenced payment amount, without adjustment, until we have empirical evidence for a change, which could increase or decrease the home dialysis training add-on payment amount. Additionally, we are also finalizing the home and self-dialysis training add-on budget neutrality adjustment factor.

3. Final CY 2017 ESRD PPS Update

a. Final CY 2017 ESRD Market Basket Update, Productivity Adjustment, and Labor-Related Share for the 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 proposed to reduce the amount of the market basket percentage increase by 1.25 percent and to further reduce it by the productivity adjustment.

We proposed 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 the IHS Global Insight (IGI), Inc. 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.

As a result of these provisions, and using 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), the proposed CY 2017 ESRD market basket increase was 0.35 percent. This market basket increase was 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) of the Act), 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, we proposed that 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.

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

We did not receive any comments on the proposed market basket update, multi-factor productivity (MFP) adjustment, or labor-related share.

Final Rule Action: As noted, the final CY 2017 market basket update and MFP adjustment in the ESRD PPS final rule will be based on the most recent forecast of data available. Therefore, using the most recent data available, the final CY 2017 ESRDB update is 0.55 percent. This is based on a 2.1 percent market basket update, less a 1.25 percent adjustment as required by section 1881(b)(14)(F)(i)(I) of the Act, as amended by section 217(b)(2)(A)(ii) of PAMA, and further reduced by a 0.3 percent MFP update. The CY 2017 ESRDB market basket update and MFP adjustment are based on the IGI 3rd quarter 2016 forecast with historical data through the 2nd quarter 2016.

b. The Final 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 Area (CBSA)-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 stated that we would continue to use the same methodology as finalized in the CY 2011 ESRD PPS final rule (75 FR 49117) for determining the wage indices for ESRD facilities. Specifically, we are updating the wage indices for CY 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 final CY 2017 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the final 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 discussed the findings in

detail in the CY 2017 proposed rule (81 FR 42817)

Therefore, for CY 2017, we solicited 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 did not propose to change the wage index floor for CBSAs in Puerto Rico, but requested public comments in which stakeholders can provide useful input for consideration in future decision-making. Specifically, we solicited comment on the useful suggestions that were submitted in last year's final rule (80 FR 69007) and reiterated above.

The comments and our responses to the comments for the proposal and solicitation are set forth below.

Comment: An LDO that operates 27 ESRD facilities in Puerto Rico pointed out that the continued gradual reduction in the wage index floor has impaired operations in Puerto Rico since all areas of the island have been subject to the floor due to low wage index values. This commenter appreciates CMS' recommendation to apply a wage index of .40 to areas with a wage index below the floor for CY 2017, but believes the Agency must do more. Until CMS is able to adjust the wage index used to calculate ESRD facility reimbursements and fully take into account the totality of circumstances challenging facilities operating in Puerto Rico, they recommend that the wage index floor be re-instituted at a level that will avoid a negative impact on dialysis facilities. They recommend that CMS consider using the wage index for Guam or the Virgin Islands as they are similar to Puerto Rico in their island and U.S. territory status. The commenter believed CMS' policy to utilize the same wage index as Guam for the Northern Marianas and American Samoa could serve as a precedent for doing the same thing for Puerto Rico. The commenter does not believe maintaining a wage index of 0.40 for CY 2017 in Puerto Rico is adequate to offset the poor economic conditions to which patients and dialysis facilities are exposed.

An organization of community stakeholders agreed, suggesting that CMS apply ESRD wage indexes in Puerto Rico that are consistent with other territories through the use of a temporary proxy. This group is requesting urgent administrative action from CMS. They are requesting that CMS: (1) Re-establish a fair and meaningful wage index floor given factual uncertainties and the demonstrated anomalies with the wage index for Puerto Rico; (2) Establish a temporary alternative wage index for Puerto Rico, given the observed disadvantage and the inconsistencies with the indexes used for other Territories; and (3) Ensure the corresponding adjustment in MA benchmarks for ESRD to secure the appropriate support to the Medicare program that serves 90 percent of all the Medicare A & B beneficiaries in Puerto Rico.

However, an industry organization expressed support for our current methodology for determining the wage indices and the continued application of the wage index floor of 0.4000.

Response: For the commenters that asked us to take an administrative action to establish a temporary alternative wage index value for Puerto Rico until we are able to correct the anomalies, we unfortunately, are unable to do so for several reasons. First, we did not propose an alternative to the wage indices for Puerto Rico based on reported hospital wage data. Rather, we presented various alternatives and requested public comment on those alternatives. We would need to have proposed changes to the Puerto Rico wage index in order to finalize a change in their wage index. With regard to the corresponding adjustment in MA benchmarks for ESRD to secure the appropriate support to the Medicare program, we note that this comment is beyond the scope of the proposed rule.

One of the commenters who addressed the proposed wage index alternatives expressed an interest in basing the wage indices for Puerto Rico CBSAs on the wage values applied to other U.S. Territories and another commenter suggested applying the wage value for the U.S. Virgin Islands. The only other recommendation was maintenance of the current floor of 0.4000 with no comment on the alternatives in the proposed rule.

When we developed the wage indices for the Pacific Rim territories in the CY 2014 ESRD PPS final rule (78 FR 40845), we applied 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. Those policies were finalized in the CY 2011 and CY 2012 ESRD PPS final rules (75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively). 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.

As we explained in the CY 2014 ESRD PPS final rule (78 FR 72172 through 72173), in the case of American Samoa and the Northern Mariana Islands, we determined that Guam represented a reasonable proxy because the islands are located within the Pacific Rim and share a common status as United States Territories. In addition, the Northern Marianas and American Samoa are rural areas with no hospital data. Therefore, we used the established methodology to compute an appropriate wage index using the average wage index values from contiguous CBSAs, to represent a reasonable proxy. While the islands of the Pacific Rim are not actually contiguous, we determined that Guam is a reasonable proxy for American Samoa and the Northern Marianas.

The primary difference between how we handled the wage index for the Pacific Rim islands and the situation in Puerto Rico is that we were able to rely upon existing policy for determining a wage index for areas with no hospital data for the Pacific Rim islands. We have hospital data upon which to base wage index values for Puerto Rico CBSAs, so our policy for CBSAs without wage index data does not apply to Puerto Rico, despite the fact that its, wage index data results in very low wage index values compared to other Territories and mainland CBSAs. This is a complex policy issue that cannot be resolved for CY 2017. We intend to continue analysis in this area so that we can address this issue in a future rulemaking.

Final Rule Action: After considering the public comments we received regarding the wage index, we are finalizing the CY 2017 ESRD PPS wage indices based on the latest hospital wage data as proposed. In addition, we are maintaining a wage index floor of 0.4000.

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. CY 2017 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 that were or would have been covered under Part D for outlier eligibility purposes and in order to provide unit prices for calculating imputed outlier services. In addition, we also identify through our monitoring efforts items and services that are either incorrectly being identified as eligible outlier services or any new items and services that may require an update to the list of renal dialysis items and services that qualify as outlier services, which are made through administrative issuances.

Our regulations at 42 CFR 413.237 specify the methodology used to calculate outlier payments. An ESRD facility is eligible for an outlier payment if its actual or imputed MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus the fixed-dollar loss amount. In accordance with § 413.237(c) of 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 used 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 proposed 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 proposed that 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 did not propose any change to the methodology used to compute the MAP or fixed-dollar loss amounts. Rather, we proposed 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 final 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 estimates for this final rule. The estimates for the final 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 final outlier policy forCY 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	$38.77	$47.00
Adjustments				
Standardization for outlier services	0.9951	0.9729	1.0078	0.9770
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$39.20	$50.81	$38.29	$45.00
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$62.19	$86.97	$68.49	$82.92
Patient months qualifying for outlier payment	5.8%	6.5%	4.6%	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; $82.92) 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 $45.00. For pediatric patients, there is an increase in the fixed-dollar loss amount from $62.19 to $68.49, and a decrease in the adjusted average MAP for outlier services from $39.20 to $38.29.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2017 will be 6.7 percent for adult patients and 4.6 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 0.93 percent of total payments, close to the 1 percent target. 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 final 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.

The comments and our responses to the comments for the proposal to update the outlier thresholds using CY 2015 data are set forth below.

Comment: A national industry organization stated they were pleased that CMS has refined the outlier pool to align the dollars paid out more closely with the estimated amount used to create the outlier pool. However, they noted that the alignment has not yet addressed the fact that the outlier pool is consistently paying out less than the amount removed from the base rate. Commenters estimate the outlier pool underpaid $0.68 per treatment in 2015. Other Medicare payment systems at times pay out less than the estimate and at other times pay out more. This fluctuation above and below the estimate indicates that the outlier pool amount is appropriate. The organization strongly encouraged CMS to further refine the outlier policy so that it is more consistent with how outlier policies in other Medicare payment systems work.

Other industry organization indicated that, since the outlier threshold has not been met since the implementation of the ESRD PPS and continues to fall short of 1 percent, CMS should propose a 0.5 outlier percentage for CY 2018. This 0.5 percent outlier percentage would reduce the offset to the base rate yet continue to provide payment for extraordinary costs. An MDO would prefer that CMS remove the outlier provision from the payment system, however, they understand that an outlier policy is statutorily required. Since CMS does not have the authority to remove the provision, they also suggested that the outlier percentage be reduced to 0.5 percent.

A professional association stated that they appreciate the efforts of CMS to recognize that the needs of all patients are not universally equal, and that a minority of patients will require treatments that carry markedly higher costs than the average ESRD patient. They support the concept of an outlier policy to sufficiently reimburse dialysis facilities for implementing necessary dialysis-related treatments to meet the needs of these patients and established therapeutic goals. However, in their view the outlier payments amount should equal the withhold amount.

As CMS continues to assess the outlier policy in future years, they suggested that future adjustments to the threshold for outlier payments be done annually to fully expend the withholding or adjust the withholding based on the running average expenditures from the prior 3 years (not to exceed 1 percent).

Response: We appreciate the commenters' support for the outlier policy. As we explained above, our analysis of ESRD PPS claims show that outlier payments reached 0.93 percent of the 1.0 percent outlier target in 2015. Specifically, outlier payments were made for 200,544 patient months, totaling $82,419,791 ($103,024,739 when including patient or secondary insurer obligations). For these patient months, outlier payments represented 17.2 percent of total Medicare ESRD payments. About 6,540 facilities received at least one outlier payment. Eighteen percent of outlier payments in dollars were received by independent

facilities and another 16 percent were received by facilities that were part of a multi-facility organization other than the three largest chains. As we stated in the CY 2016 ESRD PPS final rule (80 FR 69010), outlier payments are particularly important for small dialysis organizations and independent dialysis facilities because they often lack the volume of patients necessary to offset the high cost of certain patients. The 1.0 percent outlier target is small compared to outlier policies in other Medicare payment systems and was not designed to cover a large number of claims. As indicated in Table 1, we estimate that the percentage of patient months qualifying for outlier payments in CY 2017 will be 6.7 percent for adult patients and 4.6 percent for pediatric patients, based on the 2015 claims data.

Also discussed in the CY 2016 ESRD PPS final rule (80 FR 69010 through 69011) we acknowledge that the 1.0 percent target has not been achieved since 2011 primarily because our annual update of the fixed-dollar loss amounts and MAP amounts could not keep up with the continued decline in the use of outlier services (primarily ESAs). That is, facilities incurred lower costs than anticipated, and those savings accrued to facilities more than offsetting the extent to which the consequent outlier payments fell short of the 1.0 percent target. In last year's rule we stated that we believed that decline was leveling off, which would make our projections of outlier payments more accurate. Using the most recent data, we found outlier payments to come close to the 1 percent target (at 0.93 percent). Outlier payments may not have reached 1 percent during 2015 primarily due to patterns in ESA utilization. There is evidence in the 2015 claims of increased use of epoetin beta, which may have been used as a lower cost substitute for other ESAs (at a clinically equivalent dose) and contributed to a decrease in the average outlier service MAP amounts for 2015.

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

Final Rule Action: After consideration of the public comments, we are finalizing the updated outlier thresholds based on CY 2015 data.

d. Update of the ESRD PPS Base Rate for CY 2017

i. Background

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. Payment Rate Update for CY 2017

The ESRD PPS base rate for CY 2017 is $231.55. 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) of the Act, 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 final multi-factor productivity adjustment for CY 2017 is 0.3 percent, yielding an update to the base rate of 0.55 percent for CY 2017 ($0.85 - 0.3 = 0.55$ percent). Therefore, the ESRD PPS base rate for CY 2017 before application of the wage index and training budget-neutrality adjustment factors would be $231.66 ($230.39 \times 1.0055 = $231.66).

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 did not propose any changes to the methodology used to calculate this factor which is described in detail in CY 2014 ESRD PPS final rule (78 FR 72174). The CY 2017 wage index budget-neutrality adjustment factor is 0.999781. Therefore, the ESRD PPS base rate for CY 2017 before application of the training budget-neutrality adjustment factor would be $231.61 ($231.66 $\times$ 0.999781 = $231.61).

Home and Self-Dialysis Training Add-on Budget-Neutrality Adjustment Factor: Also, as discussed in section II.B.2.e of this final rule, we are establishing 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 0.999737, which is applied to the CY 2017 ESRD PPS base rate. This application yields a CY 2017 ESRD PPS base rate of $231.55 ($231.61 $\times$ 0.999737 = $231.55).

In summary, the final CY 2017 ESRD PPS base rate is $231.55. This amount reflects a payment rate update of 0.55 percent, the CY 2017 wage index budget-neutrality adjustment factor of 0.999781, and the home dialysis training add-on payment adjustment budget-neutrality adjustment of 0.999737.

The comments and our responses to the comments for the base rate proposals are set forth below:

Comment: Generally, commenters were supportive of the CY 2017 proposed base rate. One commenter contended CMS should increase the proposed ESRD base rate for 2017 positing that, as proposed, the base rate is too low for dialysis facilities—particularly small and medium facilities—working to provide high-quality, patient-centered care to this highly vulnerable adult and pediatric patient population. Another commenter supported CMS' continued labor-related share of 50.673 percent that recognizes the enhanced role of registered dietary nutritionists and other providers in improving outcomes and promoting therapy adherence, including dialysis treatments, dietary recommendations, and medication regimes.

Response: We appreciate the commenters' support of the CY 2017 proposed base rate. We also thank the commenter's support of the labor-related share and the perspective that it supports interdisciplinary staff roles in enhancing patient care. With regard to the comment on the base rate being too low for dialysis facilities, as discussed in section II.A.3, the base rate is updated annually by the ESRD bundled market basket. For CY 2017, CMS is mandated by legislation to reduce this increase by two factors. The first factor is the multi-factor productivity adjustment discussed in section II.B.3.d.ii. The second factor is a specified reduction amount determined in section 217(b)(2)(A) of PAMA. For CY 2017, this reduction is 1.25 percentage point. For CY 2018, the reduction will be 1.00 percentage point.

Final Rule Action: As stated above the final CY 2017 ESRD PPS base rate is $231.55.

4. Miscellaneous Comments

We received many comments from Medicare beneficiaries, family members, ESRD facilities, nurses, physicians, professional organizations, renal organizations, and manufacturers related to issues that were not specifically addressed in the CY 2017 ESRD PPS proposed rule. Some of these comments are discussed below.

Comment: A pharmaceutical company believes that the transitional drug add-on payment adjustment (TDAPA) should be paid for innovative therapies for at least 2 years so that innovation will not be stifled and ESRD patients will not be denied access to the benefits of improved clinical outcomes. This commenter also states that CMS should revisit and refine the drug designation process finalized in the 2016 ESRD PPS final rule and provide transitional add-on payment for new innovative products that are neither generic nor biosimilar to products already included within the ESRD PPS bundle. Another pharmaceutical company believes that CMS should use the TDAPA to incentivize the development of products that will prevent catheter-related bloodstream infections and clarify the anti-infective functional category to ensure that new drugs qualify for the TDAPA.

A congressional delegation also submitted a comment regarding the application of the TDAPA for an injectable drug that replaces iron and maintains hemoglobin in dialysis patients. An industry organization, an MDO, and a pharmaceutical company had similar concerns, adding that the benefits of new injectable drugs must be accounted for as an increase in the bundle, and specifically pointed to an injectable calcimimetic that has not received FDA approval to date.

An LDO and an MDO stressed that the drug designation policy is a critical issue for ESRD providers and urges CMS to confirm and clarify how the drug designation policy will be implemented. These commenters also asked for clarification regarding how payment for oral-only drugs that will be transitioned into the bundle as well.

Response: We appreciate and understand how important the implementation of this policy is and have begun developing the administrative guidance for the TDAPA which will be forthcoming. In the 2016 Final Rule (80 FR 69023), we explained that we anticipate that there may be new drugs that do not fall within the existing ESRD PPS functional categories and therefore, are not reflected in the ESRD PPS bundled payment. Where a new injectable or intravenous product is used to treat or manage a condition for which there is not a functional category, we would pay for the new injectable or intravenous product using a transitional drug add-on payment adjustment under the authority of section 1881(b)(14)(D)(iv) of the Act. We proposed that the transitional drug add-on payment adjustment would be based on the ASP pricing methodology and would be paid until we have collected sufficient claims data for rate setting for the new injectable or intravenous product, but not for less than 2 years.

With regard to the application of the TDAPA for an injectable anemia management drug, the anemia management functional category is one of the drug categories for which we have included dollars in the base rate and that has been updated with the annual ESRD market basket percentage increase factor. As a result, there is no separate transitional drug-add-on payment adjustment available for drugs and biologicals that manage an ESRD beneficiary's anemia. As we stated above, the transitional drug add-on adjustment payment is intended to capture those drugs and biologicals that are not reflected in the base rate. We note that drugs and biologicals that are accounted for in the ESRD PPS base rate could qualify as an outlier service when the manufacturer reports the Average Sales Price to CMS.

Comment: One patient expressed concern that copays for dialysis can be expensive on Medicare Part B, and the commenter would prefer to have a Medicare Advantage plan because of the out-of-pocket maximum. Another patient commented that his facility has told him that they are doing too many blood tests related to his polycystic kidney disease and that he may have to pay for them himself because Medicare will not. This commenter also states that he or she believes their treatment is not about patient care, but is about money and that his care team does not have compassion toward him.

Response: We are saddened to hear of these situations that beneficiaries have shared with us. We thank commenters for sharing their experience regarding the dialysis care they receive at their facilities, and we note that when care is less than desirable we encourage beneficiaries to reach out to their ESRD Network or Quality Improvement Organization (QIO) for their state. ESRD Networks were mandated by the Congress and are accountable for, among other things, assuring the effective and efficient administration of benefits, improving quality of care for ESRD patients, collecting data to measure quality of care, providing assistance to ESRD patients and facilities, and evaluating and resolving patient grievances. More information on the ESRD Networks is available on the CMS Web site: *https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations/index.html.* QIOs are groups of health quality experts, clinicians, and consumers organized to improve the care delivered to people with Medicare. QIOs work under the direction of the CMS to assist Medicare providers with quality improvement and to review quality concerns for the protection of beneficiaries and the Medicare Trust Fund. We value each of our beneficiaries and want them to receive the best care experience. We urge any beneficiary who requires assistance or

has a grievance to contact the ESRD Networks for help. The ESRD Network can also ensure that beneficiaries receive the care they need for their specific condition. With regard to joining a Medicare Advantage plan, they are open to ESRD beneficiaries under specific circumstances: (1) If you're already in a Medicare Advantage Plan when you develop ESRD, you may be able to stay in your plan or join another plan offered by the same company; (2) If you're already getting your health benefits (for example, through an employer health plan) through the same organization that offers the Medicare Advantage Plan; (3) If you had ESRD, but have had a successful kidney transplant, and you still qualify for Medicare benefits (based on your age or a disability), you can stay in Original Medicare, or join a Medicare Advantage Plan; and (4) You may be able to join a Medicare Special Needs Plan (SNP) for people with ESRD if one is available in your area.

Comment: An industry organization suggested refinements to the low-volume payment adjustment to address the rare change of ownership instance wherein the new owner accepts the provider agreement but the ownership change results in a new provider number because of provider type classifications. In this example, due to the issuance of a new provider number, this facility would be deemed ineligible for the Low-Volume Payment Adjustment (LVPA).

Response: We appreciate the commenter bringing this scenario to our attention; we will consider updating our policies and regulations to address this specific instance in the future.

Comment: A health system recommended that other professional specialties be allowed to bill for their services from the ESRD facility site of service. Because ESRD patients spend hours each week immobile while they receive their treatment, this would be an opportune time for patients to receive care from other specialists (cardiologists, psychiatrists, endocrinologists, vascular surgeons, etc.).

Response: We appreciate the commenter's suggestion for providing other specialties of care to beneficiaries while they receive dialysis. This is an interesting perspective that would require changes across programs, but it is one we will consider exploring in the future.

Comment: Several commenters expressed concern that the inaccuracy of the case-mix adjusters causes leakage from the ESRD PPS. Another commenter recommended that case-mix adjusters included in the payment system should be selected based on the policy goal of improving patient access and that some adjusters may work together while others may cancel each other out. The commenter encourages CMS to ensure that the adjusters truly cover the costs of providing care for those patients with more health care needs. Commenters also suggest that CMS eliminate the remaining four comorbid case-mix adjusters for the same reason that bacterial pneumonia and monoclonal gammopathy were removed. Additionally, another commenter suggested that CMS discard the changes made to the age categories in the CY 2016 final rule by returning to the CY 2015 methodology. These same commenters stated that CMS should address the way that the body size (that is, the low body mass index (BMI) and body surface area (BSA)) adjusters cancel each other out and ultimately benefit very few beneficiaries. Another commenter believes that using the age range of 70–79 as the reference age group is inappropriate since facilities would not receive an adjustment for this age range, however, they would receive an adjustment for patients between the ages of 60 and 69. This commenter also had concerns about the rationale for using both a BSA and a BMI adjustment and encourages CMS to adopt a BMI adjustment for overweight and underweight patients that will better account for costs of treatment.

Finally, another commenter urges CMS to reevaluate and update the pediatric case mix adjuster utilizing the most recent data available. This commenter elaborates that pediatric patients have an increased level of acuity of nursing care when compared to adult dialysis patients, these patients often need developmental or behavioral specialists, social workers or school-based specialists to assist with optimizing school performance, as well as increased assessments from dietitians to adjust formulas and diet for the patient's growth and nutrition requirements. The array of dialysis supplies required by these patients is also broader.

Response: With regard to the comments regarding the ESRD PPS refinement implemented in CY 2016, as we stated in the CY 2016 ESRD PPS final rule (80 FR 68974) we continue to believe that the CY 2016 updated model aligns with our goals for the prospective payment system in establishing accurate payments and safeguarding access for Medicare beneficiaries. We modeled the ESRD PPS using methodologies that were tested under the Basic Case-Mix Adjusted (BCMA) composite rate payment system and in using the most recently available data, we made our best estimate for predicting the payment variables that best reflect cost variation among ESRD facilities for furnishing renal dialysis services to a vulnerable population of patients. This refinement uses data that illustrates a fully bundled prospective payment system and reflects the practice patterns under such environment. We continue to believe that it would not be appropriate to both perpetuate certain payment adjusters into the future that were developed using pre-PPS data and update the other adjusters using ESRD claims data and cost reports from 2012 and 2013. We thank the commenters for their views about the pediatric case mix adjustment. We describe in the detail how we reevaluated and updated the pediatric case mix adjusters utilizing the most recent data available in the CY 2016 Final Rule (80 FR 69001).

Comment: One commenter expressed support for the ESRD PPS refinement based upon an updated regression analysis and established in the CY 2016 ESRD PPS final rule (80 FR 68973) and the low-volume and rural payment adjustments. This commenter agrees that these adjustments are necessary to ensure beneficiaries' access to services where they may otherwise lack dialysis options. This commenter also urged CMS to ensure that stagnation in the base rate does not negatively impact patient care, specifically with regard to payments to rural ESRD facilities and for facilities that treat pediatric patients. This commenter appreciates CMS' consideration of the potentially disproportionate impact of the ESRD PPS on those facilities. Another commenter stated that CMS should eliminate the rural adjuster and add a second tier, low-volume adjuster for facilities with 4,001–6,000 treatments per year. An industry organization expressed their concern that there is an incentive for facilities to limit access to specific locations in order to meet the requirements for the LVPA.

Response: We appreciate the support and agree that our diligence with regard to the base rate needs to be ongoing. We appreciate the useful suggestions for refining the LVPA from the commenters. However, significant changes to the eligibility criteria would need to be adopted through notice and comment rulemaking. We believe that the finalized CY 2016 policy changes represent improvement in the targeting of the payment adjustments. We will certainly consider these suggestions for future refinement. We plan to continue to monitor the utilization of renal

dialysis services furnished in low-volume and rural facilities.

Comment: An LDO commented that increasing costs and utilization of certain clinical diagnostic laboratory services have not yet been recognized through a corresponding adjustment to the base rate, which undermines the integrity of the ESRD PPS bundled payment.

Another LDO urged CMS to repair the underlying methodology of the ESRD PPS, which, based on their analysis, results in millions of dollars intended by CMS for patients' care to leak from the system. The organization stated that returning resources to the ESRD base rate will improve treatment for all Medicare dialysis beneficiaries, including home dialysis patients.

An industry organization commented that the ESRD PPS has underpaid providers by over $1 billion since 2011 and are predicting negative profit margins through 2018. The organization provided the same critique of the ESRD PPS regression methodology that they provided in response to the CY 2016 ESRD PPS proposed rule, reiterating their view that the ESRD PPS refinement regression methodology used by CMS violates the core assumptions for a valid analysis.

Response: As we stated in the CY 2011 ESRD PPS final rule (75 FR 49054), we included payments for all laboratory tests billed by ESRD facilities and independent laboratories for ESRD patients in calculating the final base rate in order to appropriately account for such tests as renal dialysis services. The ESRD PPS base rate is updated annually (as discussed in section II.B.3. of this final rule) by the ESRD bundled market basket. Therefore, we believe the base rate reflects price increases for laboratory renal dialysis services. With respect to increases in utilization of laboratory renal dialysis services, we continue to monitor utilization of laboratory services under the ESRD PPS and encourage ESRD facilities to report all laboratories services that they furnish. With regard to repairs to the ESRD PPS, we received comments of this nature last year and responded to them in the CY 2016 ESRD PPS final rule. As we stated in the CY 2016 final rule (80 FR 68974), we thoroughly reviewed these comments in consultation with our research team and other internal experts. We examined the outcomes of the current ESRD PPS specifically looking at access and quality of the PPS and based on our comprehensive monitoring of health outcomes and access under the ESRD PPS, we believe the current payment model has been successful in allocating payments across facilities and patients while supporting access and quality. While we recognize there can be theoretically optimal approaches to addressing payment model design, the availability of data is often an important factor in the approach ultimately undertaken. This is true with the ESRD PPS and the use of a two-equation model that relies on both claims and cost report data, as other payment systems do under Medicare.

Comment: One commenter expressed concern about the lack of transparency in the use of data regarding the factors used in calculating payments. Although they appreciate that CMS has made more data available, the commenters stated that there continue to be differences in the calculations between what providers believe is the correct amount to adequately care for ESRD patients and the ESRD PPS base rate. The best way to resolve the differences would be through full transparency by releasing all data and calculations used in development of payment rates and adjusters.

Response: Transparency is important to us. Therefore, we make the Limited Data Set (LDS) available with each rule. More information is located: *https://www.cms.gov/research-statistics-data-and-systems/files-for-order/limiteddatasets/standardanalyticalfiles.html*. We believe the data provided and the availability of technical reports explaining the methodology is sufficient to enable stakeholders to provide meaningful feedback, however, we have asked industry partners to identify specific instances in which the results of the calculations vary from what we have developed so that the CMS contractors can reconcile the variance.

Comment: Several commenters provided information on the barriers that they believe minimize the growth of home dialysis and gave suggestions on how to increase the utilization of home modalities. Commenters expressed concern about medical staff providing misinformation on home dialysis in an effort to keep new patients coming in-center for treatment rather than choosing home dialysis. They attributed this to poor patient education and improperly incentivized facilities. Other commenters suggested creating payment incentives to encourage home dialysis and stated whatever needs to be done to encourage people to take their dialysis home, should be done even if that means increasing payments to clinics for training. These commenters suggested that CMS fund wages and salaries for nurses and technicians to train because there is confusion and misinformation coming from medical professionals that scares patients away from home dialysis when they should be doing just the opposite.

One commenter noted that the U.S. Food and Drug Administration approvals for dialysis machines for home use require that the patient have a care partner who can assist in emergencies. This requirement prevents people who live alone (or whose care partner is temporarily absent) from doing home HD, and may place an undue burden on the family unit. The commenter believes that a dialyzer should be able to choose to perform home HD with or without a care partner, as their training and comfort level dictates. The ESRD facility should discuss with the patient the risks of dialyzing alone, assess the dialyzer's ability to perform his or her own treatments without assistance, and discuss alternate safety precautions available to the patient if the patient chooses to forego having a care partner.

One LDO expressed concern that some home HD machines are designed in such a way that the patient must dialyze more frequently than three times per week and has found that a significant number of patients ''burn out.'' That is, they begin therapy on home HD but later decide they cannot effectively manage such a complex task at home and choose to dialyze in-center instead. The LDO's own data indicate that the average year-over-year ''burn out'' rate for home HD is 42 percent, compared to 24 percent for their PD patients. The primary cause for the drop-off among home HD patients is the burden on the patient's care partner.

Another commenter suggested that CMS standardize the elements of the training manuals across dialysis machine manufacturers for patients. The commenter noted that they appreciated having a professionally written training manual, which was provided by one manufacturer, and believes that similar manuals would enhance dialyzer's confidence in what they were learning. Another improvement the commenter suggested is to require that training clinic managers be more experienced. The commenter described their experience of having a training clinic that only required 3 months of training experience for their clinical nurse managers. The commenter believes that this amount of training experience does not seem sufficient for them to manage their staff and know how to evaluate and improve their work. The commenter also suggested that CMS implement a requirement for ongoing home dialysis training because in the commenter's experience when some training clinics

re-write their procedures, the only people that find out about the changes, besides the nurses, are the new patients and the long-term dialyzers are not informed of things that could make their treatments more efficient or safer. The commenter also suggested an increase in training dollars for clinics expressing that in the long run, it is money well spent since the cost of home dialysis is less than the cost of dialyzing in center.

Response: The goal of our policy with regard to the treatment of ESRD is for ESRD facilities to provide the most appropriate care available for the beneficiary, whether in home or in-center. With the increased training add-on finalized in this rule, we hope that facilities will encourage home dialysis for beneficiaries who can benefit from it. Not all ESRD facilities are appropriately certified to provide training for home dialysis but we expect that if a beneficiary would like to receive home dialysis, the facility would refer the beneficiary to a home dialysis training facility. We encourage all ESRD facilities to be knowledgeable in all aspects of dialysis in order to educate beneficiaries. We appreciate the comments regarding barriers to home dialysis and will consider them for future policy changes, as appropriate.

Comment: One commenter stated that although patients often receive pre-dialysis education in group settings, they know of no one who has been trained to perform home HD in a group setting in recent years. The commenter expressed concern that CMS has received comments to the contrary, and wanted to indicate that such instances should be extremely rare in light of the Conditions of Participation and should not affect the calculation of the costs of home HD training.

Response: We appreciate the commenter's concern about the utilization of group training for home dialysis. As the commenter indicates, we have received many comments to the contrary and with this mixed information from the industry, we find that more analysis needs to take place in order for us to develop an appropriate methodology for computing the home dialysis training add-on based on updated cost report data.

Comment: We received comments from SDOs, healthcare investment companies, and a nursing facility company indicating the benefits of Skilled Nursing Facility (SNF)/Nursing Facility (NF) patients receiving their home HD in the SNF/NF. They highlight lower readmission rates, decreased lengths of stay, and improved social outcomes when patients receive dialysis in the SNF/NF as opposed to being transported to an ESRD facility. One commenter stated that their patients benefit greatly from staff-assisted, more frequent HD within their SNF.

Response: We recognize that receiving renal dialysis services in a SNF or NF can be beneficial to the patient. As we stated in the CY 2011 ESRD PPS final rule (75 FR 49057), nursing home patients are regarded as home dialysis patients because they are considered residents of the nursing home and receive dialysis treatments at the nursing homes and not at dialysis facilities. In addition, we note that the Medicare Benefit Policy Manual (Pub 100–02, chapter 11, section 40.D (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c11.pdf*)) indicates that Medicare ESRD beneficiaries who permanently reside in a nursing home or long term care facilities and who meet the home dialysis requirements set forth under 42 CFR 494.100 are considered home dialysis patients. All home dialysis items and services will be paid under the ESRD PPS and no separate payment will be made to the facility. Also in the Medicare Benefit Policy Manual we indicated in section 30.1.C that staff-assisted home dialysis using nurses to assist ESRD beneficiaries is not included in the ESRD PPS and is not a Medicare covered service. We appreciate the commenter's suggestions for furnishing renal dialysis services in a SNF or NF and will consider them for future rulemaking.

Comment: One dietician and nutritionist organization supports the ''implementation of the outlier statute'' and notes that registered dietitian nutritionists are able to assist in addressing the patient conditions that may increase facility costs when furnishing dialysis care and recommends that CMS make available the reimbursement for these services.

Response: Response: We appreciate the commenters bringing these services to our attention. We agree that dietary needs are very important in the multidisciplinary care for ESRD beneficiaries and will consider these comments for future policy refinement; however, it's unclear what the commenters mean by the ''implementation of the outlier statute''.

Comment: One dialysis equipment supplier commented on the Kidney Disease Education benefit and suggested that we allow regional training centers to have management contracts with ESRD facilities to provide the home dialysis training in a centralized location. They also recommended defining a minimally adequate form of modality education as well as a minimally acceptable frequency of administration, and link this to eligibility for the payment model. In addition they noted that programs focusing on educational efforts have historically been very effective. Studies of focused, unbiased ESRD modality education, offered in the months prior to dialysis initiation have demonstrated that nearly one third of patients begin home dialysis when they have completed a balanced education program. In the field of diabetes, the American Diabetes Association, the Association of Diabetes Educators, and other organizations have developed extensive tools, assessments, and professional standards to deliver the education required by CMS in the provision of Diabetes Self-Management Education. Unfortunately, this success has not generally extended to the education of kidney patients, where the Kidney Disease Education Benefit is historically underutilized and too narrow in scope to meet the needs of patients approaching dialysis. Thus, incident dialysis patient awareness and knowledge of self-management (home dialysis) treatment modalities is highly variable. The commenters believe that, without minimal standards, dialysis modality education will fall victim to provider priority conflicts or short-term economic disincentives. With demonstration of a balanced and effective chronic kidney disease education program as a baseline requirement, and with the percentage target of home dialysis utilization described above, the market will make training better and more consistent, allowing patients to make truly informed decisions and increasing the likelihood that patients choose and remain on a home dialysis therapy option.

Another commenter noted that home dialysis innovations are limited by the local scale of the provider census and the resultant experience of providers' training programs. In the current ESRD market, home dialysis training is a small percentage of the activity at any single center; therefore, the level of expertise needed to develop certain skills and cost benefits is unattainable for many. As an alternative to the current model, many have identified the need for regional home training centers that service a network of traditional dialysis centers. Yet regional training centers are not the norm because centers do not want to refer patients to other programs for fear of losing the patient and their corresponding revenue. The commenter stated that CMS should strive to

eliminate barriers to establishment of regional training centers. For example, modification of ESRD facility certification processes to allow for a CMS certified management service organization that provides transitional care, home dialysis training, and home dialysis ongoing management under a traditional management services construct could dramatically improve scale, skill, etc. The outsourcing of training and transitional care of incident patients or those moving from one modality to another would allow the ''home and transition care'' to be done in specialized programs that are contracted by the patients' originating centers. Coordination of care would occur naturally, as training centers could focus exclusively on the best means of providing home training and transitional care, without threatening the interests of patients' originating center in retaining home patients. Smaller centers, unable to support the requirements of home training services mandated by the Conditions for Coverage would likely be willing to refer patients for training, without fearing that their patients will be lost to another center. Under this paradigm, patients benefit by getting access to true centers of excellence for home dialysis training and support, physicians benefit by placing the care of their patients in the most expert hands, and providers benefit by having access to therapy services that may otherwise be economically infeasible due to scale, geography or other limiting factors.

Response: We appreciate the suggestions with regard to regional training centers and other training delivery models. While these comments are out of scope of this final rule, we will consider them for future rulemaking.

III. Final 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. 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 Social Security Act (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) of the Act 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) of the Act.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

The proposed rule, titled ''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'' (81 FR 42802 through 42880), was published in the **Federal Register** on June 30, 2016, with a comment period that ended on August 23, 2016. In that proposed rule, for the Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI), we proposed several payment policies in order to implement subsection (r) of section 1834 of the Act and the amendments to section 1881(s)(2)(F) of the Act. We received approximately 30 public comments on our proposals, including comments from ESRD facilities; national renal groups, nephrologists and patient organizations; patients and care partners; manufacturers; health care systems; and nurses.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the Coverage and Payment for Renal Dialysis Services Furnished to Individuals with AKI. Comments related to the impact analysis are addressed in the ''Economic Analyses'' section in this final rule.

C. Final 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 proposed 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) of the Act. 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) of the Act because the individuals do not have ESRD. We proposed to codify the statutory definition of individual with acute kidney injury at 42 CFR 413.371 and we solicited comments on this definition.

The comments and our responses to the comments for this proposal are set forth below.

Comment: Many individual commenters as well as dialysis nursing associations, dialysis industry associations, and a large dialysis organization supported the legislation allowing the coverage of and payment for renal dialysis services furnished to individuals with AKI in an ESRD facility. The commenters believe that it will decrease inpatient hospital lengths of stay and hospital-acquired infections, utilize the resources available in the outpatient setting, and that this access will be paramount to the care of beneficiaries with multiple co-morbidities, frequent procedures or diagnostics, and specialist visits. These commenters also believe that access to these services in ESRD facilities for beneficiaries with AKI is important in

the management of patients with delayed graft function post-kidney transplant when patients may need dialysis until the transplant begins to function. One individual commenter expressed gratitude that these policies will assist patients if their kidney disease progresses and they ultimately must make the emotional and clinical transition to maintenance dialysis at the ESRD facility.

Response: We appreciate the support and agree that these policies, described in detail below, provide individuals with AKI the option to receive dialysis in either the hospital outpatient department or, if able, in their community ESRD facility. We would like to note that this benefit is for beneficiaries already Medicare eligible, that have AKI and need dialysis. Specifically, needing dialysis for AKI does not entitle these individuals to Medicare and is not the same as being certified as ESRD and initiating life-sustaining maintenance dialysis.

Comment: Many commenters, including dialysis industry organizations and a health system, support the proposed definition of an individual with AKI. Industry organizations commended CMS for its recognition and acknowledgement of the unique acute medical needs of the AKI population, noting that AKI dialysis patients are, by definition, in a transitory state. The commenters indicated that utilization of renal dialysis services furnished to beneficiaries with AKI may substantially differ from that of patients with ESRD in other ways.

One industry organization commented that CMS should reaffirm the distinct needs of AKI patients and support the flexibility for physicians to determine the classification, frequency of treatment, and types of services provided to these patients. A dialysis organization stated that the most meaningful definition for an AKI patient would be ''a patient needing dialysis who does not require acute inpatient care for whom the nephrologist believes that there is a reasonable chance of kidney function recovery, and for whom the nephrologist therefore declines to sign the form 2728 (the physician's certification that a patient has reached stage 5 chronic kidney disease, or end-stage renal disease)''. A patient advocacy group recommended that CMS convene a technical expert panel of dialysis clinicians, nephrologists, and beneficiary organization to discuss how AKI patients can have guaranteed access to this new benefit.

Response: We appreciate commenter's support of the CMS definition of AKI. We also acknowledge the alternative definitions suggested. We continue to believe that the definition set forth in the statute provides an appropriate way to distinguish an individual with AKI from an individual with ESRD. We believe the broad nature of the definition ensures access to renal dialysis services in an ESRD facility to those beneficiaries that have an acute loss of renal function.

Final Rule Action: After review and consideration of our proposal, the statute, and the comments, we are finalizing § 413.371 as proposed in the regulation text 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) of the Act.

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) of the Act. We proposed 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. The ESRD PPS per-treatment base rate is 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) of the Act, 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 proposed to codify the AKI dialysis payment rate in our regulations at 42 CFR 413.372 and solicited comment on this proposal.

The comments and our responses to the comments for this proposal are set forth below.

Comment: A health system and an industry group support the proposed payment rate but believe that the AKI payment rate should not include legislative and policy decisions that directly impact ESRD PPS services, but not AKI services.

Response: We believe that the statute was clear in that we would pay ESRD facilities for renal dialysis services furnished to beneficiaries with AKI in the amount of the ESRD PPS base rate. Specifically, we believe the statute requires us to utilize the wage-adjusted ESRD PPS base rate as the payment rate for AKI. As discussed below, ESRD facilities will receive payment based on Part B fee schedules for other items and services that are not considered to be renal dialysis services. In addition, and also discussed below, there is no weekly limit on the number of treatments that will be paid. We continue to believe that these payment considerations are sufficient for Medicare payment of renal dialysis services furnished to beneficiaries with AKI and as these services evolve we can address any changes in future rulemaking.

Final Rule Action: Therefore, for CY 2017 and subsequent years, we are finalizing the AKI dialysis payment rate as set forth in § 413.372 as proposed.

The CY 2017 final ESRD PPS base rate is $231.55. Accordingly, we are finalizing a CY 2017 payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI as $231.55.

Comment: An industry organization commented that the ESRD Network fee should not be removed from the AKI payments since Networks focus on ESRD, not AKI.

Response: Thank you for bringing the ESRD Network fee portion of payment to our attention. We agree with the commenter that section 1834(r) of the Act, as added by section 808(b) of TPEA does not give CMS the authority to reduce the AKI payment rate by the 50

cent network fee. Specifically, section 1881(b)(7) of the Act provides that ''[t]he Secretary shall reduce the amount of each composite rate payment under this paragraph for each treatment by 50 cents . . . and provide for payment of such amount to the organizations (designated under subsection (c)(1)(A) of this section) for such organizations' necessary and proper administrative costs incurred in carrying out the responsibilities described in subsection (c)(2) of this section''. This language provides that (1) the reduction can only be taken from the payment provided for in section 1881(b)(7) of the Act—the composite rate—a payment system that was later subsumed by the ESRD PPS and (2) the reduction can only be used for the costs incurred in carrying out the network organization's responsibilities in (c)(2), which pertain to the ESRD population. After consideration of the comment and review of the statutory provision, we will not apply the per treatment reduction of $0.50 to the AKI dialysis payment rate.

Comment: MedPAC expressed concern regarding the payment rate variance for furnishing outpatient dialysis to AKI beneficiaries in a hospital outpatient department as compared to the ESRD facility and suggested that this variance may cause Medicare and beneficiaries to pay more than necessary. MedPAC suggested that CMS should not pay more in one setting versus another for the same treatment.

Response: We appreciate MedPAC's comments regarding site-neutral payment, however, section 808(b) of TPEA did not address payments to hospital outpatient departments for dialysis furnished to beneficiaries with AKI.

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) of the Act, as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. 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 proposed to apply the same wage index that is used under the ESRD PPS that is based on the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient prospective payment system that are unadjusted for occupational mix to the AKI dialysis payment rate. 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. We explained in the CY 2017 ESRD PPS proposed rule (81 FR 42821) that the AKI dialysis payment rate would be adjusted by the wage index for a particular facility in the same way that the ESRD PPS base rate is adjusted by the 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 proposed 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.

The comments and our responses to the comments for these proposals are set forth below.

Comment: Several commenters supported the proposal to apply the same wage index that is used under the ESRD PPS to the AKI dialysis payment rate.

Response: We appreciate the commenters' support.

Final Rule Action: We are finalizing application of the wage index to the AKI dialysis payment rate and the accompanying regulation at § 413.372(a) as proposed.

4. Other Adjustments to the AKI Payment Rate

Section 1834(r)(1) of the Act 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) of the Act) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act. For purposes of payment for AKI dialysis, we did not propose 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 did not propose to apply any of the optional payment adjustments under subparagraph (D) of section 1881(b)(14) of the Act. We proposed to codify our authority to adjust the AKI payment rate by any of the adjustments under section 1881(b)(14)(D) of the Act in our regulations at 42 CFR 413.373.

The comments and our responses to the comments for these proposals are set forth below.

Comment: A large dialysis organization and dialysis industry associations supported CMS' decision not to apply ESRD-based case-mix adjusters to the AKI dialysis payment rate. Another dialysis industry group explained that the ESRD case-mix adjusters were not designed to target the costs involved in treating individuals with AKI.

A health system disagreed with the CMS' proposal of paying the ESRD base rate with no adjustments and expressed that the AKI patients cost substantially more than ESRD patients. The commenter suggested that CMS develop an AKI adjustor to be applied to the ESRD PPS base rate. A dialysis industry association suggested that in the future, CMS apply patient and facility-level adjustments to the AKI dialysis payment rate, similar to how CMS adjusts for ESRD beneficiaries.

Response: We appreciate the thoughtful comments on the adjustments to the ESRD PPS base rate applicable to the AKI dialysis payment rate and we will consider the suggestions for future rulemaking. As discussed above, the AKI dialysis payment rate will be the finalized ESRD PPS base rate adjusted by the wage index that is used under the ESRD PPS. We are not adjusting the payment amount by any other factors at this time, but may in future years.

With regard to the higher costs associated with AKI patients as compared to ESRD patients, we are finalizing a policy of paying for all treatments provided to a patient, without applying the monthly treatment limits applicable under the ESRD PPS. We are also finalizing a policy to pay separately for all items and services that are not part of the ESRD PPS base rate. Once we have substantial data related to the AKI population and its associated utilization, we will determine the appropriate steps toward further developing the AKI payment rate.

Final Rule Action: After consideration of the comments we are finalizing our authority to adjust the AKI dialysis payment in the regulations text at § 413.373 as proposed.

Comment: One individual commenter asked CMS to clarify how treatments for patients with AKI would count toward the attestation for the Low-Volume Payment Adjustment (LVPA) and asked if the 4,000 limit should be increased to account for the impact of this new policy.

Response: Since the implementation of the LVPA, we have indicated that for purposes of determining eligibility for the LVPA (defined in § 413.232(b)), ''treatments'' mean total hemodialysis

equivalent treatments, that is, Medicare and non-Medicare. Since the total treatment count includes all treatments furnished by the ESRD facility regardless of payer, we believe that AKI dialysis treatments also count toward the number of treatments furnished by an ESRD facility and should be reported to the MAC in the facility's attestation for the LVPA. More information regarding the eligibility criteria of the LVPA is available in the Medicare Benefit Policy Manual (Pub 100–02, chapter 11, section 60.B.1 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c11.pdf*)). At this time, we do not believe that the eligibility criteria for the LVPA need to be changed, however we will monitor utilization of the LVPA for future refinements. Facilities should include AKI dialysis treatment in their counts for purposes of the LVPA.

5. Renal Dialysis Services Included in the AKI Payment Rate

Section 1834(r)(1) of the Act provides that the AKI 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. We proposed 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 proposed 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 proposed to 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 proposed to pay for these items and services separately when they are furnished to beneficiaries with AKI receiving dialysis in ESRD facilities. We proposed to codify this policy at 42 CFR 413.374(b).

The comments and our responses to the comments for these proposals are set forth below.

Comment: Generally, commenters agreed with the proposal to consider renal dialysis services as defined in § 413.171 to be renal dialysis services for AKI patients. However, some commenters expressed concern that over time the adequacy of the ESRD PPS base rate for such services may be questionable. Specifically, dialysis nursing organizations, an individual, and an LDO commented that it is important for CMS to recognize that AKI patients utilize treatments, drugs, labs, and other services differently than ESRD beneficiaries. For example, AKI patients may require more frequent laboratory services, antibiotic administration, and infection monitoring. The commenter further warned that these patients may be more likely to miss treatments due to recurrent illnesses, hospital-based treatments, or debility. The commenters suggested that CMS work with the dialysis community to determine if the AKI payment rate should be adjusted for adequacy as a result of more frequent utilization in the future.

The commenters cautioned CMS that when analyzing historic utilization that the data may not be representative of the actual prevalence of AKI patients who require dialysis. A dialysis industry association urged CMS to closely track the utilization of items and services that patients with AKI dialysis receive that are in the bundle because the utilization could be higher.

A dialysis industry organization supported CMS' decision not to modify payment until there is more experience with these patients in the ESRD facility setting. Another dialysis industry organization concurred with CMS' intent to monitor separately billable services for appropriate utilization and urges CMS to strike a careful balance between monitoring and recognizing that utilization will be higher. A different dialysis industry organization commented that CMS should reaffirm the distinct needs of AKI patients and be supportive of flexibility for physicians to determine AKI versus ESRD classification, frequency of treatment, and the types of services provided.

Response: We appreciate the comments from stakeholders regarding the utilization of drugs, labs, and other services by patients with AKI. We continue to believe that since the basis of payment is the ESRD PPS base rate, payment for renal dialysis services is accounted for through the per treatment AKI dialysis payment rate. Additionally, as discussed below, other items and services furnished to beneficiaries with AKI are separately payable.

We acknowledge the commenters' concerns regarding AKI patients' more frequent use of renal dialysis services when compared to ESRD beneficiaries. We encourage the reporting of all items and services furnished to beneficiaries with AKI. We also expect ESRD facilities to continue to report all services that are furnished to ESRD beneficiaries. We plan to monitor the utilization of these items and services to support any necessary changes in future rulemaking.

With regard to the flexibility for physicians to determine when an AKI patient has regained kidney function, or whether the transition must be made to ESRD treatment, we agree that this is a medical decision that should be supported by lab tests and a dialysis scheduling protocol, including withdrawing dialysis to determine the extent of recovery of renal function. The goal of AKI should be to have the kidneys return to normal functioning.

Comment: Several commenters, including dialysis industry associations and large dialysis organizations, are supportive of the CMS proposal to pay separately for 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.

Response: We appreciate the support on this issue. We continue to believe what commenters have explained, that AKI patients have various treatment needs and outcomes that may not be the same as an ESRD patient. We acknowledge that this distinction between the two populations is important and will monitor the

utilization of items and services along with health outcomes.

Final Rule Action: After consideration of public comments, we are finalizing in § 413.374(a) 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 are also finalizing in § 413.374(b) that 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.

D. 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 did not propose 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 proposed to allow ESRD facilities to furnish vaccines to beneficiaries with AKI and bill Medicare in accordance with billing requirements in the Medicare Claims Processing Manual (Pub. 100–04, Chapter 18 Preventive and Screening Services, section 10.2 which is located on the CMS Web site: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c18.pdf*). We solicited comment on the proposal for ESRD facilities to administer vaccines to beneficiaries with AKI.

The comments and our responses to the comments for these proposals are set forth below.

Comment: Many commenters, including dialysis nursing organizations, dialysis organizations, and dialysis industry associations applauded CMS for proposing to pay for all treatments provided to AKI patients in a week and suggested that we finalize the policy as proposed. One dialysis physician association and a couple of dialysis organizations requested that CMS clarify that both peritoneal dialysis (PD) and hemodialysis (HD) modalities will be available to these patients and that the beneficiaries should be allowed to complete their PD treatment at home.

Response: We thank the commenters for their support. We continue to believe and expect to continue to see through monitoring initiatives that individuals with AKI will only need dialysis for a finite number of days while they recover from kidney injury. As we stated above, we recognize that the intent of dialysis for patients with AKI is curative as opposed to long term. Therefore, we are finalizing the policy to provide payment for all hemodialysis treatments furnished to beneficiaries with AKI in a week, even if the number of treatments exceeds the 3 times-weekly limitation we apply to HD treatments furnished to beneficiaries with ESRD.

With regard to the commenter's concern regarding modalities, we agree with commenters that individuals with AKI should have the ability, if they are candidates, for other modalities of dialysis while they are in the facility. Therefore, in response to commenters we will apply our policy of payment for AKI dialysis to both in-center PD and HD. We are finalizing payment for both of these dialysis modalities furnished to individuals with AKI in a week, including peritoneal dialysis when clinically appropriate, when the dialysis is furnished in the ESRD facility. Further discussion regarding home dialysis is below.

Comment: Many commenters supported the policy proposals regarding uncompleted dialysis treatments and vaccine administration. One dialysis industry organization requested additional clarification in regard to the ESRD policies that do not apply to AKI. Another dialysis industry group encouraged CMS to work with the community to understand the specific treatment needs of this population.

Response: We thank the commenters for their support regarding our policies on vaccine administration and uncompleted treatments. We are finalizing these policies as proposed.

With regard to the commenter's suggestion to clarify the ESRD policies that do not apply to AKI, as we stated below, we anticipate that most of the policies laid out in Chapter 8 of the Medicare Claims Processing Manual will also apply to claims for dialysis furnished to individuals with AKI. In the timeframe available for the implementation of the payment for dialysis furnished to individuals with AKI, we believe that it is prudent to move into CY 2017 with payment policies that ESRD facilities are accustomed to following. As we monitor utilization of renal dialysis services and other items and services that the ESRD facilities furnish to individuals with AKI, we plan to engage the dialysis community to determine through rulemaking the continuation or discontinuation of certain policies which are or are not applicable to this population.

Comment: One dialysis industry association urged CMS to consider adding renal dialysis services furnished to individuals with AKI to the list of telehealth eligible services.

Response: Telehealth services are Part B benefits that are outside of the scope of the ESRD PPS, and therefore, outside of the scope of this final rule. We note that telehealth dialysis services are limited to renal dialysis services for home dialysis patients. For more information on telehealth services, we refer readers to the Medicare Claims Processing Manual Chapter 12, section 190. (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf*). As discussed below, we do not believe at this time that it is appropriate for individuals with AKI to be trained to perform home dialysis. The dialysis industry has repeatedly shared with us

that this population of patients is unstable and needs close physician supervision while they receive renal dialysis services. The literature characterizes this population as needing meticulous attention to fluid, acid-base, and electrolyte balance, as well as the removal of uremic toxins (*http://www.uptodate.com/contents/use-of-peritoneal-dialysis-for-the-treatment-of-acute-kidney-injury-acute-renal-failure*).

Comment: A dialysis industry association suggested that CMS use the data when dialysis is initiated for individuals with AKI for purposes of determining transplant wait-list priority status and Medicare entitlement for patients who transition from AKI to ESRD. This commenter urged CMS to explicitly include the transplant recipients who develop AKI and need dialysis after having a functional allograft, in the rules governing delivery of care, reporting, and conditions for coverage for individuals with AKI and on dialysis as they believe the restoration of allograft function in transplant recipients with AKI dialysis is a critical outcome.

Response: We appreciate the comments related to individuals with AKI dialysis and kidney transplantation as well as the request for clarification. If an individual has had a kidney transplant and is just receiving temporary dialysis for AKI, then facilities could receive payment for their services under the AKI benefit, provided the beneficiary meets the criteria for being an AKI patient. If however, the beneficiary is a kidney transplant recipient and they're beginning a regular course of dialysis because their ESRD has returned, then they'd be entitled to the ESRD benefit. Dialysis furnished to kidney transplant recipients would be covered, whether the dialysis is necessary because of AKI or ESRD. With regard to AKI beneficiaries who develop AKI after having a functional allograft and need dialysis. We note that payment would be made for dialysis furnished to these beneficiaries under this policy.

Comment: An individual commenter believes that CMS should not restrict renal dialysis services furnished to individuals with AKI to the ESRD facility and should allow for home dialysis. They believe that this particularly impacts patients with ambulation problems, with an immunosuppressed status, or those that reside in a long term care facility. This comment is in direct contrast to a comment received from a patient advocacy organization, a large health system, a dialysis industry association, and dialysis nursing organizations who agree with our proposal to limit AKI dialysis to in-center treatments since most AKI patients will not use home dialysis because the modality takes time to initiate. An LDO suggested that CMS specifically define requirements for patients that reside in a facility that could be designated as a home. A dialysis industry organization requested that CMS reconsider a blanket rejection of home dialysis care pointing out that PD, initially begun in the facility, could be appropriate in the home and would be particularly helpful to patients for whom transportation is a challenge.

Response: We appreciate the feedback regarding allowing AKI patients to dialyze at home. This policy decision is one that we will monitor for future changes. Multiple sources in the industry, however, including, physicians, patient advocacy groups, and dialysis organizations of all sizes, have communicated to us that this population of patients is unstable. Some commenters stated that patients require close attention while they receive their dialysis, which is why alternatively the service was primarily available in the hospital outpatient setting prior to the TPEA amendments. In addition, based on the data we have received, at this time we believe that this population will dialyze primarily in an ESRD facility. Therefore we are finalizing as proposed. However, as we gather data on the AKI population and the extent of home training necessary to safely self-administer PD in the home, we may consider the use of PD in the home for the AKI patient in the future as we may find that there are be subsets of patients whose injury may lend itself, after an initial treatment period, to PD in the home. (*http://www.uptodate.com/contents/use-of-peritoneal-dialysis-for-the-treatment-of-acute-kidney-injury-acute-renal-failure*).

Final Rule Action: We will keep this option as one to consider in the future.

E. 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 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 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.

The comments and our responses to the comments for this approach are set forth below.

Comment: An LDO and dialysis industry associations encouraged CMS to consult with stakeholders regarding monitoring of these patients and to also be transparent regarding AKI utilization data collected for payment and delivery of AKI services. Another dialysis industry association appreciated that CMS recognizes the importance of monitoring and suggests that a monitoring add-on payment is appropriate. A third dialysis industry association commented that nephrologists and other dialysis caregivers should implement active measures to promote and to monitor renal recovery.

Response: We appreciate the support on this issue. We will be developing formal monitoring programs for utilization to inform future payment policy. When we refer to monitoring, we are referring to data review based on claims data, not physician monitoring. Physician oversight for these beneficiaries would be included in the AKI dialysis payment rate or payable through the appropriate fee for service benefit, if not a renal dialysis service. We will develop public use files for the utilization of these services, but do not anticipate that this data will be available for at least 1 year. If stakeholders have data, we would welcome the receipt of that data.

F. 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 proposed 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 (Pub. L. 114–27, June 29, 2015) (TPEA), and are finalizing this change as proposed.

We did not propose changes to the CfCs specific to AKI, but did request comment from the dialysis community as to whether revisions to the CfCs might be appropriate for addressing treatment of AKI in ESRD facilities. We received 11 timely comments addressing this issue and thank the commenters for their input. While we are not formally responding to the comments at this time, the comments are summarized (with some clarification on our part), below.

All commenters agreed that we do not need to revise the ESRD CfCs to address AKI at this time. About half of the commenters recommended that we not revise the CfCs to directly address AKI at all, while the remaining commenters suggested we consider revisions to requirements addressing the comprehensive patient assessment, care planning, modality options, and transplantation. A few commenters recommended that we not revise the ESRD CfCs to address AKI because AKI and ESRD are different diseases. We understand the reasoning behind this statement but wish to clarify that the ESRD CfCs apply to ESRD *facilities,* not to ESRD *patients,* and note that the ESRD CfCs would be the appropriate regulatory location for standards addressing care provided to AKI patients in ESRD facilities.

We thank the commenters, and will consider their comments for future rulemaking and regulatory guidance.

G. 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.

The comments and our responses to the comments for these proposals are set forth below.

Comment: Industry organizations, an LDO, and an MDO made claims processing and cost report modification suggestions. Another industry organization commented that reimbursement policy should be clearly and unequivocally conveyed to all MACs. Another industry organization agrees with the creation of a specific payment code and corresponding Current Procedural Terminology code to distinguish AKI patients from ESRD patients. Another industry organization made suggestions for modifications to the cost report. Yet another industry organization suggested the CMS develop an intake form, a treatment form, and a recovery form with data elements specific to AKI.

Response: We appreciate the thorough and thoughtful responses provided in regards to claims processing and cost report changes. We have completed a similar analysis and administrative guidance will be forthcoming. The usage of other forms will be considered for future updates as well.

H. 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 proposed 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 welcomed comments on announcing the AKI payment rate for future years.

The comments and our responses to the comments for this proposal are set forth below.

Comment: We received several comments from industry organizations encouraging CMS to allow for notice and comment rulemaking when updating the AKI payment rate.

Response: Because we believe we are required under section 1834(r) to utilize the ESRD PPS base rate as adjusted by the wage index, we do not believe it is necessary to adopt that rate through notice and comment rulemaking as we don't believe we have discretion to adopt an amount other than that, except to the extent that we apply other payment adjustments to that amount. As noted above, any methodology changes or payment adjustments that are applied to the AKI dialysis payment rate will be adopted through notice and comment rulemaking.

Final Rule Action: We are finalizing the announcement of the AKI payment as proposed and revising the regulations text at § 413.375 to reflect this proposal.

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 final rule discusses each of these elements and our policies for their application to the ESRD QIP.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)

The proposed rule, titled ''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'' (81 FR 42802 through 42880), was published in the **Federal Register** on June 30, 2016, with

a comment period that ended on August 23, 2016.

In that proposed rule, for the ESRD QIP, we proposed updates to the ESRD QIP, including updates for the PY 2018 through PY 2020 programs. We received approximately 50 public comments on our proposals related to the ESRD QIP, including comments from large dialysis organizations, ESRD facilities; national renal groups, nephrologists, patient organizations, patients and care partners, manufacturers, health care systems; nurses, and other stakeholders.

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

We received comments about general policies and principles of the ESRD QIP. The comments and our responses are set forth below.

Comment: Many commenters expressed concern about CMS' continued reliance on process measures and recommended that CMS seek to use risk-adjusted outcome measures that capture the effective management of dialysis patients. Commenters stressed that CMS should strive to adopt evidence-based measures that promote the delivery of high-quality care and improved patient outcomes. Commenters also stressed the importance of working with stakeholders in the nursing community when developing and implementing measures because nephrology nurses in particular are integral to the collection and processing of quality improvement data and it is vitally important to represent their perspective during the measure development and implementation process.

Many commenters raised particular concerns about the lack of measures in the QIP that adequately address the needs of the pediatric population or of home hemodialysis patients. They argued that the current measurement criteria do not take their unique needs into consideration. Commenters asked CMS to ensure that the reporting structure is viable for all providers, whether they service patients in-center or at home. Many of the smaller facilities enter data manually into CROWNWeb, and commenters argued that given the current structure of the QIP, many pediatric facilities in particular are unable to participate. They recommended that CMS focus its attention on aligning quality metrics and value-based programs with the goal of achieving a high quality of care for pediatric patients. One commenter argued that it is counter-productive to subject providers who care for unique populations to penalties for not achieving results which are unrealistic in their populations.

Response: We appreciate the commenters' commitment to the adoption of evidence-based measures that address high-quality care and improved patient outcomes. We share this commitment, which is why we've made an effort to incorporate measures that address patient experiences of care, readmissions and hospitalizations, and bloodstream infections. We hope to continue this trend in the future. We are cognizant of the issues around adequately assessing the quality of care provided for pediatric and home hemodialysis patients and we continue to investigate options to more effectively incorporate measures relevant to those patient populations. We continue to believe that existing data sources used to capture data for calculating ESRD QIP measures, (that is, CROWNWeb and NHSN) are viable for facilities that provide home as well as in-center hemodialysis, because they utilize web-based applications that can be accessed with a personal computer. Facilities providing home dialysis should also not experience any undue burden using claims to report clinical data if they are also able to submit claims for reimbursement.

Comment: One commenter questioned why CMS believed it was necessary to develop Dialysis Facility Compare in addition to the QIP, because the commenter believes having two quality systems may lead to confusion for beneficiaries and their families. The commenter recommended that CMS align measurement methodologies and reporting requirements across CMS ESRD quality programs or, in the alternative, move toward using one quality measurement system that could be based on a reasonable number of outcomes-based performance measures as this would reduce administrative costs and confusion.

Response: The ESRD QIP and Dialysis Facility Compare program have different purposes, which in certain cases necessitates divergent measure specifications and scoring methodologies. However, we continuously review measure specifications and scoring methodologies across the programs and will continue to create alignments where appropriate. The recently developed ESRD Measures Manual may help ease some of the confusion for facilities because it provides a comprehensive list of detailed measure specifications. The ESRD Measures Manual can be found here: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/CMS-ESRD-Measures-Manual-Final-v1_0.pdf*.

Comment: One commenter sought additional information about whether any data collected under the ESRD QIP measure set shows the impact of these measures on patient outcomes or Medicare spending on patients with ESRD.

Response: We thank the commenter for their question. Unfortunately, with so many interdependent factors influencing the quality of care provided at dialysis facilities (for example, payment policies in the prospective payment system, FDA labeling policies, and independent advancement in the treatment of ESRD), it is difficult to disentangle the impact of ESRD QIP policies from other policies and developments in the field. CMS is actively monitoring the impact of ESRD QIP measures on the quality of care received by patients with ESRD, and has yet to identify any unintended consequences caused by policies or measures implemented by the program. In the future, as more studies are conducted and results become available, we will consider releasing these types of monitoring studies for review by the community.

One objective measure we can examine is the improvement of performance standards over time. Table 2 below shows that as the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the program, performance standards have generally continued to rise. We view this as evidence that facility performance is objectively improving. It remains difficult to disentangle these results from the impact of the ESRD QIP policies or those of other policies and developments in the field, but they show a steady rise in the quality of care received by patients with ESRD.

TABLE 2—IMPROVEMENT OF PERFORMANCE STANDARDS OVER TIME

Measure	PY 2015	PY 2016	PY 2017	PY 2018	PY 2019
Hemoglobin > 12 g/dL	1%	0%			
Vascular Access Type:					
% Fistula	60%	62.3%	64.46%	53.51%	53.72%
% Catheter	13%	10.6%	9.92%	16.79%	17.06%
Kt/V:					
Adult Hemodialysis	93%	93.4%	96.89%	91.08%	.....
Adult, Peritoneal Dialysis	84%	85.7%	87.10%	75.42%	.....
Pediatric Hemodialysis	93%	93%	94.44%	84.16%	.....
Pediatric Peritoneal Dialysis	.....	.....	.....	43.22%	.....
Hypercalcemia	.....	1.7%	1.30%	3.92%	4.21%
NHSN Bloodstream Infection SIR	.....	.....	.....	1.812%	1.812
Standardized Readmission Ratio	.....	.....	0.996	0.996	1.276
Standardized Transfusion Ratio	.....	.....	.....	1.470	1.470

Comment: One commenter expressed concerns that if the ESRD QIP continues to take payment reductions from facilities, some facilities may be forced to close. They added that accountability for the outcomes facilities can influence is appropriate but it is important that CMS not become overzealous in its implementation of new measures.

Response: Section 1881(h) of the Act requires that we implement the ESRD QIP program each year. We have carefully constructed policies related to each of the requirements specified in Section 1881(h). Our policies related to payment reductions for the ESRD QIP have been constructed 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. The largest payment reduction the ESRD QIP applies is 2 percent of a facility's total payment for the year. Additionally, we finalized a Small Facility Adjuster which ensures that small facilities are not adversely impacted by their small number of patients or by any outlier patients who may adversely impact their scores on quality measures included in the program. We believe the ESRD QIP's scoring methodology combined with payment reductions is the best way to ensure that facilities are held accountable for the care that they provide and are only penalized for providing care to their beneficiaries which does not meet a certain threshold. 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.

Regarding commenter's concern that facilities may be forced to close based upon the ESRD QIP's payment reductions, we have reviewed data on facility closures from 2008 through 2013 and we have seen a steady decrease in the number of facilities that have closed from 80 in 2010 to 56 in 2013. We recognize that the absolute number rose slightly from 45 in 2012 to 56 in 2013. However these numbers must be looked at in context. As a percentage of the total number of dialysis facilities nationwide, the number of facilities closing each year is not significant. Additionally, facility closures cannot be definitively attributed to any single factor. The ESRD QIP policies may play a small role in these numbers, but many other factors, both within and outside of healthcare, have an impact. Table 3 below shows the number of facilities closed from 2008 through 2013.

TABLE 3—ESRD FACILITY CLOSURES, 2008 THROUGH 2013

Closed facilities					
2008	2009	2010	2011	2012	2013
50	82	80	72	45	56

Comment: Several commenters expressed concerns about the number of measures included in the QIP and about the addition of more measures, and argued that too many measures dilute the impact of quality programs. One commenter suggested that with the current measure set, patients are no longer being held responsible for their own care and urged CMS to consider more measures that assess patient compliance with treatment and medication. Another recommended that CMS look into developing a system to allocate Medicare benefits for patients depending on their responsibility in their medical treatment and care. One commenter argued this dilution of measure impact is evidenced by a close examination of the measure weights CMS proposed for PY 2020. Specifically, the small percentage assigned to each measure means that critical measures such as reducing catheter use are weighted in a similar manner to measures of less importance, such as the hypercalcemia clinical measure, which is ''topped out'' under the criteria previously finalized by the ESRD QIP. Commenters encouraged CMS to refrain from continuing to develop more measures and instead to work on finding a small set of measures to use in the program on an ongoing basis. One commenter encouraged CMS to pause its measure-development efforts in favor of working with the entire kidney care community (as opposed to a small group of TEP members) in order to identify a small set of core measures that matter. Commenters recommended that new measures be limited to evidence-based outcomes measures that promote the delivery of high-quality care and improved patient outcomes, and that they should be the most impactful measures. One commenter also stressed

that CMS should consider which measures might be ready to be retired from the program, and they pointed out that critically important measures, such as the VAT: Catheter measure, are competing for percentage points with other measures that have less clinical significance to patients. This work would likely require addressing some of the underlying problems with existing measures. For example, commenter urged CMS to focus on developing a new bone mineral metabolism measure before pursuing other measure development to make sure the statutory requirement in PAMA is met.

In developing this core set of measures, commenters urged CMS to adopt a set of minimum global exclusions that would be automatically applied to all measures. Specifically, they recommended the following exclusions: (1) Beneficiaries who die within the applicable month; (2) Beneficiaries who receive fewer than 7 treatments in a month; (3) Beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented good faith effort to have them participate in such a visit during the applicable month; (4) Transient dialysis patients; (5) Pediatric patients (unless the measure is specific to pediatric patients); and (6) Kidney transplant recipients with a functioning graft. Additionally, commenter asked that CMS clarify that beneficiaries must have treatment for at least 60 days to be assigned to a facility. One commenter added that CMS should particularly consider the needs of small facilities, pediatric patients, and patients who have received a transplant when developing exclusions which would apply across the board.

Response: We understand that there are a number of measures we proposed to be added to the ESRD QIP for PY 2019 and PY 2020. Although we recognize that adopting more measures in the ESRD QIP increases costs to facilities as well as CMS, we believe these increased costs are outweighed by the benefits to patients of incentivizing quality care in the domains that the measures cover. We are constantly re-examining the measures that are included in the program to ensure that they are capturing a variety of information about the care that patients receive, and we carefully consider whether measures should be retired from the program. In an effort to ensure that the impact of the program is not diluted and that each measure receives an appropriate weight, we are finalizing changes to the weighting of measures and of the measure domains for both PY 2019 and PY 2020. We believe the weights we are finalizing will preserve the program's strong incentives for facilities to achieve high scores on the clinical measures and to fully and accurately report data for the reporting measures. In future years of the program, we will consider the feasibility of including measures that assess patient compliance with treatment and medication.

As we stated in the CY 2015 ESRD PPS Final Rule (79 FR 66164), we considered applying these six global exclusion criteria in response to comments on the CY 2014 ESRD PPS proposed rule (78 FR 72192). We agree with commenters that exclusion criteria for the ESRD QIP measures should be consistent, where feasible. We further believe, however, that exclusions also need to take into account the population to which a measure applies and the settings for which the measures were developed (for example, in-center hemodialysis as opposed to home hemodialysis). As stated in previous rules, we will continue to look for ways to align exclusion criteria for measures in the ESRD QIP, as long as there is evidence to support such consistency.

Comment: One commenter made several recommendations regarding the preview period and the Performance Score Report (PSR) provided to facilities as part of the preview period. First, commenter recommended that CMS consider lengthening the preview period from 30 to 60 days, because smaller facilities find it difficult to review their scores in detail, research patients and labs, write up comments and questions and submit formal inquiries within 30 days. Second, commenter requested that the PSR be updated to include the number of eligible patients and patient-months for each measure and for each facility rather than just including the number of patient-months. Third, commenter requested that CMS consider including new measures in the PSR the first year the measure is included in the QIP without counting scores towards a facility's TPS so that facilities may see how they would be scored and how they would rate but they could be given time to work on internal improvement before the new measure is officially finalized. Commenter also noted this would also give facilities time to prepare and update necessary billing system changes, policies and procedures and record-keeping/patient forms. Fourth, commenter requested that CMS release summary statistics each year about the Preview Period—specifically, how many formal inquiries are received, how many are received from each dialysis organization, how many are overturned and how many result in score changes, and how many systemic changes are approved. Finally, commenter requested that the PSR be updated to include actual numerical percentages rather than ''requisite percentages'' because this would avoid many questions and would help personnel understand how measures are scored.

Response: We thank the commenter for their suggestions on ways to improve the Preview Period experience for facilities as well as ways to ensure that the PSR provides as much helpful information to facilities as possible. We will consider the feasibility of implementing some of these recommendations in future years of the program.

Comment: One commenter questioned why CMS must make so many changes each year to the ESRD QIP Program—specifically, why new measures must be added, why the scoring methodology is changed, why new exclusion and eligibility criteria are added each year, etc. and argued that these changes are overly demanding and burdensome for facilities.

Response: As new policies are implemented and new measures are added to the program, we are continually evaluating the program to ensure that we are capturing a broad range of information about the care that dialysis facilities are providing to patients and to ensure that our policies are in line with the goals we are seeking to achieve. As measures undergo maintenance and are evaluated by measures developers and by the NQF, new exclusion and eligibility criteria are added to ensure that each measure is specified appropriately to include only those patients who should be included in the measure's numerator and denominator. As these changes are incorporated into the program, other changes must follow, but we seek to provide facilities with as much notice as possible through rulemaking and other means of communication so that they are given appropriate time to make necessary changes within their own programs and policies.

Commenter: One commenter asked whether CMS will allow Calcium, Phosphorus, and Kt/V to be obtained from outside sources the way hemoglobin (Hgb) is able to be collected from outside sources.

Response: In response to the commenter's question, Calcium, Phosphorus, and Kt/V can all be obtained from outside sources in the same way that Hgb can be collected from outside sources. In fact, in the CY 2013 ESRD PPS Final Rule (77 FR 67473), we finalized that if a patient is hospitalized or transient during a claim

month, the facility could monitor the serum calcium and serum phosphorus readings for that patient for the month if a patient has labs drawn by another provider/facility, those labs are evaluated by an accredited laboratory (a laboratory that is accredited by, for example, Joint Commission, College of American Pathologists, AAB (American Association of Bioanalysts), or State or Federal Agency), and the dialysis facility reviews the serum calcium and serum phosphorus readings. The Kt/V can also be obtained from outside sources in the same way, provided those same conditions are met.

C. Requirements for the Payment Year (PY) 2018 ESRD QIP

1. 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). In that rule we proposed 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, in this year's rule making we proposed 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 90th percentile of national facility performance.

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

Comment: One commenter expressed concerns about the SFA, arguing that the inclusion of very small sample sizes leads to many facilities' scores being driven more by luck than by actual performance, and stressed that this effect is particularly exacerbated for the standardized ratio measures.

Response: We thank the commenter for their concern regarding the SFA. We want to clarify that this adjuster provides a positive adjustment to eligible small facilities' measure scores which we believe is sufficient to counteract the negative effects of a small patient census on facility scores.

Final Rule Action: We are finalizing our proposal 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 90th percentile of national facility performance. The purpose of this policy change is to ensure that small facilities are not adversely impacted by outlier patients and that facilities are being fairly scored on their actual performance regardless of their size.

2. 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 3-month study period.

We proposed 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 of 2014 (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 sought comments on this proposal. The comments and our responses are set forth below.

Comment: Several commenters requested clarification regarding the technical specifications for the Hypercalcemia Clinical Measure, noting that there is an apparent discrepancy. Specifically, they asked whether the exclusion ''patients without at least one uncorrected serum calcium value at that facility during the 3-month study period'' should be applicable for PY's 2017 through 2020.

Response: We understand why there may be some confusion, however there is no real discrepancy in the technical specifications published at the time of the proposed rule. The technical specifications for PY 2017 are correct, and do not include the exclusion ''patients without at least one uncorrected serum calcium value at that facility during the 3-month study period'' because the updates to the measure were proposed for PY 2018 and future years. The PY 2018 Technical Specifications published at the time of the proposed rules reflected the change that we proposed. We note below that we are now delaying implementation of this change until PY 2019, so updated Technical Specifications for PY 2018 are now published on the CMS Web site. The Technical Specifications proposed for PY 2019, published at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/PY-2020-NPRM-NHSN-Dialysis-Event-tech-spec-for-PY-2019.pdf* only included specifications for the measure being added to the program for PY 2019 (that is, the proposed NHSN Dialysis Event Reporting Measure's Specifications). The Technical Specifications proposed for PY 2020 included all measures previously finalized for inclusion in the ESRD QIP for PY 2020, as well as the substantive changes described above

which we proposed for the Hypercalcemia Clinical Measure.

Because we are now finalizing the changes proposed to the Hypercalcemia Clinical Measure for PY 2019, we have provided updated Technical Specifications for PY 2018 at *https://www.cms.gov/Medicare/Quality-INitiatives-Patient-Assessment-Instruments/ESRDQIP/index.html*. The Technical Specifications that we are finalizing for PY 2019 and PY 2020 already contain these changes to the measure.

Comment: One commenter recommended that CMS consult with stakeholders to determine whether a different Performance Standard should apply to Home Dialysis patients for the Hypercalcemia Clinical Measure, because the commenter believes the standards established in the rule are difficult for home dialysis programs to achieve due to dependence upon patient adherence and compliance. While in-center hemodialysis patients are generally given their medication through IV while they are in the dialysis center, home dialysis patients need to pick up their medications and adjust dosing as directed.

Response: We thank commenter for their recommendation. However, ''hypercalcemia is usually an inadvertent complication of the management of CKD mineral and bone disorder, so therapy should be focused on preventing the development of sustained serum calcium greater than 10.2 mg/dL. The TEP felt that the measure's threshold (≤10.2 mg/dL) addressed concerns about adverse events in patients that exceeded the upper limit of normal and therefore was a safety concern for all ESRD patients. That safety concern, we argue, is irrespective of whether patients are on in-center hemodialysis or home peritoneal dialysis therapies (home HD, or PD), and we note that the TEP did not consider for discussion separate thresholds based on modality. Based on the TEP's reasoning, we feel there is an expectation that facilities are responsible for ensuring home dialysis patients as well as in-center patients avoid elevated calcium levels ''above the normal range'' as per clinical practice guideline recommendations. [KDIGO 2009]. As such, we believe it is appropriate to include home dialysis patients in the denominator of the hypercalcemia measure.

Comment: Several commenters expressed concerns that the Hypercalcemia clinical measure is not impactful and is not the best indicator of clinical care because it is topped out and recommended that CMS instead focus its measure development efforts on developing and testing a more appropriate measure to meet the statutory requirement of PAMA, particularly in light of NQF's conclusion that there is very little room for improvement and that the performance gap identified by the developer did not warrant a national performance measure. One commenter specifically argued that the Hypercalcemia measure should not be characterized as a measure specific to conditions treated with oral-only drugs because Hypercalcemia is not only treated with oral-only drugs and because it may sometimes be treated with a calcimimetic when calcium levels have risen due to treatment with active Vitamin D, which is typically given intravenously during hemodialysis.

Commenters also asserted that the measure provides no value to the patient and does not relate to the provision of quality care. Despite these concerns, they expressed an understanding that maintaining this measure in the ESRD QIP measure set meets the statutory requirements of PAMA, and encouraged CMS to work with the kidney care community to find replacement measures. They added that CMS should continue to track hypercalcemia, but stated that linking hypercalcemia to specific medications without including the influence of active Vitamin D is problematic and unlikely to produce reliable data. In the interim, commenters expressed support for the proposed changes to the measure to ensure that the measure continues to satisfy NQF recommendations, but urged CMS to continue monitoring the Food and Drug Administration's (FDA's) approach to new injectables because that may require CMS to reconsider its approach.

Response: We thank the commenters for their comments. Hypercalcemia is the only measure of which we are aware that meets the statutory requirements in PAMA for an NQF-endorsed quality measure of conditions treated with oral-only medications. The measure has been recommended for reserve status endorsement by the NQF in part because of its utility as an important safety measure for dialysis patients. The NQF recommends measures for ''reserve status'' when they are ''highly credible, reliable, and valid measures that have high levels of performance due to quality improvement actions. The purpose of reserve status is to retain endorsement of reliable and valid quality performance measures that have overall high levels of performance with little variability so that performance could be monitored in the future if necessary to ensure that performance does not decline.'' [1] While hypercalcemia (as defined in the measure's technical specifications, as the serum calcium level of 10.2) is not a common complication among ESRD patients, it is still associated with elevated risks for mortality, suggesting that when it occurs, it can have serious consequences for patients.

We recognize that the Hypercalcemia measure is not a comprehensive measure of all oral-only medications, but limitations in available evidence have prevented us from developing measures that might address oral-only medications more broadly used in the ESRD dialysis population. We will continue to work with the community to develop more comprehensively applicable measures that meet these requirements. Three TEPs have been convened in 2006, 2010, and 2013 to address the topic of mineral bone disease measures, but the limited clinical evidence available has prevented those panels from recommending any measures that identify elevated levels of parathyroid hormone (PTH) or phosphorus. We have consulted with the dialysis community on this matter and will continue to do so, but we are unaware of any other specified and NQF-endorsed measure that would meet the requirements in PAMA. As evidence evolves to support more comprehensive measures of conditions treated by and these measures earn consensus endorsement, we agree that it will be appropriate to carefully consider the role of the Hypercalcemia measure in the ESRD QIP.

Comment: One commenter expressed concerns about the effect the proposed changes to the Hypercalcemia clinical measure may have on facilities' TPSs and requested that CMS evaluate the impact of these changes on facility scores to ensure that no facility is penalized due to a change in methodology.

Response: We have conducted additional analyses, the results of which are published here: *https://www.cms.gov/Medicare/Quality-INitiatives-Patient-Assessment-Instruments/ESRDQIP/index.html*. An analysis of the effect the changes to the Hypercalcemia clinical measure will have on payment reductions shows that only 11 additional facilities would receive a payment reduction under the new methodology compared to the old methodology. Table 4 below shows

[1] Glossary of Terms, National Quality Forum, *https://www.qualityforum.org/Measuring_Performance/.../NQF_Glossary.aspx*.

simulated payment reductions for PY 2020 using the old Hypercalcemia methodology (on the left) and the new Hypercalcemia methodology (on the right).

TABLE 4—PY 2020 SIMULATED PAYMENT REDUCTIONS COMPARING PRIOR HYPERCALCEMIA METHODOLOGY TO NEW HYPERCALCEMIA METHODOLOGY

Reduction	Simulated payment reductions for PY 2020 using prior hypercalcemia methodology (N(%))	Simulated payment reductions for PY 2020 using new hypercalcemia methodology
0/5	3322 (55.2%)	3311 (55.0%).
0.5%	1552 (25.8%)	1538 (25.5%).
1.0%	823 (13.7%)	832 (13.8%).
1.5%	255 (4.2%)	269 (4.5%).
2.0%	69 (1.2%)	71 (1.2%).

Comment: One commenter expressed concern that the ESRD QIP has not adopted a measure specific to bone mineral disorder. The commenter noted that CMS correctly identified calcimimetics and phosphate binders as two types of oral-only drugs but argued that CMS incorrectly identified the three conditions that are treated with these two classes of drugs, and encouraged CMS to continue looking at measures specific to Chronic Kidney Disease (CKD) Mineral Bone Disease (MBD) broadly. They specifically recommended a composite measure which would focus on the three biochemical parameters associated with Chronic Kidney Disease Mineral Bone Disease: Calcium, phosphorous, and PTH, rather than focusing on one individual biochemical parameter in isolation.

Response: We thank the commenter for raising concerns about adopting measures specific to bone mineral disorder. At present, we have two measures that address mineral bone disorder (MBD). We finalized a measure of hypercalcemia (NQF #1454) beginning with the PY 2016 program and we are finalizing the implementation of a phosphorus reporting measure (NQF #0255) beginning with PY 2020.

The 2013 Mineral and Bone Disorder TEP recognized the current limited evidence supporting development of a new MBD measure. They repeatedly raised the issue of the overall lack of evidence that was available due to the lack of randomized clinical trials that exist in order to inform recommendations for proposed measures, and meet the criterion of scientific acceptability. The TEP did discuss the strength of evidence regarding PTH as a risk factor in light of recent randomized trials including EVOLVE (2012) and the ADVANCE study (2011).[2] The TEP lacked agreement over the strength of the evidence but also concluded that these two trials are the current strongest bodies of evidence that exist since the 2010 TEP was convened. The 2013 TEP recognized that the previously cited problem with PTH assay variability could be overcome if the same assay is used each time; and that given the normal physiologic oscillations in PTH, measurement should be conducted more often to minimize variability. To that end, the TEP recommended a process measure that included documenting measurement of PTH and documentation of assay used. This measure still needs to undergo testing once required data elements are available for collection from dialysis facilities via CROWNWeb, or another system.

The 2013 TEP members agreed that the combination of laboratory values (PTH with calcium and phosphorus) may be more predictive of mortality, but since each lab value changes individually, it would be very difficult to make a recommendation based on a combination. It should also be noted that, the kidney care community would more readily support such a composite measure if each constituent measure were NQF endorsed. Previously one PTH measure, and two phosphorous measures were submitted to NQF (in 2010). These measures, respectively, were not endorsed due to the lack of evidence supporting a PTH target or range, and similarly lack of evidence to support a target for phosphorous. The suggested composite measure may be conceptually satisfying, but we are concerned that we lack sufficient evidence to justify implementing such a measure at this time.

Comment: One commenter objected to the continued inclusion of the hypercalcemia measure in the QIP and encouraged CMS to consult with stakeholders to develop a more appropriate measure specific to the conditions treated with oral-only drugs. One commenter added that until CMS develops and implements a more suitable measure, calcimimetic agents should not be included in the ESRD PPS base rate.

Response: We continue to believe that the hypercalcemia measure most effectively meets current statutory requirements as defined by MIPPA to include measures of mineral metabolism, and by PAMA, to include measures specific to conditions treated with oral-only drugs that are NQF-endorsed. As far as we are aware, there are no other clinical performance measures that currently meet these criteria.

Comment: One commenter opposed the implementation of technical changes to the Hypercalcemia Clinical Measure for PY 2018 and recommended a delay until PY 2019 because facilities are currently in the performance period for PY 2018. They argued that it is inappropriate to change the technical specifications half way through a performance period.

Response: We thank the commenter for their suggestion, and we agree that it would be unfair to facilities to make this change for PY 2018, given that the changes were not proposed until over half way through the performance period. The substantive modifications to the Hypercalcemia clinical measure were made during the NQF measure maintenance process that concluded at

[2] Raggi P, Chertow GM, Torres PU, et al. ''The ADVANCE study: A randomized study to evaluate the effects of cinacalcet plus low-dose vitamin D on vascular calcification in patients on hemodialysis.'' Nephrology, dialysis, transplantation: Official publication of the European Dialysis and Transplant Association—European Renal Association (2011) 26; 1327–39. PMID 21148030.

EVOLVE Trial Investigators, Chertow GM, Block GA, et al. ''Effect of cinacalcet on cardiovascular disease in patients undergoing dialysis.'' The New England journal of medicine (2012) 367:2482–94. PMID: 23121374.

the end of last year, and while we believe it is crucial to keep measures in the ESRD QIP measure set consistent with NQF-endorsed specifications, we also recognize that notice should be given to facilities prior to making such substantive changes. The changes to the Hypercalcemia Clinical Measure will not affect the way in which facilities provide care to their beneficiaries or the reporting requirements for the measure. Rather, this change will affect the way this measure is calculated because the denominator definition has 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. Eligible facilities that do not report data for 3 consecutive months will be included in both the numerator and denominator for this measure's calculations. Functionally, facilities do not need to make any changes in response to the changes proposed.

Final Rule Action: In consideration of the comments received, we are finalizing the changes to the hypercalcemia measure's technical specifications for PY 2019 and future years, rather than for PY 2018 as proposed. We note that these changes will positively impact data completeness, as facilities typically use plasma calcium blood tests and including patients with unreported calcium values in the measure calculation will encourage more complete data. Lastly, these measure changes will ensure alignment with NQF and satisfy the statutory requirements set forth in PAMA.

D. Requirements for the PY 2019 ESRD QIP

1. New Measures for the PY 2019 ESRD QIP

a. 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 Centers for Disease Control and Prevention (CDC); and (2) submit 3 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 to80 percent of dialysis events are under-reported.[3] [4]

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, 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 in the proposed rule (see sections IV.C.2. and IV.C.8. of the proposed rule (81 FR 42824)), 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.

Beginning with PY 2019, we proposed that 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 proposed 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;

[3] 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.*

[4] 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 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.

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

Comment: Several commenters did not support the proposal to reintroduce the Expanded NHSN Dialysis Event Reporting Measure, calling into question the validity and reliability of the clinical measure. They argued that the 60–80 percent of under-reporting of dialysis events demonstrates that the NHSN BSI Clinical Measure is not valid, and added that with that lack of validity comes uncertainty about whether the measure results in accurate findings. They argued that CMS should not finalize the measure, because giving facilities extra credit will not move the needle in ensuring that all events are reported, nor will this change the difficulties facilities have in obtaining information from hospitals. Several commenters also urged us to include the NHSN BSI Measure as a Reporting Measure for PY 2018 and PY 2019, and discontinue the inclusion of the NHSN BSI Clinical Measure until reliability and validity testing of the Clinical Measure has been completed.

Response: Although previous studies have suggested that 60–80% of bloodstream infections might be underreported to NHSN, these results must be considered in the proper context. First, it is important to note that these studies have largely attributed under-reporting to poor communication of reportable positive blood cultures (PBCs) from hospitals to dialysis centers when bloodstream infections are identified in hospitals. Second, these studies are based on small sample sizes. Although we are aware that underreporting can occur in all dialysis facilities, the degree of variation in underreporting across facilities is unknown and this is a truer reflection of the reliability of the ESRD QIP measure. Underreporting by itself does not lead to an unreliable measure.

The NHSN BSI measure has been endorsed by the National Quality Forum (NQF). The quantitative centerpiece of the NQF-endorsed NHSN Dialysis Event Bloodstream Infection Measure is the Standardized Infection Ratio (SIR), which is the ratio of observed to predicted events. Because the SIR has withstood scrutiny from NQF, which explicitly considered the measure's reliability, we continue to believe that it is reliable enough to remain in the ESRD QIP measure set.

We recognize that there are shortfalls in BSI ascertainment for purposes of reporting and that more needs to be done to improve the quality and completeness of data used in the NHSN BSI measure. Nevertheless, the measure itself remains an important tool for assessing the quality of care and closing performance gaps when and where they are identified, and there is no other measure available that would serve this purpose. We believe that further improvements in the reliability of NSHN data can be achieved through more complete communications between hospitals and dialysis facilities of relevant measure data, in particular the results of diagnostic microbiology testing by hospitals that are indicative of bloodstream infections in dialysis patients. We also believe that more robust validation of measure data, such as the validation approach we are finalizing, offer additional safeguards against incomplete case finding and shortcomings in measure data. Additionally, the CDC has encouraged dialysis providers, especially large dialysis organizations, to perform a validation of their own data. The CDC has provided a validation toolkit, available for any facility to use on its own. The goal of the validation, whether performed internally or by an external observer, is to improve the quality of the data. Taking all these considerations into account, we believe that on balance the ESRD QIP and patients' interests are best served by retaining the NHSN BSI measure in the ESRD QIP measure set.

Comment: Several commenters supported the reintroduction of the NHSN Dialysis Event Reporting Measure, as well as the continued inclusion of the NHSN BSI Clinical Measure and creation of the NHSN BSI Measure Topic as BSIs are serious events in ESRD patients. They argued that the integrity of the data that is submitted is essential for accurate analysis and benchmarking to improve BSI prevention, and that underreporting can be a serious hindrance to the data accuracy. One commenter suggested that scoring should be modified to incentivize reporting only for 12 complete months of data, awarding no points for incomplete reporting. One commenter recommended that CMS ensure facilities that are accurately reporting are not singled out as having worse outcomes because of being engaged in quality improvement projects and to develop a process whereby CMS would provide monthly feedback to providers so they can identify inconsistencies in their own reporting. One commenter also recommended that both the CDC and CMS should validate the data in a timely manner, and that NHSN data should be bi-directional such that a facility could review submitted data, analyze it to determine why there are inconsistencies, and make any necessary corrections to their process.

Response: We thank commenters for their support and we agree that this approach will appropriately address bloodstream infections in ESRD patients. We agree that the integrity of the data submitted is essential for accurate analysis and benchmarking and that is precisely the reason we have taken the approach proposed. We hope that by incentivizing complete reporting, we will obtain as much information as possible to accurately

analyze and benchmark the data for the NHSN BSI Clinical Measure, and by incentivizing the reduction of infections among facilities' patients, we will encourage facilities to pay close attention to these important events. Similarly, we believe that the increased data validation study we are finalizing and our updated data validation methodology will help us to determine the extent and types of underreporting that are occurring. We disagree that the scoring methodology should be modified to incentivize reporting only for 12 complete months of data because there is still some value in reporting 6–11 months of data. We believe our scoring methodology makes it clear that 12 complete months are ideal, but we still value the effort facilities are making in reporting 6–11 months of data and we believe it is important to recognize that through the methodology. Regarding commenter's suggestion to institute a bi-directional data validation process, NHSN data are already bi-directional. The data are immediately available within NHSN to be viewed and edited. CDC encourages all facilities to review their data on a regular basis to identify and correct errors. A dialysis data review tool is available here: *http://www.cdc.gov/nhsn/pdfs/dialysis/3-steps-to-review-de-data-2014.pdf*. It can be found on the following page under ''Analysis Resources to Create Reports'': *http://www.cdc.gov/nhsn/dialysis/event/index.html*.

Final Rule Action: For the reasons stated above, we are finalizing our proposal to reintroduce the NHSN Dialysis Event Reporting Measure to the ESRD QIP beginning with PY 2019 as proposed.

b. Scoring the NHSN Dialysis Event Reporting Measure

With respect to the NHSN Dialysis Event Reporting measure, we proposed to score facilities with a CCN Open Date on or before January 1, 2017. Using the methodology described below, we proposed 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 proposed that facilities will receive 10 points for submitting 12 months of data. Second, we recognized, 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 stated that we would need at least 6 months of data in order to calculate reliable scores on the NHSN BSI Clinical Measure. For these reasons, we proposed 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 6 months of data. For that reason, we proposed that a facility will receive 0 points on the NHSN Dialysis Event Reporting Measure if it reports fewer than 6 months of data.

The proposed scoring methodology for the 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.

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

Comment: One commenter supported CMS's proposed methodology for scoring the proposed NHSN BSI Measure Topic and the NHSN Reporting Measure because it rewards dialysis facilities that have made investments to support robust surveillance programs by allowing for monthly data input. The commenter added that the proposed scoring methodology strongly encourages facilities to report all 12 months of data, which serves to improve the integrity of the data.

Response: We thank the commenter for its support, and we agree that our proposed scoring methodology will encourage facilities to report all 12 months of data and that this will in turn improve the integrity of the data.

Comment: Several commenters did not support the proposal for scoring the proposed NHSN Dialysis Event Reporting Measure because it inappropriately penalizes facilities and, combined with the proposed weight of the measure for PY 2019, does not accurately distinguish among facilities that fail to report varying amounts of data. Commenters noted that missing one month of reporting is not the same as missing 5 months, yet the proposed scoring methodology treats these situations the same. One commenter expressed concern about facilities that may miss something very insignificant for 1 month and then lose 8 points, and recommended that the measure be scored in the same way that the Mineral Metabolism reporting measure is currently scored, because it would still encourage a facility to report 12 months. Two commenters argued that a sliding scale would me more appropriate. One commenter specifically recommended that CMS consider 0 points for 0 months of data, 1 point for 1–2 months of data, and so on. Another commenter recommended that CMS change the weight of the NHSN BSI Clinical Measure to make it one quarter the weight of the other clinical measures.

Response: We thank commenters for their suggestions, however we disagree that the proposed scoring methodology for the NHSN Dialysis Event Reporting Measure inappropriately penalizes facilities. In fact, we believe the scoring methodology appropriately rewards facilities for complete reporting and for their efforts at preventing infections, and that this scoring approach is consistent with the ESRD QIP's goal of incentivizing complete and accurate reporting as well as successful efforts to prevent bloodstream infections appropriate given the goals we are trying to accomplish. Unlike the Mineral Metabolism Reporting measure, facilities need to report all twelve months of data to NHSN in order to appropriately score and baseline the NHSN BSI Clinical Measure because there is seasonal variability in bloodstream infection rates. A sliding scale would not appropriately incentivize facilities to report the full 12 months' worth of data, which is needed to accurately score the NHSN BSI clinical measure. Additionally, we do not believe that reporting 1–2 months' worth of data significantly contributes to national prevention campaigns and internal quality improvement initiatives, and we therefore do not believe that it is appropriate to allocate any points on the reporting measure for this level of reporting. We want to incentivize facilities to report the full 12 months of data because without this data, the surveillance program that the CDC has established to monitor

bloodstream infections will not function to its fullest extent. Scoring the reporting measure on a sliding scale is therefore inconsistent with the need to provide strong incentives for facilities to report the full 12 months of data. We recognize that facilities occasionally have difficulty accessing the NHSN system and the CDC is diligently working to ensure that facilities have the information and training that they need to report successfully, but we believe that the system functions appropriately and does not impose impediments that would prevent facilities from reporting data on a monthly basis. Although the NHSN BSI clinical measure cannot be scored accurately on the basis of less than 12 months of data, from the perspective of national prevention strategies and internal quality improvement initiatives, there is still some value in collecting between 6 and 11 months of data. This is why we have proposed to give facilities that do so 2 points on the Reporting Measure, even though they will continue to receive a score of zero on the NHSN BSI clinical measure.

Final Rule Action: After consideration of the comments above we are finalizing the proposal for scoring the NHSN Dialysis Event Reporting Measure, described above, beginning in PY 2019. We believe this is the best way to incentivize complete and accurate reporting of NHSN data.

2. New Measure Topic Beginning With the PY 2019 ESRD QIP—NHSN BSI Measure Topic

Beginning with PY 2019, we proposed to create a new NHSN BSI Measure Topic. We proposed that this measure topic would consist of the following two measures:

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

(ii) NHSN Dialysis Event Reporting Measure.

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

Comment: Two commenters supported the proposed creation of the NHSN BSI Measure Topic because it encourages accurate reporting as well as the prevention of bloodstream infections, but one commenter recommended that in an effort to avoid confusion, the two measures that comprise the Measure Topic should be renamed to avoid referring to them as either ''Clinical'' or ''Reporting'' measures. They suggested instead that CMS change the ''NHSN Bloodstream Infection in Hemodialysis Patients Clinical Measure'' name to ''NHSN Bloodstream Infection in Hemodialysis Patients'' without referring to it as a Clinical Measure and suggested changing the name of the ''NHSN Dialysis Event Reporting Measure'' to ''NHSN Dialysis Event Surveillance'' or ''NHSN Dialysis Event Participation'' or even ''NHSN Dialysis Event Data Entry''.

Response: We thank commenters for their support of the proposed NHSN BSI Measure Topic. However, we disagree that the names of the measures should be changed as the commenter recommended. The NHSN BSI Clinical measure is correctly referred to as a Clinical Measure because it measures the Standardized Infection Ratio (SIR) of BSIs among patients receiving hemodialysis at outpatient hemodialysis centers and is therefore a measure of the care being provided to beneficiaries. Similarly, the NHSN Dialysis Event Reporting Measure is correctly referred to as a Reporting Measure because it measures the number of months for which facilities report NHSN Dialysis Event data to the CDC's NHSN system and is therefore a measure of the completeness of a facility's data reporting. We agree with commenter that the proposed Measure Topic is neither purely clinical nor purely reporting, which is why we have proposed to place it within its own Safety Domain. However, the two measures that make up the Measure Topic are still fundamentally different in that one is a Clinical Measure and one is a Reporting Measure.

Comment: In light of reliability issues discussed above, commenters encouraged CMS to retain the NHSN BSI Measure as a Reporting Measure, and to not finalize the NHSN BSI Measure Topic or the proposed addition of the Safety Measure Domain in the QIP until CMS can resolve issues surrounding reliability and validity of the Clinical Measure before including it in the QIP's measure set.

Response: We thank commenters for their suggestion, however we have decided to finalize the NHSN BSI Measure Topic and the Safety Measure Domain. As discussed above, the studies conducted on the reporting of bloodstream infections to NHSN were largely attributed to poor communication of reportable positive blood cultures from hospitals to dialysis centers and were based on small sample sizes. We do not believe they are generally indicative of any issues of reliability or validity with the NHSN BSI measures. And we continue to believe that it is essential to retain the NHSN BSI clinical measure because it is absolutely critical to evaluate facilities' efforts to prevent bloodstream infections. In light of this this need to retain the NHSN BSI clinical measure, we continue to believe that the introduction of the NHSN BSI Measure Topic and the addition of the Safety domain is the best way to ensure complete and accurate reporting of data, while at the same time hold facilities accountable for preventing bloodstream infections.

Comment: Commenter offered support to work with CMS to address the validity issues in the NHSN BSI measure and stated that ensuring the appropriate sharing of patient information between hospitals and dialysis facilities is a priority, but until that problem is solved and the validity of the NHSN Bloodstream Infection measure has been affirmed, they cannot support the proposed approach to NHSN.

Response: We agree that it is vitally important to ensure the appropriate sharing of patient information between hospitals and dialysis facilities. We have addressed commenter's concerns about the validity of the NHSN BSI measure above, in section IV(D)(1)(a). Regarding commenter's suggestions surrounding communication between dialysis facilities and hospitals, we encourage facilities to implement processes and procedures to ensure that they are best able to receive information from local hospitals and that they are coordinating the care of their patients in the most effective ways possible.

Comment: One commenter expressed concerns that the data specifications for the NHSN BSI Clinical Measure require

collection of events from dialysis center and non-dialysis outpatient laboratories. They added that this measure originated in the hospital setting where all cultures are sent to a single lab, but extra data collection efforts are needed in the dialysis setting because cultures are performed at a variety of sites of care. They requested additional data testing to show that this is actually occurring. They added that the providers who are complying with the data specifications will likely appear to have a higher infection rate as more infections will be captured, whereas those who are not collecting data from other providers may not be accurately reporting all infections.

Response: We are aware that underreporting can occur, and in some studies, has been largely attributed to poor communication of reportable positive blood cultures (PBCs) from hospitals to dialysis centers. The measure did not originate in the hospital setting. It has always been an outpatient dialysis center measure. The reporting of PBCs within one calendar day of a hospital admission is a necessary element of the BSI measure. Without it, facilities could refer most or all patients to an ED or hospital for suspected BSI and the measure would be compromised. We recognize that obtaining this information from hospitals can be challenging, and requires knowledge and implementation of the NHSN protocol. However, CDC, CMS and other stakeholders in the dialysis community agree that good communication across care transitions is important for not just surveillance, but optimal clinical care of patients. ESA dose, hepatitis B status, and communication of antibiotics prescribed and planned duration of treatment are just a few examples of information that should routinely be shared across healthcare facilities. A positive blood culture and organism identification and susceptibility results are equally important to communicate. CDC hosts protocol trainings that users should attend yearly to ensure NHSN participants are aware of the protocol requirements. CDC has also made available data validation tools that facilities can use to assess their knowledge and adherence to the reporting protocol. Facilities are given 90 days from the end of a quarter (before the reporting deadline) to facilitate obtaining records from hospitals and EDs. CDC is working with ESRD Networks and others to try to improve hospital-to-dialysis center communication. Networks will target facilities that have challenges obtaining these data from hospitals to assist them in developing more effective communication strategies. Together, we are actively seeking best practice strategies that can be shared with other facilities.

Comment: One commenter requested that the CDC and CMS address potential data quality issues before the NHSN BSI Clinical Measure is used in the QIP and specifically requested that the CDC produce a histogram of infection events to determine if a bimodal distribution exists, which would suggest data reporting issues. They also recommended that CMS update the data submission process for CROWNWeb to improve data accuracy and reduce costs. They suggested that one solution may be to enable dialysis providers to ''copy and paste'' their entire database to CMS and that CMS and CDC should release histograms to determine if the NHSN BSI metric is truly valid and should be used in the QIP as currently structured.

Response: We thank commenter for their suggestions and we will consider developing histograms of this nature for future analysis. We are constantly seeking ways to improve data accuracy and to reduce costs for facilities. We will take commenter's ideas about improving the data submission process for CROWNWeb into consideration for future updates of the CROWNWeb system.

Comment: A commenter requested that CMS establish a minimum threshold for data submission completeness before using CROWNWeb data for the ESRD QIP or for other purposes and suggested that this could be accomplished by comparing the number of Medicare beneficiaries at a given facility who have claims with the number of patients with accepted data in CROWNWeb. One commenter also recommended that CMS validate patient counts against provider Electronic Medical Records to determine when the minimum threshold for the use of both Medicare and non-Medicare CW data is met.

Response: We thank commenter for their suggestions. At this time, we are not proposing to establish a minimum threshold for data submission completeness however, as we stated in the CY 2014 ESRD PPS Final Rule (78 FR 72210), we encourage facilities to ensure that their patient censuses are accurately reflected in CROWNWeb. In this way, facilities can compare for themselves the number of Medicare beneficiaries they have seen and who have claims with the number of patients with accepted data in CROWNWeb attributed to their facility. With regards to validation, we agree that updates should be made to CROWNWeb to ensure that accurate data passes validation testing while also ensuring that inaccurate data is not used to calculate scores on ESRD QIP clinical performance measures, and we are in the process of enhancing CROWNWeb to accomplish this task. Nevertheless, facilities are ultimately responsible for ensuring that patient data is accurately reflected in CROWNWeb.

Comment: One commenter urged CMS to change the definition of ''positive blood culture'' for the NHSN BSI Clinical Measure to ensure that positive blood cultures are only counted toward the measure calculation if the suspected source of blood culture was ''vascular access,'' not any of the other three options.

Response: As we stated in the CY 2014 ESRD PPS Final Rule (78 FR 72205), NQF endorsed a bloodstream infection measure (NQF #1460, the measure upon which the proposed NHSN BSI Clinical Measure is based) because BSIs can be objectively identified. NQF raised concerns about an access-related bloodstream infection measure because determining the source of infections (for example, determining whether an infection was related to vascular access) requires subjective assessments. The NHSN BSI Clinical Measure avoids this subjectivity by including all positive blood cultures. This makes it simpler and more reliable than an access-related bloodstream infection measure. While we recognize that the NHSN BSI Clinical Measure may occasionally misattribute BSIs to dialysis facilities, we believe that the measure's objectivity, simplicity, and reliability make it the most appropriate measure for assessing facility performance. NHSN relies upon use of standard definitions to ensure that infection events are reported in the same manner across facilities. The vast majority of reported bloodstream infection events represent true HAIs that are not the result of misclassification or misattribution. Therefore, considering the benefits to patients associated with strong incentives to reduce BSIs, we believe that these technical issues are not significant enough to warrant changing the definition of ''positive blood culture'' for purposes of this measure. CDC will continue to assess the possibility that certain facility-related factors could systematically overestimate infection rates, and it will consider risk-adjusting the measure to take these factors into account.

Comment: Commenter argued that when entering data for NHSN, it would be more logical for facilities to report the number of patients who were treated

on the last two working days of the month, not the first two. Growing clinics' census numbers can increase dramatically over the course of a month, and entering a small number on the first two days as opposed to a larger number on the last two days will cause the estimated amount of blood cultures to be lower. This then impacts facility scoring, because the denominator derived from the first two working days of the month is not representative of the patient population treated at the facility during that full month.

Response: To reduce the burden of manual denominator data collection, the National Healthcare Safety Network (NHSN) uses the number of patients dialyzed at a clinic during the first two working days of a reporting month as a proxy measure for the total number of patient-days-at-risk during that month.

In a small study, CDC compared the NHSN denominator to various denominator measures including the last 2 days of the month and the entire month using electronically captured data and found that the first two working days was a generally good estimate of the entire month denominator.

Specifically, the results revealed a strong correlation between monthly total denominator and NHSN denominator and between the NHSN denominator and the other denominator methods [$p < 0.0001$].[5]

We note that although a ''growing clinic'' might have an NHSN denominator that is low in one month (if there is a drastic increase during that month), the denominator should be a good estimator of the number of patients at the facility for all subsequent months. If the growth is more gradual, then the NHSN denominator is still a relatively good estimator of the month census. The only way this would not be the case is if census fluctuated drastically within each month so that the first 2 days were always somehow different than the rest of the month (for example, patients always added in the middle of the month and then removed before the start of the next month). We have not encountered a systematically occurring example of this type of phenomenon.

Comment: One commenter recommended that CMS add some patient-level exclusions to the NHSN BSI Clinical Measure, and specifically urged CMS to exclude positive blood cultures for transient patients. They also urged CMS to consider implementing a threshold for number of patient months for a facility to qualify for the NHSN BSI Clinical Measure.

Response: NHSN is designed to capture dialysis events for all dialysis patients (including transient patients). BSIs are important in all patients, including transient patients and meeting the ''transient'' definition does not exclude the patient from having an infection that could have been acquired in the dialysis center. Measure inclusions and exclusions were considered by the NQF when they reviewed and endorsed the BSI measure. NHSN has a field facilities can use to identify dialysis events that occurred in transient patients. This information can be used to inform internal QI purposes. See dialysis event protocol here: *https://www.cdc.gov/nhsn/pdfs/pscmanual/8pscdialysiseventcurrent.pdf.* We use claims to determine whether facilities meet the 11-patient minimum to be eligible for the NHSN BSI Clinical Measure.

Final Rule Action: After considering the comments received, we are finalizing our proposal to include the NHSN BSI Measure Topic in the ESRD QIP. This new Measure Topic will consist of the NHSN Dialysis Event Reporting Measure and the NHSN BSI Clinical Measure, as described above. We believe these two measures are mutually reinforcing in that one measure rewards reporting and the other uses reported data to assess facilities' efforts to prevent dialysis events.

3. New Safety Measure Domain

We currently use two domains in the ESRD QIP for purposes of scoring. The first domain, 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). Second is a Reporting Measure Domain, in which scores on reporting measures are weighted equally (79 FR 66218 through 66219).

In section IV.C.2 of the proposed rule (81 FR 42825), we described the NHSN BSI Measure Topic. We believe that this measure topic, consisting of both the 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. Placing these two measures together in a single measure topic to which we can assign 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. Therefore, it does not appropriately belong in either the Reporting Measure Domain or the Clinical Measure Domain.

Because of these fundamental differences, we proposed to remove the Safety Subdomain from the Clinical Measure Domain for PY 2019 and future payment years. We proposed 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 proposed 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 in section IV.C.6 of our proposed rule (81 FR 42826), and note that these three Domain scores will be combined and weighted to produce a Total Performance Score (TPS) for each facility.

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

Comment: Several commenters supported CMS' goals of reducing BSIs and specifically supported the proposed creation of the new Safety Domain separate from the Clinical and Reporting Domains because the NHSN BSI Measure Topic does not belong solely in either in the Reporting or the Clinical Domains. They added that inclusion of both the Clinical and the Reporting measures for NHSN will encourage improvement and provide additional incentives for complete reporting.

Response: We thank the commenters for their support, and we agree that inclusion of both the Clinical and the Reporting Measures for NHSN will encourage improvement and provide additional incentives for complete reporting.

Comment: One commenter did not support CMS's proposal to establish a safety measure domain due to the reliability and validity issues of the NHSN BSI measure. The commenter further stated they do not believe the reintroduction of the NHSN Dialysis

[5] Poster Abstract Session: HAI Surveillance and Public Reporting, October 10, 2014. *https://idsa.confex.com/idsa/2014/webprogram/Paper46611.html.*

Event Reporting Measure is appropriate or necessary, nor do they believe the Measure Topic is necessary and they therefore believe the creation of the Safety Measure Domain is also unnecessary.

Response: We have addressed the concerns raised by the commenter about the reliability and validity of the NHSN BSI Clinical Measure above (see section IV.D.1.a.). We believe that combining the NHSN Dialysis Event Reporting Measure together with the NHSN BSI Clinical Measure in a single NHSN BSI Measure Topic, as proposed, within the proposed Safety Measure Domain is the best way to ensure that the incentives for complete and accurate reporting and for the prevention of BSIs are appropriately calibrated. Combining the clinical and reporting measure into a hybrid measure topic accomplishes this objective because it reflects aggregated performance and reporting requirements.

Final Rule Action: After careful consideration of the comments received, we are finalizing our proposal to remove the Safety Subdomain from the Clinical Measure Domain for PY 2019 and future payment years, and to add a new third domain, the Safety Measure Domain, to the ESRD QIP's scoring methodology. We believe that this approach is the best way to ensure complete and accurate reporting, while also incentivizing facilities to lower the incidence of BSIs among their patients.

4. Scoring for the NHSN BSI Measure Topic

We proposed to assign significant weight to the 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 proposed 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 sought comment on this proposal. The comments and our responses are set forth below.

Comment: One commenter supported CMS's proposal for scoring the NHSN BSI Measure Topic and believes that the 40/60 split between the Reporting and Clinical Measures will encourage both accurate reporting and strong clinical performance.

Response: We thank the commenter for their support, and we agree that assigning 40 percent of the Measure Topic Score to the NHSN Dialysis Event Reporting Measure and 60 percent of the Measure Topic Score to the NHSN BSI Clinical Measure is the best way to incentivize both strong performance on the clinical measure and thorough and accurate reporting.

Final Rule Action: Based upon the comments received, we will finalize the scoring for the NHSN BSI Measure Topic as proposed. We will assign 40 percent of the measure topic score to the NHSN Dialysis Event Reporting Measure and 60 percent of the measure topic score to the NHSN BSI Clinical Measure.

5. 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 50th, 15th and 90th percentile, respectively, of national performance in CY 2015, because this will give us enough time to calculate and assign numerical values to the proposed performance standards for the PY 2019 program prior to the beginning of the performance period. (80 FR 69060). At the time the proposed rule was published, we did not have the necessary data to assign numerical values to the proposed performance standards, achievement thresholds, and benchmarks because we did not yet have complete data from CY 2015. Nevertheless, we were able to estimate these numerical values based on the most recent data available at the time. For the Vascular Access Type, Hypercalcemia, NHSN BSI and ICH CAHPS clinical measures, this data came from the period of January through December 2015. For the SRR and STrR clinical measures, this data came from the period of January through December 2014. In Table 5, we provided the estimated numerical values for all of the finalized PY 2019 ESRD QIP clinical measures.

TABLE 5—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 proposed 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 proposed 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 sought comments on this proposal. The comments and our responses are set forth below.

Comment: Several commenters supported our continued reliance on the methodology used to set the Performance Standard, Achievement Threshold, and Benchmark at the 50th, 15th and 90th percentiles respectively of national facility performance for PY 2019. One commenter requested that CMS clarify in Table 2 of the proposed rule (81 FR 42826) whether the Benchmarks, Achievement Thresholds and Performance Standards listed for the ICH CAHPS measures are the percent of responses or the percent of top box responses. Another commenter asserted that if the national average for the NHSN BSI Clinical Measure is 5.15, then the benchmark of an SIR of 0.0 cannot be correct.

Response: We thank the commenter for their support. In Table 2 of the proposed rule (81 FR 42826), the Benchmarks, Achievement Thresholds and Performance Standards listed for the ICH CAHPS measures represent the percent of top box responses. Table 2 in the proposed rule (81 FR 42826) indicates that the Achievement Threshold for the NHSN BSI SIR is 1.812, the Benchmark is 0 and the Performance Standard (that is, the average national performance) is 0.861. These values were estimated numerical values using the most recently available data at the time the proposed rule was published, and we have ensured that they were calculated correctly.

Final Rule Action: Since the time that the Proposed Rule was published, we have collected the data needed to calculate finalized performance standards for the PY 2019 ESRD QIP. After consideration of the comments, we will finalize the performance standards, achievement thresholds, and benchmarks for the clinical measures included in the PY 2019 ESRD QIP as updated below, using the most recently available data. Table 6 below lists the finalized numerical values for all of the finalized PY 2019 ESRD QIP clinical measures.

TABLE 6—FINALIZED 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	53.66%	79.62%	65.93%
%Catheter	17.20%	2.95%	9.19%
Kt/V Composite	87.22%	97.74%	93.16%
Hypercalcemia	4.15%	0.32%	1.83%
Standardized Transfusion Ratio	1.564	0.336	0.894
Standardized Readmission Ratio	1.289	0.624	0.998
NHSN Bloodstream Infection	1.738	0	0.797
SHR measure	1.244	0.665	0.967
ICH CAHPS: Nephrologists' Communication and Caring	56.41%	76.93%	65.87%
ICH CAHPS: Quality of Dialysis Center Care and Operations	52.88%	71.15%	60.74%
ICH CAHPS: Providing Information to Patients	72.10%	85.54%	78.54%
ICH CAHPS: Overall Rating of Nephrologists	49.37%	76.54%	62.17%
ICH CAHPS: Overall Rating of Dialysis Center Staff	48.63%	77.41%	62.24%
ICH CAHPS: Overall Rating of the Dialysis Facility	51.10%	80.45%	65.02%

Data sources: VAT measures: 2015 Medicare claims; SRR, STrR: 2015 Medicare claims; Kt/V: 2015 Medicare claims and 2015 CROWNWeb; Hypercalcemia: 2015 CROWNWeb; NHSN: CDC; SHR: 2014 Medicare claims, CAHPS: 2015 ICH CAHPS surveys.

6. Weighting for the Safety Measure Domain and Clinical Measure Domain for PY 2019

As discussed in section IV.C.3 of the proposed rule (81 FR 42825), we proposed 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 (TPSs).

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. of the proposed rule (81 FR 42823) 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 proposed 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 proposed 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.[6] 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 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 proposed to change the Clinical Measure Domain weighting for the PY 2019 ESRD QIP. Specifically, we proposed 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 also proposed to apportion six percent of the Clinical Measure Domain to the standardized readmission ratio (SRR) and In-center hemodialysis consumer assessment of healthcare providers and systems (ICH CAHPS) measures, and to apportion the remaining 5 percent to the standardized transfusion ratio (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 proposed to use the following weighting system in Table 7 below, for calculating a facility's Clinical Measure Domain score for PY 2019. For comparison, in Table 8, 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 7—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 proposed that the Clinical Domain will make up 75 percent of a facility's TPS. The percentages listed in this Table represent the measure weight as a percent of the Clinical Domain Score.

TABLE 8—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

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

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 proposed a change to this policy. Specifically, for PY 2019, we proposed 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 proposed this change in policy to avoid a situation in which a facility is eligible to receive a TPS when it only receives a score for a single measure topic. We did not propose 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 sought comments on these proposals. The comments and our responses for these proposals are set forth below.

Comment: Two commenters did not support our proposal for weighting the proposed safety domain within the TPS or our proposal to change the weighting of the clinical measure domain for PY 2019. They suggested that CMS consider re-weighting the Subdomains in the Clinical Measure Domain and reduce the weight of the Patient and Family Engagement/Care Coordination Subdomain because the measures within this subdomain—Readmissions and ICH CAHPS—may not have any relation with clinical performance. Specifically, one commenter argued that the SRR measure accounts for readmissions due to foot ulcers or cancer treatment and may have nothing to do with facility performance. Likewise, the Patient Satisfaction survey scores may be skewed, commenter argued, due to end of life grief, loss, chronic illness, anger with diagnosis, organic brain diagnosis or other cognitive disabilities. For these reasons, the commenter urged CMS to reduce the weight of the Patient and Family Engagement/Care Coordination Subdomain to 20 percent or less of the Clinical Measure Domain score and give more weight to the Clinical Measures themselves. One commenter also argued that the current weighting proposal is not balanced and recommended that CMS either reduce the weight of the Patient and Family Engagement Subdomain back to 30 percent, consider adding another measure to the subdomain, or reduce the number of completed ICH CAHPS surveys needed to be eligible for that measure.

Response: We thank commenters for their suggestions. We proposed the weighting structure for several reasons, outlined in more detail in the proposal. We carefully considered the criteria finalized in the CY 2015 ESRD PPS Final Rule (79 FR 66213 through 66216) to construct the proposed scoring methodology. Specifically, we considered the number of measures and measure topics within a subdomain, the experience facilities have had with the measures, and how well the measures align with CMS' highest priorities for quality improvement for patients with ESRD. We have weighted the SRR and ICH CAHPS measures as proposed because facilities will have had more experience with these measures than they will have had with the STrR measure, and because the focus on patient satisfaction and care coordination constitutes and important policy priority for CMS. Furthermore, we disagree with the commenters that the SRR measure does not have any relation with clinical performance. The SRR measure is carefully risk adjusted to account for comorbidities and patient characteristics relevant to the ESRD population. Additionally, while the causes of readmissions are multifactorial, our analyses demonstrate that facilities are able to exert an influence on readmissions that is roughly equivalent to that exerted by the discharging acute care hospital. We believe that coordination of care requires interaction between multiple providers, including those discharging the patient, and those continuing patient care following discharge. While cultural factors and patient noncompliance can lead to hospital admissions, this is no less true for the acute care hospitals, long-term care hospitals, inpatient rehabilitation facilities, nursing homes, and home health agencies, and it does not negate the deleterious consequences readmissions can have for those patients. At this time there are no additional measures that can appropriately be added to the Patient and Family Engagement Subdomain. However we are constantly working with the kidney care community to identify measures that are appropriate for the ESRD QIP program. Finally, the ICH CAHPS measure cannot be reliably scored on the basis of fewer than 30 completed surveys, so we do not believe it is appropriate to reduce this aspect of the minimum data requirements for the measure. It is important to note that the weight allocated to ICH CAHPS in the TPS will be distributed evenly throughout the measures on which a facility received a score, in the event that the facility does not obtain the 30 completed surveys needed to score the ICH CAHPS measure.

Comment: Two commenters supported CMS's criteria for weighting measures but recommended adding three additional criteria: (1) Strength of Evidence; (2) Opportunity for Improvement; and (3) Clinical Significance.

Response: We thank the commenters for their support. We agree with the commenters that these criteria encompass important considerations for evaluating measures. As stated in the CY 2015 ESRD PPS Final Rule with comment period (79 FR 66216) and the CY 2016 ESRD PPS Final Rule with comment period (80 FR 69063), we take these criteria into account when making decisions about whether to adopt a measure in the ESRD QIP, because it would be inappropriate to adopt a measure that did not meet these criteria. Based on this understanding, we developed the three criteria discussed above for determining subdomain weighting within the Clinical Measure Domain (80 FR 37849). We believe these criteria account for the programmatic and operational concerns associated with scoring facilities on the ESRD QIP while also reflecting our focus on improving the quality of care provided to ESRD patients. This analysis also implicitly includes a review of the strength of the clinical evidence supporting the measure, the opportunity for improvement among facilities, and the clinical significance of the measure because these issues are inextricably linked with an assessment of the measure's appropriateness and importance of measurement within the ESRD QIP. Because the additional criteria recommended by the commenter are used as a threshold for adopting ESRD QIP measures and are sub-components of the three previously finalized measure weighting criteria, we do not believe it would be appropriate to also factor these criteria into decisions about how much weight to give measures in a facility's Clinical Domain Score.

Final Rule Action: After consideration of the comments, we will finalize the weighting structure for PY 2019 as proposed. We are also finalizing the new policy described above 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. This policy will ensure that facilities will not be eligible to receive a TPS if they only receive a score for a single measure topic.

The weights we are finalizing appear in Table 9, below:

TABLE 9—FINAL 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, the Clinical Domain will make up 75 percent of a facility's TPS. The percentages listed in this Table represent the measure weight as a percent of the Clinical Domain Score.

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

In this section, we provide examples 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:

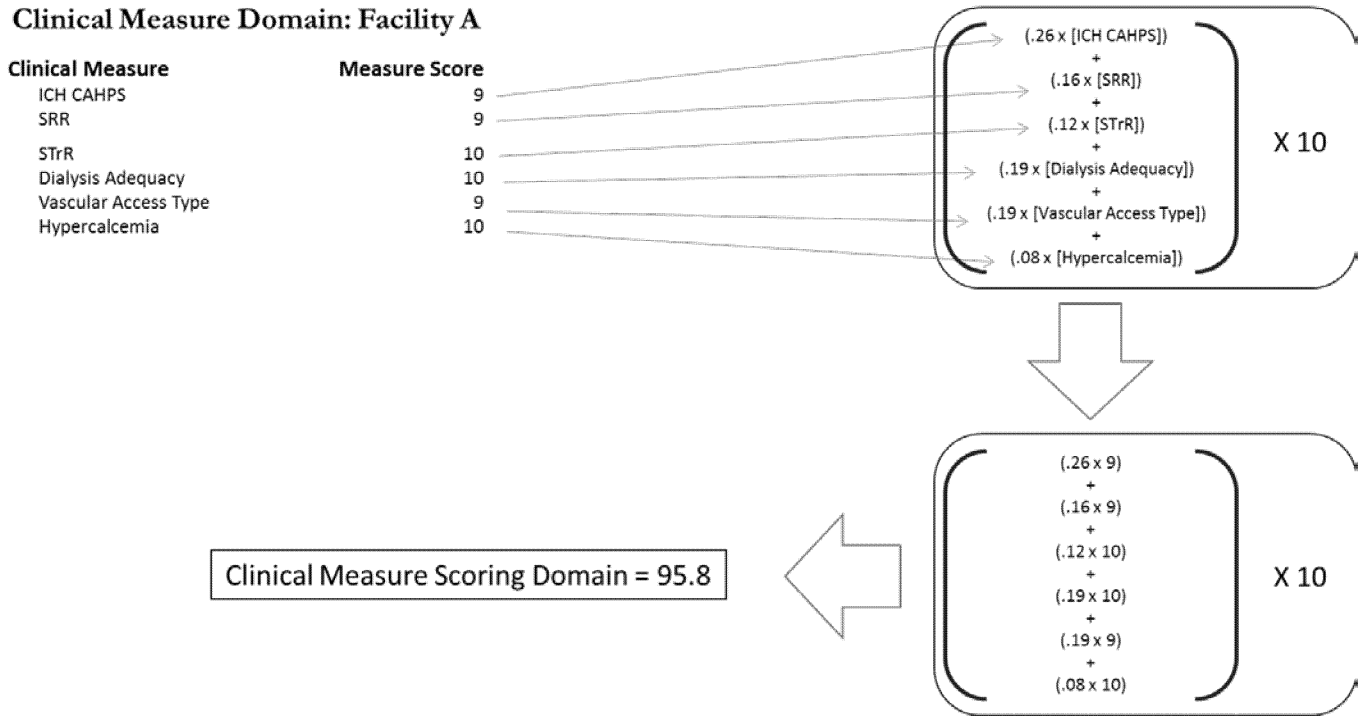


Figure 2 illustrates the general methodology for calculating the Reporting Measure Domain score for Facility A.

FIGURE 2:

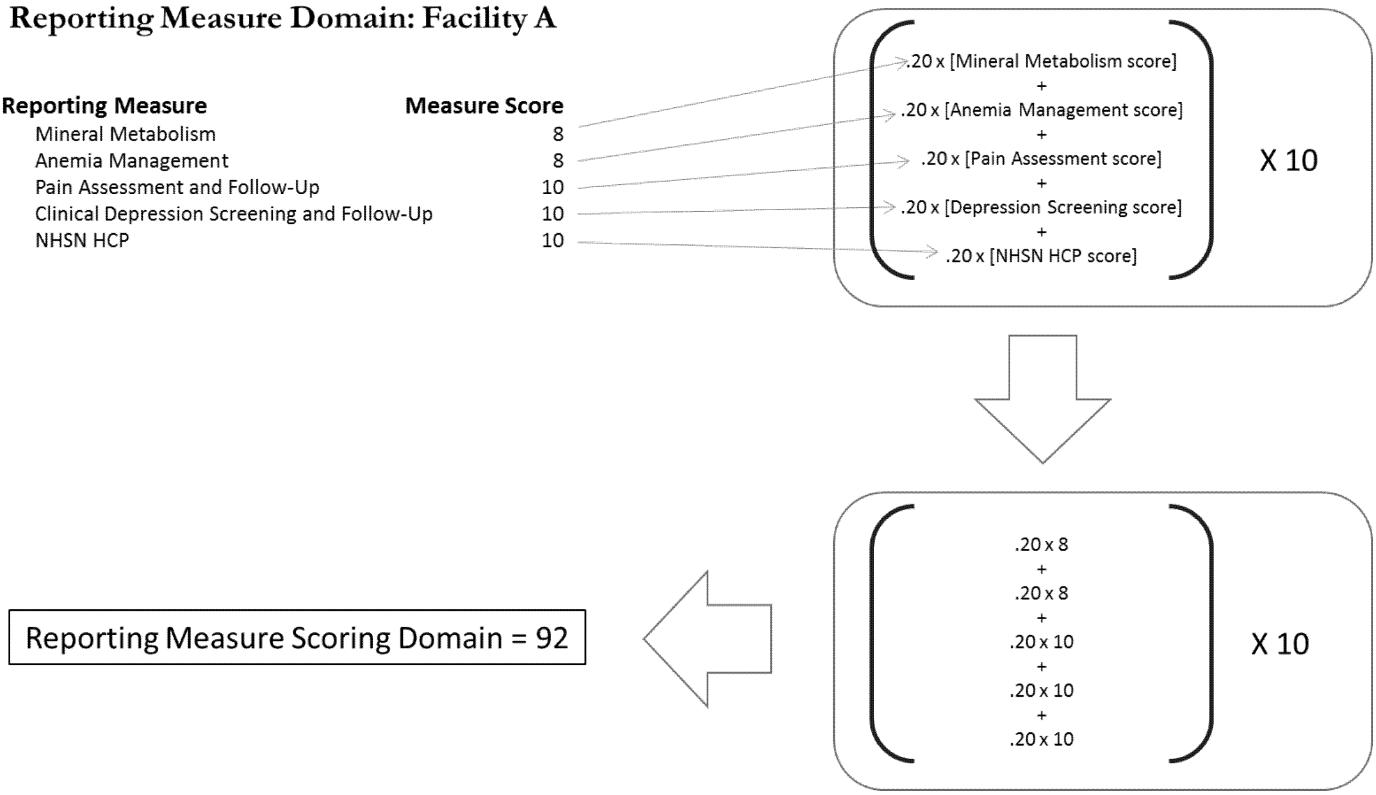


Figure 3 illustrates the methodology used for calculating the Safety Measure Domain score for Facility A.

FIGURE 3:

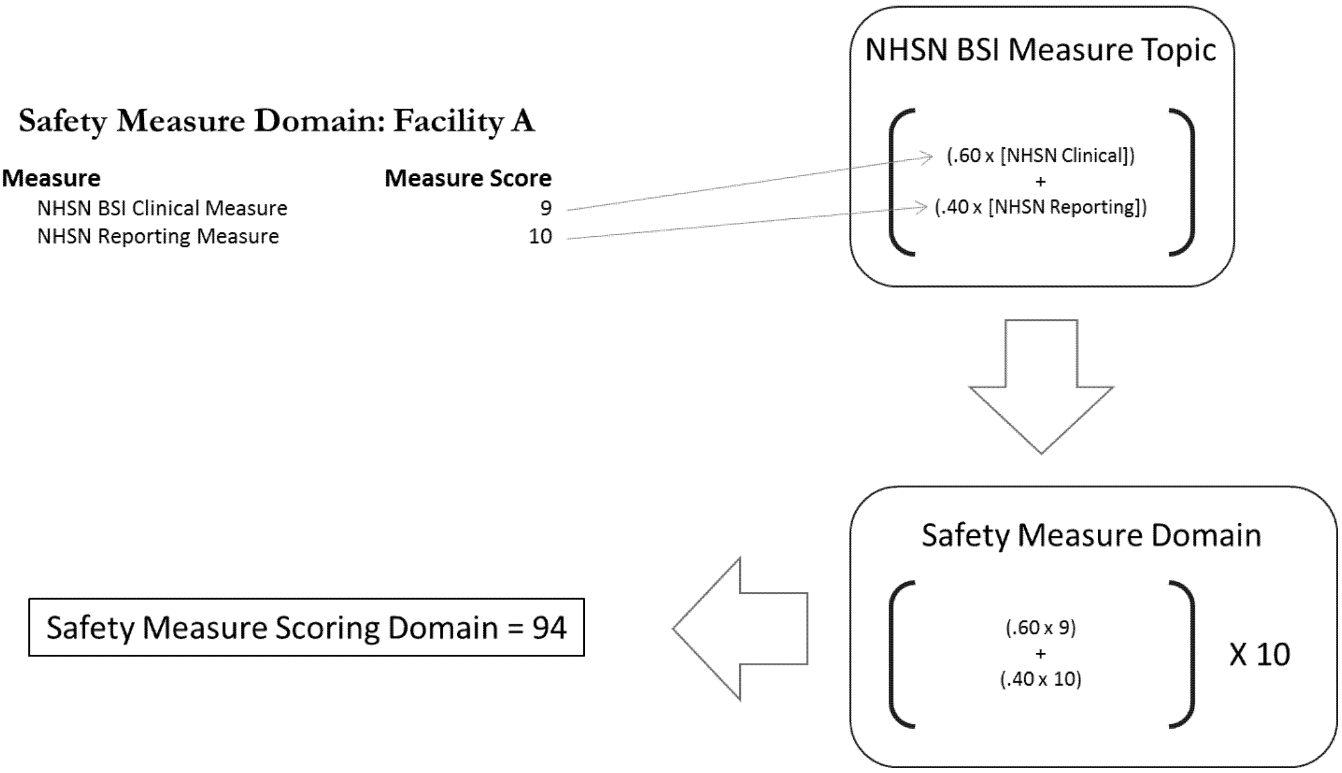


Figure 4 illustrates the methodology used to calculate the TPS for Facility A.

FIGURE 4:

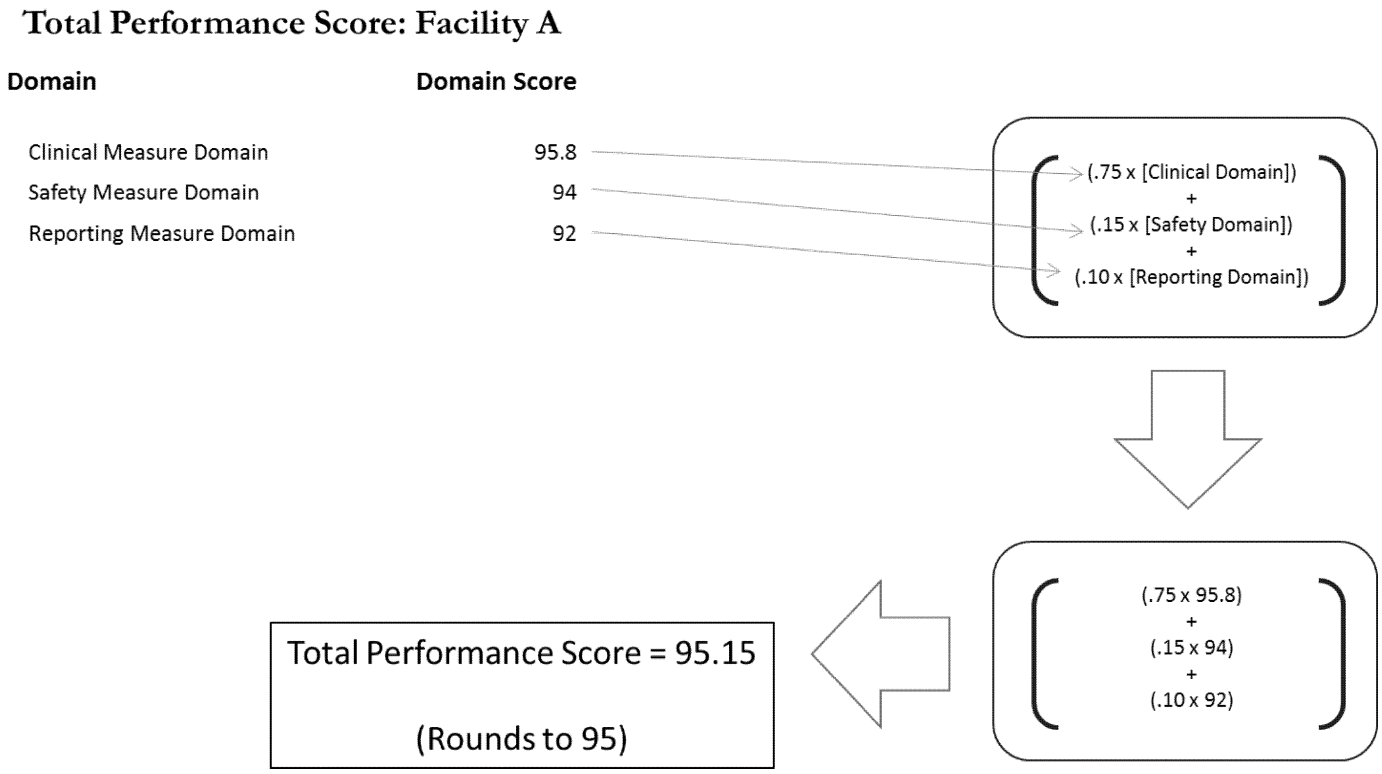
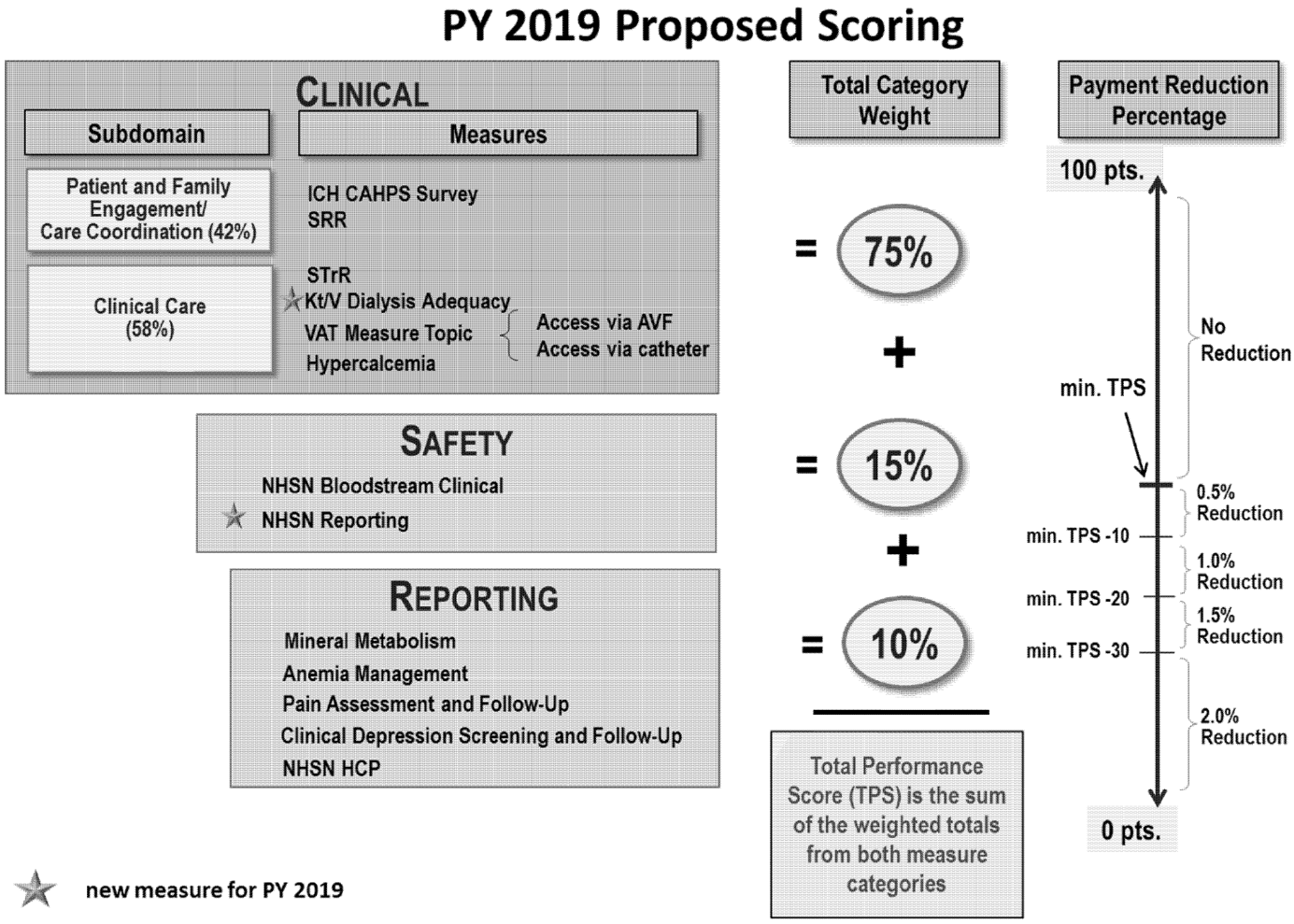


Figure 5 illustrates the full scoring methodology for PY 2019.

FIGURE 5:



8. 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 estimated 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 proposed 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 10.

TABLE 10—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 sought comments on these proposals. The comments and our responses are set forth below.

Comment: Two commenters did not support our proposed payment reductions for the PY 2019 ESRD QIP. One commenter expressed the following concerns with the proposed Scoring Methodology. First, they are concerned about the unresolved methodological issues surrounding the validity and reliability of the NHSN BSI Measure. Second, CROWNWeb data transmission issues remain a concern. Third, CMS seems to be pursuing a strategy of including ESRD QIP measures that are outside the dialysis facility's direct sphere of influence. One commenter argued that all three of these issues could result in an artificial deterioration in dialysis facility performance with respect to the ESRD QIP performance scoring, in the absence of a demonstrable change in the quality of care delivered. One commenter urged CMS to delay increasing the stringency of ESRD QIP scoring until these issues have been addressed. Another commenter argued that the current scoring methodology unfairly penalizes small facilities, particularly those that are affiliated with academic medical centers, and they were troubled by CMS's assertion that the care they provide to their patients is anything less than high quality. One commenter suggested that TPSs should not be calculated for low-volume dialysis programs because doing so may cause an inappropriate distribution of payments across facilities, which is contrary to Section 1881(h)(3)(A)(ii) of the Act.

Response: We thank commenters for sharing their concerns. We have several policies in place designed to address the commenters' concerns. Specifically, the SFA is designed to ensure that small facilities, many of which are affiliated with academic medical centers, are not adversely affected by a small number of outlier patients. We have addressed concerns about the reliability and validity of the NHSN BSI Clinical Measure in section IV.D.1.a in this rule. We believe it is important to include even the low-volume dialysis facilities in the ESRD QIP and to calculate a TPS for them so that these facilities receive appropriate incentives to deliver high quality care to their patients. We are continually striving to improve the data submission process in CROWNWeb to make the process easier for facilities, and we note that low rejection rates achieved by certain batch-submitting organizations demonstrates that CROWNWeb is equipped to accept this mode of data submission. Additionally, we believe that all of the measures in the ESRD QIP measure set evaluate the quality of care that is within the dialysis facility's sphere of influence, included to SRR measure, because our analyses demonstrate that the facility exerts an influence on readmissions roughly equivalent to that exerted by the discharging acute care hospital. Finally, we are constantly examining our policies and methodologies to ensure that they fairly and accurately assess the quality of care provided by dialysis facilities, and we do not believe that the proposed payment reduction policies constitute increased stringency because this policy has remained constant since the PY 2014 program (76 FR 70282).

Comment: Several commenters supported our continuation of the current policy for determining payment reductions, including the process for setting the minimum TPS. One commenter argued that it is critical to ensure that the ESRD QIP performance scoring is well thought-out and fair to all facilities, including low-volume facilities which service sicker-than average populations.

Response: We thank the commenters for their support and we believe that the ESRD QIP's scoring methodology is fair to all facilities. We also note that we finalized the SFA specifically to ensure that low-volume facilities are not unfairly penalized for a few outlier patients who could significantly impact their measure scores.

Final Rule Action: After careful consideration of the comments received and an analysis of the most recently available data, we are finalizing that the minimum TPS for PY 2019 will be 60. We are also finalizing the payment reduction scale shown in Table 11.

TABLE 11—PAYMENT REDUCTION SCALE FOR PY 2019 BASED ON THE MOST RECENTLY AVAILABLE DATA

Total performance score	Reduction (%)
100–60	0.0
50–59	0.5
40–49	1.0
30–39	1.5
0–29	2.0

9. Data Validation

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. We began a pilot data validation program in CY 2013 for the ESRD QIP, and 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 proposed 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 BSI 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 proposed 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 sought comments on this proposal. The comments and our responses for these proposals are set forth below.

Comment: Several commenters supported our proposed changes to Data Validation in the ESRD QIP. One commenter specifically supported our proposed extension of the data validation pilot study as well as the proposal to validate NHSN data. They also supported our proposal to implement a penalty for failure to comply with the 30-day response window. One commenter specifically supported our proposed NHSN Data Validation methodology because providers do not always report dialysis events or do not report them in accordance with the CDC's NHSN Dialysis Event Protocol and they argued that this validation study, if done correctly, will better hold facilities accountable for the quality of care they provide to patients. One commenter added that validation, when coupled with meaningful accountability, is the best way to guarantee that the dialysis events of ESRD patients are reported accurately and appropriately.

Response: We thank commenters for their support.

Comment: Two commenters raised concerns that the two data validation studies are masked attempts at auditing quality data submissions and that CMS is actually conducting the study because the CROWNWeb validation study showed that CROWNWeb is not reliable or valid as a collection tool and because the NHSN BSI Measure has not been appropriately validated. They argued that if the actual goal of the validation studies is to audit facilities, then CMS should provide a mechanism to appeal adverse decisions before points are taken away from facilities' total performance scores. The commenter offered support in working with CMS to ensure the validity and reliability of the data submitted to NHSN but argued that the validation studies is not the appropriate way to address concerns that CMS has and asked that CMS state clearly in the final rule the reason that such studies are necessary and whether or not the purpose of them is to audit facilities.

Response: As stated previously in the CY 2015 final rule with comment period (79 FR 66188) and the CY 2016 final rule with comment period (80 FR 69049), we agree that one of the purposes of the validation studies is to identify instances in which facilities are reporting invalid data either to CROWNWeb or to NHSN. However, we continue to believe it is inappropriate to designate the validation studies as ''audits'' of facility data, because the ultimate objective of the studies is to improve the validity of data reported to CROWNWeb and to NHSN, rather than to penalize facilities for reporting invalid data. We further note that we did not propose to penalize facilities for reporting invalid data for either of the validation studies. If we propose to do so in future rulemaking, we will consider implementing an appeal process that facilities can use to contest CMS determinations that invalid data was reported to either CROWNWeb or to NHSN. The purpose of these studies is not to audit facilities but to improve the validity of the data by identifying instances of intentional or unintentional under-reporting.

Comment: One commenter suggested that CMS consider providing resources to state health departments so that they can conduct on-site data validation as this would also help with educating facility staff on surveillance, reporting, and infection prevention, identify areas of misunderstanding and improve communication, and provide technical assistance to facilities in reporting and data validation efforts. Another commenter requested that CMS release the results of the CROWNWeb validation study and that CMS stop using CROWNWeb as part of the ESRD QIP until it has been appropriately validated. Two commenters offered suggestions for expanding the Data Validation Studies. If financial barriers are a concern, the commenter suggested an alternative approach would be to require facilities to engage in a self-validation exercise module which would still be a burden of labor on the facility but would provide useful information to both CMS and the facility. They offered examples of such self-validation modules, available through the California Department of Public Health. One commenter recommended that CMS increase the size of the validation study to include at least 5 percent of facilities, arguing that a larger, more representative sample is needed for validation, especially considering that this data will soon be publicly available for the first time via

Dialysis Facility Compare. Another commenter specifically recommended that CMS perform validation on at least one percent of (or at least 70) facilities. They also recommended increasing the number of records reviewed at each facility from the 10 proposed in the rule. They also encouraged CMS to conduct validations of facilities that do not report dialysis events or that report zero events, because these non-compliant facilities could be skewing national averages, negatively impacting those facilities that do comply with the measure requirements.

Response: We thank commenters for their recommendations about ways to improve the NHSN BSI validation study and increase the size of the study. We appreciate the commenter's recommendation to require facilities to conduct a self-validation module as a means to overcome these resource limitations, and we will consider the feasibility of such an approach in the future. We also appreciate the recommendation to provide funding to state health departments to conduct validation studies; we agree that these agencies have conducted very successful studies of this nature and will consider the feasibility of this approach. We also appreciate the suggestion to selectively sample facilities that report zero dialysis events for validation, and we will investigate the utility of using a non-random sample in the future. Unfortunately, at this time, resource limitations prevent us from increasing the size of the NHSN BSI Validation Study, both respect to the number of facilities sampled, as well as the number of records from each facility that are validated. We believe the proposed study methodology will provide the CDC and CMS with greater insights than previous studies because this study will yield information about the types of under-reporting, the extent of under-reporting and the reasons for under-reporting to the NHSN system. We look forward to continuing to refine this study to ensure that we are collecting as much reliable and useful data about bloodstream infections as possible.

CDC agrees that there are substantial benefits that occur when health departments conduct on-site assessments of facility data and direct education of staff to improve surveillance practices. The CDC supports the suggestion of providing state health departments with funds to conduct data validation activities. Few states are currently funded via the CDC cooperative agreement (Epidemiology and Laboratory Capacity grant) to conduct external HAI data validation. These states have conducted data validation of patient safety modules that resulted in an improvement in states' understanding of gaps in HAI reporting, commonly made errors, improved partnerships and communication between state health departments and healthcare facilities.

Comment: Several commenters did not support our proposal to decrease the response time for the NHSN Data Validation Study for facilities from 60 to 30 days, and argued that the reduced response time, coupled with the penalty for non-response, is too harsh compared with the problem identified by the studies, particularly in light of a lack of due process for facilities that are found to be non-compliant.

With respect to the proposed reduced response time, one commenter argued that facilities often do not receive the faxed or written request for records or they are lost, leaving them with less time to respond to the request, and recommended that CMS instead email the requests to all of the NHSN users within each facility to ensure that the request is received. Another argued that 30 days is simply too short a period of time to ensure the request is received and can be completed. One commenter also added that providers often must obtain documentation from other healthcare providers in order to respond to the request and that 60 days is simply not enough time to receive the request, coordinate with other providers, and send in the required documentation. One commenter suggested that while the data validation study is ongoing, CMS should not reduce a facility's TPS since the purpose of the study, as commenter sees it, is to assess future policies to ensure the accuracy of the data submitted to NHSN.

With regards to the penalty for non-response, commenters urged CMS to eliminate the proposed 10-point reduction in a facility's TPS due to non-compliance with the NHSN Data Validation Study for two reasons. First, they argued that compliance with a data validation study is unrelated to the quality of care provided at a facility and therefore is inappropriate for inclusion in a facility's TPS. Second, they suggested that reducing a facility's TPS score confuses and misinforms patients, caregivers and families about the quality of care provided at a given facility.

Response: Based upon the comments received, we are not going to finalize the 30-day response time. Instead, we will give facilities 60 days to respond to record requests. However, facilities should not need to collect records from other healthcare facilities solely for the purposes of the data validation record request.

We disagree with the comment about deducting points from a facility's TPS for noncompliance with the CROWNWeb and NHSN validation studies. As stated previously at (79 FR 66189), our policy to deduct points from a facility's TPS is consistent with section 1881(h)(3)(A)(i) of the Act, because it is part of our methodology for assessing the total performance of each provider of services and renal dialysis facility based on performance standards with respect to the measures selected. The main purpose of these studies is to assess whether facilities are reporting accurate data, and we have determined that review of medical records is integral to that determination.

Comment: One commenter pointed out that being admitted to a hospital should not qualify as a reportable Dialysis Event for purposes of the Data Validation Study.

Response: The validation study includes positive blood cultures collected or identified in patients during the first day of a hospitalization because these events are included in the calculations for the NHSN BSI clinical measure. In order to report these events, facilities will need to obtain medical records from hospitals that capture these results.

Final Rule Action: After careful consideration of the comments received, we are finalizing the methodologies for Data Validation with one change. Specifically, we are increasing the amount of time facilities will have to respond to record requests for the NHSN Data Validation Study from 30 days to 60 days. We believe this should give facilities ample time to collect and submit the required records.

E. Requirements for the PY 2020 ESRD QIP

1. 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 12.

TABLE 12—PY 2020 CLINICAL MEASURES INCLUDING FACILITIES WITH AT LEAST 11 ELIGIBLE PATIENTS PER MEASURE

Measure	N	75th/25th Percentile	90th/10th 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	[1]90.1	5.16	<0.01	Yes.
Serum Calcium >10.2	6257	0.91	0.32	0.049	No	[1]97.8	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 operations.	3349	66.2	71.2	0.134	No	60.9	6.20	0.10	No
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 percent – truncated mean) for measures where lower score = better performance.

As the information in Table 12 indicates, none of these clinical measures are currently topped-out in the ESRD QIP. Accordingly, we did not propose 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 proposed 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 in section IV.D.2.c.i. of the proposed rule (81 FR 42838)

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

Comment: Many commenters supported the replacement of the Mineral Metabolism Reporting Measure with the Serum Phosphorus measure. They noted that NQF 0255 is topped out because of high facility performance and minimal room for improvement, so it's not the best indicator of quality, but they understand that CMS is required to comply with PAMA. They further encouraged CMS to work with the kidney care community to identify more appropriate measures to satisfy the statutory requirement.

Response: We appreciate the commenters' support, and we agree that it would be desirable to have more robust measures on bone mineral metabolism. We note that neither the Mineral Metabolism nor the Serum Phosphorus measures can be topped out in the same sense as other clinical measures, because reporting measures are scored on the basis of how much data are reported, and clinical measures are scored on the basis of what the data represent. In the case of clinical measures, uniformly high performance indicates that the measure may no longer be necessary because high quality care is being delivered virtually across the board. In the case of reporting measures, by contrast, high levels of reporting do not obviate the need for the measure, because the measures are largely put in place to capture data on an ongoing basis.

Comment: Commenters asked CMS for two clarifications regarding the proposed Serum Phosphorus Reporting Measure. First, commenters noted that plasma is absent from the measure title and from the measure's Technical Specifications, although it is mentioned in the ''additional information'' in the Serum Phosphorus Technical Specifications and recommended that the title of the measure be modified to clearly denote plasma as an acceptable

substrate and that the specifications make this abundantly clear. Second, commenters requested that CMS review the measure's specifications and standardize the exclusions between the Mineral Metabolism Measure and the Serum Phosphorus Measure.

Response: We thank commenter for their suggestion, however at this time we are not proposing to change the title of the proposed Serum Phosphorus Reporting Measure. This measure is based upon an NQF-endorsed measure, #0255 Measurement of Serum Phosphorus Concentration. The measure's technical specifications clearly indicate that plasma is an acceptable substrate and we do not believe it is necessary to indicate this in the title of the measure. The differences in the exclusions between the Mineral Metabolism Measure and the Serum Phosphorus measure appear in the technical specifications of the measures and pertain to the determination of patient eligibility (that is, Mineral Metabolism uses number of treatments in claims to determine this, but Serum Phosphorus uses days at the facility as indicated in CROWNWeb). As we indicated in the proposed rule, we proposed this change because of our intention to increasingly use CROWNWeb as the data source for calculating measures in the ESRD QIP and because this reporting measure is based upon an NQF-endorsed measure.

Final Rule Action: After considering the comments received, we are finalizing our proposal to replace the Mineral Metabolism Reporting Measure with the Serum Phosphorus Reporting Measure beginning in PY 2020. This measure change is consistent with our intention to increasingly use CROWNWeb as the data source for calculating measures in the ESRD QIP, and it brings measure exclusion criteria into alignment with other measures used in the ESRD QIP program.

2. 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 13. 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 proposed to replace the Mineral Metabolism Reporting Measure with the Serum Phosphorus Reporting Measure and we proposed to reintroduce the NHSN Dialysis Event Reporting Measure into the ESRD QIP measure set beginning with PY 2019.

TABLE 13—PY 2019 ESRD QIP MEASURES BEING CONTINUED IN PY 2020

NQF No.	Measure title and description
0257	Vascular Access Type: AV Fistula, a clinical measure. Percentage of patient-months on hemodialysis during the last hemodialysis treatment of the month using an autogenous AV fistula with two needles.
0256	Vascular Access Type: Catheter ≥ 90 days, a clinical measure. Percentage of patient-months for patients on hemodialysis during the last hemodialysis treatment of month with a catheter continuously for 90 days or longer prior to the last hemodialysis session.
N/A	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.
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.
N/A	NHSN Dialysis Event Reporting Measure (Proposed for PY 2019 in section IV.C.1.a. of the proposed rule (81 FR 42823)).

We received general comments on the PY 2020 measure set. The comments and our responses for these proposals are set forth below.

Comment: Commenter argued that the measures being proposed for inclusion in the ESRD QIP do not take a patient-

centric approach to care because they do not take into consideration the fact that many of these patients have multiple comorbidities and that dialysis is just one treatment being offered to them. Commenter added that the patient's primary care physician should be at the center of the complex care plan model used for patients with ESRD.

Response: We thank the commenter for sharing these concerns. The SRR, SHR, and STrR do consider patient comorbidities through standardized risk adjustment models that incorporate a variety of comorbidities that contribute to the risk of poor health outcomes. We agree that a patient's primary care physician should be involved in the complex care planning required for many ESRD dialysis patients, and coordination between the facility and the primary care physician is part of the responsibility of the interdisciplinary team. We also believe that the SRR and SHR epitomize our aim to include patient-centered measures in the ESRD QIP measure set, because these measures assess outcomes that deeply matter to patients, and because high performance on these measures requires a patient-centered orientation that emphasizes care coordination and special attention to patients in precarious situations (for example, those who are at-risk for a hospitalization and/or readmission).

Comment: Two commenters argued that the technical specifications for the Kt/V measure, the hypercalcemia measure, and the phosphorus measure may be creating barriers to accessing home dialysis due to the ways in which they address patients who switch from hemodialysis to home dialysis. They recommended that CMS modify the exclusion criteria for these measures to remove these barriers. Specifically, commenter pointed out that under the current specifications, if a patient is on in-center HD for more than 90 days and then switches to home PD, the patient is included in the QIP calculation as soon as they have a PD-related Medicare claim. The patient who switches from in-center HD to PD and has no Kt/V during the month is viewed as not meeting the standard. However, if a new patient begins dialysis as a home PD patient, the specs provide a 90-day grace period during which no Kt/V data is expected. The current specifications therefore encourage facilities to perform a Kt/V on PD patients during training which is not clinically necessary. To address this concern, commenter recommended that CMS modify the exclusion criteria from ''patients on dialysis for less than 90 days'' to ''patients on the PD modality for less than 90 days.''

For Hypercalcemia and Phosphorus, commenter recommended that CMS modify the exclusion criteria to state: ''home dialysis patients for whom a facility does not submit a claim during the claim month or PD patients with fewer than 15 billable days or home HD patients with fewer than seven treatments during claim month.'' Commenter argued that the way the specifications are currently written, home patients are required to receive a lab result while in-center patients have a six-treatment grace period. Additionally, if a home patient receives a treatment on the first of the month and then goes to the hospital for the remainder of the month, the patient-month will be counted as not meeting the standard. Patients are therefore being treated to medically unnecessary tests, and the commenter argued that this modification to the specifications for these measures will address this problem for patients who sift from in-center HD to home PD in relation to the hypercalcemia and phosphorus measures.

Response: We thank the commenters for their concerns. The Kt/V measure does provide a longer timeline for completion of Kt/V assessment for a new ESRD patient beginning dialysis on PD than it does for a patient who has previously been on In-center HD and subsequently switches modality. The commenter's suggestion to change the denominator exclusion to ''patients on the PD modality for less than 90 days'' would effectively provide similar timelines for completion of the first Kt/V assessment. However, it is not certain that this proposed approach is the most appropriate one. Patients new to dialysis whose initial modality is PD almost always have significant residual renal function that allows initiation of less aggressive PD prescriptions during and for several weeks after initial training. Since Kt/V for PD is defined as a combination of both residual renal function and dialytic Kt/V, the contribution of residual renal function is typically substantial in this situation. For patients having previously been treated with In-center HD who subsequently change modality, the likelihood of having persisting significant residual renal function is much lower. In this scenario, the clinical team may well need to provide more aggressive initial PD prescription to compensate for absent residual renal function in order to provide adequate PD. Whether or not allowing 120 days for the provider to assess delivered Kt/V in these very different scenarios has not been carefully evaluated. Prior to revising the current specifications, more study is needed to assess the safety impact of this revision. Finally, the comment that the current specifications encourage facilities to perform a Kt/V on PD patients during training is not necessarily correct. The current specifications encourage providers to perform Kt/V as soon as possible after initiation of PD in order to evaluate the adequacy of the initial dialysis prescription in this setting where residual renal function may be reduced.

With regard to hypercalcemia and phosphorus, the commenter describes a claims-based exclusion paradigm that is not used for the hypercalcemia or phosphorus measures, nor is it consistent with the DFC specification of Kt/V. Irrespective of modality, patients are included in the measures' denominator based primarily on CROWNWeb admission and discharge data and not primarily on the number of Medicare Claims treatment events. In addition, assessment of calcium and phosphorus concentrations and avoidance of hypercalcemia apply equally to both In-center HD and home dialysis patients.

Comment: Commenter expressed dismay at the fact that there is no health-related quality of life measure in the ESRD QIP and recommended that starting in CY 2018 (for PY 2020), each facility must report in CROWNWeb whether each eligible patient completed the KDQOL. Commenter argued that this is the most important measure because it is a patient-reported outcome measure which predicts hospitalization and survival in dialysis patients as strongly as dialysis dose and serum albumin.

Response: We thank commenter for their suggestion. We agree that it is vitally important to examine the quality of life of patients with ESRD, and for that reason, we have included important measures such as the Pain Assessment and Follow-Up Reporting Measure and the Depression Screening and Follow-Up Reporting Measure. The CMS Dialysis Conditions for Coverage already requires, under Condition 494.90, that facilities complete an annual psychosocial evaluation for each patient, and facilities typically use the KDQOL survey for this purpose. Therefore, adding an additional measure on how many patients receive the KDQOL survey for the ESRD QIP would be unnecessarily duplicative and would unnecessarily dilute the significance of other measures in the ESRD QIP measure set. We will continue working with the community to identify appropriate patient-reported outcome measures for use in the ESRD QIP.

Comment: Several commenters supported our proposal to study the impact of the SRR and STrR measures on quality of care.

Response: We thank commenters for their support and we look forward to sharing the results of the study with the community when they become available.

Comment: Commenters generally supported the continued inclusion of the ICH CAHPS measure in the ESRD QIP but expressed some concerns and made several recommendations for improving the measure as implemented in the program.

The concerns expressed by commenters include: (1) Patients need to be involved with the survey in a meaningful way; (2) The ESRD National Coordinating Center (NCC) LAN Affinity Group is in the process of trying to address #1; (3) Patients remain concerned with inconsistencies in the administration and understanding of the survey; (4) Patients remain concerned that while a minority of patients may see benefits from the results of the survey, it will not improve the patient experience of care or have a meaningful impact on process change at the facility level as it currently exists; (5) In light of these concerns, the current weight being assigned to this metric appears to be excessive. They recommended reconsideration for the weighting assigned to the CAHPS measure until these concerns are addressed.

The changes commenters recommended include: (1) Provide a specific list of the exclusions that would exclude homeless patients as well; (2) Expand the ICH CAHPS survey to include peritoneal dialysis and home hemodialysis patients in future rulemaking; (3) Administer the survey consistent with the AHRQ specifications, including by dividing it into three sections that were independently tested; (4) Require that the survey be administered only once each year, consistent with the findings of the American Institutes for Research/RAND et al.; (5) Coordinate with the ESRD Networks to reduce duplication in its administration; (6) Implement a mechanism for facilities to ensure that patients' contact information is as accurate and up-to-date as possible; (7) Review the lingual translations of the surveys to ensure that they are accurate.

Response: We appreciate the concerns listed by the commenters. We will address each one separately. (1) A specific list of the exclusions from the ICH CAHPS survey is published in the In-Center Hemodialysis CAHPS® Survey Administration and Specifications Manual, which can be found on the survey technical Web site, *https://ichcahps.org* under the Survey and Protocols tab. We explicitly chose not to exclude homeless persons based on the advice of our technical expert panel, which indicated that some homeless persons can be contacted for survey research. (2) We are considering creating an ICH CAHPS survey for home and peritoneal dialysis patients. However, we do not currently have concrete plans for this expansion. (3) The commenter suggests using the AHRQ specifications for administering the ICH CAHPS Survey. The AHRQ specifications are not designed to support public reporting of survey data. The CMS specifications are much more detailed because they are to ensure, to the extent possible, that the survey is conducted the same way by all vendors. This improves the quality of the data for public reporting purposes. We do not understand the comment that the survey should be divided into three sections that were independently tested. The entire ICH CAHPS survey has been tested. (4) We considered the option of doing the survey once a year, but realized that a single administration could miss patients and that it would cover patient experiences for only part of the year. We decided to require that the survey be conducted twice a year to increase opportunities for patients to make their experiences known. (5) We are already working with the ESRD networks and are receptive to suggestions for reducing duplication. (6) We currently ask that survey vendors contact facilities for updated patient contact information. However, we ask that the vendor request updated information for all patients, not just those that are in the sample, in an effort to protect patient confidentiality. (7) We are currently reviewing translations of the questionnaires.

Comment: Commenter appreciates that the current ICH CAHPS measure is not appropriate for assessing the care of home patients but urged CMS to invest in the development and adoption of a patient experience instrument validated for assessing the home dialysis population. Commenter added that it is extremely important for CMS to recognize that PD and HHD are distinct from each other and from in-center dialysis and to keep these important differences in mind when developing a survey instrument that would be more appropriate for the home dialysis population.

Response: We thank the commenter for their comments and suggestions. We are considering the possibility of developing an additional CAHPS survey for home and peritoneal patients. However, we do not have specific plans for this survey at this time.

Comment: One commenter opposed the continued use of the ICH CAHPS measure as a clinical measure and expressed concerns that the twice annual survey requirement does not allow sufficient time for facilities to make improvements based on the first survey responses before the second survey is due to be conducted. They added that the current required timing is contrary to the goal of improving the patient experience and urged CMS to reconsider the requirement for two annual surveys.

Another commenter supported CMS's willingness to consider expanding the ICH CAHPS survey in future years to include peritoneal dialysis, home hemodialysis patients, and homeless patients. In the interim, they recommended that CMS consider certain modifications to the measure to make it less burdensome to facilities and patients. First, they recommended addressing concerns about the burden on patients by aligning the ICH CAHPS measure specifications with those AHRQ relied upon when testing the measure. Specifically, they recommended that CMS divide the survey into three sections, which were each independently tested, and they suggested reducing the requirement to a single administration of the survey each year. They also urged CMS to work with facilities to develop a mechanism to ensure that patients' contact information is accurate and up-to-date so that facilities are not penalized for non-response when the patient's address was incorrect and encouraged CMS to ensure that the ICH CAHPS survey is correctly translated for all foreign-language speakers, and that the translation is meaningful and accurate.

Response: One of the goals of the ICH CAHPS survey is to encourage quality improvements. We are aware that some improvement efforts will take more than one survey period to be reflected in the data. This is particularly true for the publicly-reported data, which is reported for two survey administration periods. However this does not mean that the facility cannot or should not undertake quality improvement efforts.

The AHRQ guidelines were not designed to support public reporting. They are, therefore, less detailed than the CMS guidelines, which are designed to improve data quality for public reporting. We conduct the survey twice a year in order to provide patients with multiple opportunities to report their experiences. We also report the data from two survey administrations to improve the possibility that the sample

sizes will be large enough to provide useful information.

Comment: Commenters generally supported the continued inclusion of the NHSN Healthcare Personnel Influenza Vaccination Reporting Measure in the ESRD QIP, as well as the elimination of the requirement for written documentation, but they made several recommendations for improving the measure. Most importantly, commenters recommended changing the Performance Period for the NHSN HPI Vaccination Reporting Measure to align with CDC guidelines and to set it as October 1 through March 31 so that facilities are not penalized for complying with established clinical guidelines and so that patients are not placed at increased risk early in the influenza season. Second, commenters recommended that exemptions should be in place for short-term visitors and that the performance period be extended to allow for early vaccination. Third, commenters expressed concerns about the third part of the denominator, requiring students/trainees and volunteers to be vaccinated. They argued that facilities often have such individuals on a very short-term basis and documenting their vaccination status is difficult, highly burdensome and diverts resources away from important clinical care. Finally, commenters recommended that CMS include a baseline reporting threshold for the measure, similar to what is required for inpatient rehab hospitals and other healthcare facilities.

Response: The current performance period for NHSN's measure of healthcare personnel influenza vaccination is from October 1 through March 31. All personnel who physically work in a reporting facility for at least one day from October 1 through March 31 are eligible for inclusion in the measure denominator. The numerator of the measure begins ''as soon as vaccine becomes available'' for a given influenza season. Personnel who are working in the reporting facility during the denominator reporting period (October 1 through March 31) may be vaccinated as early as August or September and this vaccination would be included in the NHSN measure; therefore, there is no penalty for early vaccination built into the NHSN measure.

Since short-term visitors can transmit or acquire influenza even when in a healthcare facility for a limited amount of time, all healthcare personnel working one day or more during the reporting period are included in the NHSN measure. Facilities are encouraged to develop tracking systems that will capture these data from short-term HCP when they come into the facility during the reporting period. Among short-term healthcare personnel, adult students/trainees and volunteers may be reasonably anticipated to have substantial contact with patients and/or other healthcare personnel in a healthcare facility, increasing the risk of acquiring or transmitting influenza infection during the influenza season. To alleviate the challenges associated with collecting data on groups that do not regularly work in a facility, CDC encourages facilities to devise tracking systems to reach these individuals. CDC developed an information sheet that lists methods and strategies on how this can be accomplished, based on interviews conducted with a sample of acute care facilities that collected these data during the 2012–2013 influenza season: *http://www.cdc.gov/nhsn/PDFs/HPS/General-Strategies-HCP-Groups.pdf.*

Comment: Two commenters urged CMS to establish batch submission to NHSN as soon as possible for the NHSN HPI Vaccination Measure, arguing that it's very problematic that facilities are not yet able to do this.

Response: One of CDC's goals is to minimize reporting burden. Due to the development time needed to support batch submission, CDC is not able to rapidly transition to this data collection system. Currently, CDC anticipates the batch submission of healthcare personnel influenza vaccination data will be available for the 2018/2019 influenza season (PY 2021 QIP).

Comment: Several commenters expressed concerns about the effect the SRR measure is having on patient access to care, but they added that they are looking forward to seeing the results of the access to care study, to better understand the impact the SRR and STrR measures are having on access to care. One commenter recommended evaluating the effectiveness of these two measures at measuring the actual care provided in dialysis facilities, and urged CMS not to use the measures in the program until it has been determined whether they have a positive or negative impact on dialysis patients.

Response: We thank commenters for sharing their concerns. We look forward to sharing the results of the access to care study with the community once they become available. We believe these two measures are vitally important to continue including in the ESRD QIP measure set because they measure important aspects of patient care. We are continually evaluating the effectiveness of all of the measures included in the program and we have policies in place to determine when a measure should be retired from the program (77 FR 67475). Neither of these measures meet the criteria established through rule-making.

Comment: One commenter recommended that CMS exclude patients with an incomplete claims history from the SRR measure.

Response: We considered excluding patients without a full 1-year Medicare history but decided in the end that this was not necessary. Many patients without a full year of claims history are not Medicare eligible when they begin dialysis. They subsequently become Medicare eligible and may experience a hospitalization and a readmission in the first year. In the event of a readmission, CMS has the data from the diagnoses of the index discharge, and these data provide substantial detail on comorbidities and are available for all patients. The availability of these data enables adequate risk adjustment. We additionally note that the SRR does make use of the hierarchical condition categories (HCCs) to capture comorbidities. Excluding such patients would eliminate much of the incentive to avoid readmissions in a highly vulnerable population during their first year of care. We believe care coordination is important in this population and strive to include assessment of appropriate populations where feasible.

Comment: Commenter supports efforts to reduce hospital readmissions that are directly related to the care provided by dialysis facilities, but is concerned that the SRR measure does not provide actionable information that promotes quality improvement in facilities.

Response: High readmission rates may indicate the facility may be missing opportunities to improve care transitions during and after hospital discharge. A few pilot studies have shown that better care coordination between the facility and the hospital can reduce readmissions. The SRR measure development TEP considered the possibility of constraining the assessment of readmissions to those directly related to the care provided by dialysis facilities, but could not reach a consensus defining such events. The TEP recommended moving forward with the development of the SRR as an all-cause readmission measure. We have met with kidney community stakeholders regarding methods that can make measure data more actionable, including the provision of patient-level quality data and more timely reporting. While we believe we have improved upon this, we also agree that we should work toward continuing enhancement

of the quality information made available to facilities for this measure and others.

Comment: One commenter recommended that CMS work to develop an appropriate risk model that accounts for hospital-specific patterns and adjusts for physician-level admitting patterns as there is great geographic variability in both of these factors that need to be accounted for. They also urged CMS to align the standardized risk measures methodology with that used for other Medicare programs and other providers such as MA plans, by using the CMS claims-data available for the hierarchical conditions categories (CMS–HCC).

Response: The SRR risk adjustment model does adjust for hospital effects by including hospital-level random effects. Our methodology uses past-year comorbidities that are obtained from ICD–9/ICD–10 diagnoses codes from Medicare claims. These diagnoses are grouped using the HCC. This approach is aligned with the methodology for the CMS Hospital Wide Readmission measure. Our position on the adjustment for physician-level admitting patterns has not changed, however. The treating nephrologist is, by definition, part of the inter-disciplinary team that treats patients under the aegis of the dialysis facility, as outlined in the Conditions for Coverage. As a consequence, any component of care provided by the treating nephrologist that influences risk for readmissions is appropriately attributable to the dialysis facility, and not appropriate for risk adjustment.

Comment: One commenter recommended that CMS consider adding a page in CROWNWeb for the patient's medical history with start and end dates in order to gather all the patient's medical history and to ensure that STrR excludes the correct patients. This medical history page would be a part of the patient's information, which would mean it would travel with them from facility to facility.

Response: We are constantly evaluating the effectiveness and usability of CROWNWeb and we will consider adding a page for the patient's medical history with start and end dates in future updates of the system.

Comment: One commenter expressed concerns that the STrR measure is flawed and that facilities could be unfairly penalized for transfusions they had no opportunity to avoid or control.

Response: While we recognize most transfusions occur in the hospital, facilities are directly responsible for appropriate anemia management based on the Medicare Conditions for Coverage and Medicare payment policies. Since dialysis facilities have a direct role in determining achieved hemoglobin as a result of their anemia management practices, which influences the risk for transfusion in dialysis patients, dialysis facilities share responsibility with other providers for transfusion events. The responsibility of the dialysis facility for achieved hemoglobin outcomes (and transfusion risk related to achieved hemoglobin) is strengthened by applying an extensive list of exclusions for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication.

Comment: Commenter suggested that the timely monitoring and reporting of transfusions for patients on dialysis are extremely important and recommended the ongoing collection of data and timely reporting on the percentage of patients with Hgb levels between 6 and 10. This data could be merged, they suggested, with an individual patient's transfusion history to determine the Hgb level or levels that are typically associated with a transfusion, and can be used to see whether low Hgb levels in a dialysis center are contributing to the increase in transfusions across all clinical settings. These data could also be used to develop future transfusion best practice guidelines for people on dialysis and for those hoping to get a kidney transplant.

Response: We thank the commenter for offering this suggestion. Studies investigating this issue are available in the published medical literature. We note that dialysis facilities already monitor hemoglobin concentration for the patients they treat as part of their responsibility for anemia management under the Medicare ESRD Conditions for Coverage. The dialysis receives the results of the hemoglobin test results drawn in the outpatient setting and is able to respond with appropriate changes to the patients' medical needs.

Comment: Commenter argued that a transfusion avoidance measure should be stratified to appropriately capture blood transfusions that could have been prevented by the dialysis facility and should exclude those that resulted from acute or chronic medical conditions outside the scope of practice of the facility or nephrologist caring for the patient. Commenter acknowledged that tracking blood transfusion data is critical to understand patient safety issues and that will be difficult because most transfusions are not provided in the dialysis setting, and they expressed concern that the STrR measure alone does not completely counteract the potential to under-treat anemia and may permit patients hemoglobin levels to fall below the range recommended in the KDOQI Anemia Management guidelines. Finally, commenter argued that the transfusion avoidance measure does not take into account patients' quality of life or cardiovascular risks associated with low hemoglobin levels.

Response: We are not aware of data that allow us to directly distinguish between transfusion events that are preventable and those that are not. In lieu of this, the STrR includes an extensive list of patient comorbidity exclusions, based on Technical Expert Panel input. These exclude patients with malignancy, hereditary anemias and other bone marrow conditions that are associated with erythropoiesis stimulating agent (ESA) hyporesponsiveness and/or increased risk of ESA use. This exclusion approach excludes many patients with medical conditions that complicate anemia management by the treating nephrologist and dialysis facility. We agree that the STrR does not address all aspects of clinical anemia management, including patient quality of life related to anemia. However, it assesses an important outcome of anemia management provided by the dialysis facility and we believe its use encourages avoidance of unacceptably low hemoglobin levels.

Comment: One commenter expressed concerns that the STrR Measure is not driving improvement in patient outcomes and is therefore not useful or appropriate for inclusion in the QIP. Instead, they recommended an alternative measure that would assess erythropoietin dosage levels compared to hemoglobin outcomes as a better measure to ensure that patients are receiving appropriate amounts of erythropoietin.

Response: We believe that STrR contributes to quality of care in ESRD anemia management by reporting on dialysis facility results in the important area of transfusion avoidance, which is an area of substantial concern in the kidney community, as indicated by the numerous comments we received when removing the Hgb <10 measure from the ESRD QIP (79 FR 66172 through 66174). Blood transfusion in dialysis patients has been associated with increased HLA sensitivity and may adversely affect access to kidney transplantation. Additionally, it is not clear to us what evidence exists to establish requirements for particular dosage levels, or how comparing them to hemoglobin levels would be

operationalized for a measure in the ESRD QIP.

Comment: One commenter expressed concerns that the STrR measure is not the right measure to use for evaluating anemia management in the dialysis setting for several reasons, and they offered support to CMS to help identify a different measure for use in the QIP that would monitor anemia management in dialysis facilities, consistent with the changes in the FDA labeling for ESAs. Their first concern is that dialysis facilities do not provide or direct transfusions; rather, patients typically receive transfusions in the hospital setting. Second, the decision to provide a transfusion is typically based upon hospital protocols that rarely take into account the unique nature of dialysis patients. Finally, the NQF Renal Standing Committee echoed these concerns and added that this measure more accurately reflects transfusion practices and behaviors at the hospital level rather than at the dialysis facility level, and they identified the potential for such coding inconsistencies to be a threat to measure validity.

Commenter explained that one of the most problematic aspects of the STrR measure is that dialysis facilities are not always able to obtain information from other providers about patient transfusions that they need to understand the metric and act upon it. If this measure is going to be of value, dialysis facilities need to obtain quarterly data bout the raw transfusion, hospitalization, readmissions, and mortality data using DFR calculations, and the six-month lagged data file. Without this important information, facilities have no insight on patients who may or may not be receiving transfusions.

Response: We thank the commenter. We believe the STrR, developed after the 2011 changes to Food and Drug Administration labeling for ESAs, reflects those revised recommendations. The FDA position defines the primary indication of ESA use in the CKD population as transfusion avoidance, reflecting the assessment of the relative risks and benefits of ESA use versus blood transfusion.

Dialysis providers are responsible for anemia management as part of the ESRD Conditions for Coverage. Best dialysis provider practice should include effective anemia management algorithms that focus on (1) prevention and treatment of iron deficiency, inflammation and other causes of ESA resistance, (2) use of the lowest dose of ESAs that achieves an appropriate target hemoglobin that is consistent with FDA guidelines and current best practices including transfusion avoidance, and (3) education of patients, their families and medical providers to avoid unnecessary blood transfusion so that risk of allosensitization is minimized, eliminating or reducing one preventable barrier to successful kidney transplantation.

The STrR measures dialysis facility performance in avoidance of transfusions for their patients. We agree that the majority of blood transfusions occur during hospitalization. However, the results of pre-hospitalization anemia management, reflected in achieved hemoglobin concentration prior to hospitalization, are a significant contributor to transfusion risk. The decision to transfuse blood is intended to improve or correct the pathophysiologic consequences of severe anemia, defined by achieved hemoglobin or hematocrit, in a specific clinical context for each patient situation (8). Consensus guidelines in the U.S. and other consensus guidelines defining appropriate use of blood transfusions are based, in large part, on the severity of anemia (9–11). Given the role of hemoglobin as a clinical outcome that defines anemia as well as forms a basis for consensus recommendations regarding use of blood transfusion, it is not surprising that the presence of decreased hemoglobin concentration is a strong predictor of subsequent risk for blood transfusion in multiple settings, including chronic dialysis (12–21). For example, Gilbertson, et al. found a nearly four-fold higher risk-adjusted transfusion rate in dialysis patients with achieved hemoglobin <10 gm/dl compared to those with >10 gm/dl hemoglobin. (19) In addition to achieved hemoglobin, other factors related to dialysis facility practices, including the facility's response to their patients achieved hemoglobin, may influence blood transfusion risk in the chronic dialysis population (22, 25). In an observational study recently published by Molony, et al. (2016) comparing different facility level titration practices, among patients with hemoglobin <10 and those with hemoglobin >11, they found increased transfusion risk in patients with larger ESA dose reductions and smaller dose escalations, and reduced transfusion risk in patients with larger ESA dose increases and smaller dose reductions (25). The authors reported no clinically meaningful differences in all-cause or cause-specific hospitalization events across groups.

We appreciate the offer to consider additional measures that might more comprehensively assess anemia management care provided by dialysis facilities and are willing to discuss this issue with stakeholders in the future. We are also aware of the desire within the community for more granular detail with regard to quality of care and we will look into ways to provide this level of detail. The recently released ESRD Measures Manual does provide a great amount of detail on technical microspecifications related to the ways in which measures are calculated and we are continuing to find ways to make the process more transparent for the community. The commenter mentioned the DFRs, and it may be that other quality programs, such as Dialysis Facility Compare and the DFR offer more opportunity for this type of quality improvement data.

Comment: Many commenters generally supported the continued inclusion in the ESRD QIP of Dialysis Adequacy measures, but expressed concerns with the Comprehensive Dialysis Adequacy Measure finalized in the CY 2016 ESRD PPS Final Rule, and which they characterized as a ''pooled'' dialysis adequacy measure. Commenters argued that it is not appropriate to draw conclusions about quality from one group (the larger adult population) to quality for the pediatric population at that facility, and expressed concerns that the vast clinical differences between these two groups makes it difficult to accurately assess a facility's quality. Specifically, commenters are concerned that by combining pediatric and adult PD and HD patients into a single adequacy metric, the transparency provided for pediatric and home dialysis metrics will be lost and the larger adult and HD populations will mask actual facility performance for pediatric and PD patients. Commenters believe that because these categories of patients are clinically different, pooling of the measures is inappropriate. Additionally, they stated that the MAP supported the measure when it was characterized as a composite measure and they therefore did not review the issue of pooling. Furthermore, they stated that the NQF Renal Standing Committee recommended against endorsement of this measure and found that it failed on the performance gap criterion and the threshold requirement for further discussion on factors such as validity and reliability. Commenters recommended that rather than continuing to use the Comprehensive Dialysis Adequacy Clinical Measure in the program, CMS should return to the four individual dialysis adequacy measures as separate measures or that they should work to develop and implement a true composite measure.

Response: As we stated in the CY 2016 ESRD PPS Final Rule (80 FR 69055), we acknowledge that there might have been some confusion surrounding our use of the term ''composite'' in the title of the Comprehensive Dialysis Adequacy Clinical Measure, especially because we are now aware that the NQF uses a specific set of criterion to determine whether a measure is a composite for endorsement purposes. However, as we noted in the CY 2016 ESRD PPS Final Rule, the measure specifications presented in the CY 2016 ESRD PPS proposed rule were identical to those submitted for review by the Measure Applications Partnership, and the calculation methodology uses a pooled approach.

The Comprehensive Dialysis Adequacy Clinical Measure does not clinically co-mingle different groups of patients. Rather, peritoneal dialysis patients are assessed based on clinical standards appropriate for these patients, while hemodialysis patients are assessed based on clinical standards appropriate for them. Similarly, adult and pediatric patients are assessed based on clinical standards that are appropriate for each of those groups. We understand that patient groups that comprise a smaller percentage of a facility's total population will have less impact on the facility's performance score for the Comprehensive Dialysis Adequacy clinical measure. The alternative, however, is to implement individual measures for each subpopulation in the Comprehensive Dialysis Adequacy clinical measure, as we had done previously. This would reintroduce the problem of limiting our ability to assess dialysis adequacy for patients in facilities large enough to provide reliable assessments using the Comprehensive Dialysis Adequacy clinical measure, but also lacking enough patients within the individual subpopulations to provide reliable assessments using the more granular measures of dialysis adequacy previously implemented in the ESRD QIP.

With regard to the question of whether the measure was described as ''pooled'' or ''composite'' at the Measures Application Partnership, we don't believe characterizing it as a composite measure at the time of MAP review changes the substance of what the MAP discussed; ''pooled'' was always part of the measure concept. The measure design and specifications are not substantively changed from those reviewed by the MAP.

Finally, this measure was not endorsed due to a limited performance gap criterion. This was also identified for some the previously implemented Kt/V dialysis adequacy measures that had been previously endorsed and implemented on ESRD QIP, but exhibited limited variation in performance. These measures retained a ''reserve'' endorsed status, which reflects that while other NQF criteria are met, performance on the measure is extremely high. The Comprehensive Dialysis Adequacy measure is not eligible for this designation by NQF because it had not been previously endorsed. However, it is methodologically aligned with these ''reserve'' measures, leading us to conclude that it is methodologically sound. Returning to the use of the more granular measures of dialysis adequacy would not address the underlying concern reflected in this comment, which is that the performance gap is limited, as this is reflected by these measures current ''reserve'' status. Under MIPPA, we are required to assess dialysis adequacy as part of the QIP. Because the Comprehensive Dialysis Adequacy clinical measure allows us to assess dialysis adequacy among the greater number of dialysis patients, we believe its continued implementation is appropriate.

Comment: Commenter disagreed with CMS's assertion in the CY 2016 ESRD PPS Final Rule that including the pediatric population into a pooled measure is more beneficial than having a separate measure because the ''pooled'' measure does not ensure that pediatric patients are receiving adequate dialysis since the pediatric population is not evaluated separately from the adult population.

Response: The Comprehensive Dialysis Adequacy Clinical Measure assesses pediatric patients based on clinical standards that are appropriate for the respective pediatric PD and HD patient populations. To address the concerns about the combined measure that incorporates both adult and pediatric populations and modality types, CMS found that a significant number of facilities that have <11 pediatric patients would now be assessed for dialysis adequacy in the new combined measure. Currently these facilities are excluded from the individual pediatric specific measures due to small facility size. This leads to the systematic exclusion of these facilities from assessment on these measures because of the reporting requirements. We believe it is important that patients at these facilities also be included in the assessment of adequate dialysis. This provides a mechanism to assess adequate, with respect to these small patient subpopulations.

Comment: Commenter argued that there are other tests which would be better indicators of dialysis adequacy than Kt/V. Specifically, commenter recommended the Beta-2 microglobulin or a 24-hour urine test when applicable, arguing that these tests, though more costly, would contribute more accurate information about the patient's dialysis adequacy.

Response: Assessment of small solute clearance during dialysis using urea-based metrics has been the industry standard for decades. This statement is reflected in widely accepted standards of practice, evidenced by KDOQI clinical guidelines and multiple endorsed NQF quality metrics based on urea clearance and expressed as Kt/V. These standards are reflected in the Comprehensive Dialysis Adequacy Clinical Measure.

Comment: One commenter noted that the evidence for the Kt/V targets for the hemodialysis population is based on three times per week dialysis, not four, and that therefore the dialysis adequacy goals may not be appropriate for patients who dialyze more than three times per week. Another commenter recommended that CMS revise the technical specifications for the Comprehensive Dialysis Adequacy Clinical Measure to include only the evidence-based Kt/V threshold because when the measure was reviewed by the NQF Renal Standing Committee, they recommended that the upper Kt/V threshold exclusions be removed from the measure's specifications due to insufficient evidence supporting the selected values.

Response: The Kt/V measure included in ESRD QIP did not include an upper limit for the Kt/V value; the value only needs to be greater than the target value for the specific population to be included in the numerator. The measure is also limited to those who dialyze three times per week. Therefore, we believe the goal is appropriate.

Comment: Two commenters supported the continued inclusion of the Vascular Access Type Measures in the QIP but asked that CMS adjust the weights to place more emphasis on reducing catheters in order to encourage the use of fistulas and grafts. One commenter recommended that CMS give credit for the fistula measure only if the catheter has been removed because the presence of a catheter increases the risk of infection even if it is not in use.

Response: We thank the commenter for sharing concerns relating to the presence of a catheter increasing the risk

of infection, even when not in use. We will assess this concern and consider its implications for future measurement in the ESRD QIP through our ongoing measure develop and maintenance process. We note that this issue was raised during the development of a new set of vascular access measures in 2015. These measures are currently being reviewed by the National Quality Forum Standing Renal Committee for consensus endorsement. Once these measures have completed the NQF endorsement process, we will consider whether they are appropriate for inclusion in the ESRD QIP. In the interim, we continue to believe that the weights associated with the Vascular Access Type measures, and their relative weighting within the Vascular Access Type measure topic, appropriate disincentivize the use of catheters and appropriately incentive the use of fistulae. Because existing measures on vascular access type do not include adjustments to take into account cases where grafts are more appropriate than fistulae, we believe the existing weights and measure specification are appropriately neutral with respect to the use of grafts.

Comment: One commenter supported CMS's submission of changes to the NQF Renal Standing Committee for the Vascular Access Type Measures that modify the measure to address the small number of patients for whom a catheter may be the most appropriate vascular access type when life expectancy is limited. They also added that they would like the measure to include all patients with a catheter in place for the reporting period in the numerator, whether the catheter is in continuous use or not.

Response: We thank you for your comment and note that the measures submitted to the NQF Renal Standing Committee this year are not part of the proposed rule.

Comment: One commenter encouraged CMS to modify the depression screening measure to require that the same methodology for detecting depression be used across facilities, or at a minimum that facilities be required to report how they screened for depression.

Response: We do not believe it is appropriate for CMS to dictate the depression screening tools that facilities use, and that facilities are in a better position to determine which tools are appropriate for their patient populations. We also appreciate the suggestion to require reporting of the screening tool used, and we will take this consideration into account in the future.

Comment: Two commenters supported the pain and depression measures but expressed concern that pain in ESRD patients may be treated with medication when emotional pain is really the cause of the patient's pain, because emotional and physical pain are so closely related. One of the commenters also raised concerns that depression needs to be clearly differentiated from fatigue or fear and that appropriate identification of these issues is important to enable dialysis facility social workers to identify which patients and families might benefit from additional social and family support.

Response: We thank commenter for their support and for sharing their concerns. The Pain and Depression measures are measures that assess how well facilities report rates of screening for these conditions. They are not designed to differentiate among different causes of pain or depression. Nor are they designed to evaluate the intensity and completeness of facilities' screening efforts.

Comment: One commenter supported the continued inclusion of the Pain Assessment measure in the QIP along with the modification to the measure from the CY 2016 ESRD PPS Final Rule that based a facility's score solely on the percentage of eligible patients treated in one six-month period if the facility treated no eligible patients in the other six-month period.

Response: We thank commenter for their support.

Comment: One commenter argued that the Pain & Depression measures included in the ESRD QIP measure set are global measures of patient well-being which are not specific for dialysis and should be under the purview of the patients' primary care physician. They argued that nephrologists and dialysis care teams should not be held responsible for all medical conditions of the dialysis patients because often the nephrologist's only option is to inform the patient's PCP and refer out to appropriate specialists.

Response: We thank commenter for sharing their concerns. These measures are designed to assess not the treatment of pain or depression but whether facilities report data on how and whether they screen their patients for these conditions, document an appropriate plan of care, and refer their patients to other healthcare providers when necessary. Nephrologists themselves are not being held responsible for these medical conditions, and we believe that dialysis facilities' close connections with patients (due to the regular need for dialysis treatment) often places them in a better position to provide such screenings and assessments, in comparison with primary care providers who typically see ESRD patient far less frequently.

Comment: Two commenters requested an extension of the reporting deadline for the Pain Assessment Reporting Measure in CROWNWeb. They expressed that due to system downtime, they were unable to submit their data by the August 1, 2016 deadline, and they requested that CMS extend the submission deadline to September 16, 2016.

Response: We thank commenters for their comments regarding the systems issues encountered during system downtime for CROWNWeb, and we appreciate that the fulfillment of ESRD QIP requirements is dependent upon facilities' ability to access CROWNWeb. In an effort to avoid similar issues in future years of the ESRD QIP, we are making updates to the reporting deadlines for all measures with CROWNWeb reporting deadlines beginning in PY 2019 (ICH CAHPS (76 FR 70269), Mineral Metabolism Reporting Measure (76 FR 70271), Anemia Management Reporting Measure (78 FR 72199), Pain Assessment and Follow-Up Reporting Measure (79 FR 66204), Clinical Depression Screening and Follow-Up Reporting Measure (79 FR 66200)) as well as those being finalized for PY 2020 (Serum Phosphorus Reporting Measure (81 FR 42838) and Ultrafiltration Rate Reporting Measure (81 FR 42839)). Rather than being required to submit data or attestations by a certain calendar date, facilities will now be required to submit data or attestations in CROWNWeb for the following measures before the clinical month closes in CROWNWeb: Hypercalcemia, ICH CAHPS, Mineral Metabolism/Proposed Serum Phosphorus Reporting Measure, Anemia Management Reporting Measure, Pain Assessment and Follow-Up Reporting Measure, Clinical Depression Screening and Follow-Up Reporting Measure, and Ultrafiltration Rate Reporting Measure.

Comment: One commenter supported the anemia management reporting measure and requested that CMS require facilities to note the Hb level at the first treatment of the week before dialysis is initiated. They also requested that CMS work to establish an anemia clinical measure to protect those on dialysis.

Response: Thank you for supporting the measure and for your recommendation.

Comment: One commenter requested information about their specific NHSN BSI Data. Specifically, their center

incurred 11 cases of BSI. Out of the 11 cases, 5 were access related. Of the remaining 6, 2 were related to foot gangrene, 1 to a UTI, 2 were due to infected sacral decubiti, and 1 was for a perforated abdomen. The facility requests clarification as to why BSI infections extend beyond access related bacteremia.

Response: CDC submitted several NHSN Dialysis Event measures to the National Quality Forum (NQF), an independent organization that evaluates healthcare measures. This includes the NHSN BSI measure, and a measure of access-related BSI (ARBSI), which is also captured in NHSN. Determining the source of a positive blood culture is inherently challenging and introduces significant subjectivity to (and opportunity for gaming) any measure of ARBSI. NQF evaluated these measures, but only endorsed the BSI measure because of its standardization and objectivity, and only that measure is included in the ESRD QIP. Because BSI includes *all* positive blood cultures regardless of suspected source, it's an objective and more reliable measure, relatively easily captured with electronic data alone, and well suited for use in assessment and inter-facility comparisons.

We thank commenters for their suggestions on improving the measures included in the program and we will consider the feasibility of making some of their recommended changes in future years of the program.

b. New Clinical Measures Beginning With the PY 2020 ESRD QIP

i. 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.[7] Hospitalizations account for approximately 40 percent of total Medicare expenditures for ESRD patients.[8] 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.

At the end of 2013 there were 661,648 patients being dialyzed, of which 117,162 were new (incident) ESRD patients.[9] In 2013, total Medicare costs for the ESRD program were $30.9 billion, a 1.6 percent increase from 2012.[10] 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 Web site.

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 proposed 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 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 have proposed 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 proposed 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

[7] 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.

[8] USRDS Annual Data Report (2015).

[9] USRDS Annual Data Report (2015).

[10] 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.

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 proposed 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 14 below shows the IURs for the 1-year SHR.

TABLE 14—IUR FOR 1-YEAR SHR, OVERALL AND BY FACILITY SIZE, 2010–2013

Facility size (number of patients)	2010		2011		2012		2013	
	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 studies 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 sought comments on our proposal to adopt the SHR measure for the ESRD QIP beginning with PY 2020. The comments and our responses for these proposals are set forth below.

Comment: One commenter fully supported the proposed addition of the SHR measure. Several commenters supported the fact that the SHR measure now accounts for prevalent co-morbidities but stated that they could not support the incorporation of the measure into the QIP until its reliability at the proposed facility size has been demonstrated. The commenter stated that CMS's own data points out the significant issues of reliability, particularly for smaller facilities, with the 1-year SHR, and commenters expressed concerns that facilities will be penalized for performance due to what they termed ''random chance,'' noting that the reliability statistics for medium and small facilities fall significantly short of the 0.7 IUR threshold generally recommended and considered the minimum by the NQF. Specifically, commenters expressed concerns that only facilities with <5 patient-years at risk during the performance period are not eligible for the measure. They also asked CMS to align specifications across the standardized ratio measures, pointing out that the SHR measure uses a <5 patient-years at risk threshold while the SMR and STrR use <10 patient-years at risk. One commenter requested that CMS wait to incorporate the SHR measure until its reliability at the proposed facility size has been tested and demonstrated.

Several commenters appreciated CMS's proposal to cast the SHR measure in terms of patient-years rather than patient numbers but noted that even under a scenario of a small facility with 50 patients, for example, where all 50 contribute 12 months of data to the denominator, the data indicate that the facility's performance score would still be more due to random chance than actual performance. These commenters stated that smaller facilities will have even lower reliability, possibly low enough to make the measure completely unreliable. One commenter added that even for medium sized facilities, the IUR is below the 0.7 threshold and argued that it is therefore inappropriate to penalize facilities when so much of their performance on the measure is due to random chance.

Response: The SHR was recently reviewed and recommended for endorsement by the National Quality Forum Standing Renal Committee (report available here: *http://www.qualityforum.org/Renal_2015-2017.aspx*) based on the reliability statistics referenced in the comment, which is consistent with our assessment that the SHR is sufficiently reliable for use in quality programs. All components of measure reliability were reviewed in detail at the NQF ESRD Standing Committee's meeting in June, 2016. The reliability result reported in the NQF submission showing the overall IURs of 0.70–0.72 across all facilities was determined acceptable by the NQF Standing Committee as the measure passed on the reliability criterion, and passed on scientific acceptability overall. The evaluation and voting process and result adhered to consensus development guidelines in the evaluation, thereby reinforcing acceptance of the reliability results.

Given the established effect of sample size on IUR calculations, it is expected that large facilities will have higher IUR values and small facilities will have lower IUR values for any given measure. CMS and consensus-endorsement bodies consider the overall reliability in determining the acceptability of the measure. We are aware of no published literature standard requiring an IUR of 0.7 for quality measure implementation, and are aware of no standard by NQF requiring this threshold as the minimum for endorsement or implementation. Nonetheless, the SHR does achieve an overall IUR of >.7.

Comment: One commenter requested that CMS release the reliability statistics for the proposed SHR measure using the patient-years at risk construction so that additional analyses can be performed on the measure's reliability.

Response: We thank the commenter for their request and we have provided the reliability statistics for the proposed SHR measure below. The Inter Unit Reliability (IUR) for assessing the reliability of a measure is defined as:

$$IUR = \frac{\sigma_b^2}{\sigma_b^2 + \frac{\sigma_w^2}{n'}}$$

Where:

σ_b^2 is the between-facility variance,
σ_w^2 is the within-facility variance of the response for a single individual, and
n' is (approximately) the average number of patients in a facility.

Table 15 below stratifies facilities into three strata based on patient years at risk for each facility.

TABLE 15—IUR FOR 1-YEAR SHR, OVERALL AND BY FACILITY SIZE (PATIENT YEARS AT RISK), 2010–2013

Facility size	2010		2011		2012		2013	
	IUR	N	IUR	N	IUR	N	IUR	N
All	0.72	5407	0.71	5583	0.70	5709	0.70	5864
<32.02	0.60	1811	0.56	1874	0.53	1884	0.53	1919
[32.02, 58.64)	0.63	1788	0.64	1830	0.57	1891	0.56	2032
>=58.64	0.81	1808	0.80	1879	0.81	1934	0.82	1913

Table 16 below stratifies into three strata based on the number of patients for each facility.

TABLE 16—IUR FOR 1-YEAR SHR, OVERALL AND BY FACILITY SIZE (NUMBER OF PATIENTS), 2010–2013

Facility size	2010		2011		2012		2013	
	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

Comment: Several commenters asked CMS to update the exclusion criteria for the SHR and SRR measures such that a facility is not penalized twice for certain readmissions. As the measures are currently specified, a readmission occurring within 30 days of the index discharge will be captured as a hospitalization by the SHR and a readmission by the SRR, such that a facility is penalized twice for each such readmission. Commenters urged CMS to modify the SHR specifications to incorporate an exclusion for hospitalizations that occur within 29 days of the index discharge such that the two measures will appropriately measure two different types of events. One commenter questioned why CMS is proposing to include both the SRR and the SHR measures in the QIP concurrently.

Additionally, commenters are concerned that the proposed SHR measure inappropriately penalizes facilities for hospitalizations over which they have little to no control, such as from foot ulcers, lupus flare-ups, myocardial infarction, congestive heart failure, etc. They pointed out that many providers are involved in the care of ESRD patients and that while there is a need to coordinate with other providers, it is not always feasible. Providers struggle with different EMR systems which often do not communicate with one another and there is often a lack of resources on either side which prevents effective communication efforts. Commenters recommended that rather than implementing an all-cause hospitalization measure, CMS should consider specific measures such as hospitalization for catheter infection, hospitalization for volume overload, hospitalization for anemia/blood transfusions, etc. so that facilities are only being held accountable for hospitalizations related to conditions directly related to the patient's dialysis treatment.

Response: It is true that the SHR and SRR may simultaneously capture the same hospitalization event. We believe this is appropriate because it places additional emphasis on the importance of avoiding hospitalizations for dialysis patients. In addition, while the SRR and SHR are moderately correlated with one another, as might be expected, it is possible for a facility to score relatively well on one measure, and relatively poorly on the other. We also believe that the measures capture distinct aspects of the quality of care provided by a dialysis facility. While the SRR assesses the coordination of care transitions as dialysis patients are discharged from an acute care hospital into the care of a dialysis facility, the SHR evaluates the facility's overall performance in reducing hospitalizations.

The 2007 TEP that participated in developing the SHR considered the possibility of developing cause specific SHRs, but recommended the use of all-cause SHR measures due to various reasons including the lack of clear research to indicate what causes (that is, reason for admission) should be selected as valid indicators of poor ESRD care, and issues associated with inter-rater reliability in assessing cause of hospitalization. The TEP reached a strong consensus that the all-cause measure would be reliable and valid and the measure would typically be related to quality of care. We have some crude measures of cause of hospitalization which we have used to assess the relationship between the all-cause measure and cause specific components. These measures are useful in assessing the overall SHR measures, but we caution that the cause specific hospitalizations have not been tested or validated at this time. All correlations are in the expected direction and highly significant, ($p<0.0001$). Thus these preliminary analyses show that the overall hospitalization rate also correlates with specific causes that are commonly thought to be potentially related to poor quality of care.

Comment: Several commenters strongly supported CMS's use of prevalent comorbidities in the risk models for the SMR and SHR, and commended CMS for moving to incorporate prevalent comorbidities in the proposed specifications for the SHR measure. One commenter encouraged CMS to review co-morbidities as they relate to the pediatric ESRD population since these measures include all patients with ESRD. Commenters also requested that CMS allow for the CMS Medical Evidence Reporting Form 2728 be permitted to be updated because the UB04 and 8371 forms are unable to accommodate the vast number of diagnosis codes that patients with ESRD often present with. These commenters stated that patients often develop additional comorbidities after beginning dialysis, and facilities would be disincentivized to treat patients if recently developed comorbidities were not included in the risk-adjustment calculation. Some commenters supported CMS's proposal to include a risk adjustment for 210 prevalent comorbidities in addition to the incident comorbidities from the 2728 Form. One commenter asked CMS to confirm whether providers will be able to report all conditions/diagnoses on 72X claim forms, not just those related to ESRD or the medications and treatments given. Specifically, they asked whether the Medicare Contractor and their system would be able to accommodate this much information or whether including additional comorbidities would cause a billing issue, cause claims to pend, or cause claims to get stuck in T-status.

Response: We thank commenters for their suggestions, and we agree wholeheartedly that prevalent comorbidity data should be collected from multiple sources. We would like to clarify that prevalent comorbidity information for the measure is obtained from all Medicare claims data from all facility settings (not limited to dialysis claims only), and CROWNWeb data, and as such, we are not limited to the comorbidities filed on 72X claim forms.

Comment: Commenter agrees that strategies to reduce hospitalizations are an important area to focus on because they will save the government money and improve the quality of life for patients, however commenter urged CMS to modify the SHR measure to ensure that facilities are not unfairly penalized when they have had no impact on the reason for the hospitalization. They recommended that CMS develop exclusions for patients

admitted before being treated at a dialysis unit, patients admitted for other comorbidities not related to kidney failure, and patients who repeatedly fail to adhere to their treatment regime. Additionally, commenter argued that hospitals need to be mandated to share their discharge information to ensure optimal continuum of care.

Response: The SHR does contain adjustments for comorbidities that were determined likely not to be the result of facility care (as determined by a 2015 Technical Expert Panel). We also exclude patients from a facility if they have not had ESRD for more than 90 days, or if they have not been receiving treatment at the facility for more than 60 days, which precludes the risk of patients being included in a facility's SHR prior to treatment. However, the measure is an all-cause hospitalization measure, reflecting hospital admissions regardless of cause. The measure's design accounts for hospitalizations that are random occurrences by assessing facilities' performances relative to one another. At present, we are aware of no means of distinguishing what hospitalizations are related to dialysis facility treatment. The SHR was originally endorsed as an all-cause measure, and this is consistent in approach to other NQF-endorsed measures, such as the SRR (NQF #2496). Finally, we appreciate the suggestion to mandate hospitals to share discharge information with dialysis facilities and we will take it under advisement.

Comment: Commenter supported the proposed SHR measure but expressed concerns about the potential for it driving unintended changes in practice. Specifically, they want CMS to make sure that any error in measure rates due to small number of cases will not adversely affect facility payment.

Response: In order to avoid allowing small numbers of cases to adversely affect facility payment, for the purposes of the SHR measure, facilities with fewer than 5 patient-years at risk during the performance period are not eligible for the measure. Additionally, a small facility adjustment will be applied to small facilities deemed eligible for the measure.

Comment: Commenter agreed with CMS that outcome measures need to be emphasized more in pay-for-performance programs. But they disagreed that rankings should result from nationwide ''tournaments'' because this format disadvantages certain providers based on not on the quality of care they deliver but on the demographics of the geographic area they serve.

Response: We agree with the commenter on the importance of including outcome measures in the ESRD QIP, which is one reason why we proposed to adopt the SHR measure. We also note that unlike other CMS value-based purchasing programs (for example, Hospital Value-Based Purchasing), the ESRD QIP does not introduce a ''tournament'' mentality because payment increases from some facilities are off-set by payment reductions from other facilities. Rather, all facilities that receive a TPS that is greater than the minimum TPS will avoid a payment reduction, and this means that a facility's payment is not impacted by scores received by another facility.

Comment: Commenter requested that for the Standardized Hospitalization Ratio Clinical Measure, CMS clearly define what counts as a comorbid condition because, given the definition of ''comorbid condition'' in the ESRD PPS, there is confusion surrounding this term and whether it is only referring to the 4 payable ''comorbid conditions'' or whether it refers to all conditions outside of ESRD that ail the patient.

Response: We encourage the commenter to refer to the SHR methodology report, which contains specific information about the comorbidities that are adjusted for in the SHR. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/SHR-Methodology-Report.pdf.*

Comment: Commenter supported the limit of the denominator for the SHR measure to Medicare patients because they understand the trade-off to now limit the denominator population due to claims data availability.

Response: We thank you for your comment and supporting this aspect of the SHR.

Final Rule Action: After consideration of the comments received, we are finalizing the Standardized Hospitalization Ratio Clinical Measure for inclusion in the ESRD QIP measure set beginning in PY 2020.

c. Reporting Measures Beginning With the PY 2020 ESRD QIP

i. Serum Phosphorus Reporting Measure

As mentioned above, for PY 2020 we proposed 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 proposed 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 sought comments on this proposal. The comments and our responses are set forth below.

Comment: One commenter specifically recommended that CMS work to create a mineral metabolism composite measure which would

include Hypercalcemia, intact-PTH and Phosphorus. One commenter urged CMS to convene a TEP to identify measures on Mineral Bone Disease that drive quality outcomes and are within the facility's domain to manage because Serum Phosphorus levels remain highly dependent on patients' adherence to prescribed medications.

Response: We thank commenters for their support. We have worked with the community in an attempt to find measures that are more appropriate for assessing bone and mineral metabolism. Unfortunately, we are not aware of any measures which are appropriate for inclusion in the ESRD QIP at this time. We will take commenters' suggestions into consideration as we continue to work on identifying more appropriate measures. We will also consider convening a TEP to identify measures on Mineral Bone Disease.

Comment: One commenter pointed out that the deadlines listed for the Serum Phosphorus Reporting Measure are 30 days sooner than the deadlines for the other measures submitted in CROWNWeb and requested that CMS align the reporting deadlines so that all of January data is required to be submitted by March 31. It would be very confusing, they argued, to have to submit just phosphorus by February 28th but everything else by March 31.

Response: We thank commenter for sharing their concerns, however we believe that the reporting deadlines are consistent across measures submitted in CROWNWeb. Facilities are granted at least 1-month window after the end of the applicable month to report data. In section IV(E)(2)(a) above, we have finalized a new policy that, for measures reported in CROWNWeb, facilities must report data for the relevant clinical month by the date on which the clinical month closes in CROWNWeb. For example, under our old policy, February data was required to be submitted by March 31st. Under our revised policy, February data will need to be submitted by the date on which the February clinical month closes in CROWNWeb. In normal circumstances, this data would be required by March 31st, but this policy provides an exception in the event that CROWNWeb is not available on that day. The NHSN measures are an exception to this approach to reporting deadlines; in the cases of those measures, facilities have more time to report because they are only required to do so on a quarterly basis.

Comment: Commenters noted that the exclusions between the proposed Serum Phosphorus Reporting Measure and the Mineral Metabolism measure differ and they argued that changing the exclusion criteria causes unnecessary confusion. They urged CMS to harmonize the measure specifications across measures. Specifically, though they agree with the exclusions, the previous exclusion of ''in-center HD patients treated at the facility <7 times during the claim month'' has been replaced with ''transient dialysis patients (in unit <30 days).'' Additionally, another exclusion expanding on this is provided: ''Patients not at the facility for the entire month (''Admit Date'> the first day of the month and ''Discharge Date'' < the last day of the month).'' One commenter also pointed to the exclusion from the Mineral Metabolism measure of ''in-center HD patients treated at a facility fewer than 7 times during the claim month'' and noted that the proposed Serum Phosphorus Reporting Measure specifies instead the exclusion of ''transient dialysis patents'' and of ''patients not at the facility for the entire month'' and requested an explanation for why these differences exist.

Response: We thank commenters for their suggestions. However, the differences in the exclusion criteria between the Mineral Metabolism Reporting Measure and the proposed Serum Phosphorus Reporting Measure can be explained by our rationale for making this proposed replacement. As we explained above, we are proposing to replace the Mineral Metabolism Reporting Measure with the Proposed Serum Phosphorus Reporting Measure to align with NQF specifications. The Proposed Serum Phosphorus Reporting Measure is based on an NQF-endorsed measure, NQF #0255 Measurement of Serum Phosphorus Concentration, which includes the same exclusion criteria we have included. Treatments per month and time at facilities represent different methods for determining patient eligibility. We are updating the exclusion criteria to be more consistent with the other measures included in the ESRD QIP measure set. The Dialysis Adequacy clinical measures use the same exclusion criteria as the proposed Serum Phosphorus Reporting Measure and it is likely that as measures undergo review at NQF, they will also be updated for consistency. Additionally, we are proposing to use admit and discharge data from CROWNWeb as part of our intention to increasingly use CROWNWeb as the data source for calculating measures in the ESRD QIP.

Comment: One commenter argued that the proposed serum phosphorus measure inappropriately penalizes facilities and care teams for patients' non-compliance with their medication. They stated that compliance with phosphorus binders is a challenging problem and that dialysis units are working to address it by having dieticians reviewing the importance of compliance with their patients, as well as handing out educational handouts and presenting webinars to patients.

Response: We disagree that the Serum Phosphorus measure penalizes facilities for patient non-compliance with their medical regime. Because Serum Phosphorus is a reporting measure, facilities are evaluated on the basis of how much data they submit, as opposed to what those data represent.

Final Rule Action: After consideration of the comments received, we are finalizing the adoption of the Serum Phosphorus Reporting Measure into the ESRD QIP Measure set beginning in PY 2020. As discussed above, this measure will replace the Mineral Metabolism Reporting Measure and will ensure that exclusion criteria come into alignment across the ESRD QIP measure set as well as moving the program in the direction of relying increasingly on CROWNWeb as a data source rather than claims.

ii. 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,[11] 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

[11] Flythe S.E., Kimmel S.E., Brunelli S.M. Rapid fluid removal during dialysis is associated with cardiovascular morbidity and mortality. Kidney International (2011) Jan; 79(2): 50–7. Flythe J.E., Curhan G.C., Brunelli S.M. 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.

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 proposed 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, 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 proposed that facilities will be granted a 1-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 sought comments on this proposal. The comments and our responses for these proposals are set forth below.

Comment: One commenter noted that CMS's proposal to adopt the UFR measure for the QIP seems inconsistent with the proposed payment restrictions for patients receiving dialysis more frequently than 3 times per week. The UFR measure restricts the amount of fluid that can be removed from a patient per session, which results in the medically justified need for extra dialysis sessions for some patients. The commenter argued that CMS should therefore allow for payment for extra dialysis sessions for those patients whose UFR rates exceed the proposed QIP threshold. Another commenter questioned the value in implementing UFR as a reporting measure when there is an NQF-endorsed clinical measure that, if implemented, would be more meaningful to patient outcomes. Commenter instead encouraged CMS to implement NQF #2701 as a Clinical Measure in the ESRD QIP.

Several commenters expressed concern about the clinical rationale behind the UFR measure's technical specifications. Specifically, one commenter noted that the KDOQI hemodialysis adequacy clinical practice guidelines do not include a target for UFR and instead recommend minimizing UFR as much as possible to maximize hemodynamic stability and tolerability of the hemodialysis procedure. The commenter stated that the reason for this is that there is limited evidence for setting a specific target, and that one study suggested an increased risk for individuals with heart failure with a UFR between 10–14 ml/h/kg but improvements for those without heart failure with a UFR in that range. The commenter therefore stated that they would support the implementation of NQF #2701 in the QIP with the knowledge that there will be challenges in the implementation process that will require efforts from facilities, staff, physicians and patients to ensure patient participation and adherence to their dialysis prescription and fluid restrictions. The commenter stated that the KCQA measure excludes patients who dialyze for less time than the average patient, and commenter urged CMS to include this exclusion. Commenters added that due to individualized patient responses to fluid removal, it is difficult to arrive at a single rate for UFR that is ''too high'' for patients. Rather than the UFR >/= 13 ml/kg/hr that CMS has proposed, commenters urged CMS to consider a measure of UFR >/= 10 ml/kg/hr. One commenter suggested that they would not recommend excluding patients who dialyze more than 3 times per week, transient patients or patients who are new to ESRD because these patients would not be expected to be at risk of developing intradialytic hypotension when compared to the general ESRD population. Another commenter specifically recommended that CMS exclude patients with <3 hemodialysis treatments in the facility during the reporting month. One commenter also suggested that patients who are new to ESRD and in their first 90 days of treatment should not be excluded from any UFR reporting requirements because of their particularly high mortality risk. Finally, one commenter stated that they would support efforts by CMS to ensure that time on dialysis is adjusted in such a way that patients would not suffer from symptoms related to rapid ultrafiltration. The commenter stated that monitoring Kt/V solely instead of taking into consideration the greater role of fluid management and removal is likely to result in more problems with sickness for patients, potentially impacting quality of life, and that while correction of uremia remains important, limiting our focus on the rate of fluid removal is to the detriment of patients, leading to an increase in the risk of cardiovascular disease.

Response: We thank the commenters for support of the measure's implementation, despite the challenges inherent in implementation described in the comment. We recognize that successful fluid management in this setting requires a multidisciplinary approach, including patient education. Regarding the KDOQI reference, we believe that those clinical practice guidelines are relatively outdated, having been published before most of the recent literature related to the association between high UFR and patient risk. We note that both NQF 2700 and 2701 UFR measures passed NQF review criteria for strength of evidence. Regarding the statement ''The KCQA measure excludes patients who dialyze for less time than the average patient, and commenter urged CMS to include this exclusion'', the statement is not factually correct. NQF 2701 provides a numerator exclusion for patients dialyzing for > or equal to 240 minutes. The average duration of dialysis session length for U.S. patients on thrice weekly dialysis is approximately 210 minutes, with a minority of U.S. dialysis patients receiving 240 or more minutes of dialysis per session.

The rate threshold of >13 ml/kg/hr was chosen to be consistent with the NQF endorsed threshold, and is also consistent with most of the published evidence demonstrating associations of poorer outcomes with UFR between 10–15 ml/kg/hr.

We thank the commenter for generally supporting the importance of the UFR

measure. Patients new to ESRD do have increased mortality risk in general, but there is no convincing evidence to suggest that the observed risk is directly related to high UFR. In addition, fluid management generally and, response to high UFR in particular, may include varied clinically appropriate interventions by the dialysis provider, including patient education, counselling and dietary planning by Renal Dietitian and assessment and interventions by social workers and other members of the Interdisciplinary Care Team to address root causes for large interdialytic weight gains. Patients new to dialysis often have not received much of this education and support. Excluding patients new to dialysis increases the opportunities for dialysis providers to include these interventions and ultimately enhances the attribution of the measure outcome to the dialysis facility. We agree that both small solute removal (for example, Kt/V) and appropriate fluid management (UFR) are important measures of overall adequate care of dialysis patients.

Comment: Several commenters supported fluid management as an important quality improvement area, but stated that they would support the inclusion of the NQF-endorsed measure, 2701: Avoidance of Utilization of High Ultrafiltration if CMS incorporated it consistent with the specifications reviewed and endorsed by the NQF rather than with the modifications CMS has proposed. They expressed concerns about the changes that CMS proposed to the measure and asked for justification for the approach taken to the measure's exclusion criteria.

Specifically, commenters requested that CMS retain the exclusion of facilities with 25 or fewer patients, rather than the modified ''fewer than 11 patients'' that CMS proposed, because commenters believe this modification would hurt small facilities. Additionally, commenters requested that CMS expressly state that reporting the number of hemodialysis sessions delivered during the Kt/V week will be required for the reporting measure because the NQF-endorsed measure excludes patients regularly prescribed >3 sessions/week. They noted that CMS has not indicated this requirement and that NQF 2701 excludes patients regularly prescribed >3 sessions/week. Commenters asked for confirmation that the intent is to implement this measure as specified for those patients receiving thrice weekly HD. Commenters requested clarification as to whether excluding patients on dialysis <90 days at the beginning of the reporting month, an exclusion not present in the KCQA measure, was a data collection issue, or whether CMS has any additional justification for this approach.

Response: We appreciate the comments. We first note that we have not proposed the NQF-endorsed #2701: Avoidance of Utilization of High Ultrafiltration, but a reporting based upon that measure. This is because the reporting measure is not a measure of clinical performance, as is 2701, but a measure that collects data relevant to the quality of care provided by dialysis facilities. The reporting measure does not limit the measure to patients receiving dialysis less than 3 weekly sessions as ultrafiltration is considered consequential for these patients as well. At a later date, CMS may consider through rulemaking the implementation of NQF #2701 as a clinical performance measure, at which point such an exclusion could be calculated, as specified, using the required data elements for each treatment in the week for which the Kt/V is reported to us.

Comment: Several commenters supported the proposal to adopt the UFR measure but expressed concerns with CMS's definition of qualifying patients, and requested clarification regarding the exclusions listed in the technical specifications. Commenter urged CMS to clarify how dialysis facilities should report patients who may be assigned to a facility for a full calendar month but not physically present during a portion of that month due to events such as hospitalization. They suggested that CMS use the same exclusion criteria as for other measures, that is, to exclude patients who dialyze at the facility less than seven times during the applicable month. Another commenter requested clarification regarding the exclusion of patients on dialysis for more than 90 days at the beginning of the reporting month.

Response: As with other measures, such as the Comprehensive Dialysis Adequacy Measure finalized for PY 2019, we define the population for this reporting measure by assignment to a facility for a full month. While a patient may spend part of that month hospitalized, the facility is still required to provide data for dialysis adequacy, and we believe it is appropriate to require reporting of ultrafiltration data for these patients as well, since the data elements are products of ongoing dialysis treatment. We do not restrict facilities from coordinating with hospitals to obtain relevant data, and we believe that such coordination is appropriate. We proposed to require providers to report the number of HD treatments received by each patient in the reporting month, which should alert us to unintended consequences of defining the population as we have.

Comment: Several commenters urged CMS to exclude transient patients from the UFR measure, and encouraged CMS to include a standard specification for transient patients within the measure specifications. One commenter pointed out that ''number of HD sessions delivered during the month'' is included as a data element but the transient exclusion is not included in the qualifying patients' description. They also pointed out that the Mineral Metabolism measure had an exclusion for patients with <7 treatments, while the Serum Phosphorus measure defines transient patients as ''in unit <30 days'' but the proposed UFR measure seems to lack this exclusion altogether, despite its having been present in the measure's original specifications.

Response: As proposed, transient patients are excluded from the Ultrafiltration Rate Reporting Measure. We wish to clarify that the denominator is defined by patients who are assigned to the facility for an entire month, similar to the Serum Phosphorus measure referenced in the comments.

Comment: Two commenters supported the proposed UFR measure but recommended that CMS review the reporting deadlines for the measure. Specifically they suggested that rates for January 2018 be due on or before March 31, 2018 rather than February 28 to align with the reporting of other clinical values for January 2018 and to avoid confusion.

Response: The Proposed Ultrafiltration Rate Reporting measure requires facilities to report data to CROWNWeb for all hemodialysis sessions during the week of the monthly Kt/v draw for that clinical month. We are finalizing that facilities are required to report ultrafiltration rates for January 2018 by the date on which the clinical month closes in CROWNWeb, which is approximately 1-month after the end of that month. These requirements are consistent with our newly finalized policy for other measures reported monthly in CROWNWeb. For example, the proposed Serum Phosphorus Reporting Measure requires facilities to report data monthly to CROWNWeb. Data for January, 2018 must be reported by the date on which the clinical month closes in CROWNWeb.

Comment: Several commenters supported the proposed UFR measure but encouraged CMS to further investigate whether the threshold should be set at UFR >10 ml/Kg/Hr or at 13 ml/kg/hr. They recommended that paying for HD hourly rather than by treatment would likely resolve concerns

about overly aggressive ultrafiltration amounts and rates as the reluctance of providers to offer longer treatments is financial, and they recommended that the UFR measure be used for home HD as well as in-center. Commenters also urged CMS to continue efforts to identify an improved fluid management measure for use in the ESRD QIP.

Response: We appreciate the comments. We agree that all in the dialysis community should be pursuing ongoing enhancements of quality measures. Regarding the specific recommendation for UFR >10 threshold, the rate threshold of >13 ml/kg/hr was chosen to be consistent with the NQF endorsed threshold, and is also consistent with most of the published evidence demonstrating associations of poorer outcomes with UFR between 10–15 ml/kg/hr.

Comment: One commenter expressed concerns that the administrative and financial burden associated with the UFR measure is too much for facilities to take on and urged CMS to adopt a transition period for complying with this measure.

Response: We thank the commenter for expressing their concerns, and we appreciate that the proposed Ultrafiltration Rate Reporting Measure does require a large number of data elements. We believe that there are important clinical and clinical quality reasons for collecting and monitoring these data which outweigh the administrative and financial burden concerns expressed by the commenter. As we indicated in the proposed rule, higher ultrafiltration rates are associated with higher mortality and higher odds of an ''unstable'' dialysis session. 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.

Final Rule Action: After a careful consideration of the comments received, we are finalizing the Ultrafiltration Rate Reporting Measure for inclusion in the ESRD QIP measures set beginning in PY 2020.

3. Performance Period for the PY 2020 ESRD QIP

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

Comment: Commenters generally supported setting CY 2018 as the Performance Period for PY 2020 but many commenters expressed concern about the performance period for the NHSN HCP Influenza Vaccination Reporting Measure and urged CMS to align with the NHSN protocol upon which the measure is based, and with NQF's Standardized Influenza Immunization Specifications, which define the acceptable immunization period as beginning on ''October 1 or when the vaccine became available'' so that facilities are not penalized for early vaccination, which is generally recommended to protect patients before the virus begins spreading through the community. One commenter suggested that the performance period should span the entire calendar year, while others recommended that the performance period go from October 1, 2017 through March 31, 2018.

One commenter also expressed concerns with the CCN Open Date criteria for the NHSN HCP Influenza Vaccination Reporting Measure. They suggested that if the flu season spans from October 1, 2016 through March 31, 2017, then the CCN open date should be January 1, 2016 rather than January 1, 2017. Similarly, for the flu season that spans from October 1, 2017 through March 31, 2018, facilities should be required to have a CCN open date of January 1, 2017. The reason for this is that if a facility is certified on December 31, 2016, they are still required to report this data for the full 2016/2017 flu season even though they were not certified for the full flu season and they should not be required to create a detailed employee log to track the vaccination status of each employee while also having to focus on opening a new facility, keeping track of new admits, and registering for CROWNWeb and NHSN access.

Response: We thank commenters for their support. As we stated in the CY 2015 ESRD PPS Final Rule (79 FR 66207) under the NHSN HCP Influenza Vaccination reporting measure, the performance period for the denominator (the number of healthcare personnel working in a facility) is from October 1 through March 31. However, the numerator measurement (vaccination status) includes vaccines obtained ''as soon as vaccine is available.'' As a result, HCP working at the facility as of October 1 who were vaccinated in September would be considered vaccinated for the performance period under this measure. Facilities are not penalized in any way for vaccinating their employees prior to the start of the performance period.

With regards to commenter's suggestion about our CCN Open Date policy, we accounted for this concern in the CY 2015 ESRD PPS Final Rule (79 FR 66212). We stated that facilities with a CCN open date *after* January 1, 2016 would not be eligible to receive a score on the NHSN Healthcare Personnel Influenza Vaccination reporting measure in the PY 2018 program. We acknowledged that it takes time for facilities to register with NHSN and become familiar with the NHSN Healthcare Personnel Safety Component Protocol.

4. 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. 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 proposed 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 sought comments on these proposals. The comments and our responses for these proposals are set forth below.

Comment: Two commenters supported our continued reliance on the methodology used to set the Performance Standard, Achievement Threshold, and Benchmark at the 50th, 15th and 90th percentiles respectively of national facility performance for PY 2020, as well as the continuation of our current policy for determining payment reductions, including the process for setting the minimum TPS.

Response: We thank the commenters for their support.

Final Rule Action: After considering the comments received, we will finalize the performance standards, achievement thresholds, and benchmarks for the clinical measures included in the ESRD QIP for PY 2020.

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. 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 did not propose 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 did not propose any changes to these policies.

For the proposed Ultrafiltration Rate Reporting Measure, we proposed 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 proposed 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 proposed to set the performance standard as successfully reporting 12 months of data from CY 2018.

We sought comments on these proposals. We did not receive any comments on these proposed policies for setting Performance Standards for the PY 2020 Reporting Measures.

Final Rule Action: We are finalizing the performance standards for the Reporting Measures as proposed for the PY 2020 ESRD QIP

5. 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 proposed to continue using this methodology for all clinical measures except the ICH CAHPS clinical measure. The facility's achievement score would be calculated by comparing its performance on the measure during CY 2018 (the proposed performance period) to the achievement threshold and benchmark (the 15th and 90th percentiles of national performance on the measure in CY 2016).

We sought comment on this proposal. We did not receive any comments on this proposal.

Final Rule Action: We are finalizing our policy for scoring facility performance on clinical measures based on achievement as proposed.

b. Scoring Facility Performance on Clinical Measures Based on Improvement

In the CY 2014 ESRD PPS Final Rule, we finalized a policy for scoring performance on clinical measures based on improvement (78 FR 72215 through 72216). In determining a facility's improvement score for each measure under the PY 2020 ESRD QIP, we proposed to continue using this methodology for all clinical measures except the ICH CAHPS clinical measure. Under this methodology, facilities receive points along an improvement range, defined as a scale running between the improvement threshold and the benchmark. We proposed to define the improvement threshold as the facility's performance on the measure during CY 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 sought comment on this proposal. The comments and our responses are set forth below.

Comment: Commenter expressed concerns that the QIP's scoring and assessment methodology is so complex that facilities are unable to evaluate their progress in real time so they can take action during the performance period to strengthen their performance. They urged CMS to consider ways of simplifying the scoring methodology or to develop a secure Web site that can provide each facility with an ongoing scorecard. Another commenter asked that CMS clarify whether a facility needs a score on either measure in the Safety Domain in order to receive a TPS for PY 2020.

Response: We thank the commenter and will consider ongoing scorecards and facility level feedback on a quarterly or semiannual basis in future rule making. Under our finalized policy for both PY 2019 and PY 2020, facilities need to have a score on at least one measure in the Clinical Domain and at least one measure in the Reporting Measure Domain to receive a TPS.

Final Rule Action: After considering the comment received, we will finalize our policy for scoring facility performance on clinical measures based on improvement as proposed.

c. Scoring the ICH CAHPS Clinical Measure

In the CY 2015 ESRD PPS final rule, we finalized a policy for scoring performance on the ICH CAHPS clinical measure based on both achievement and improvement (79 FR 66209 through

66210). We did not propose 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 sought comments on this proposal.

Final Rule Action: We did not receive comments on our proposal for scoring the ICH CAHPS Clinical Measure. Accordingly, we will finalize our policy for scoring the ICH CAHPS Clinical Measure as proposed.

d. Calculating Facility Performance on Reporting Measures

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

With respect to the proposed Ultrafiltration Rate and Serum Phosphorus reporting measures, we proposed 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 sought comments on these proposals. We did not receive comments on these proposals.

Final Rule Action: We did not receive any comments on our proposals for calculating facility performance on reporting measures. Accordingly, we will finalize these policies as proposed.

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

a. Weighting of 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 of the proposed rule (81 FR 42826), 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 proposed to weight the following measures in the following subdomains of the proposed clinical measure domain as follows (see Table 17):

TABLE 17—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 proposed that the Clinical Domain make up 80 percent 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 proposed 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 proposed to reduce the weight of the Safety Measure Domain from 15 percent

to 10 percent. In future years of the program, we stated that 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 proposed 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 also proposed 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 proposed 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 proposed 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. of the proposed rule (81 FR 42833)). 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 proposed to reduce the weights of the following measures by 1 percentage point each from what we 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 proposed 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 sought comments on these proposals. The comments and our responses to are set forth below.

Comment: Another commenter pointed out an error in the VAT measure weight as a percent of the TPS for PY 2020 in Table 10 of the proposed rule (81 FR 42841), reproduced as Table 17 above. Specifically, the table in the proposed rule indicated that the VAT measure topic would be weighted as 18.8 percent of the TPS in PY 2020, however both Table 10 and Figure 6 indicated the combined VAT measure will be weighted as 18.0 percent of the Clinical Measure Domain. Commenter's analysis found that the 18.0 percent combined VAT weight and the 80 percent Clinical Domain Weight results in a combined VAT measure that would comprise 14.4 percent of the TPS rather than 18.8 percent.

Response: We thank commenters for bringing this calculation error to our attention. We acknowledge that our calculation was incorrect. The column showing the weights within the clinical measure domain was correct but when we calculated the measure weights as a percent of the TPS, we miscalculated the weight of the VAT measure. The column showing measure weights as a percent of the TPS is provided for illustrative purposes only. We note, however, that we are not finalizing the weights as proposed. Section IV.E.5.b of this rule describes the policy and weighting that we are finalizing for PY 2020.

Comment: One commenter requested that CMS assign less weight to the ICH CAHPS measure because of the subjective nature of the survey. They argued that administering it twice a year may become bothersome to patients, thus leading to less honest and less valid responses, and fewer responses in general.

Response: We believe that the subjective nature of the ICH CAHPS survey should not factor into the weight assigned to the measure within the Clinical Measure Domain. Response to the ICH CAHPS Survey is completely voluntary. Patients may refuse to respond if they find the survey bothersome or if they do not wish to respond for any other reason. The survey data reflects the reported experiences of the respondents. The fact that the data may be subjective does not mean that it is incorrect. Instead the survey reflects the patients' perspectives on their care, and we continue to believe that this measure is vitally important because it is the only measure in the ESRD QIP which measures the patients' experience of the care they receive.

Final Rule Action: In response to the comments received, we are not finalizing the weighting as proposed. Instead, we are finalizing a revised weighting structure. Specifically, for PY 2020 we are finalizing that the Clinical Measure Domain will continue to comprise 75 percent of the TPS, the Safety Measure Domain will comprise 15 percent of the TPS and the Reporting Measure Domain will comprise 10 percent of the TPS. Table 18 below shows the weights being finalized for PY 2020.

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 proposed 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. 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.

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

Comment: One commenter did not support CMS's proposed modifications to the weighting of the safety measure domain and clinical measure domain for PY 2020 because they do not believe addition of the proposed Safety Measure Domain is necessary. They also argued that CMS is proposing too many measures that focus little attention on patient outcomes and recommended

that CMS evaluate the existing and proposed measures for PY 2020 and remove those that are less relevant to quality of care.

Response: We thank commenter for their recommendations. We are not finalizing the weighting of the safety measure domain and clinical measure domain as proposed and instead we are finalizing a revised weighting structure. We believe it is crucial to emphasize the importance of the NHSN BSI Measure Topic so that facilities prioritize their efforts to accurately and completely report to NHSN their Dialysis Event data, while at the same time mount significant efforts to reduce bloodstream infections. Accordingly, we are going to maintain the Safety Measure Domain at 15 percent of the TPS for PY 2020. We have prioritized outcome measures for inclusion in the ESRD QIP, and we will continue to try identifying appropriate outcome measures, specified for use in dialysis facilities, which we believe will contribute to improved patient outcomes. We have clearly identified criteria for use when determining which measures should be removed from the program. At this time, we are not proposing to remove any measures from the ESRD QIP's measure set.

Comment: A commenter recommended that CMS maintain the Safety Measure Domain at 15 percent of the TPS for PY 2020, arguing that the reintroduction of the NHSN Dialysis Event Reporting Measure compensates for any concerns regarding the validity of the NHSN BSI Clinical Measure, along with the more robust data validation methodology. Commenter argued that lowering the weight of the Safety Measure Domain would dis-incentivize reporting to NHSN.

Response: We thank the commenter for their recommendation and we agree that for PY 2020, in order to ensure that facilities continue to be appropriately incentivized both for reporting to NHSN, through the NHSN Dialysis Event Reporting Measure, and for continued efforts to reduce infections among their patients, through the NHSN BSI Clinical Measure, we should maintain the Safety Measure Domain at 15 percent of the TPS rather than reducing the weight of that Domain to 10 percent in PY 2020. By maintaining the Safety Measure Domain at a higher percentage of the TPS, we are ensuring that facilities continue to report complete and accurate data beyond PY 2019. Therefore, we have provided updated weights for the Clinical Measure Domain for PY 2020 in Table 18.

TABLE 18—FINALIZED 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 (updated)
Patient and Family Engagement/Care Coordination Subdomain	40	.....
ICH CAHPS measure	25	18.75
SRR Measure	15	11.25
Clinical Care Subdomain	60	.....
STrR measure	11	8.25
Dialysis Adequacy measure	18	13.5
Vascular Access Type measure topic	18	13.5
Hypercalcemia measure	2	1.5
SHR measure	11	8.25

Note: We initially proposed that the Clinical Domain make up 80 percent of a facility's TPS for PY 2020. We are finalizing a different weighting structure: For PY 2020 we are maintaining the Clinical Domain at 75 percent of a facility's TPS. The percentages listed in this Table represent the measure weight as a percent of the Clinical Domain Score.

Final Rule Action: After consideration of the comments received, we are not finalizing these policies as proposed. Instead, as discussed above, we are finalizing the weighting structure shown in Table 18 above. We are going to maintain the Safety Measure Domain at 15 percent of a facility's TPS for PY 2020. Accordingly, the measure weights in the Clinical Measure Domain Score have not changed but the Measure Weights as a Percent of TPS have changed as shown. We believe this change to our proposal will ensure that facilities continue to be appropriately incentivized both for reporting to NHSN and for continued efforts to reduce infections among their patients.

7. Example of the PY 2020 ESRD QIP Scoring Methodology

In this section, we provide an example to illustrate the 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 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:

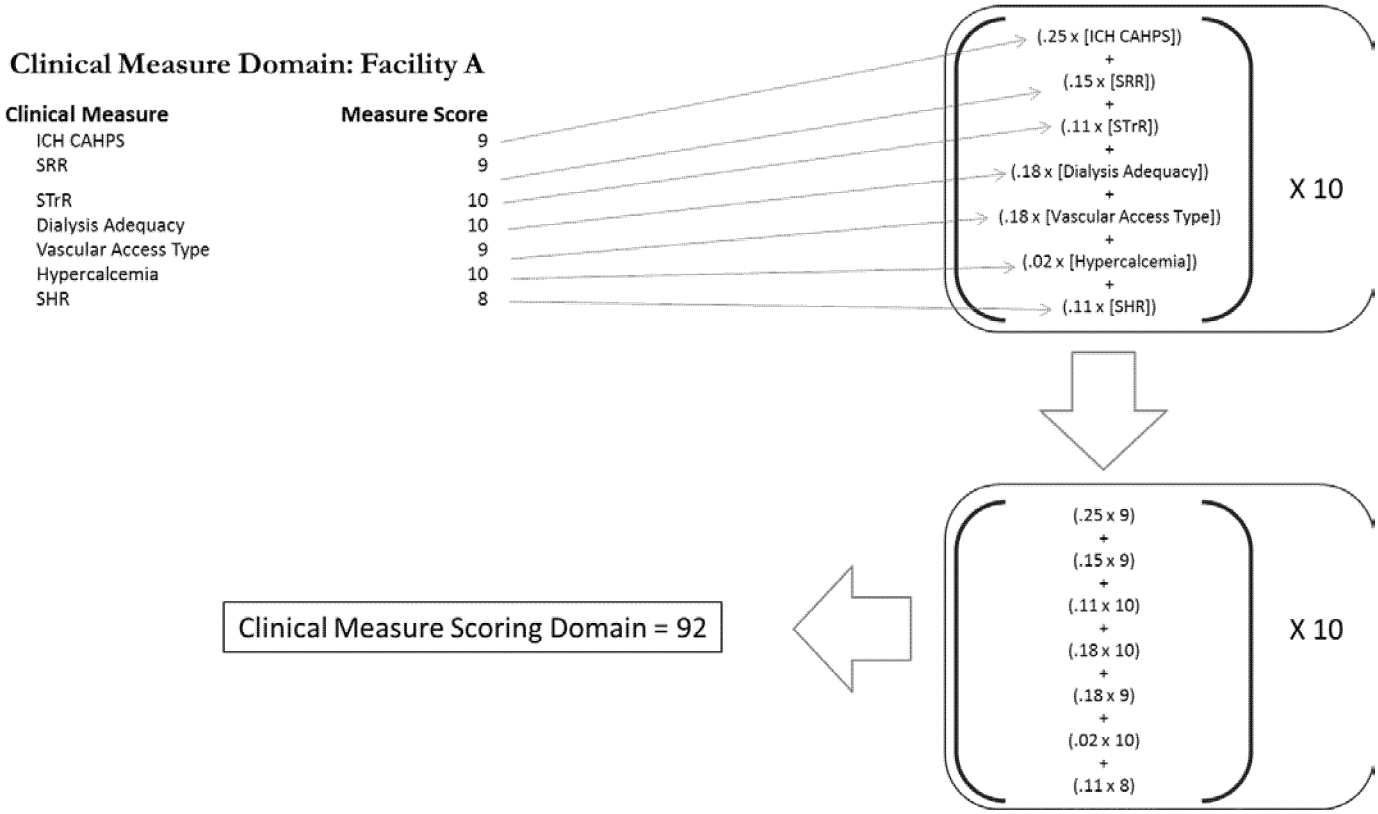


Figure 7 illustrates the general methodology for calculating the Reporting Measure Domain score for Facility A.

FIGURE 7:

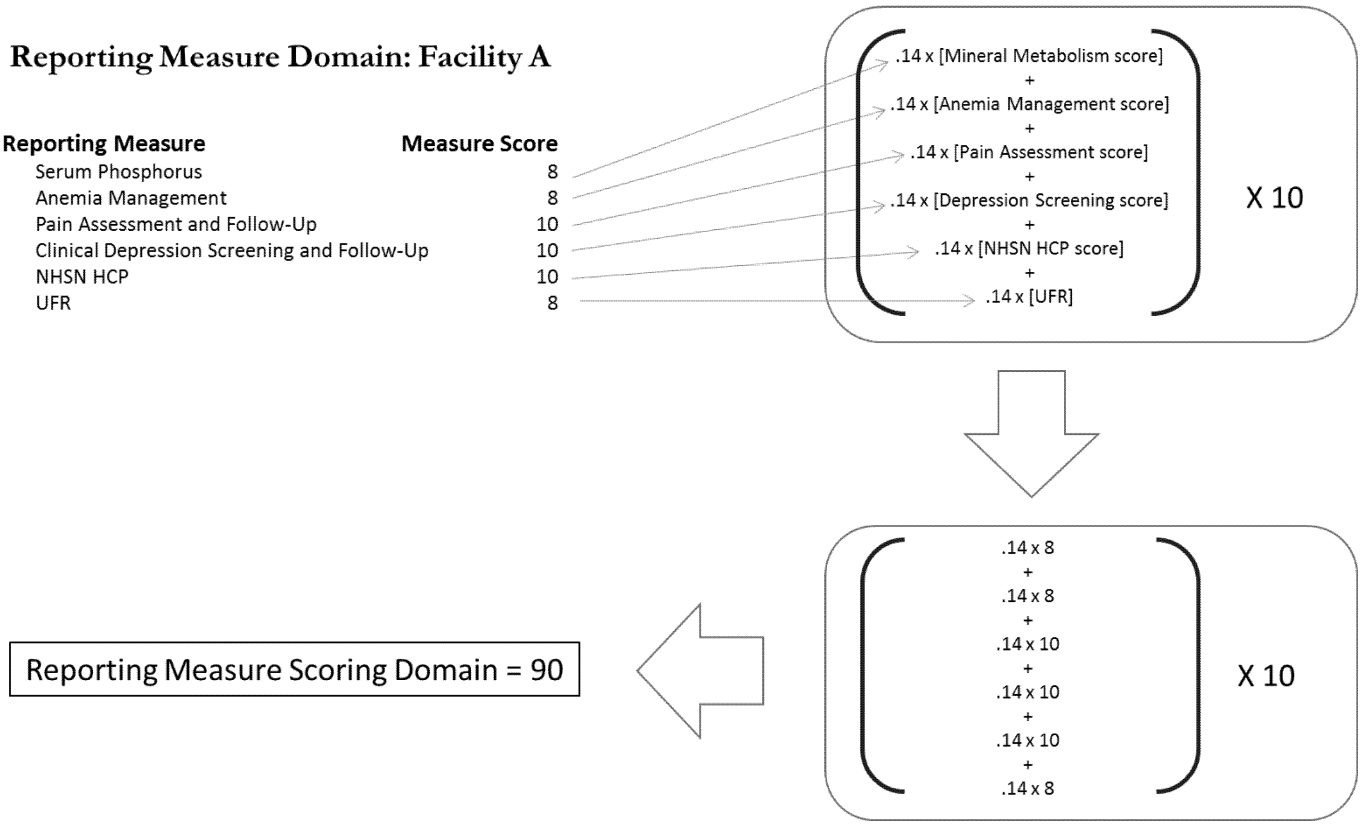


Figure 8 illustrates the methodology used for calculating the Safety Measure Domain score for Facility A.

FIGURE 8:

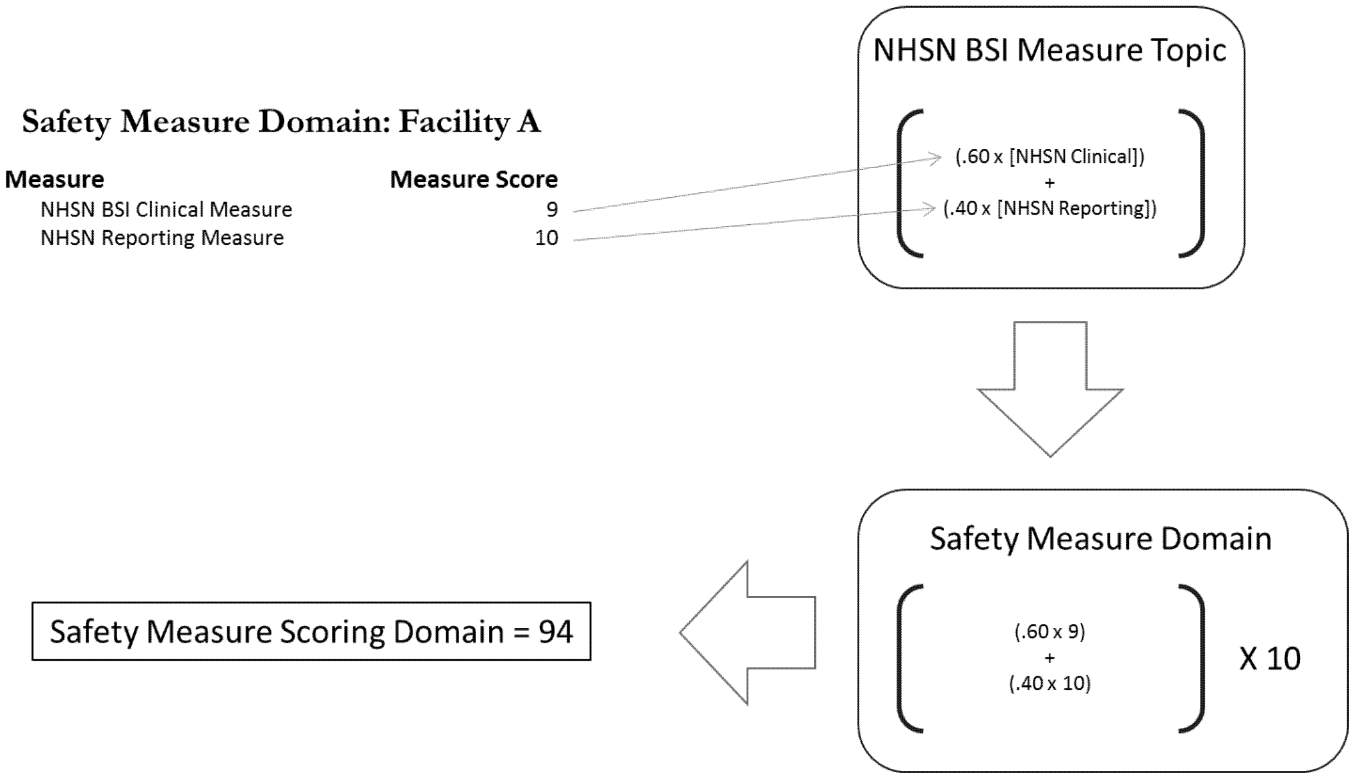


Figure 9 illustrates the methodology used to calculate the TPS for Facility A.

FIGURE 9:

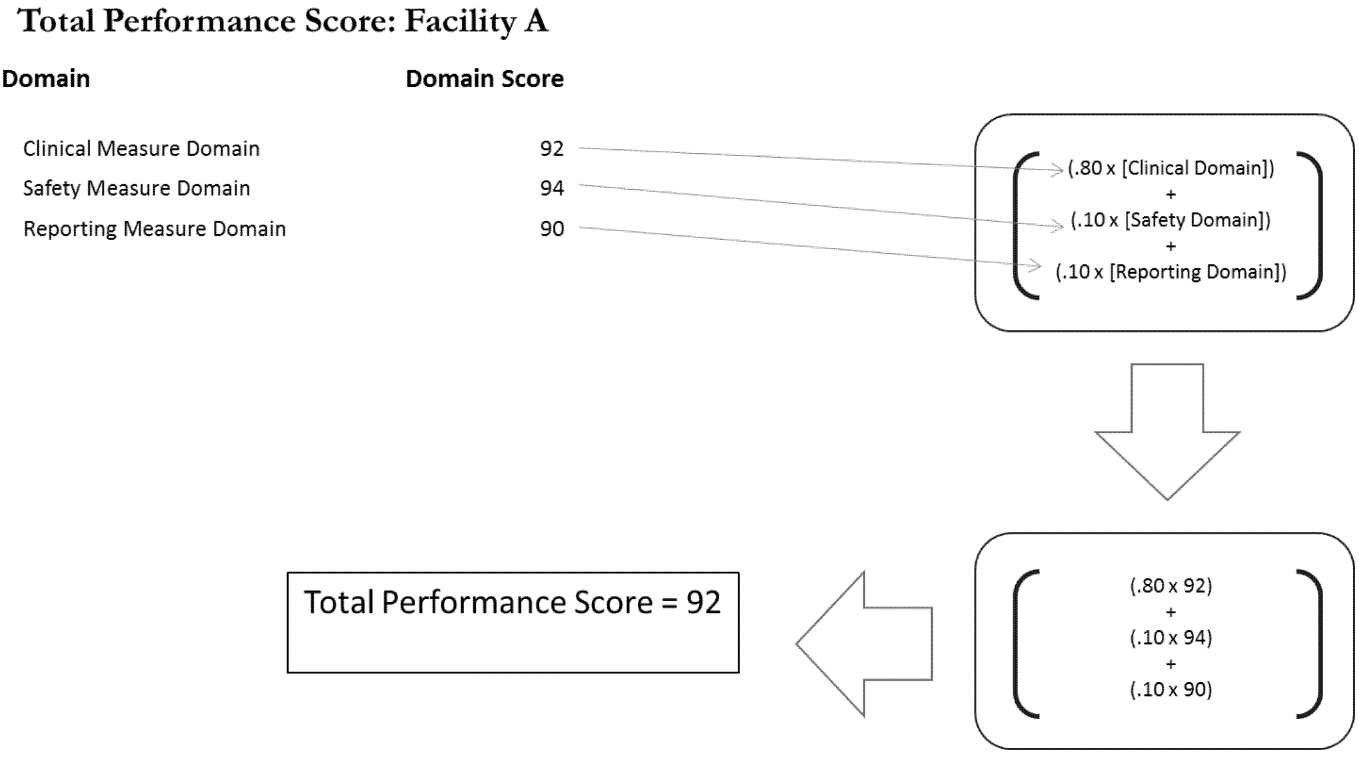
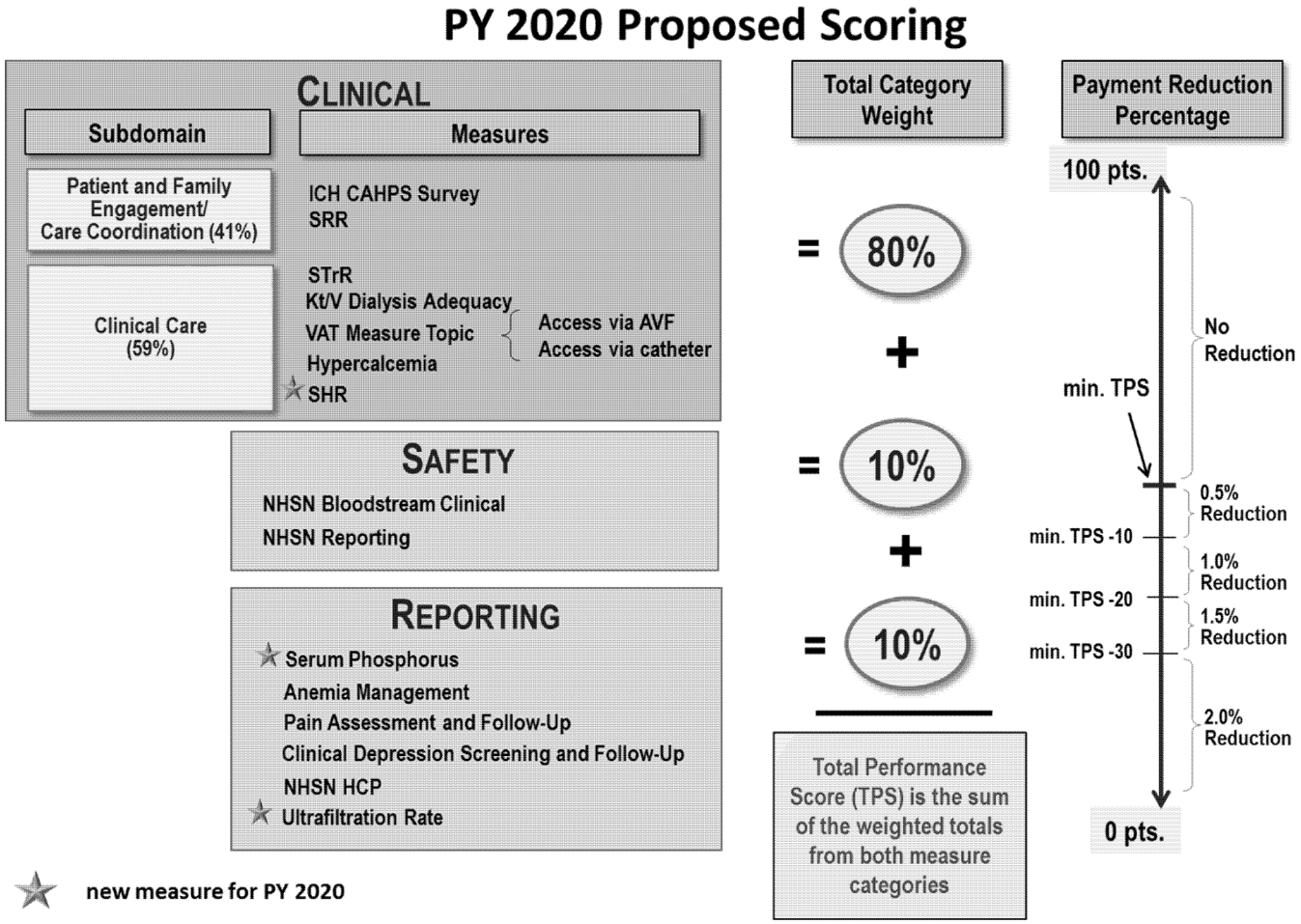


Figure 10 illustrates the full scoring methodology for PY 2020.

FIGURE 10:

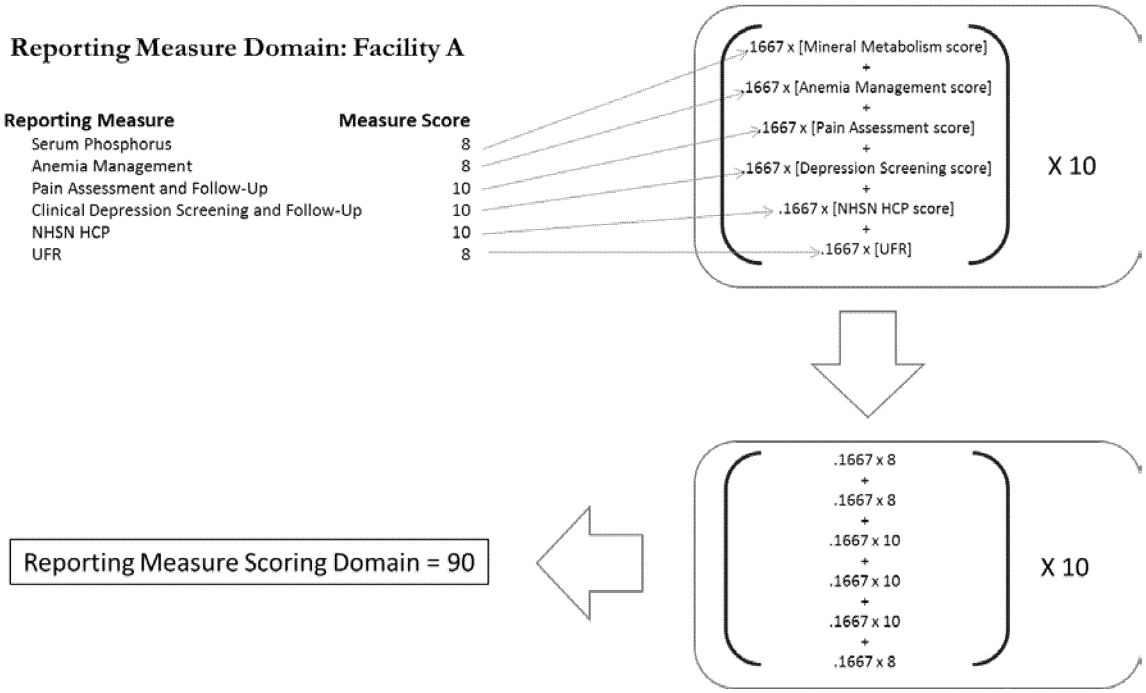


We received comments on the Figures provided in this example. The comments and our responses are set forth below.

Comment: Two commenters identified calculation errors in Figure 7 of the proposed rule (81 FR 42843) and requested clarification. Specifically, commenters pointed out that each of the six measures in the Reporting Domain should be weighted as 16.67 percent rather than 14 percent, as presented in Figure 7 of the CY 2017 ESRD PPS proposed rule.

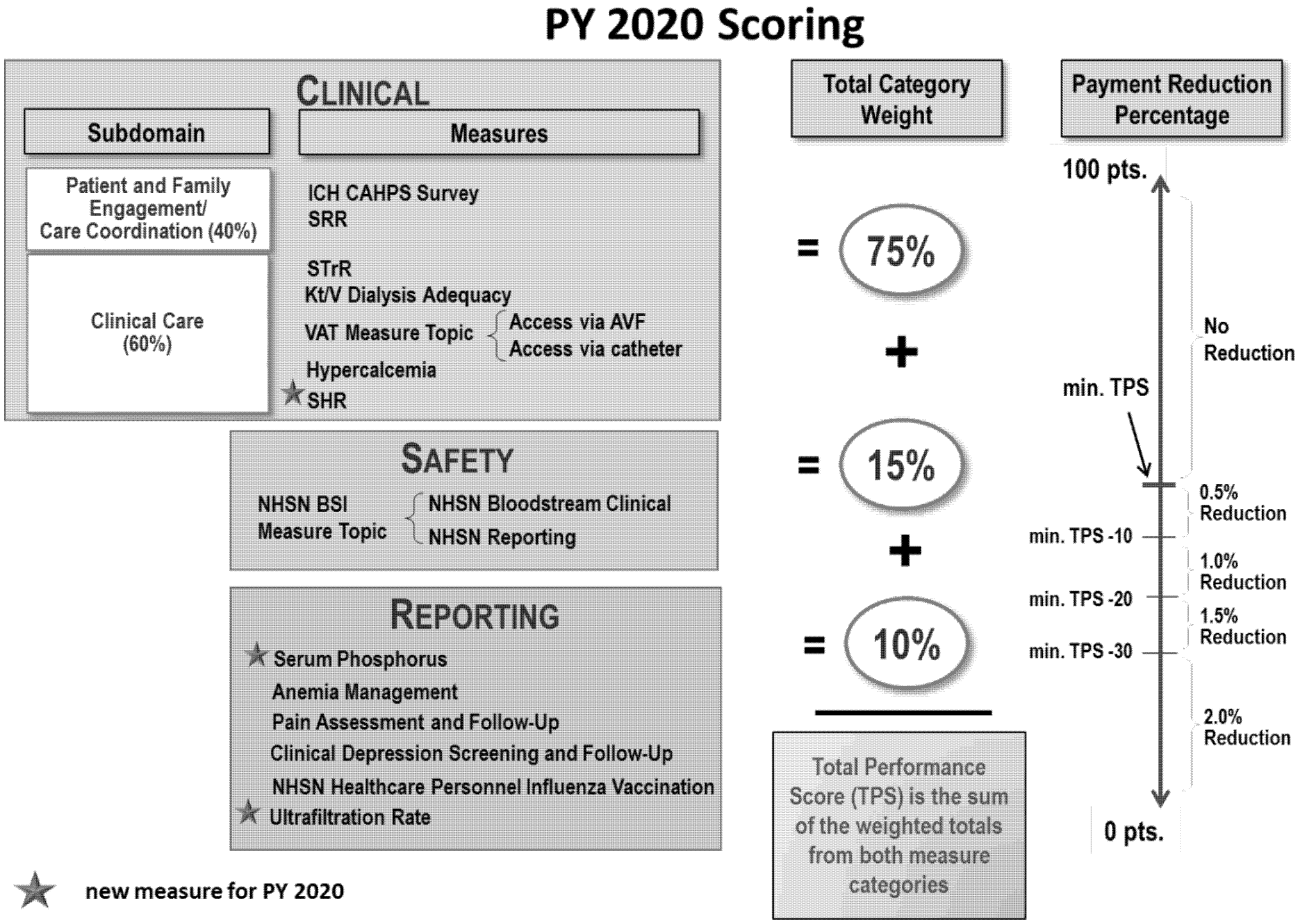
Response: We thank the commenters for bringing this calculation error to our attention. Figure 11 below has been updated to correct the calculation errors which appeared in the proposed rule.

FIGURE 11:



Additionally, in light of the weighting structure we are finalizing for PY 2020, we have created an updated figure, Figure 12 below, showing the weights we are finalizing. For PY 2020, the Safety Measure Domain will comprise 15 percent of the TPS, the Clinical Measure Domain will make up 75 percent of the TPS and the Reporting Measure Domain will make up 10 percent of the TPS.

FIGURE 12:



8. 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 did not propose to change these minimum data policies for the measures that we proposed to continue including in the PY 2019 ESRD QIP measure set. For the proposed Ultrafiltration Rate and Serum Phosphorus Reporting Measures, we also proposed that facilities with at least 11 qualifying patients will receive a score on the measure. We believe that setting the case minimum at 11 for these reporting measures strikes the appropriate balance between the need to maximize data collection and the need to not unduly burden or penalize small facilities. We further believe that setting the case minimum at 11 is appropriate because this aligns with case minimum policy for the vast majority of the reporting measures in the ESRD QIP.

Under our current policy, we begin counting the number of months for which a facility is open on the first day of the month after the facility's 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 proposed 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.

Table 19 displays the proposed patient minimum requirements for each of the measures, as well as the proposed CCN Open Dates after which a facility would not be eligible to receive a score on a reporting measure.

TABLE 19—PROPOSED MINIMUM DATA REQUIREMENTS FOR THE PY 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.
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.

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

Comment: Several commenters expressed concerns about the numbers included in the Minimum Data Table (Table 11) in the proposed rule (81 FR 42846) because of the effect on small facilities with very small sample sizes. Commenters asserted that performance scores for many such facilities are random and may not reflect actual performance. One commenter requested additional detail from CMS so they can better understand CMS's rationale for these values and for the unit of analysis. They pointed out that NQF considered patients as the unit of analysis for reliability testing, while CMS proposed to use patient-years at risk as the unit of analysis in the QIP. Commenters argued that these values are too low and will result in too much random volatility in performance scoring under the QIP. Commenters urged CMS to adopt consistent criteria for the establishment of minimum data requirements and ranges for the SFA, particularly for the Standardized Ratio Measures, and mentioned that the NQF uses 0.7 as a recommended IUR value to limit random noise as much as possible. Several commenters specifically urged CMS to set the minimum data requirement for each measure at the sample size at which the IUR reaches 0.70. Alternatively, if CMS does not choose to implement this change, they recommended that the top end of the SFA range be set at a sample size adequate to reach an IUR of 0.7 so that enough of the observed result for each measure is due to actual performance rather than to random ''noise'' due to small sample numbers.

Commenters offered the STrR as an example of the problem with the small sample sizes used. This measure was found to have very low reliability, particularly for small facilities. The IUR for facilities with sample sizes below 46 patients was about 0.4, suggesting that 60 percent of inter-facility difference was due to random noise rather than underlying performance. The SFA in this case only raises the scores for very small facilities but does not offset the substantial effect of random variation for small sample sizes.

Response: We thank the commenters for their recommendations. We recognize the importance of the scientific standard of measure reliability, and note that the STrR satisfied this condition. All components of measure reliability were reviewed in detail at the NQF ESRD Standing Committee's meeting in June, 2016. The reliability result reported in the NQF submission showing the overall IURs of 0.60–0.66 across all facilities was determined acceptable by the NQF Standing Committee as the measure passed on the reliability criterion, and passed on scientific acceptability overall. The evaluation and voting process and result adhered to consensus development guidelines in the evaluation, thereby reinforcing acceptance of the reliability results.

Given the established effect of sample size on IUR calculations, it is expected that large facilities will have a higher IUR and that smaller facilities will have lower IUR values for any given measure. Reliability results by facility size were not required by NQF. However, the decision to include reliability based on tertiles of facility size was intended to enhance interpretation of the detail provided in the measure submission.

Regarding the commenter's recommendation to use an IUR of 0.7, we are not aware of any formal or prescriptive NQF guideline or standard

that sets or requires this test result value as a minimum threshold for passing reliability. The commenter may be referring to a non-peer reviewed prior RAND Report referenced by NQF as an example of signal to noise method that can be used for reliability testing. Additionally, there is no formal required threshold identified by NQF, as demonstrated in the endorsement of other quality metrics that have a range of reliability statistics, several of which are below the threshold of 0.7. Specifically, the STrR reliability results are comparable to the reliability test results for other NQF-endorsed risk adjusted outcome measures used in public reporting. For example, four NQF endorsed, cause-specific hospital mortality measures demonstrated similar levels of reliability (for example, #0229 Heart Failure Measure, ICC: 0.55; #0468 Pneumonia Mortality Measure, ICC: 0.79; #1893 COPD Mortality Measure, ICC: 0.51; #2558 CABG Mortality Measure, ICC: 0.32).

Final Rule Action: After consideration of the comments received, we are finalizing these policies as proposed. For the reasons described above, at this time, we do not believe it would be appropriate to establish a minimum IUR threshold.

9. 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 proposed 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 noted this proposed policy for PY 2020 is identical to the policy finalized for PY 2019 and we recognized that we were not proposing a policy regarding the inclusion of measures for which we were 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 stated that we did not propose 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 stated that we would 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 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 did not propose 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 sought comments on this proposal regarding our policy to determine payment reductions for PY 2020.

Final Rule Action: We did not receive comments on this proposal. Accordingly, we are finalizing this policy as proposed.

F. 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 IV.E.2.b.i. above, we proposed 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'' (Measures Application Partnership #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, we did not propose 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, Measures Application Partnership #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.

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 sought comments on these issues, including whether data for a patient-level influenza immunization clinical measure should be collected through CROWNWeb or through NHSN.

Comment: Commenters supported CMS's future policy for consideration which would allow for the use of rates rather than ratios for the SRR and STrR measures because they are easier to understand and because the current ratio measures have a wide range of uncertainty that does not provide an accurate view of a facility's performance when the ratio is reduced to a single number. One commenter argued that this approach will improve accuracy, transparency and clinical relevance. They recommended that CMS use the year-over-year difference between normalized rates, currently available from DFR data until they can be replaced by risk-standardized rate measures.

Despite support for the general concept, several commenters urged CMS to carefully consider the methodology used if it is decided to convert ratios to rates. They suggested that the use of the national median rate as the conversion factor would be potentially misleading in certain regions of the country where typical performance varies significantly from the national rate.

One commenter offered two simulations of possible methodologies to convert rates to ratios: First, using the median rate to convert the ratio to a rate; second, using the mean rate to convert the ratio to a rate. In both of these scenarios, QIP scores remained identical—dialysis facilities received the same scores regardless of the ratio or rate methodology. The commenter concluded that they would likely support this proposal but would need to see additional analyses regarding the methodology to be used.

Response: We thank commenters for their suggestions and for sharing the two simulations provided. We will take their suggestions into consideration as we consider the possibility of introducing this policy in future years of the ESRD QIP. If we consider proposing this policy for future years of the program, we will share the proposed methodology through rulemaking.

Comment: A commenter stated that they would likely support a proposal to report national performance standards and individual facility performance as rates, as opposed to ratios, but they would need to see the complete proposal first. They also supported CMS's discussion about possibly using rates instead of ratios for the readmissions and transfusion measures because the current ratios are problematic in that they have a wide range of uncertainty that does not provide an accurate view of a facility's performance when the ratio is reduced to a single number. There are also problems with regard to the reliability of a standardized ratio. Commenter suggested that CMS could immediately switch to rates and encouraged the Agency to use the year-over-year difference between normalized rates currently available from DFR data until they can be replaced by risk standardized rate measures. Commenter also suggested that the use of the national median rate as the conversion factor for ratios may be misleading in parts of the country where typical performance varies significantly from the national rate. Using rates instead of ratios would make the measure results more meaningful by expressing results in terms that have intrinsic meaning.

Response: We thank the commenter for sharing their suggestions and concerns, which we will carefully consider as we consider the possibility of introducing this policy in future years of the ESRD QIP program.

Comment: One commenter recommended that CMS consider calculating rates in the same manner currently utilized in DFC rather than by calculating a ratio and then converting it into a rate because the latter approach may be methodologically flawed and create unnecessary complexity.

Response: We thank commenter for their suggestion and, as we continue to consider the possibility of introducing this policy in future years of the ESRD QIP, we will consider the feasibility of calculating rates in the same manner currently utilized in DFC.

Comment: Commenters submitted a great deal of feedback on the possible introduction of an influenza immunization measure in the ESRD QIP. One commenter pointed out that despite recommendations, vaccines are consistently underutilized in the adult population and urged CMS to consider developing and implementing a comprehensive composite measure for all vaccines recommended for ESRD Patients, as such a measure would be of great benefit to ESRD patients and to the ESRD QIP. Alternatively, they recommended that CMS consider including reporting measures for pneumococcal and hepatitis B vaccination in addition to the existing and proposed Influenza vaccination measures. Several commenters stated that they would support the adoption of NQF #0226, Influenza Immunization in the ESRD Population, in the QIP because it fully aligns with NQF's specifications for influenza vaccinations, and because it is endorsed by the NQF. They also appreciate that the measure is standardized with NQF's 2008 immunization report which set the measurement timeframe as October 1 through March 31, or when the vaccine becomes available. They expressed serious concerns about MUC #XDEFM for several reasons. First, it does not follow the NQF specifications for a measurement timeframe of October 1 through March 31 or when the vaccine became available,'' and second it has not been fully tested or specified. They added that scientific acceptability should be considered an essential component of a measure's properties and that measure developers should be required to show that data elements can be reliably reported and that the measure is valid.

Commenters also supported the proposal to use CROWNWeb to collect patient-level influenza clinical measure data, because KCQA specified and tested the patient-level influenza measure using facility data with the intention that such data would be submitted through CROWNWeb. They added that using NHSN would introduce another factor that would require reliability and validity testing as well as increasing the burden on dialysis facilities because of manual entry issues. They strongly recommended that if CMS does add a patient-level influenza immunization clinical measure, it should add NQF #0226 unchanged and collect the data through CROWNWeb.

Response: We thank commenters for their support and for their suggestions regarding the potential future introduction of a patient-level influenza immunization measure into the ESRD QIP for future years of the program. We will take their suggestions into consideration as we evaluate options.

Comment: Several commenters supported the influenza vaccination reporting measure for future

consideration in the QIP and suggested that NHSN be used to collect data for the measure for consistency, ease of use, and access purposes. Given that the NHSN HCP Influenza vaccination measure is already collected in NHSN, adding the patient-level measure to the existing reporting system would provide consistency and continuity for facilities. Additionally, commenters pointed out that state health departments, LDO's and ESRD Networks can gain access to the data reported in NHSN and continued use of this system would more easily facilitate sharing of data with other entities engaged in the oversight of infection prevention. One commenter added that if NHSN is used to collect data, it will serve as a single repository for influenza vaccination data, and therefore could be used by regulatory agencies and local health departments who are able to access the data and use it for quality improvement and other public health purposes. One commenter also recommended that CMS consider adding an additional incentive for facilities that report vaccination rates, above the proposed required vaccination information.

Response: We thank commenters for their support, and we will take their suggestions into consideration as we consider the feasibility of introducing a patient-level influenza immunization measure into the ESRD QIP's measure set in future years of the program.

Comment: One commenter expressed concerns about the potential use of Measures Application Partnership #XDEFM as the basis for a future clinical measure because it does not follow the NQF standardized specifications for a measurement timeframe and given that the vaccine is often available in late July or early August, omitting patients who were vaccinated before October 1 unfairly penalizes those facilities who are able to obtain the vaccine early and serves as a disincentive to early and thorough vaccination.

Another commenter disagreed with CMS's concerns that NQF #0226 would exclude patients who die from influenza, but might not have died if they had been vaccinated. The measure specifications do not include such an exclusion and in fact the measure excludes unvaccinated patients who die prior to March 31. This exclusion does not penalize facilities for patients who could still have received a vaccination within the timeframe specified by the Agency's own measurement timeframe. The commenter recommended setting the denominator such that it is aligned with the NHSN protocol and NQF specifications and that CMS clearly state that the CDC would determine the date when a vaccine is made available each year.

Response: We thank commenters for sharing their suggestions regarding the future potential introduction of either NQF #0226 or Measures Application Partnership #XDEFM, and we will take them into consideration when considering the future adoption of a patient-level influenza immunization measure.

Comment: Commenters submitted a great deal of feedback on the possible introduction of a Standardized Mortality Ratio measure in the ESRD QIP. Several commenters stated that they would potentially support the adoption of an SMR measure into the QIP but expressed a few concerns with the measure. Two commenters stressed that any mortality measure would need to be carefully tailored to the actions of the dialysis facility and they recommended that CMS work more closely with stakeholders to establish an appropriate measure that focuses on year-over-year, facility-specific improvement before considering its addition into the QIP, particularly in light of the decision of the NQF's Renal Standing Committee not to recommend the revised SMR Measure. Commenters urged CMS to update the SMR Specifications to make them less ambiguous and more precise, and they argued that the 1-year period is inappropriate based on the testing data. Instead, they recommended at minimum a 4-year period and they encouraged CMS to consider including a larger list of relevant prevalent comorbidities as identifiable in Medicare claims data because they feel it's important to adapt the SHR and SMR in a way that takes into account the effect that such comorbidities have on hospitalization and mortality rates. Commenters appreciated that the introduction of an SMR measure in the QIP would promote high quality care for ESRD patients and recommended that the measure reflect a rolling average of facility performance due to the potential for a small number of outliers to impact facility performance substantially on the measure and further recommended that the measure include an adjuster for small facilities so that those with small sample sizes are not inappropriately penalized. Finally, they recommended that CMS adopt an NQF-endorsed SMR measure.

Response: We thank the commenters for sharing their suggestions regarding the potential implementation of a Standardized Mortality Ratio Measure in future years of the ESRD QIP. We will take these comments and suggestions into consideration as we consider whether to propose such a measure in the future.

Comment: Commenters provided a great deal of feedback regarding the possible introduction of a Transplant Measure in future years of the ESRD QIP. One commenter agreed that referrals and patient education about transplants are important concepts to measure, but stated that they could not support the two transplant-related wait list measures proposed by a recent TEP because they are not appropriate for the QIP based upon the most recent specifications released by CMS because they measure the success of being waitlisted and attribute that to dialysis facilities when that responsibility rests solely with the transplant center. Instead, the commenter recommended that CMS focus efforts on developing measures related to patient education, referral to a transplant center, initiation of the waitlist evaluation process, or completion of the waitlist evaluation process, and care coordination. Another commenter had specific concerns about the proposed future adoption of a transplant measure. Specifically, they argued that transplants carry a level of risk that patients must assume, so it is important to require that all patients be assessed for transplant, however commenter expressed concern with the expectation that a percentage of a facility's patients be required to actively pursue a transplant. Another commenter stated that as CMS moves toward a more bundled care environment, it is important for the ESRD QIP to implement a transplant measure. They added that it would be beneficial to track and report the number of transplant patients, number of transplants, and the employment status of these patients in order to identify key indicators and best practices to help patients get transplanted and retain employment.

Response: We thank the commenters for sharing their suggestions regarding the potential implementation of a Transplant Measure in future years of the ESRD QIP. We will take these comments and suggestions into consideration as we consider whether to propose such a measure in the future.

Comment: Commenters agreed that emergency department (ED) visits are an important marker of healthcare utilization and cautiously supported the concept of measuring Emergency Department Utilization but added that it would be a complex measure which would require careful construction and risk modeling. One commenter stated that without more information about the potential emergency department utilization measure, they could not

support such a measure for inclusion in the QIP. Another commenter stated that any such measure would need to include dialysis-related emergency room visits. Commenters stated that much work would need to be done to appropriately construct an ED visit measure for dialysis facility accountability and that such a measure would need to include risk modeling to account for many factors that may influence the frequency of ED visit. It would need to account for the fact that there are a wide variety of circumstances that lead to ED visits, many of which are completely beyond the control or the knowledge of the facility at the time they are occurring. Commenters stressed that CMS will need to carefully consider the specifications for the measure as certain facilities may not be able to achieve low rates of unnecessary patient utilization of the ED. They provided two examples: A facility that is only open three days a week should not be penalized if their patients utilize the ED on a day that they are not open. Second, patients in urban settings may live close enough to the hospital that they have the option to go home and see if their illness subsides sufficiently without having to go to a hospital ED, while patients in rural settings may not have that option. Facilities in more rural settings should not be penalized simply because their patients live in rural settings and feel the need to go to the ED out of an abundance of caution.

Response: We thank the commenters for sharing their suggestions regarding the potential implementation of an ED Utilization measure in future years of the ESRD QIP. We will take these comments and suggestions into consideration as we consider whether to propose such a measure in the future.

Comment: Many commenters supported CMS's proposal to consider the inclusion of a Medication Reconciliation measure in future years of the ESRD QIP, and specifically stated that they would support the adoption of NQF #2988: Medication Reconciliation for Patients Receiving Care at Dialysis Facilities, which is currently under evaluation by the NQF Patient Safety Standing Committee. They supported this measure because it is an important patient safety process for patients with ESRD given that many of them have multiple prescriptions and because it would help providers identify unnecessary medications, duplicate therapies or incorrect dosages, thus reducing the risk of patients experiencing adverse drug events. One commenter added that such a measure would incentivize providers to perform medication reconciliation across the continuum of care and would increase the focus on patient safety, resulting in improved patient outcomes.

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

Comment: One commenter stated that, provided they are outcome measures, rather than process measures, they would support all of the following measures for consideration in future payment years of the ESRD QIP: The SMR Measure, an ED Utilization Measure, a Medication Reconciliation measure, and a measure examining kidney transplants in ESRD patients.

Response: We thank commenter for their support of these measures under future consideration.

Comment: A commenter argued that future pediatric measure development should consider the entire pediatric population, beyond Medicare beneficiaries and include the full range of pediatric patients without regard to provider in order to ensure the greatest knowledge of their health status and to provide meaningful and appropriate data about the quality of pediatric care. The commenter also urged CMS to examine the appropriateness of including measures that evaluate adult and pediatric patients together and to work on finding measures that are more appropriate for assessing small numbers of pediatric patients who are dialyzed at adult facilities.

Response: We thank the commenter for their suggestions and we agree that it is vitally important to measure the care being provided for pediatric patients, both in pediatric facilities and in facilities that treat adult and pediatric patients together. Unfortunately, in large part due to the small numbers of pediatric patients, there are currently very few measures available that focus on the care furnished to pediatric patients with ESRD. For example, as we noted in the CY 2015 ESRD PPS Final Rule (79 FR 66172), using 2013 data, there were only 10 facilities that were eligible to receive a score on the Pediatric Hemodialysis Adequacy measure. We will continue to work with the ESRD community to identify measures for inclusion in the ESRD QIP that examine the care of this vulnerable population.

Comment: One commenter urged CMS to reinstitute a measure establishing a minimal standard for anemia management to ensure that patients are neither over-treated nor under-treated.

Response: When we retired the Hemoglobin Less Than 10 g/dL measure, we did so for important clinical reasons which we continue to believe warrant including this measure only as a Reporting Measure and not as a Clinical Measure (76 FR 70257). Specifically, we could not identify a specific hemoglobin lower bound level that has been proven safe for all patients treated with ESAs. Additionally, at the time the measure was retired, we discussed with the FDA our proposal to retire the Hemoglobin Greater than 10 g/dL measure starting in PY 2013. Because the measure encouraged providers/facilities to keep hemoglobin above 10 g/dL, the FDA agreed that retiring the measure was consistent with the new labeling for ESAs approved by the FDA. We are also not aware of, nor have any stakeholders noted, any studies that identify a specific hemoglobin level which should be maintained to increase quality of life or minimize transfusions or hospitalizations. However, if any new evidence or studies emerge, we will take such evidence into consideration in adopting future measures for the ESRD QIP. Factors that impact anemia management, including optimal iron stores, dialysis adequacy, avoidance of infections, reduction of inflammation, and other factors should be addressed by the health care team to improve patient health. We urge patients and providers to work together to achieve optimal hemoglobin levels for each individual patient. We will continue to monitor and evaluate practice patterns and outcomes for all segments of the Medicare ESRD population as we develop and refine our measurement of the quality of anemia management.

Comment: A commenter urged CMS to consider developing quality measures for use with patients with AKI. Some of their specific recommendations were to develop a Kt/V measure specific for AKI patients with a target of 3.9. They also recommended a BSI measure specific to AKI patients, arguing that AKI patients should not be included in the same measure pool as ESRD patients given that they have a higher risk of infections and have additional complex complications. Finally, they urged CMS to develop patient-reported outcomes measures specific to AKI patients, including assessments of patient satisfaction.

Response: We thank the commenter for their recommendations. We agree that patients with AKI must be ensured a high quality of care, however given the measures that are currently available for use in Dialysis Facilities, we are unable to measure care for patients with AKI at this time. The quality measures

currently in use in the ESRD QIP specifically include patients with end-stage renal disease and are not designed to measure the care of patients with AKI. In the event that measures are developed that include patients with AKI, we will consider the feasibility of including those measures in our measure set in future years of the program.

Comment: One commenter argued that recovery time is an important and powerful indicator of day-to-day quality of life and is associated with patient survival and recommended that CMS start collecting and reporting data on recovery time as a meaningful clinical outcomes measure.

Response: We thank the commenter for their suggestion and we agree that recovery time is an important and powerful indicator of the quality of life of patients with ESRD. However, at this time, we are not aware of any clinical quality measures that are available to measure this important outcome. Should one become available, we will consider the feasibility of including it in the measure set for the ESRD QIP in future years of the program.

V. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

A. Background

Section 1847(a) of the Social Security Act (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 of the Department of Health and Human Services (the Secretary) to establish and implement the Competitive Bidding Program (CBP) in Competitive Bidding Areas (CBAs) throughout the United States for contract award purposes for the furnishing of certain competitively priced Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (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, as 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 product category and 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. Section 1847(b)(2)(A)(v) 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. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the DMEPOS CBP

The proposed rule, titled ''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'' (81 FR 42802 through 42880), was published in the **Federal Register** on June 30, 2016, with a comment period that ended on August 23, 2016. In the proposed rule for the DMEPOS Competitive Bidding Program, we made proposals to implement statutory requirements for bid surety bonds and state licensure for the DMEPOS CBP, as well as to revise the 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. We received approximately 14 public comments on our proposals, including comments from homecare associations, a surety association, DME manufacturers, and individuals.

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

1. Bid Surety Bond Requirement

At proposed § 414.402, we proposed 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 (81 FR 42877).

At proposed § 414.412, ''Submission of bids under a competitive bidding program,'' we proposed adding 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 (81 FR 42879). 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 (81 FR 42879).

At proposed § 414.412(h)(2) ''Bid Surety Bond requirements,'' we proposed that 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 the 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 (81 FR 42879).

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. We proposed setting the bid surety bond amount at $100,000 for each CBA in which a bidding entity submits a bid (81 FR 42879). 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. The CBP has historically had a contract acceptance rate exceeding 90 percent, and we believe that this acceptance rate will increase with this rule. We considered 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 therefore, specifically solicited comments on whether to establish a lower bid surety bond amount for certain types of suppliers (81 FR 42848).

Proposed § 414.412(h)(3) specifies conditions for forfeiture of the bid surety bond and return of the bond liability (81 FR 42879). 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 provision at proposed § 414.412(h) 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 (81 FR 42879).

We proposed 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 proposed 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 are included in proposed § 414.412(h)(4).

We sought comments on these proposals. We note that we did not receive any comments on whether a lower bid surety bond amount would be appropriate for a particular subset of suppliers, for example, small suppliers, as defined at § 414.402.

The comments and our responses to the comments for these proposals are set forth below.

Comment: A majority of commenters supported setting the bid surety bond amount at $50,000, with some commenters suggesting that the bid surety bond amount could be raised in the future if necessary. One commenter stated that this is a ''new requirement'' and that ''little is known about how [bid surety bonds] will work''. Another commenter stated that they do not ''know of any real-life experience'' with obtaining a bid surety bond. Another commenter stated that due to the unknown nature and specifics regarding the new bid surety bond, the requirement of $100,000 per CBA would be ''administratively burdensome to qualify for and obtain the [bid surety] bond.'' A commenter suggested that the large expenditure potentially required by suppliers bidding in multiple CBAs could ''deter some highly qualified suppliers from choosing to participate in the bidding process.''

Response: We agree with commenters that there may be unknown variables associated with obtaining this new bid surety bond, as well as the potential financial and administrative burdens that will be placed on bidders. We believe that a lower bid surety bond amount would be appropriate to encourage continued participation of bidders in the CBP and are therefore revising the bid surety bond amount to $50,000 in the final rule. While we acknowledge that there will be a number of entities that are required to make large expenditures in order to obtain a bid surety bond for each CBA in which they are submitting a bid, we anticipate that this revision on the bid surety bond amount from $100,000 to $50,000 will reduce that overall burden on all suppliers. We intend to monitor the implementation of the bid surety bond requirement and will consider increasing the bid surety bond amount in future rulemaking if necessary.

Comment: Several commenters proposed setting the bid surety bond amount higher for National Mail Order (NMO) suppliers with a suggested range from $100,000 to $1,000,000 since the NMO has a ''national scope'' and that NMO suppliers ''operate nationally.''

Response: We appreciate the comments suggesting that NMO suppliers should be required to obtain a higher bid surety bond amount since they provide competitively bid items nationwide. MACRA section 522(a) requires CMS to set the bid surety bond requirement in a competitive acquisition area within a range of $50,000 to $100,000. We proposed to implement the requirement to obtain a bid surety bond for each CBA in the manner required by MACRA. We proposed that the bid surety bond amount be applied in a consistent manner and will not vary by CBA. A ''nationwide competitive bidding area'' is defined in regulation at § 414.402 as a CBA that includes the United States, its Territories, and the District of Columbia. In the proposed rule, we did not contemplate setting a different bid surety bond amount for the NMO competition since the NMO competition, by definition, is a *single* CBA (emphasis added) and the NMO competition is not a specific subset of suppliers. The contract acceptance rate for the original NMO competition and the NMO Recompete were 95 percent and 100 percent, respectively. This indicates to us that a higher bid surety bond amount for an NMO competition is not necessary at this time. Furthermore, the highest bid surety bond amount we are permitted to set under section 522(a) of MACRA is $100,000. In this final rule, we will be setting the bond amount at $50,000 for all suppliers.

Comment: One commenter suggested implementing stronger penalties for submission of false bid surety bonds such as a prohibition from participation in all future rounds of the CBP.

Response: We did not propose to prohibit an entity from participation in all future rounds of the CBP in this rulemaking and do not think it is necessary at this time because we believe that referring bidding entities that provide a falsified bid surety bond to the Office of the Inspector General and Department of Justice for further investigation is sufficient.

Comment: A commenter inquired as to why the bid surety bond was only required until January 1, 2019.

Response: This commenter's interpretation that the bid surety bond is only required until January 1, 2019 is incorrect. Section 1847(a)(1)(G) of the Act provides that the bid bond requirement is applicable to rounds of competition beginning not earlier than January 1, 2017 and not later than January 1, 2019. Thus, the bid surety bond will be required by bidders submitting bids starting with the Round 1 2019 competition.

Comment: Several commenters suggested that CMS create a limit on either the amount of bid surety bonds required to be purchased by an entity, or the amount of bid surety bonds that could be forfeited by an entity in the event of default.

Response: Section 1847(a)(1)(G) of the Act does not provide us with the authority to limit the number of bid surety bonds purchased by an entity or to place a cap on the forfeiture amount. Section 1847(a)(1)(G) of the Act explicitly states that a bid surety bond must be purchased for each competitive acquisition area in which a bidder is submitting a bid.

Comment: One commenter suggested that CMS add a provision that sets forth the discharge of the authorized surety more explicitly.

Response: For purposes of responding to this comment, we are assuming that the term discharge refers to the return of the bid surety bond liability. We will issue guidance (for example, in the Request for Bids instructions) prior to the opening of the bidding window on the mechanism for the return of the bid surety bond liability to the bidding entity.

Final Rule Action: As a result of the comments received regarding the bid surety bond requirement, and our reevaluation of the potential impact to the CBP, in this final rule we are adopting a lower amount of $50,000 for the bid surety bond instead of $100,000 for each CBA and revising § 414.412(h)(2)(i)(H) accordingly. We agree that there are a number of unknown variables associated with bid surety bonds and there will be financial and administrative burdens that will be placed on bidders. Therefore, we have revised the bid surety bond amount to $50,000. After considering the comments and for the reasons we set forth previously, the provisions at § 414.412 (h)(1) through (h)(2)(i)(G) for bid surety bonds will be finalized. However, we have updated § 414.412(h)(2)(i)(D) to reference § 414.412(h)(3), which specifies the conditions of the bond. In addition, proposed § 414.412(h)(3) through (4) will be finalized as proposed.

2. State Licensure Requirement

We proposed 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 (81 FR 42848). 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) stated that ''[e]ach supplier must have all State and local licenses required to perform the services identified in the request for bids.'' Therefore, we proposed revisions to § 414.414(b)(3) to align with the language of section 1847(b)(2)(A) of the Act as revised by section 522(b) of MACRA, to state that a contract will not be awarded to a bidding entity unless the entity meets applicable State licensure requirements (81 FR 42878). We noted, however, that this does not reflect a change in policy as§ 414.414(b)(3) already requires suppliers to have applicable State and local licenses (81 FR 42848).

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

Comment: One commenter stated that ''state licensure for DMEPOS will add an extra layer of unnecessary regulation. Currently, we must also be accredited which costs thousands of dollars for the privilege just to have a license.''

Response: We are not adding requirements or additional layers of regulation. Suppliers currently are required to have applicable state and local licenses under § 414.414(b)(3). The regulation we are finalizing at § 414.414(b)(3) simply captures the language of section 1847(b)(2)(A)(v) of the Act, as added by section 522 of MACRA, which prohibits CMS from awarding a contract to any entity in a CBA unless those requirements are met (81 FR 42848). Therefore, the change we are adopting in this final rule does not represent a change in policy.

Comment: We received a number of comments on our proposed revisions to § 414.414(b)(3) that were beyond the scope of the proposed rulemaking.

Response: These comments were beyond the scope of the proposed rulemaking, therefore, we will not be addressing these comments in our final rule.

Final Rule Action: We are finalizing § 414.414(b)(3) as proposed, to state that a contract may not be awarded to a bidding entity unless the entity meets applicable State licensure requirements. This action does not place a new burden on suppliers nor does it represent a change in policy as CMS currently requires suppliers to be in compliance with all State and local licenses. The final regulation makes it explicit that CMS may not award a contract to any entity in a CBA unless the entity meets applicable State licensure requirements, as required by section 522(b) of MACRA.

3. Appeals Process for a DMEPOS Competitive Bidding Breach of Contract Action

We believe DMEPOS suppliers should have the option to appeal all actions that CMS may take for breaches of contract. As a result, we proposed revising § 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 (81 FR 42848). While we recognize that we have the authority to take one or more actions specified in § 414.422(g)(2), the current appeals process is available for one of those actions, specifically, contract termination. Therefore, the proposed revisions would expand § 414.423 to allow appeal rights for each action specified in § 414.422(g)(2) for a breach of contract (81 FR 42848). If a supplier's notice of breach of contract includes more than one breach of contract action CMS would take, and the supplier chooses to appeal more than one action, CMS would make separate decisions for each breach of contract action after reviewing the hearing officer's recommendation (81 FR 42849). We also proposed revisions to § 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 (81 FR 42849). We proposed removing § 414.423(g)(2)(i) because a corrective action plan is already a part of the formal appeals process outlined in § 414.423, and therefore, unnecessary to list as an action CMS can impose on contract suppliers that it considers to be in breach (81 FR 42849). We also proposed removing 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 (81 FR 42849). Furthermore, we proposed revising this section to state that CMS will specify in the notice of breach of contract which actions it is taking as a result of the breach of contract (81 FR 42849).

Proposed revisions were made throughout § 414.423 to extend the appeals process to any breach of contract actions described in proposed § 414.422(g)(2) that we might take as a result of the breach, rather than just contract termination actions (81 FR 42849). We also proposed removing the references to termination throughout § 414.423 and instead cross-reference all of the breach of contract actions in proposed § 414.422(g)(2) (81 FR 42849).

In proposed revisions to § 414.423(a), we proposed deleting 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 (81 FR 42878).

In the proposed revisions to § 414.423(b)(1), we proposed deleting 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 (81 FR 42878). In addition, we proposed removing 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 (81 FR 42878). We also proposed changes to § 414.423 (b)(2)(i) and (ii) (81 FR 42878). The revised § 414.423(b)(2)(i) states that the notice of breach of contract would include the details of the breach of contract, while § 414.423(b)(2)(ii) requires CMS to include the action or actions that it is taking as a result of the breach of contract and the timeframes associated with each breach of contract action in the notice (81 FR 42878). For example, when a notice of breach of contract includes an action of preclusion, the effective date of the preclusion would 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 also proposed to add language to paragraph (b)(2)(vi) to specify that the effective date of the action or actions that CMS would take 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 (81 FR 42878–79).

We proposed revising § 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) (81 FR 42879). We proposed to revise § 414.423(e)(3) 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 (81 FR 42879).

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 or actions specified in the notice of breach of contract would take effect 45 days from the date of the notice of breach of contract (81 FR 42879). Proposed revisions to § 414.423(g)(3) were made to clarify that the hearing scheduling notice must be sent to all parties, not just the supplier (81 FR 42879).

We proposed revising § 414.423(j) to clarify that the hearing officer would 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 (81 FR 42880).

In § 414.423(k), we proposed specifying that CMS would make separate decisions for each recommendation when the hearing officer issues multiple recommendations (81 FR 42880). In addition, we proposed revisions to this paragraph to expand CMS' final determination process, clarifying that the notice of CMS' decision would be sent to the supplier and the hearing officer and would indicate whether any breach of contract actions included in the notice of breach of contract still apply and will be effectuated, and would indicate the effective date of the breach of contract action, if applicable (81 FR 42880). We also proposed expanding on § 414.423(l), effect of breach of contract action or actions, to specify effects of all contract actions described in § 414.422(g)(2) (81 FR 42880). In addition, we proposed adding proposed § 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 (81 FR 42880). We also proposed adding proposed § 414.423(l)(3) (81 FR 42880), effect of preclusion, to specify that a supplier who is precluded would not be allowed to participate in a specific round of the CBP, which would be identified in the original notice of breach of contract. Additionally, we proposed adding proposed § 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 would be included in the notice of breach of contract (81 FR 42880). Proposed § 414.423(l) also specifies the steps suppliers must take to notify beneficiaries after CMS takes the contract action or actions described in § 414.422(g)(2) (81 FR 42880). Lastly, we proposed to remove language from § 414.423(l)(2), effect of contract termination, to avoid confusion as to which supplier is providing notice to the beneficiary (81 FR 42880).

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

Comment: Numerous commenters suggested that notification of breach of contract should be sent via a manner that provided a ''verifiable and guarantee receipt.'' Some commenters suggested retaining certified mail in additional to the proposed secure manner.

Response: We will send a breach of contract notification to contract supplier via electronic means in the future once we have this functional capability. Specifically, contract suppliers will receive an email notifying them to check their secure inbox located in CMS' secure online portal for the DMEPOS CBP (currently known as ''Connexion''). Once a supplier logs in to retrieve the notice, the audit logs will record the download history for the document (for example, user name date/time stamp, etc.). However, until the portal has this functionality, we will continue to provide suppliers with notification through certified mail. We will provide advanced notice to contract suppliers when the transition to electronic breach of contract notifications occurs.

Comment: One commenter stated that in the breach of contract hearing

scheduling notice CMS should ''clearly state the parties that would receive the notice in addition to the supplier.''

Response: The supplier and CMS are the parties to the hearing (and the parties may have representatives appear on their behalf). We do not find it necessary, however, to further describe these parties in the breach of contract hearing scheduling notice or make this delineation within the text of § 414.423.

Comment: One commenter stated that CMS should address the problem of binding bids by exercising its general contracting authority to include in each competitive bidding contract severe financial penalties for any supplier that does not provide services after signing a contract. This penalty should also be referenced as part of the appeals process policies.

Response: We have adopted regulations to take one or more of the breach of contract actions outlined in § 414.422(g)(2) against contract suppliers that accept competitive bidding contracts and fail to meet the terms of the contracts. We believe those actions are appropriate and we are not considering other types of penalties at this time.

Final Rule Action: After considering the comments and for the reasons we discussed previously, we are finalizing the proposed changes to § 414.423 to expand the breach of contract appeals process to all breach of contract actions that CMS may take pursuant to § 414.422(g)(2). We are also finalizing § 414.422(g)(2) to adopt the proposed changes to the breach of contract actions that CMS may take when a supplier is in breach of its competitive bidding contract (81 FR 42949). We are removing the word ''only'' from § 414.423(c)(2)(ii) to clarify when suppliers may submit a CAP. CMS proposed affording suppliers the opportunity to submit a CAP, at CMS' discretion, when the supplier receives a subsequent notice of breach of contract action (81 FR 42849). Removing ''only'' from this section clarifies that CMS may accept a CAP in response to a subsequent termination notice and not just the initial termination notice. This final regulation provides suppliers who are in breach of contract the opportunity to appeal any breach of contact action that CMS may take rather than only having the opportunity to appeal a contract termination action. This provides greater transparency to suppliers and affords CMS greater flexibility in managing suppliers that are in breach of their competitive bidding contract. Also, in § 414.423(c)(2)(ii), we are changing ''paragraph (1)(i)'' to ''paragraph (c)(1)(i)'' to make the paragraph reference more clear.

In the final rule we are also making a revision to § 414.402, Definitions, for the term ''hearing officer''. In the revised definition, we are removing the references to ''termination'' and replacing those references with ''breach of contract'' to align with the final changes to § 414.423 that we are adopting in this final rule, as well as deleting the abbreviation ''(HO)'', which is no longer used in § 414.423 As we discuss in section XII. ''Waiver of Proposed Rulemaking,'' because these revisions to § 414.202 are technical in nature, to align the definition of hearing officer with the terminology and process finalized in § 414.423, we find good cause to waive notice and comment rulemaking for this definition revision.

VI. Method for Adjusting DMEPOS Fee Schedule Amounts for Similar Items With Different Features Using Information From Competitive Bidding Programs (CBPs)

A. Background

1. Fee Schedule Payment Basis for Certain DMEPOS

Section 1834(a) of the Social Security Act (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 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 published a final rule titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies'' on November 6, 2014 (hereinafter, the CY 2015 final rule), in which we adopted these methodologies (79 FR 66223 through 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) Web site: *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) of the Act 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) of the Act 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 fee 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. Method 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 method to address unbalanced bidding, which is a situation that results in price inversions under CBPs. We added § 414.210(g)(6) to the regulations 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 HCPCS code with higher beneficiary 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, HCPCS code B9002 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 CY 2015 proposed rule, namely, enteral infusion pumps and standard power wheelchairs. Therefore, the final regulation at § 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 § 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. Summary of the Proposed Provisions on the Method for Adjusting DMEPOS Fee Schedule Amounts for Similar Items With Different Features Using Information From Competitive Bidding Programs

The proposed rule, titled ''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'' (81 FR 42802 through 42880), was published in the **Federal Register** on June 30, 2016, with a comment period that ended on August 23, 2016. During the comment period, we issued a correction to the proposed rule with minor technical edits, including corrections to several HCPCS codes we listed describing groupings of similar items with different features (81 FR 42825). The correction notice, which went on public display on August 2, 2016, was published in the **Federal Register** on August 3, 2016 (FR Doc. C1–2016–15188) (81 FR 51147).

In the proposed rule, for the Method for Adjusting DMEPOS Fee Schedule Amounts for Similar Items with

Different Features using Information from Competitive Bidding Programs, we proposed changes to the methodologies for adjusting fee schedule amounts for DMEPOS items using information from CBPs and for submitting bids and establishing single payment amounts under the CBPs for certain groupings of similar items with different features.

After performing 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 proposed a rule that would 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 final 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 20, 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 20—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) are 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: Codes 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 21. 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 21—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 a 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 proposed to adopt a definition of price inversion in our regulations at proposed § 414.402 as any situation where the following occurs: (a) 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, an alarm, or Group 2 performance); (b) 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 (c) following a competition, the SPA for the code with the feature is lower than the SPA for the item without

that feature (81 FR 42877). We proposed 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 (81 FR 42854). For this adjustment, we considered two methodologies.

The first method 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 (81 FR 42854). 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 method 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 22 below.

TABLE 22—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 that 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 the section. We stated in the proposed rule that, if method 1 is finalized, we would indicate that additional price inversions involving additional sets of two items to which this rule would apply would be identified in a table in the preamble of the final rule (81 FR 42854). An example of such a table is provided below in Table 23 using codes for walkers, seat lift mechanisms, and TENS devices:

TABLE 23—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 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 method we considered and proposed (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 (81 FR 42855). 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 24.

TABLE 24—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 the 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 proposed to use method 2 because it took into account the supplier bids for all of the similar items when 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 (81 FR 42855). 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. We solicited comments on both method 2, which we proposed, and method 1, which we considered.

In summary, we proposed to expand use of the method at § 414.210(g)(6) to other situations where price inversions occur under CBPs. First, we proposed to revise 42 CFR 414.402 to add the definition of price inversion as any situation where the following occurs (81 FR 42856, 42877):

- 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 proposed 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) (81 FR 42877). We proposed that the adjustments to the SPAs would be made using method 2 described above (81 FR 42855). We also proposed 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) (81 FR 42856, 42877). We proposed to apply this rule to price inversions as defined in the proposed rule for the groupings of similar items listed in the Table 18 of the proposed rule and identified again below in Table 25 (81 FR 42856). For the purpose of calculating the weighted average at proposed § 414.210(g)(6)(iii), we proposed 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 (81 FR 42856, 42877). We proposed 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 proposed 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 (81 FR 42856). 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 25—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.
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*.

C. Response to Comments on the Method for Adjusting DMEPOS Fee Schedule Amounts for Similar Items With Different Features Using Information From Competitive Bidding Programs

We solicited comments on the method for adjusting DMEPOS fee schedule amounts for similar items with different features using information from competitive bidding programs and received 8 public comments on our proposals, including comments from DMEPOS manufacturers and suppliers.

The comments and our responses to the comments for these proposals are set forth below.

Comment: Some commenters suggested there are underlying/additional issues to price inversions and suggest that CMS analyze the history of the product group and how payment rates for the applicable codes were originally established. Comments suggested other factors may have caused price inversions such as the method used to ''gap-fill'' fee schedule amounts for items when the data mandated by the statute for calculating the fee schedule amounts does not exist, awarding contracts under the CBP based on composite bids (individual bids for items multiplied by item weights), and establishing single payment amounts under the CBP based on the median of bids submitted. Some commenters suggested that these underlying issues should be addressed and the competitions re-competed in order to address the situation.

Response: We appreciate the comments but do not agree with these comments. The fee schedule amounts for walkers, TENS devices, and hospital bed codes E0250 through E0261 were established based on average reasonable charges from 1986 and 1987 as mandated by section 1834(a) of the Act. The fee schedule amounts for these items, based on supplier's average reasonable charges, are higher as more features are added to the items (for example wheels, folding, 4 lead rather than 2 lead, with mattress, variable height, and semi-electric). The fee schedule amounts for hospital beds without side rails (for example E0294) were gap-filled using the fee schedule amounts for hospital beds with side rails (for example E0260) and subtracting the fee schedule amounts for side rails (E0305 and E0310). We do not agree that the establishment of fee schedule amounts contributed to price inversions since the fee schedule amounts increased with addition of a feature when fees were established under both the reasonable charge and gap-filling methodologies. The fee schedule amounts for heavy duty hospital beds (E0301 thru E0304) were established based on manufacturer suggested retail prices and are higher than the fee schedule amounts for the standard weight versions of these beds to reflect the ability to accommodate heavier patients. The fee schedule amounts for electric and non-electric seat lift mechanisms are very similar, with the fee schedule amounts for electric seat lift mechanisms being slightly higher than the fee schedule amounts for the seat lift mechanisms without the power feature. The fee schedule amounts for power wheelchairs are based on manufacturer suggested retail prices and in no case does the fee schedule amount for a Group 1 power wheelchair exceed the fee schedule amount for the Group 2 version of the same type of power wheelchair. The fee schedule amounts for enteral infusion pumps (code B9000 for the pump without alarm and code B9002 for the pump with alarm) are the same. For hospital beds, power wheelchairs, and enteral infusion pumps, in no case was a fee schedule amount for an item without a feature established so that it exceeded the fee schedule amount for an item with the feature. For this reason, we do not believe that the methods used to establish fee schedules contributed to price inversions. The fee schedule amounts for Group 2 support surfaces (mattresses and overlays) are addressed below. We do not believe that using composite bids to select contract suppliers for contract award or median bids to establish single payment

amounts under the competitive bidding program are underlying causes for the price inversions.

Establishing single payment amounts based on the median of bids (as opposed to the highest bid) is applied consistently to each item in the product category and reflects the bids of all of the winning suppliers rather than just one. It is also similar to how the DME fee schedule amounts were initially established for each item, either based on average reasonable charges or average supplier prices (as opposed to the highest charge or price). We fail to see how establishing SPAs under the CBP using median bid amounts is an underlying cause of price inversions. We believe that use of composite bids is necessary when a competition under the CBP is for a group of items versus a single item. It is the method used to determine which bids are the most competitive (that is, generate the most savings) for the items in the product category as a whole. Use of a composite bid would not be necessary if the competition under the program were for a single item (for example, for one HCPCS code for oxygen and oxygen equipment used to bill and receive payment for all items and services furnished on a monthly basis related to oxygen and oxygen equipment). Therefore, we do not believe price inversions are caused by use of composite bids and item weights alone. Based on our analysis and the examples we discussed previously, we believe the problem results when there are multiple codes for items that can be substituted for one another because they serve the same general purpose (for example, standard power wheelchairs), but have different item weights that may vary significantly. As discussed in the proposed rule, price inversions result under the CBP when different item weights are assigned to similar items with different features within the product category. To prevent this from occurring under future competitions, we proposed, and as discussed in this final rule, an alternative ''lead item'' bidding method addressed in the section on submitting bids and determining single payment amounts for certain groupings of similar items with different features under the DMEPOS CBP (81 FR 42862).

In the interim period before this new bidding method, which we are adopting in this final rule, can be implemented, we must maintain the current contracts and payment amounts currently in effect, as required by section 1847(a) of the Act. We do not believe that other changes are necessary to address price inversions during this interim period. Under the final regulation, we will adjust inverted SPA prices prior to adjusting the fee schedule amounts for items that have been specifically listed in the rule.

Comment: Some commenters suggested that a definition be established for a ''grouping of similar items or products'' to require that all items included in the grouping be comprised of items with the exact same features or some subset of those features. A few commenters suggested further sub-groupings of items into smaller groups with similar features, such as a separate grouping for heavy duty hospital beds. These commenters also suggested that a definition be established for ''product feature(s)'' to require that feature(s) differentiating products within the group subject to the rule provide additional functional or clinical necessity.

Response: We appreciate the comments but do not agree that either definition is necessary because this specific groupings of items and the specific items within each grouping that would be subject to the proposed rule were listed in the proposed rule, and the definition of price inversion was included in the proposed rule, to identify situations where the SPA's for these items would be considered inverted.

We do not believe that a definition of product feature(s) is needed because we believe that situations where one item includes a certain feature and another item does not include that feature is clear, and generally Medicare should not pay more for the item without the feature than with a feature under any circumstances. Items without features should be paid less or equal to an item with a feature because the addition of a feature adds value to an item. We believe, for example, the Medicare payment rate for a non-electric hospital bed with side rails and mattress should not be higher than the payment rate for a semi-electric hospital bed with side rails and mattress. The Medicare program would be paying more for less features such as the non-electric bed. Likewise, we believe the Medicare payment rate for a semi-electric hospital bed without a mattress should not be higher than the Medicare payment rate for a semi-electric hospital bed with a mattress.

We do not believe that establishing smaller ''subgroupings'' of items is necessary because the groupings of items, relate to the items where existing price inversions have been identified for two or more of the codes in at least one CBA. In some cases, a code in a grouping may not be involved in a price inversion with another code in the grouping, and no adjustment is therefore necessary to adjust the difference in the SPAs for the two codes. In the case of heavy duty hospital beds, we have not determined that any price inversions have occurred where the SPA for a standard weight bed exceeds the SPA for a heavy duty version of the same bed. As such, there would be no situation where an SPA for a heavy duty bed will be adjusted using a weighted average of an SPA for a standard weight bed and an SPA for a heavy duty bed. The price inversions that have occurred for heavy duty beds within the grouping of codes for hospital beds have involved situations where the SPA for a heavy duty bed without a mattress is higher than the SPA for the same type of heavy duty bed with a mattress (the exact same feature). The changes we are finalizing to the regulation for addressing this situation are to adjust the SPAs for both heavy duty beds based on the weighted average of the SPAs for both heavy duty beds. The SPAs for standard weight beds would not be affected by this adjustment. Therefore, we are finalizing as we proposed.

Comment: Some commenters believe that that the grouping for mattresses and overlays (HCPCS codes E0277, E0371, E0372 and E0373) should not be subject to the rule. The commenters believe that there may be valid reasons why the cost of a non-powered mattress or overlay falling under the general category of Group 2 support surfaces may be higher than the costs of a powered mattress or overlay falling under the general category of Group 2 support surfaces. For example, a non-powered mattress or overlay product cannot be billed to Medicare until it has been classified under a HCPCS code by the Medicare Pricing, Data Analysis, and Coding (PDAC) contractor. These are costs that a powered mattress or overlay system do not incur. The commenters stated that there is no evidence that the powered systems are more effective or are superior to the non-powered mattresses and overlays.

Response: We appreciate the comments, however we do not agree. The fee schedule amounts for all four codes for Group 2 support surfaces (E0277, E0371, E0372, and E0373) were established from 1992 to 1996 using the same gap-filling methodology. Manufacturer suggested retail prices were used from the same general timeframe for various products falling under each code. The fee schedule amounts for the Group 2 overlays (E0371 and E0372) established in 1996 initially as codes K0413 and K0414, respectively, and non-powered mattress (E0373) established in 1997 initially as

code K0464, did not exceed the fee schedule amounts for powered mattress code E0277, but would have been limited to the fees for code E0277 if they had exceeded those amounts. The position of CMS in 1996 and 1997 and today is that the fee schedule amounts for overlays should not exceed the fee schedule amounts for mattresses, and that the fee schedule amounts for a non-powered Group 2 mattress should not exceed the fee schedule amounts for a powered Group 2 mattress. The addition of power or a complete mattress rather than an overlay that sits on top of a standard mattress are recognized as additional features. This position is supported by the structure of fee schedule amounts for Group 1 support surfaces calculated using average reasonable charges from 1986 and 1987. The fee schedule amounts for Group 1 mattresses are higher than the fee schedule amounts for Group 1 overlays, and fee schedule amounts for powered overlays are higher than the fee schedule amounts for non-powered overlays. We believe our proposal, which we are finalizing as proposed, provides a solution to address price inversions for this grouping of items that is necessary to avoid the risk of beneficiaries receiving items with less functionality (for example, a non-powered overlay), and preventing access to items with more functionality (for example, a powered mattress system), only because the payment amounts for the non-powered items are higher than the payment amounts for the powered items, or, as has occurred in 128 out of 130 competitive bidding areas, because the payment amounts for a non-power overlay (a support surface that is neither powered, nor mattress size) are higher than the payment amounts for a powered mattress system. The cost incurred to have a product code verified by the PDAC under codes E0371 or E0373 is a one-time, insignificant cost and prevents products from being classified as Group 1 products paid below $200 under the current fee schedule rather than Group 2 products paid at fee schedule amounts exceeding $3,000 under the current fee schedule.

Comment: Four of the eight commenters provided comments regarding the method to be used for adjusting SPAs in situations where price inversions have occurred. Three commenters preferred the proposed method 2, where a weighted average of the SPAs for the items involved in the price inversion is used to establish the payment amount for all of the items. The commenters favored this method because it takes into account the SPAs and supplier bids for all of the items involved in the price inversion rather than simply limiting the SPA for the lower volume item without a certain feature(s) to the higher volume item with the feature(s). One commenter preferred alternative method 1, where the SPA for the lower volume item without a certain feature(s) is limited to the SPA for the higher volume item with the feature(s). Method 1 is the method in the regulations that currently addresses price inversions for enteral infusion pumps and standard power wheelchairs. This commenter stated that since method 2 calculates a weighted average single payment amount using the item volume weights for groupings for similar items assigned under competitive bidding, it has the potential to compound unintended consequences with the assumption that current pricing and volume using ''total nationwide allowed services'' for multiple products will be balanced by a weighted average.

Response: We agree with the three commenters that method 2 should be used rather than method 1 for the reasons noted above. The weighted average approach takes into account the supplier's bids for all of the items in the grouping of items and therefore addresses the commenter's concerns that the supplier bids for the lower volume items be taken into account in setting the payment amounts for the items. We do not understand what the commenter that favored method 1 versus method 2 means by ''compounding unintended consequences'' and so it is not clear why the commenter suggested method 1 over method 2.

Final Rule Action: After consideration of comments received on the proposed rule and for the reasons we set forth previously, we are finalizing the proposed revisions to § 414.210(g)(6), with two technical changes. As a result of the administrative HCPCS editorial process, code B9000 for enteral infusion pumps without alarm is discontinued, effective January 1, 2017. Since only one code (B9002), rather than a group of codes, will remain in the HCPCS for enteral infusion pumps, there will no longer be multiple codes for this category of items, and so the proposed grouping of enteral infusion pumps is being removed from this section and therefore, not being finalized. Similarly, a decision was made to discontinue HCPCS code E0628 for electric seat lift mechanisms, effective January 1, 2017, and therefore this code is being removed from the grouping of seat lift mechanisms in this section and not being finalized in the regulation. We are also finalizing the proposed definitions at § 414.402 of ''price inversion'' and ''total nationwide allowed services.''

VII. Submitting Bids and Determining Single Payment Amounts for Certain Groupings of Similar Items With Different Features Under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

A. Background on the DMEPOS CBP

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 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 aims to guarantee 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. Summary of the Proposed Provisions on Submitting Bids and Determining Single Payment Amounts for Certain Groupings of Similar Items With Different Features Under the DMEPOS Competitive Bidding Program

The proposed rule, titled ''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'' (81 FR 42802 through 42880), was published in the **Federal Register** on June 30, 2016, with a comment period that ended on August 23, 2016. Under the heading of Submitting Bids and Determining Single Payment Amounts for Certain Groupings of Similar Items with Different Features under the DMEPOS CBP, we proposed to establish an alternative bidding method in proposed § 414.412(d)(2) that could be used to avoid price inversions discussed above in section VI of the proposed rule (81 FR 42877). Under this alternative bidding method, one item in the grouping of similar items would be 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, would be considered the lead item of the grouping (8 FR 42858 through 42859). For purposes of this final rule, the lead item bidding method described below only applies to the groupings of similar items with different features identified in this rule, and does not apply to other items not listed in this rule that may be in the same product category as the items listed in this rule.

For each grouping of similar items, we proposed that the supplier's bid for the lead item would be used as the basis for calculating the SPAs for the other items within that grouping, based on the ratio of the average of the fee schedule amounts for each item for all areas nationwide in 2015, to the average of the fee schedule amounts for the lead item for all areas nationwide in 2015 (81 FR 42859, 42878). In proposed § 414.412(d)(2), we proposed to use the fee schedule amounts for 2015 for the purpose of maintaining the relative difference in fee schedule amounts for the items in each grouping as it existed prior to any adjustments being made to the amounts based on information from the CBPs (81 FR 42877). This is to avoid the impact of price inversions that have occurred in pricing items under the CBP from affecting the relative difference in fee schedule amounts for the items. Under the CBP, 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 the proposed lead item bidding method, a supplier submits one bid amount for furnishing all of the items in the grouping (for example, standard power wheelchairs), rather than submitting bid amounts for each individual HCPCS code describing each different item (81 FR 48259). The competitive bidding item in this case (for example, standard power wheelchairs) is a combination of HCPCS codes (for example, K0813 thru K0829) for power wheelchairs with different features (Group 1/Group 2, portable/standard weight/heavy duty weight/very heavy duty weight/extra heavy duty weight, sling seat/captains chair). Suppliers submitting bids under the method will understand that if their bid is in the winning range, it would be used to establish the single payment amounts for all of the codes in the grouping. Suppliers will therefore take into account the cost of furnishing all of the items described by the various codes when determining their bid amount for 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 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 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 proposed using allowed services from calendar year 2012 for the first time this bidding method is used for specific items in specific CBAs (81 FR 42859). 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 proposed 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 proposed 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 will also help to prevent price inversions in adjusted fee schedule amounts using competitive bidding SPAs. We proposed 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 (81 FR 42859).

The following Tables 26, 27, and 28 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 the proposal, when bidding for the lead item, a supplier is bidding to furnish the entire grouping of similar items. In the tables 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 (81 FR 42860).

TABLE 26—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 27 below. Under our proposal, when bidding for the lead item, a supplier is bidding to furnish the entire grouping (81 FR 42860).

TABLE 27—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 proposed to include a new § 414.416(b)(3) that would include the lead item bidding method (81 FR 42860, 42878). 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 Table 28. Under the proposal, when bidding for the lead item, a supplier is bidding to furnish the entire grouping (81 FR 42860 through 42861).

TABLE 28—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 29, Table 30, Table 31 and Table 32. Under our proposal, when bidding for the lead item, a supplier is bidding to furnish the entire grouping (81 FR 42861).

TABLE 29—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 30—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 31—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

TABLE 31—LEAD ITEM BIDDING FOR SUPPORT SURFACE MATTRESS/OVERLAY AND RELATIVE DIFFERENCE IN FEES—Continued

HCPCS	Features	Allowed services for 2012	Average of 2015 rental fees	Fee relative to lead item
E0372	Powered air mattress overlay	2,076	505.82	0.76
E0371	Nonpowered mattress overlay	1,444	416.85	0.63
E0373	Nonpowered mattress	716	576.84	0.87

TABLE 32—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

*Chair excluded from coverage by section 1861(n) of the Act.

In summary, we proposed 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 (81 FR 42862). Suppliers participating in future CBPs may be required to use this method when submitting bids for these groups of similar items. Also, we proposed to revise § 414.416(b)(3) 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 (81 FR 42878). 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 Medicare Trust Fund from paying higher amounts for items with fewer features.

C. Response to Comments on Submitting Bids and Determining Single Payment Amounts for Certain Groupings of Similar Items With Different Features Under the DMEPOS Competitive Bidding Program

We solicited comments on this section. We received 4 public comments on our proposals from medical device manufacturers and suppliers.

The comments and our responses to the comments for these proposals are set forth below.

Comment: One commenter believes that the lead item bidding method does not align with Congressional intent for basing payment for items under the competitive bidding program on bids submitted and accepted for a single item.

Response: We believe that single payment amounts under the program are based on bids submitted and accepted for covered items and services described in section 1847(a)(2) of the Act. DMEPOS items and services are also described by HCPCS codes, which group covered items and services into categories for billing purposes. For the purpose of implementing the DMEPOS competitive bidding program, the definition of ''item'' at § 414.402 states that an item is a product that is identified by a HCPCS code or a combination of codes and/or modifiers. Therefore, we maintain that under the DMEPOS competitive bidding program, an item can be a group of HCPCS codes, such as a group of codes for similar items with different features under the proposed lead item bidding method. Under the lead item bidding method, suppliers take into account the cost of furnishing all of the covered items and services into their bid for the lead item, just as they would take into account the cost of furnishing a range of covered items and services described by a single HCPCS code, as HCPCS codes rarely describe a single DMEPOS product. One alternative to the lead item bidding method for eliminating price inversions under the DMEPOS competitive bidding program is to eliminate the multiple codes from the HCPCS for similar items with different features and establish a single code that describes all the items and services (for example, one codes for ''hospital bed, any type, includes all related accessories''). This is a long term alternative we can consider in the future to address price inversions if we determine that there is no need for multiple codes for similar items.

Comment: One commenter believes that it is unreasonable to keep constant the relative price difference among items under the fee schedule, as product prices could vary over time due to market factors and other reasons.

Response: We appreciate these comments, but do not agree that the lead item bidding method would prevent suppliers from accounting for changes in costs for the items over time or that it is unreasonable to keep the relative difference in prices constant for the items and services identified in the proposed rule. If, for example, the costs of Group 1 power wheelchairs increases over time, suppliers can take these costs into account in submitting their bid for the lead item, a Group 2 power wheelchair, as their bid is used to calculate the payment amounts for all of the items in the grouping of similar items. If the costs of Group 1 power wheelchairs increases to the point where they cost more than a Group 2 power wheelchair, the supplier can elect to furnish the lower cost Group 2 power wheelchair instead, since this

product would also meet the needs of the beneficiary. Or, alternatively as a long term solution if we determine that there is not a need for multiple codes for the similar items with different features can be eliminated from the HCPCS and a single code can be established that describes all the items and services (for example, standard power wheelchair, any type). This would address the issue of price inversions as well, and the supplier would take into account the cost of furnishing the different types of standard power wheelchairs into their bid for the single code, just as they would under the lead item bidding method.

Comment: Commenters suggested that (1) other factors other than allowed services should be considered when determining lead items such as allowed payment amounts for HCPCS codes and (2) CMS analyze features defined in the existing HCPCS codes and (3) CMS segregate products that exceed the code requirements in clinically or functionally relevant ways to ensure beneficiaries don't lose access to necessary features.

Response: We appreciate the comments but do not agree. These comments are based on the assumption that the presence or absence of a feature (for example, heavy duty versus non-heavy duty) is not sufficient to determine a pricing order for similar items (for example, hospital beds). As we indicated in the section for the method for adjusting DMEPOS fee schedule amounts for similar items with different features using information from CBPs, we do not believe that a Medicare fee schedule amount for an item without a certain feature(s) should exceed the Medicare fee schedule amount for the item with that feature(s). If products within a HCPCS code exceed the code requirements in clinically or functionally relevant ways, consideration can be made to revise the HCPCS codes to separately identify these products.

Comment: One commenter wants CMS to make the process of determining the groupings and the lead item transparent and open for industry or stakeholder input.

Response: We believe that the proposed rule is transparent in identifying the groupings of similar items and the lead item. We included a proposed definition of price inversion, a listing of codes representing groupings of similar items, and a method for determining the lead item in each grouping.

Comment: One commenter wants CMS to consider the highest Medicare fee schedule amounts for the items when deciding upon a lead item.

Response: We appreciate the comments but do not agree. We believe the item with the most allowed services of any item in a group is the item that is used most often and therefore should be considered the lead item since it is likely to be the one that suppliers furnish more than any of the other items in the group of similar items. The item with the highest fee schedule amount may not be the item that suppliers furnish more than any of the other items in the group of similar items; however, in many cases the item with the highest fee schedule amount is also the item with the most allowed services of any item in the group of similar items.

Comment: One commenter specifically suggested that CMS consider heavy-duty items as a separate grouping when determining the lead item because they believed heavy duty items were more costly.

Response: We believe that that the presence or absence of a feature can be used to determine the pricing order for similar items with different features. We believe that all hospital beds are similar items used for the same purpose and that the heavy duty feature (the ability to accommodate heavier patients) is clearly an additional feature. We see no reason to single out this feature (heavy duty) from other features as warranting a separate category of hospital beds. There is no evidence that heavy-duty items are more costly than the grouping of hospital beds. We believe it is more efficient to include these items in the grouping of hospital beds so that suppliers do not have to enter additional bids for these items, increasing the chance of keying errors.

Final Rule Action: After consideration of comments received on the proposed rule and for the reasons we articulated, we are finalizing our final policy for submitting bids and determining single payment amounts for certain groupings of similar items with different features under the DMEPOS CBP (alternative bidding methodology), with two technical changes. We are finalizing the provisions of § 414.412 to add the lead item bidding method described above to prevent price inversions under the DMEPOS CBPs. This method would only replace the current method of bidding for select groups of similar items identified in the final regulation. A decision was made as part of the administrative HCPCS editorial process to discontinue code B9000 for enteral infusion pumps without alarm, effective January 1, 2017. Since only one code (B9002), rather than a group of codes, will remain in the HCPCS for enteral infusion pumps, there will no longer be multiple codes for this category of items, and so the proposed grouping of enteral infusion pumps is being removed and not being finalized in § 414.412(d). Similarly, a decision was made to discontinue HCPCS code E0628 for electric seat lift mechanisms, effective January 1, 2017, and therefore this code is being removed from the grouping of seat lift mechanisms and not being finalized in § 414.412(d).

VIII. Bid Limits for Individual Items Under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

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. 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 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 were 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. Section 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.

The April 10, 2007 final rule titled, ''Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues'', finalized requirements for providers to submit bids under the DMEPOS CBP (§ 414.412(b)) (72 FR 17992, 18088). Section 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).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the Bid Limits for Individual Items Under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

The proposed rule, titled ''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'' (81 FR 42802 through 42880), was published in the **Federal Register** on June 30, 2016, with a comment period that ended on August 23, 2016. In that proposed rule, we noted that 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 (81 FR 42863). 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 proposed 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) (81 FR 42863). We proposed 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 will continue 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.

In summary, we proposed 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 (81 FR 42863). 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) of the Act, 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 (81 FR 42863).

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 proposed 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 (81 FR 42863). We proposed 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. As discussed in the proposed rule, Table 33 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 (81 FR 42864).

TABLE 33—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
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 proposed to amend § 414.412(b) to establish this method for determining bid limits for lead items identified in accordance with section § 414.412(d)(2) in section VII. B and as referenced also in the proposed rule (81 FR 42864, 42877), which we are now finalizing.

C. Response to Comments on Bid Limits for Individual Items Under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

We solicited comments and we received approximately 13 public comments on our proposals, including comments from medical device manufacturers, suppliers, advocacy groups and coalitions, and the Medicare Payment Advisory Committee (MedPAC).

The comments and our responses to the comments for these proposals are set forth below.

Comment: Most commenters supported the bid limit provision that was proposed. MedPAC suggested that some adjustment to reflect competitive bid results should be factored in to the bid limit rather than using the unadjusted 2015 fee schedule amounts, but did not suggest what adjustment should be factored into the bid limits. In addition, commenters stated that the fee schedule amounts should continue to be adjusted in all parts of the country to take into account the information from the CBP.

Response: We agree with commenters with the proposed provision on the bid

limit to use the unadjusted 2015 fee schedule amounts. This will allow suppliers to factor in both increases and decreases in SPA. We believe the comment from MedPAC is reasonable; however, a specific recommendation for adjusting the bid limits based on this general comment was not provided. Therefore, we do not have a specific recommendation in the comments that we can act upon in establishing the final rule.

Final Rule Action: After consideration of comments received on the proposed rule and for the reasons we discussed previously, we are finalizing the proposed § 414.412(b), without changes. 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.

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.[12] As a group, dual eligible beneficiaries comprise a population with complex chronic care needs and functional impairments.[13] Compared to Medicare-only or Medicaid-only beneficiaries, dual 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. Summary of Public Comments, and Responses to Comments on Access to Care Issues for DME

The proposed rule, titled ''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'' (81 FR 42802 through 42880), was published in the **Federal Register** on June 30, 2016, with a comment period that ended on August 23, 2016. In that proposed rule, for Access to Care Issues for DME, we solicited public comment on the impacts of coordinating Medicare and Medicaid Durable Medical Equipment for dually eligible beneficiaries. We received approximately 36 public comments, including comments from individual beneficiaries, beneficiary advocates, providers, suppliers, and state organizations.

In this final rule, we provide a summary of the public comments received and our response to them.

C. Provisions of Request for Information

CMS sought 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.[14] 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 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 requested to receive additional information to help target efforts to promote timely access to DME benefits for people dually eligible for Medicare and Medicaid.

We requested public input on 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

[12] *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.*

[13] 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.*

[14] *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/FederalRegisterNoticeforComment052011.pdf.*

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.
- Other prevalent access challenges due to DME program misalignments.

We also invited 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.
- 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.

We requested specific examples to be included, when possible, while avoiding the transmission of protected information, and to include a point of contact who can provide additional information upon request.

The comments and our response to the comments for issues related to DME access for dual eligible beneficiaries are set forth below.

Comments: Overall the comments reinforced that dual eligible beneficiaries face numerous challenges navigating the two programs to obtain new DME and repairs of existing equipment. Several commenters stated that the general lack of Medicaid reimbursement for the Medicare deductibles and coinsurances for Qualified Medicare Beneficiaries (that is, due to states opting for the ''lessor of'' policy, in which they may opt to only cover those costs to the extent that Medicaid payment rate exceeds what Medicare pays for the same item) results in supplier reluctance to serve dual eligible beneficiaries generally. Several commenters pointed out that beneficiaries with complex needs often need to use multiple suppliers to obtain all needed items, as well as face long wait times to receive items. Some commenters gave examples of beneficiaries unable to access needed DME due to limited supplier options with limited inventory, especially in rural and small communities. A few commenters offered examples of how beneficiaries face difficulties obtaining and repairing equipment while in a skilled nursing facility, which may delay discharge to the community. A few commenters reported problems obtaining repairs and backup equipment when necessary. Some commenters raised concerns about challenges that arise when suppliers selected through Medicare's competitive bidding program do not accept Medicaid.

In addition to elaborating on the challenges faced, a number of commenters suggested potential changes to the administration of Medicare and Medicaid DME benefits. With respect to Medicare, some commenters suggested that CMS require that DME suppliers accept Medicaid as a condition of being selected in Medicare's competitive bidding program. One commenter suggested expansions to the Advance Determination of Medicare Coverage (ADMC) policy related to certain replacement parts. Many commenters support certain Medicare payment changes to promote easier access to needed repairs. Some commenters suggested establishing a Medicare transition policy for DME similar to the Part D transition policy that would cover suppliers and certain DME.

Commenters also suggested changes to Medicaid administrative processes. Many commenters suggested a Medicaid prior authorization process that assures suppliers of Medicaid coverage if Medicare were to deny coverage. A few commenters suggested clarifying that Medicare denial should not be required for items Medicare never covers. Finally, some commenters suggested that any such changes apply as well to Medicaid managed care organizations that enroll dual eligible beneficiaries and are contracted to provide Medicaid DME coverage.

Response: We appreciate the range and depth of comments and suggestions we received. We will consider these comments carefully as we contemplate future policies. We are also exploring ways to share best practices with the State Medicaid Agencies to promote more efficient and effective ''wrap around'' coverage at the state level.

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

A. Background

The Comprehensive ESRD Care (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 (ESRD) 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.

CMS sought input on innovative approaches to care delivery and financing for beneficiaries with ESRD. We explained that 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 stated that we would consider information received as we developed future payment models in this area, and as we launched solicitation for a second round of entry into the CEC Model to begin on January 1, 2017.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the Comprehensive End-Stage Renal Disease Care Model and Future Payment Models

The proposed rule, titled ''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'' (81 FR 42802 through 42880), was published in the **Federal Register** on June 30, 2016, with a comment period that ended on August

23, 2016. In that proposed rule, for the Comprehensive End-Stage Renal Disease Care Model and Future Payment Models, we sought comments on a range of issues affecting the development of alternative payment model (APM) and advanced APM related to the care of beneficiaries with kidney disease. We received approximately 21 public comments, including comments from ESRD facilities; national renal groups, nephrologists and patient organizations; patients and care partners; manufacturers; and nurses.

We also noted a solicitation for new entrants to the CEC model, which has since closed. New ESCOs will be announced on or before January 1, 2017, when they begin participation in the model.

C. 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 sought public input 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 APMs coordinate care for beneficiaries with chronic kidney disease and to improve their transition into dialysis?

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

3. How could participants in APMs and advanced APMs 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 advanced APMs 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 advanced APMs help reduce disparities in rates of chronic kidney disease (CKD)/ESRD and adverse outcomes among racial/ethnic minorities?

8. Are there innovative ways APMs and advanced APMs 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?

Additional information on the Comprehensive ESRD Care Model is located at: *innovation.cms.gov/initiatives/comprehensive-ESRD-care*.

The comments and our responses to the comments are set forth below.

Comment: Several commenters recognized the potential value of APM and advanced APM in the care of beneficiaries with CKD, ESRD and renal transplant. Commenters discussed the structures that might be most effective for such models, as well as the role of payment incentives, quality measures, and waivers of existing regulations. Several commenters identified attributes of existing models and programs that would be helpful in such models. In addition, several commenters described optimal care patterns around the beneficiaries' transition from CKD to ESRD and renal replacement therapy or transplant.

Response: We thank commenters for their suggestions and input. We agree that there are a number of opportunities to improve the care of and reduce the costs associated with beneficiaries with kidney disease and we appreciate the detailed suggestions offered for such improvement, however, we are not finalizing at this time. We intend to develop and address comments in future rulemaking.

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 §§ 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, we proposed 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.

We did not receive any comments on our proposed technical correction to revise the regulations text at §§ 413.194 and 413.215, therefore, we are finalizing this revision as proposed.

XII. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment prior to a rule taking effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)) and section 1871(b)(1) of the Act. We can waive this procedure, however, if the agency finds that the notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and reasons in the rule. See section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act.

We find it unnecessary to undertake notice and comment rulemaking in this instance for the additional changes we are making to the definition of ''hearing officer'' in § 414.402, because these are merely technical edits in order to conform the definition to the revised regulation we are finalizing at § 414.423, which was promulgated under the notice and comment rulemaking procedures. Removing the reference to ''contract terminations'' and the abbreviation ''(HO)'' under the existing definition of ''hearing officer'' will reconcile the definition with the terminology and appeals process we are adopting in this final rule and thus, makes additional notice and comment unnecessary. Therefore, under section 553(b)(B) and section 1871(b)(1) of the Act, for good cause, we waive notice and comment procedures.

XIII. 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.

XV. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

B. Requirements in Regulation Text

In section II and III of this final rule, we include changes to the regulatory text for the ESRD PPS in CY 2017 as well as the inclusion of subpart K to part 494 for AKI. However, we note that those changes do not impose any new information collection requirements.

In section V of this final rule, we discussed changes to the DMEPOS Competitive Bidding Program. Section V.B.1 discusses the changes to the program relative to the bid surety bond requirements imposed at § 414.412. As a result of the new bid surety bond requirements, we have revised the information collection request (ICR) associated with the DMEPOS Competitive Bidding Program. The ICR is currently approved under OMB control number 0938–1016 (CMS–10169). Specifically, we have revised Form A (Application for DMEPOS Competitive Bidding Program) in the ICR to account for the new bid surety bond requirements. The revised form was under development and not available for public review and comment when the DMEPOS Competitive Bidding Program proposed rule published. Therefore, we have published a separate 60-day **Federal Register** notice to announce the changes to the ICR. The notice published on October 14, 2016 (81 FR 71100). The notice contains instructions on how to both obtain copies of and submit comments on the revised ICR. Copies of the revised ICR can be obtained at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10169.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending.* At the conclusion of the 60-day public comment period, we will review all public comments (if applicable) and then publish a 30-day **Federal Register** notice to announce the submission to OMB as well as another public comment period.

C. Additional Information Collection Requirements

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

1. ESRD QIP

a. Wage Estimates

In 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,[15] 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.[16] 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.[17] 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 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

In our proposed rule (81 FR 42867), we outlined our data validation proposal for PY 2019. Specifically, for the CROWNWeb validation, we proposed to randomly sample records from 300 facilities as part of our continuing pilot data-validation program. Each sampled facility would be required to produce approximately 10 records, and the sampled facilities will be reimbursed by our validation contractor for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimate that it will take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities will be 750 hours (300 facilities × 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit this data, we estimate that the aggregate cost of the CROWNWeb data validation would be approximately $19,088 (750 hours × $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 proposed to randomly select 35 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 35 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities will be 35 hours (35 facilities × 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 $890.75 (35 hours × $25.45/hour) total of $25.45 ($890.75/35 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. 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 × 156 data elements/year × 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 × $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).

We sought comments on the Collection of Information proposals and did not receive any comments. Therefore, we are finalizing as proposed.

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

[15] *http://www.bls/gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

[16] *http://www.bls.gov/ooh/healthcare/registered-nurses.htm.*

[17] *http://www.whitehouse.gov/omb/circulars_a076_a76_incl_tech_correction.*

otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

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

We sought comments on the Regulatory Impact Analysis but did not receive any comments. Therefore we are not making any changes at this time and are finalizing as proposed.

2. Statement of Need

This rule finalizes a number of annual updates and several policy changes to the ESRD PPS in CY 2017. The annual updates include the CY 2017 wage index values, the wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. In addition to these annual updates, we are changing the home dialysis training policy. Failure to publish this final rule by November 1, 2016, would result in ESRD facilities not receiving appropriate payments in CY 2017 for renal dialysis services furnished to ESRD patients in accordance with section 1861(s)(2)(F) of the Act.

This rule finalizes 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 this final rule by November 1, 2016 would result in a failure to comply with the requirements of the Act, as added by the TPEA, including ESRD facilities not receiving payment for furnishing renal dialysis services to patients with AKI.

This rule finalizes requirements for the ESRD QIP, including adopting a measure set for the PY 2020 program, as directed by section 1881(h) of the Act. Failure to finalize requirements for the PY 2020 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2019. In addition, finalizing 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 finalizes 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 finalizes an appeals process for all breach of contract actions CMS may take.

This rule also finalizes a method for adjusting DMEPOS fee schedule amounts for similar items with different features using information from the DMEPOS CBPs, a method 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 finalized revisions to the ESRD PPS will result in an increase of approximately $80 million in payments to ESRD facilities in CY 2017, which includes the amount associated with updates to the outlier thresholds, home dialysis training policy, and updates to the wage index. We estimate 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.[18] For PY 2020, we estimate that the final 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.

As explained previously in this final rule, we anticipate that DMEPOS CBP bidding entities will be impacted by the bid surety bond requirement. Bidding entities will be required to purchase and provide proof of a bid surety bond for each CBA in which they bid. We estimate that the total cost for all bidding suppliers in Round 2019 will be $13,000,000. 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 DMEPOS Competitive Bidding regulations we are finalizing will have an impact on Medicare beneficiaries.

We estimate that our final methodology for adjusting DMEPOS fee schedule amounts for similar items with different features using information from the DMEPOS CBPs, changes for determining single payment amounts for similar items with different features under the DMEPOS CBPs, and revisions 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 final rule, we used the June 2016 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 final rule. Table 34 shows the impact of the estimated CY 2017 ESRD

[18] 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.

payments compared to estimated payments to ESRD facilities in CY 2016.

TABLE 34—IMPACT OF CHANGES IN PAYMENT TO ESRD FACILITIES FOR CY 2017 FINAL RULE

[Impact of changes in payments to ESRD Facilities for CY 2017 ESRD final rule]

[Percent change in total payments to ESRD facilities (both program and beneficiaries)]

Facility Type	Number of Facilities	Number of treatments (in millions)	Effect of 2017 changes in outlier policy (%)	Effect of 2017 changes in wage indexes (%)	Effect of 2017 changes in payment rate update (%)	Effect of total 2017 proposed changes (outlier, wage indexes, training adjustment and routine updates to the payment rate) (%)
	A	B	C	D	E	F
All Facilities	6,542	44.5	0.2	0.0	0.55	0.73
Type:						
Freestanding	6,106	42.0	0.2	0.0	0.55	0.7
Hospital based	436	2.5	0.3	0.1	0.55	0.9
Ownership Type:						
Large dialysis organization	4,606	31.7	0.2	0.0	0.55	0.7
Regional chain	999	6.9	0.2	0.0	0.54	0.7
Independent	578	3.9	0.1	0.0	0.54	0.7
Hospital based [1]	358	2.1	0.3	0.1	0.55	0.9
Geographic Location:						
Rural	1,225	6.4	0.2	0.1	0.54	0.9
Urban	5,317	38.2	0.2	0.0	0.55	0.7
Census Region:						
East North Central	1,056	6.2	0.2	−0.1	0.55	0.7
East South Central	528	3.3	0.2	−0.1	0.54	0.7
Middle Atlantic	713	5.5	0.2	−0.1	0.54	0.7
Mountain	375	2.2	0.1	−0.1	0.55	0.5
New England	183	1.4	0.2	−0.5	0.56	0.2
Pacific [2]	790	6.3	0.1	0.5	0.55	1.2
Puerto Rico and Virgin Islands	51	0.3	0.2	−0.3	0.54	0.5
South Atlantic	1,485	10.5	0.2	−0.2	0.56	0.6
West North Central	473	2.3	0.2	0.0	0.56	0.7
West South Central	888	6.4	0.2	0.1	0.54	0.8
Facility Size:						
Less than 4,000 treatments [3]	1,414	3.2	0.2	0.1	0.57	0.8
4,000 to 9,999 treatments	2,424	12.3	0.2	0.0	0.54	0.7
10,000 or more treatments	2,683	29.0	0.2	0.0	0.55	0.7
Unknown	21	0.0	0.3	0.2	0.59	1.0
Percentage of Pediatric Patients:						
Less than 2%	6,435	44.2	0.2	0.0	0.55	0.7
Between 2% and19%	41	0.3	0.2	0.0	0.59	0.7
Between 20% and 49%	9	0.0	0.0	0.2	0.52	0.7
More than 50%	57	0.1	0.0	−0.1	0.52	0.4

[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 1,414 ESRD facilities with less than 4,000 treatments, only 352 qualify for the low-volume adjustment. The low-volume adjustment is mandated by Congress, and is not applied to pediatric patients. The impact to these low-volume facilities is a 0.8 percent increase in payments.

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

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the final changes to the outlier payment policy described in section II.B.3.c of this final 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 0.73 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 outlier policy changes.

Column D shows the effect of the final CY 2017 wage indices. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 0.0 percent decrease to a 0.1 percent increase due to these updates.

Column E shows the effect of the final ESRD PPS payment rate update of 0.55 percent. This update reflects the final 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 0.3 percent.

Column F reflects the overall impact, that is, the effects of the outlier policy changes, the wage index, the effect of the change in the home dialysis training add-on from $50.16 to $95.60 and the effect of the payment rate update. We expect that overall ESRD facilities will experience a 0.73 percent increase in estimated payments in 2017. The categories of types of facilities in the impact table show impacts ranging from an increase of 0.7 percent to an increase

of 0.9 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 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 $9.6 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 1.4 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 0.73 percent overall increase in the ESRD PPS payment amounts in CY 2017, we estimate that there will be an increase in beneficiary co-insurance payments of 4.2 percent in CY 2017, which translates to approximately $10 million.

e. Alternatives Considered

In section II.B.2, we finalized a change 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. 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 8,047 outpatient dialysis treatments for beneficiaries with AKI that were furnished in CY 2015. We then inflated the 8,047 treatments to 2017 values using estimated population growth for fee-for service non-ESRD beneficiaries. This results in an estimated 8,234 treatments that would now be paid to ESRD facilities for furnishing dialysis to beneficiaries with AKI. Using the CY 2017 ESRD base rate of $231.55 and an average wage index multiplier, we estimate 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.

We note that in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we stated that we identified 7,155 outpatient claims with AKI that also had dialysis treatments that were furnished in CY 2015. This is an incorrect statement. We should have stated that we identified 7,155 outpatient dialysis treatments for beneficiaries with AKI.

b. Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are finalizing 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 final rule, we finalize 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 at this time.

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 proposed using 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 final 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 42 percent or 2,710 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 6,453 dialysis facilities paid through the PPS. Table 35 shows the overall estimated distribution of payment reductions resulting from the PY 2020 ESRD QIP.

TABLE 35—ESTIMATED DISTRIBUTION OF PY 2020 ESRD QIP PAYMENT REDUCTIONS

Payment reduction	Number of facilities	Percent of facilities (%)
0.0%	3311	55.0
0.5%	1538	25.5
1.0%	832	13.8

TABLE 35—ESTIMATED DISTRIBUTION OF PY 2020 ESRD QIP PAYMENT REDUCTIONS—Continued

Payment reduction	Number of facilities	Percent of facilities (%)
1.5%	269	4.5

TABLE 35—ESTIMATED DISTRIBUTION OF PY 2020 ESRD QIP PAYMENT REDUCTIONS—Continued

Payment reduction	Number of facilities	Percent of facilities (%)
2.0%	71	1.2

Note: This table excludes 432 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 36.

TABLE 36—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 2014–Dec 2014	Jan 2015–Dec 2015.
Hypercalcemia	Jan 2014–Dec 2014	Jan 2015–Dec 2015.
Standardized Transfusion Ratio	Jan 2014–Dec 2014	Jan 2015–Dec 2015.
ICH CAHPS Survey	Jan 2015–Dec 2015	Jan 2015–Dec 2015.
Standardized Readmission Ratio	Jan 2014–Dec 2014	Jan 2015–Dec 2015.
NHSN Bloodstream Infection	Jan 2014–Dec 2014	Jan 2015–Dec 2015.
SHR	Jan 2014–Dec 2014	Jan 2015–Dec 2015.

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 final 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 the proposed rule, we multiplied the total Medicare payments to the facility during the 1-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 2,710 facilities expected to receive a reduction is approximately $32 million ($31,581,441). 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 final rule would be approximately $91 million for all ESRD facilities. As a result, we estimate that ESRD facilities will experience an aggregate impact of approximately $123 million ($91,449,815 + $31,581,441= $123,031,256) in PY 2020, as a result of the PY 2020 ESRD QIP.

Table 37 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 proposed 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.

Lastly, we note that the facilities located in the US Territories and earning a payment penalty are primarily urban, Large Dialysis Organizations and we wish to confirm that we will work through the ESRD Networks to address issues of quality of care at these locations.

TABLE 37—IMPACT OF QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2020

	Number of facilities	Number of treatments 2014 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
All Facilities	6,453	40.0	6,021	2,710	−0.35
Facility Type:					
Freestanding	6,022	37.8	5,853	2,661	−0.36
Hospital-based	431	2.2	168	49	−0.22
Ownership Type:					

TABLE 37—IMPACT OF QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2020—Continued

	Number of facilities	Number of treatments 2014 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
Large Dialysis	4,541	28.6	4,433	2,025	−0.35
Regional Chain	989	6.2	929	344	−0.27
Independent	568	3.5	536	300	−0.53
Hospital-based (non-chain)	354	1.8	123	41	−0.26
Unknown	1	0.0	0	0	—
Facility Size:					
Large Entities	5,530	34.8	5,362	2,369	−0.34
Small Entities [1]	922	5.2	659	341	−0.48
Unknown	1	0.0	0	0	—
Rural Status:					
(1) Yes	1,260	6.0	1,146	355	−0.22
(2) No	5,193	34.0	4,875	2,355	−0.38
Census Region:					
Northeast	881	6.2	785	362	−0.35
Midwest	1,511	7.6	1,356	593	−0.34
South	2,853	18.2	2,744	1,356	−0.39
West	1,143	7.6	1,084	362	−0.25
US Territories [2]	65	0.4	52	37	−0.52
Census Division:					
Unknown	1	0.0	0	0	—
East North Central	1,045	5.5	951	471	−0.40
East South Central	522	3.0	515	209	−0.32
Middle Atlantic	702	4.9	623	317	−0.40
Mountain	368	2.0	336	83	−0.17
New England	182	1.3	164	47	−0.17
Pacific	782	5.7	753	282	−0.28
South Atlantic	1,458	9.4	1,389	771	−0.44
West North Central	469	2.1	406	123	−0.21
West South Central	875	5.8	841	376	−0.36
US Territories [2]	49	0.3	43	31	−0.53
Facility Size (# of total treatments):					
Less than 4,000 treatments	1,211	2.7	1,006	376	−0.33
4,000–9,999 treatments	2,401	11.0	2,324	938	−0.32
Over 10,000 treatments	2,680	26.1	2,603	1,342	−0.38
Unknown	161	0.2	88	54	−0.60

[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 $50,000 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 $13,000,000. 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 $1,000 per bid surety bond price. Given the unknown variables with this new type of bond, we sought comments on how the

authorized sureties will set the purchase amount for bidding entities in order to finalize a more accurate estimate. We received one comment which stated that a ''surety will review the capabilities and financial strength of the bid surety bond applicants and provide bid surety bonds only to those entities that the surety has determined are capable of performing the underlying obligation''. Overall, in response to the comments, we revised the bid bond amount from $100,000 in the proposed rule to $50,000 in this final rule and use the assumption that purchase price for a bid surety bond will be approximately $1,000 per CBA. We believe that there will be many variables that will impact the bidder's out of pocket cost to purchase a bid surety bond(s) and as such, believe that by lowering the bid surety bond amount that this will in turn lower the overall impact and lessen the burden for bidders.

We do anticipate that there will be an impact on small suppliers. We sought 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 Web site 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 the final 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.

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(a) 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.

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(a) 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 revision to the regulation 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 final 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 final CBP requirements for bid surety bond, state licensure and appeals process for 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 proposed that the bid surety bond be in an amount of $100,000, we sought 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. In finalizing the rule we determined that the bid surety bond will be set at $50,000 for all bidding entities based on comments received. No alternatives were considered for the state licensure requirement, as § 414.414(b)(3) of the regulations already requires suppliers to have all applicable state and local licenses.

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 we considered is to retain the current appeals process for terminations, and allow suppliers to appeal other breach of contract actions through an informal sub-regulatory process or a process similar to the existing appeals 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. Other DMEPOS Provisions

a. Effects of the Method for Adjusting DMEPOS Fee Schedule Amounts for Similar Items With Different Features Using Information From the DMEPOS Competitive Bidding Programs

For this final rule, we estimate that the method 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 final policy will also prevent beneficiaries from potentially receiving lower cost items at higher coinsurance rates. Suppliers will be impacted little by the methodological change because the final methodology we are adopting has a small saving attached to it.

b. Effects of the Final Rules Determining Single Payment Amounts for Similar Items With Different Features Under the DMEPOS Competitive Bidding Program

In this final rule, we estimate that the method 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 certain similar items without features to be priced higher than items with features. Our final policy will benefit beneficiaries who would have lower coinsurance payments as a result of this proposal. We also believe this methodology will 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 Revision to the Bid Limits Under the DMEPOS Competitive Bidding Program

In this final rule, we estimate 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 revision to the bid limits at the unadjusted fee level would have little fiscal impact in that competitions will continue to reduce prices. This final rule will benefit suppliers and beneficiaries because payments will 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 38, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this final rule.

TABLE 38—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS

Category	Transfers
ESRD PPS and AKI for CY 2017	
Annualized Monetized Transfers	$80 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[19]	
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	−$31 million.
From Whom to Whom	Federal government to ESRD providers.
Category	Costs
Annualized Monetized ESRD Provider Costs	$91 million.

DME Provisions			
Category	Transfer		
	Estimates	Year dollar	Discount rate
Annualized Monetized Transfer on Beneficiary Cost Sharing (in $Millions)	−$1.9 −$1.9	2016 2016	7% 3%
From Whom to Whom	Beneficiaries to Medicare providers		
	Transfers		
	Estimates	Year dollar	Discount rate
Annualized Monetized Transfer Payments (in $Millions)	−$7.5 −$7.8	2016 2016	7% 3%
From Whom to Whom	Federal government to Medicare providers.		

[19] We note that the aggregate impact of the PY 2018 ESRD QIP was included in the CY 2015 ESRD PPS final rule (79 FR 66256 through 66258). The 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.

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 14 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 14 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 34. Using the definitions in this ownership category, we consider the 578 facilities that are independent and the 358 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 in this final rule, a hospital-based ESRD facility (as defined by ownership type) is estimated to receive a 0.9 percent increase in payments for CY 2017. An independent facility (as defined by ownership type) is also estimated to receive a 0.7 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 final rule is not estimated to have a significant impact on small entities.

We estimate that of the 2,710 ESRD facilities expected to receive a payment reduction in the PY 2020 ESRD QIP, 341 are ESRD small entity facilities. We present these findings in Table 35 (''Estimated Distribution of PY 2020 ESRD QIP Payment Reductions'') and Table 37 (''Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2020'') above. We estimate that payment reductions will average approximately $11,653 per facility across the 2,710 facilities receiving a payment reduction, and $13,675.56 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 will decrease 0.48 percent in PY 2020.

We anticipate that the bid surety bond provision will have an impact on all suppliers, including small suppliers; therefore, we requested comments regarding the bid bond amount. No comments were received from small suppliers. The state licensure and appeal of preclusion rules are not expected to have an impact on any supplier.

We expect that finalizing our proposals for a method for adjusting DMEPOS fee schedule amounts for certain groupings of similar items with different features using information from the DMEPOS CBPs, our final change for submitting bids for a grouping of two or more similar items with different features, our final policy for determining single payment amounts for similar items with different features under the DMEPOS CBPs, and our 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 final rule would not have a significant economic impact on a substantial number of small entities. We solicited comments on the RFA analysis provided and did not receive comments.

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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this final rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 139 rural hospital-based ESRD 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 ESRD facilities will experience an estimated 0.1 percent increase in payments. As a result, this final rule is not estimated to have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this final rule 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 final rule does not include any mandates that would impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of $141 million.

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 final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of States, local or Tribal governments.

XX. Congressional Review Act

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

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

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 amends 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 Public Law 106–113, 113 Stat. 1501A– 332; sec. 3201 of Public Law 112–96, 126 Stat. 156; sec. 632 of Public Law 112–240, 126 Stat. 2354; sec. 217 of Public Law 113–93, 129 Stat. 1040; sec. 204 of Public Law 113–295, 128 Stat. 4010; and sec. 808 of Public Law 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 to 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 paragraph (a) of this section, the ESRD facility may receive payment for bad debts of Medicare beneficiaries as specified in § 413.89(h)(3).

■ 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 any 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) of this section 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 paragraph (g) of this section 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) Hospital beds (HCPCS codes E0250, E0251, E0255, E0256, E0260, E0261, E0290, E0291, E0292, E0293, E0294, E0295, E0301, E0302, E0303, and E0304).

(B) Mattresses and overlays (HCPCS codes E0277, E0371, E0372, and E0373)

(C) Power wheelchairs (HCPCS codes K0813, K0814, K0815, K0816, K0820, K0821, K0822, and K0823).

(D) Seat lift mechanisms (HCPCS codes E0627 and E0629).

(E) TENS devices (HCPCS codes E0720 and E0730).

(F) 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 revising the definition of ''Hearing officer'' and adding the definitions of ''Bidding entity,'' ''Price Inversion,'' and ''Total nationwide allowed services'' 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.

* * * * *

Hearing officer means an individual, who was not involved with the CBIC recommendation to take action for a breach of a DMEPOS Competitive Bidding Program contract, who is designated by CMS to review and make an unbiased and independent recommendation when there is an appeal of CMS's initial determination to take action for a breach of a DMEPOS Competitive Bidding Program contract.

* * * * *

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 of this part, without the application of § 414.210(g), or subpart D of this part, 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 of this part, without the application of § 414.210(g), or subpart D of this part, 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) 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).

(ii) Mattresses and overlays (HCPCS codes E0277, E0371, E0372, and E0373).

(iii) Power wheelchairs (HCPCS codes K0813, K0814, K0815, K0816, K0820, K0821, K0822, K0823, K0824, K0825, K0826, K0827, K0828, and K0829).

(iv) Seat lift mechanisms (HCPCS codes E0627 and E0629).

(v) TENS devices (HCPCS codes E0720 and E0730).

(vi) 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 as specified in paragraph (h)(3) of this section;

(E) The CBA covered by the bond;

(F) The bond number;

(G) The date of issuance; and

(H) The bid bond value of $50,000.00.

(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 in the next round of 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 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 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 (c)(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 U.S.C. 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. 1302 and 1395hh).

■ 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.

* * * * *

Dated: October 24, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: October 25, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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