DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 414

[CMS–1674–F]

RIN 0938–AT04

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program

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 (CY) 2018. It also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). This rule also sets forth requirements for the ESRD Quality Incentive Program (QIP), including for payment years (PYs) 2019 through 2021.

DATES: These regulations are effective January 1, 2018.

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.

Delia Houseal, (410) 786–2724, for issues related to the ESRD QIP.

Joel Andress, (410) 786–5237, for measure related issues with ESRD QIP.

SUPPLEMENTARY INFORMATION:

Electronic Access

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

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

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

Table of Contents

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

Acronyms

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

Affordable Care Act the Patient Protection and Affordable Care Act
ABLE Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014
AKI Acute Kidney Injury
AMP Average Manufacturer Price
ASP Average Sales Price
ASPE Office of the Assistant Secretary for Planning and Evaluation
ATRA American Taxpayer Relief Act of 2012
AV Arterial Venous
BLS Bureau of Labor Statistics
BSI Bloodstream Infection
CBSA Core Based Statistical Area
CCN CMS Certification Number
CDC Centers for Disease Control and Prevention
CEO Chief Executive Officer
CFR Code of Federal Regulations
CMS Centers for Medicare & Medicaid Services
CROWNWeb Consolidated Renal Operations in a Web-Enabled Network
CY Calendar Year
DFC Dialysis Facility Compare
DFR Dialysis Facility Report
ECE Extraordinary Circumstances Exception
EPO Epoetin
ESA Erythropoiesis Stimulating Agent
ESRD End-Stage Renal Disease
ESRDB End-Stage Renal Disease Bundled
ESRD PPS End-Stage Renal Disease Prospective Payment System
ESRD QIP End-Stage Renal Disease Quality Incentive Program
FFS Fee-For-Service
FDA Food and Drug Administration
FDL Fixed-Dollar Loss
HCPCS Healthcare Common Procedure Coding System
ICD International Classification of Diseases
ICH CAHPS In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems
IGI IHS Global Inc.
IPPS Inpatient Prospective Payment System
IQR Interquartile Range
IUR Inter-unit Reliability
Kt/V A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume
MAP Medicare Allowable Payment
MFP Multifactor Productivity
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
NHSN National Healthcare Safety Network
NQF National Quality Forum
OMB Office of Management and Budget
PAMA Protecting Access to Medicare Act of 2014
PD Peritoneal Dialysis
PPS Prospective Payment System
PY Payment Year
QIP Quality Incentive Program
RFA Regulatory Flexibility Act
SBA Small Business Administration
SHR Standardized Hospitalization Ratio
SRR Standardized Readmission Ratio
STrR Standardized Transfusion Ratio
TCV Truncated Coefficient of Variation
TDAPA Transitional Drug Add-on Payment Adjustment
TEP Technical Expert Panel
The Act Social Security Act
The Secretary Secretary of the Department of Health and Human Services
TPEA Trade Preferences Extension Act of 2015
TPS Total Performance Score
UFR Ultrafiltration Rate
VAT Vascular Access Type
WAMP Widely Available Market Price

I. Executive Summary

A. Purpose

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

On January 1, 2011, we implemented the end-stage renal disease (ESRD) prospective payment system (PPS), a case-mix adjusted, bundled prospective payment system for renal dialysis services furnished by ESRD facilities. This rule updates and makes revisions to the ESRD PPS for calendar year (CY) 2018. 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 Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning 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.

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) of the Act to an individual with AKI. Section 808(b) of TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act 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 finalizes requirements for the end-stage renal disease (ESRD) quality incentive program (QIP), including for payment years (PYs) 2019, 2020, and 2021. 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 the Centers for Medicare & Medicaid Services (CMS).

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the ESRD PPS base rate for CY 2018:* The CY 2018 ESRD PPS base rate is $232.37. This amount reflects a reduced market basket increase as required by section 1881(b)(14)(F)(i)(I) of the Act (0.3 percent), and application of the wage index budget-neutrality adjustment factor (1.000531), equaling $232.37 ($231.55 × 1.003 × 1.000531 = $232.37).
- *Annual update to the wage index:* 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 2018, 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 (0.4000) 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 (FDL) amounts for adult and pediatric patients and Medicare Allowable Payment (MAP) amounts for adult and pediatric patients for CY 2018 using CY 2016 claims data. Based on the use of more current data, the FDL amount for pediatric beneficiaries would decrease from $68.49 to $47.79 and the MAP amount would decrease from $38.29 to $37.31, as compared to CY 2017 values. For adult beneficiaries, the FDL amount would decrease from $82.92 to $77.54 and the MAP amount would decrease from $45.00 to $42.41. The 1 percent target for outlier payments was not achieved in CY 2016. Outlier payments represented approximately 0.78 percent of total payments rather than 1.0 percent. We believe using CY 2016 claims data to update the outlier MAP and FDL amounts for CY 2018 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1 percent outlier percentage.
- *Update to the pricing of drugs and biologicals under the outlier policy:* We are finalizing a change to the ESRD PPS outlier policy to allow the use of any pricing methodology available under section 1847A of the Act to determine the cost of certain eligible outlier service drugs and biologicals in computing outlier payments when average sales price (ASP) data is not available.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

We are updating the AKI payment rate for CY 2018. The final CY 2018 payment rate is $232.37, which is equal to the CY 2018 ESRD PPS base rate.

3. ESRD QIP

This rule sets forth requirements for the ESRD QIP, for payment years (PYs) 2019, 2020 and 2021 as follows:

- *Updating the Performance Score (PSC) Certificate Beginning in PY 2019:* We are updating the Performance Score Certificate (PSC) beginning in PY 2019 by shortening and simplifying it.
- *Changes to the Extraordinary Circumstances Exception (ECE) Policy:* In an effort to align our policy with the Extraordinary Circumstances Exception (ECE) policy adopted by other quality reporting and value-based purchasing programs, we are updating the ECE Policy for the ESRD QIP. Specifically, we are updating this policy to (1) allow the facility to submit a form signed by the facility's CEO or designated personnel; (2) expand the reasons for which an ECE can be requested to include an unresolved issue with a CMS data system which affected the ability of the facility to submit data; and (3) specify that a facility does not need to be closed in order to request and receive consideration for an ECE, as long as the facility can demonstrate that its normal operations have been significantly affected by an extraordinary circumstance outside of its control.
- *PY 2021 Measure Set:* Beginning with PY 2021, we are updating the Standardized Transfusion Ratio (STrR) Clinical Measure to align the measure specifications used in the ESRD QIP with those endorsed by the National Quality Forum (NQF), and replacing the two existing Vascular Access Type (VAT) measures with newly NQF-endorsed vascular access measures that address long-held concerns of the ESRD community. Specifically, we are replacing the VAT measures with the Hemodialysis Vascular Access: Standardized Fistula Rate Clinical Measure and the Hemodialysis Vascular Access: Long-Term Catheter Rate Clinical Measure.
- *Data Validation:* For PY 2020, we are continuing the pilot validation study for validation of Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) data. Under this continued pilot validation study, we will continue using the same methodology used for the PY 2018 and PY 2019 ESRD QIP. Under this methodology, we will sample approximately 10 records per facility from 300 facilities during CY 2018.

For PY 2020, we are also continuing the National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) Data Validation study that we finalized in the CY 2017 ESRD PPS final rule (81 FR 77894 through 77896), with a minor update to the sampling methodology. Under the updated sampling methodology, we will incorporate a targeted sample to select 35 facilities to participate in an NHSN dialysis event validation study for two quarters of data reported in CY 2018.

C. Summary of Costs and Benefits

In section VII 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. Final Impacts of the ESRD PPS

The impact chart in section VII of this final rule displays the estimated change in payments to ESRD facilities in CY 2018 compared to estimated payments in CY 2017. The overall impact of the CY 2018 changes is projected to be a 0.5 percent increase in payments. Hospital-based ESRD facilities have an estimated 0.7 percent increase in payments compared with freestanding facilities with an estimated 0.5 percent increase.

We estimate that the aggregate ESRD PPS expenditures will increase by approximately $60 million from CY 2017 to CY 2018. This reflects a $40 million increase from the payment rate update and a $20 million increase due to the updates to the outlier threshold amounts. We note that the decrease in the projection of aggregate ESRD PPS

expenditures from the figure in the CY 2018 ESRD PPS proposed rule ($100 million) is due to the decrease in the ESRD PPS base rate update factor (that is, from 0.7 percent to 0.3 percent). As a result of the projected 0.5 percent overall payment increase, we estimate that there will be an increase in beneficiary co-insurance payments of 0.5 percent in CY 2018, equivalent to approximately $10 million.

2. Final Impacts of Payment for Renal Dialysis Services Furnished to Individuals With AKI

We anticipate an estimated $20 million will be paid to ESRD facilities in CY 2018 as a result of AKI patients receiving renal dialysis services in the ESRD facility at the ESRD PPS base rate versus receiving those services in the hospital outpatient setting. In the CY 2018 ESRD PPS proposed rule, we estimated $2 million would be paid to ESRD facilities in CY 2018 for AKI patients. Based on actual preliminary ESRD facility claims data available after publication of the CY 2018 ESRD PPS proposed rule, we have updated this estimate for the final rule.

3. Final Impacts of the ESRD QIP

The impact chart in section VII of this final rule displays estimated impacts of the ESRD QIP for payment year (PY) 2021. The overall impact is an expected reduction in payment to all facilities of $29 million. The PY 2021 estimated total facility burden for the collection of data is $91 million, which represents a zero net increase from PY 2020.

II. Calendar Year (CY) 2018 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, 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 in the CY 2014 ESRD PPS final rule (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, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. 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) of PAMA 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. Description of the 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, which is in subpart H of 42 CFR part 413. Our other payment policies are also included in regulations in subpart H of 42 CFR part 413. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The ESRD PPS provides for the following adult and pediatric patient-level adjustments: The adult patient-level adjusters include five age categories, body surface area, low body mass index, onset of dialysis, and four co-morbidity categories; while the pediatric patient-level adjusters include two age categories and two dialysis modalities (§§ 413.235(a) and (b)).

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

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

The ESRD PPS also provides for a transitional drug add-on payment adjustment (TDAPA) to pay for a new injectable or intravenous product that is not considered included in the ESRD PPS base rate, meaning a product that is used to treat or manage a condition for

which there is not an existing ESRD PPS functional category (§ 413.234). The ESRD PPS functional categories represent distinct groupings of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD. New injectable or intravenous products that are not included in a functional category in the ESRD PPS base rate are paid for using the TDAPA for a minimum of 2 years, until sufficient claims data for rate setting analysis is available. At that point, utilization would be reviewed and the ESRD PPS base rate modified, if appropriate, to account for these products. The TDAPA is based on pricing methodologies under section 1847A of the Act (§ 413.234(c)).

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 4, 2016, we published in the **Federal Register** a final rule (81 FR 77384 through 77969) entitled, ''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; Final Rule'' (hereinafter referred to as the CY 2017 ESRD PPS final rule). In that rule, we updated the ESRD PPS base rate for CY 2017, the wage index and wage index floor, the outlier policy, and the home and self-dialysis training add-on payment adjustment. For further detailed information regarding these updates, see 81 FR 77384.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the Calendar Year (CY) 2018 ESRD PPS

The proposed rule, entitled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program'' (82 FR 31190 through 31233), hereinafter referred to as the CY 2018 ESRD PPS proposed rule, was published in the **Federal Register** on July 5, 2017, with a comment period that ended on August 28, 2017. In that proposed rule, for the ESRD PPS, we proposed to make a number of annual updates for CY 2018, including updates to the ESRD PPS base rate, wage index and outlier thresholds, and to update the pricing of certain drugs and biologicals under the outlier policy. We received approximately 58 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 2018 ESRD PPS.

1. Pricing Eligible Outlier Drugs and Biologicals That Were or Would Have Been, Prior to January 1, 2011, Separately Billable Under Medicare Part B

a. Summary of Outlier Calculation

Our regulations at 42 CFR 413.237 specify the methodology used to calculate outlier payments. Under the ESRD PPS outlier policy, an ESRD facility is eligible for an outlier payment when the facility's per treatment imputed Medicare Allowable Payment (MAP) amount for ESRD outlier services furnished to a beneficiary exceeds the predicted ESRD outlier services MAP amount for outlier services plus the fixed-dollar loss (FDL) amount, as specified in § 413.237(b). In the CY 2011 ESRD PPS final rule (75 FR 49134 through 49147), we discussed the details of establishing the outlier policy under the ESRD PPS, including determining eligibility for outlier payments. We discussed the proposed CY 2018 updates to the outlier policy in the CY 2018 ESRD PPS proposed rule (82 FR 31198 through 31200).

Under § 413.237(a)(1), ESRD outlier services include (1) certain items and services included in the ESRD PPS bundle that were or would have been separately billable under Medicare Part B prior to the implementation of the ESRD PPS, including ESRD-related drugs and biologicals, ESRD-related laboratory tests, and other ESRD-related medical/surgical supplies; and (2) certain renal dialysis service drugs included in the ESRD PPS bundle that were covered under Medicare Part D prior to the implementation of the ESRD PPS. For the Centers for Medicare & Medicaid Services (CMS) to calculate outlier eligibility and payments, ESRD facilities must identify on the monthly claim which outlier services have been furnished. CMS provides a list of outlier services on the CMS Web site, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Outlier_Services.html*, which is subject to certain additions and exclusions as discussed in the CY 2012 ESRD PPS final rule (76 FR 70246) and Chapter 8, Section 20.1 of CMS Publication 100–04 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c08.pdf*).

It is important for ESRD facilities to report the outlier services on the claim because imputed outlier service MAP amounts for a beneficiary are based on the actual utilization of outlier services. Specifically, we estimate an ESRD facility's imputed costs for ESRD outlier services based on available pricing data. In the CY 2011 ESRD PPS final rule we finalized the pricing data that we use to estimate imputed outlier services MAP amounts for the different categories of outlier services (75 FR 49141). With regard to Part B ESRD-related drugs and biologicals that were separately billable prior to implementation of the ESRD PPS, we finalized a policy to base the prices for these items on the most current average sales price (ASP) data plus 6 percent. Our rationale for this decision was that ASP data for ESRD-related drugs and biologicals is updated quarterly and was the basis for payment of these drugs and biologicals prior to the implementation of the ESRD PPS.

b. Use of ASP Methodology Under the ESRD PPS

Since the implementation of the ESRD PPS, we have referred to the use of the ASP methodology when we needed to price ESRD-related drugs and biologicals previously paid separately under Part B (prior to the ESRD PPS) for purposes of ESRD PPS policies or calculations. For example, in the CY 2011 ESRD PPS final rule, we finalized the use of the ASP plus 6 percent methodology for pricing Part B ESRD-related drugs and biologicals under the

outlier policy (75 FR 49141). In the CY 2012 ESRD PPS final rule (76 FR 20244), we stated that under the outlier policy we use the ASP methodology.

In the CY 2013 ESRD PPS final rule (77 FR 67463), we finalized that for CY 2013 and subsequent years we would continue to use the ASP methodology, including any modifications finalized in the Physician Fee Schedule final rules, to compute outlier MAP amounts. (We referred to the Physician Fee Schedule since this is typically the rulemaking vehicle CMS uses for provisions related to covered Part B drugs and biologicals, however, we note that other vehicles such as standalone rules or the outpatient prospective payment system rules, are used as well.) In the CY 2013 ESRD PPS final rule, we also finalized the use of the ASP methodology for any other policy that requires the use of payment amounts for drugs and biologicals that, absent the ESRD PPS, would be paid separately.

In accordance with this policy, in the CY 2016 ESRD PPS proposed rule (80 FR 37829 through 37833), we proposed to use ASP methodology for purposes of two policies (pricing new injectable and intravenous products included in the ESRD PPS bundled payment amount for outlier payments and determining the TDAPA under the ESRD PPS drug designation process. A detailed discussion of our proposals can be found in the CY 2016 ESRD PPS proposed rule (80 FR 37831 through 37833).

As we discussed in the CY 2016 ESRD PPS final rule (80 FR 69023 through 69024), commenters expressed concern regarding the availability of ASP data when including new injectable or intravenous products into the ESRD PPS bundled payment, for purposes of both the outlier calculation and TDAPA. A commenter pointed out that under the proposal, new products would qualify as outlier services, and if we fail to allow separate payment at launch, there would be no ASP upon which to base an outlier payment. That commenter recommended that we consider how to avoid jeopardizing beneficiary access by implementing an outlier payment based on wholesale acquisition cost (WAC) or another readily available price. We agreed with the commenter, and stated that in the event we do not establish an ASP, WAC could be used. We explained that we consider WAC pricing to be a part of the pricing methodologies specified in section 1847A of the Act, and we would use the methodologies available to us under that authority in order to accurately determine a price for the calculation of outlier payments for new injectable and intravenous drugs that fit into one of the existing ESRD PPS functional categories. However, we did not address extending this policy to Part B ESRD-related drugs and biologicals that are currently eligible for outlier consideration that may not have ASP data.

Also, in the CY 2016 ESRD PPS final rule (80 FR 69024), other commenters expressed concern regarding the use of ASP data for purposes of the TDAPA. The commenters suggested that ASP would not be truly reflective of the actual cost of the drugs. One commenter pointed out that there is often a data lag between ASP and the actual cost of the drugs and as a result, the TDAPA may not reflect the actual cost of the drug. We responded that the ASP methodology is a part of the pricing methodologies specified in section 1847A of the Act, which may also include WAC pricing during the first quarter of sales as specified in section 1847A(c)(4) of the Act. We agreed with commenters that ASP pricing may not always be the most appropriate way to calculate the TDAPA. Therefore, we revised the regulation text at § 413.234(c)(1) to refer to the pricing methodologies under section 1847A of the Act, rather than ASP pricing methodology, because these methodologies include ASP as well as WAC.

c. Pricing Methodologies Under Section 1847A of the Act

Medicare Part B follows the provisions under section 1847A of the Act for purposes of determining the payment amounts for drugs and biologicals that are described in section 1842(o)(1)(C) of the Act and that are furnished on or after January 1, 2005. While most Part B drugs (excluding those paid on a cost or prospective payment basis) are paid at ASP plus 6 percent, there are cases where ASP is unavailable. For example, when a new drug or biological is brought to market, sales data is not sufficiently available for the manufacturer to compute an ASP. In these cases, the payment amount for these drugs could be determined using WAC (as specified in section 1847A(c)(4) of the Act) or, when WAC is not available, the Medicare Administrative Contractor has discretion in determining the payment amount. Under section 1847A(d) of the Act, CMS also has the authority to substitute an Average Manufacturer Price (AMP) or Widely Available Market Price (WAMP)-based payment amount for the ASP-based payment amount when the ASP exceeds the AMP or WAMP by a threshold amount. As discussed in the CY 2013 Physician Fee Schedule final rule (77 FR 69140 through 69141), published in the **Federal Register** on November 1, 2012, the AMP price substitution policy is not utilized frequently and WAMP-based price substitutions are not currently implemented. CMS also uses a carryover pricing policy in the very rare situations when a manufacturer's ASP data for a multiple source drug product is missing, as discussed in the CY 2011 Physician Fee Schedule final rule (75 FR 73461 through 73462).

For newly approved drugs, ASP-based payment limits typically become effective two quarters after the drug's first quarter of sales (a discussion about the use of partial quarter ASP data is available in the CY 2012 Physician Fee Schedule final rule, 75 FR 73465). We note that if WAC-based partial quarter payment amounts are used, such payment amounts will typically exceed payments based on ASP. Thus, there may be circumstances where WAC-based partial quarter pricing of the drug increases the beneficiary's cost sharing payment. In order to minimize financial impact on beneficiaries, in situations where less than a quarter's worth of ASP data is available, an ASP-based payment limit will be used, if it is available.

d. Pricing Eligible Outlier Drugs and Biologicals That Were or Would Have Been, Prior to January 1, 2011, Separately Billable Under Medicare Part B

As we have described above, section 1847A of the Act provides methods that are used to determine payment amounts for most separately paid Part B drugs, that is, drugs and biologicals that are not paid on a cost or PPS basis (see section 1842(o)(1) of the Act). We are aware of several circumstances in which an ASP-based payment amount is not available. For example, an ASP-based payment amount is not available when drugs or biologicals are new to market and manufacturers have not yet reported ASP data. Based on CMS' experience with determining Part B drug payment limits under section 1847A of the Act, we believe the instances are limited when ASP data would not be available for drugs or biologicals that could qualify for the ESRD outlier calculation. Nevertheless, we believe that these drugs and biologicals, when they are determined to be an ESRD outlier service, should count toward the outlier calculation, regardless of the limited frequency.

In the CY 2018 ESRD PPS proposed rule, we proposed to extend the use of all pricing methodologies under section 1847A of the Act for purposes of the ESRD PPS outlier policy, specifically for

current ESRD-related drugs and biologicals that were or would have been separately billable under Part B prior to the implementation of the ESRD PPS and are outlier eligible for CY 2018 and subsequent years. As we noted in the CY 2018 ESRD PPS proposed rule, we have already established a policy under the drug designation process in the CY 2016 ESRD PPS final rule (80 FR 69023), whereby we use the pricing methodologies specified in section 1847A of the Act to determine the TDAPA for a new injectable or intravenous product that is not considered included in the ESRD PPS base rate (§ 413.234(c)). In addition, we have established that we use these methodologies to determine a price for the calculation of outlier payments for new injectable and intravenous drugs that fit into one of the existing the functional categories (80 FR 69023).

We explained in the CY 2018 ESRD PPS proposed rule that we believe using the pricing methodologies under section 1847A of the Act is consistent with the ESRD PPS drug designation process, including TDAPA, and how covered drugs and biologicals are paid under Medicare Part B. We stated that we believe consistency with Medicare Part B payment for drugs and biologicals would be beneficial to ESRD facilities because this is the way CMS pays for injectable drugs and biologicals reported on the ESRD claim with the AY modifier; and therefore facilities would be able to predict outlier payments. Therefore, we proposed to apply any pricing methodology available under section 1847A of the Act as appropriate when ASP pricing is unavailable for eligible drugs and biologicals under the outlier policy that were or would have been separately billable under Part B prior to the implementation of the ESRD PPS.

We noted in the CY 2018 ESRD PPS proposed rule that, in situations in which ASP data is not available and other methodologies under section 1847A of the Act do not apply (including but not limited to AMP price substitution or carryover pricing), we believe that a WAC-based payment amount can be determined instead. Based on our experience with determining Part B drug payments under section 1847A of the Act, we stated, we believe that drugs and biologicals that are approved by the Food and Drug Administration and are being sold in the United States nearly always have WAC amounts published in pricing compendia. We noted that we believe this proposal is consistent with the intent of the ESRD PPS outlier policy, which is to provide a payment adjustment for high cost patients due to unusual variations in the type or amount of medically necessary care. If there are drugs and biologicals that ESRD facilities furnish for the treatment of ESRD that qualify as ESRD outlier services and do not have ASP data, we stated that we would want these items counted toward an outlier payment since they are a part of the cost the facility is incurring. When a drug or biological does not have ASP data or WAC data or cannot otherwise be priced under section 1847A of the Act, we proposed that it would not count toward the outlier calculation. When the utilization of a drug or biological is not counted toward the outlier calculation, it may result in a lower outlier payment or no outlier payment to the ESRD facility.

We solicited comment on our proposal to use any pricing methodology available under section 1847A of the Act for purposes of the ESRD PPS outlier policy. We also solicited comment on our proposal that when pricing methodologies are not available under section 1847A of the Act, the drug or biological would not count toward the outlier calculation.

The comments and our responses to the comments on our outlier proposals are set forth below.

Comment: Most commenters on this proposal, including national dialysis provider organizations, several large dialysis organizations, a patient advocacy organization, a drug manufacturer, a health system and a professional association expressed support for the proposal to use the pricing methodologies available under section 1847A of the Act to price drugs and biologicals for the outlier policy.

Commenters noted that, historically, new drugs and biologicals used in the treatment of ESRD that come to market can be expensive and not having access to outlier payments may create an unintended barrier. While they believe that it is unlikely a new drug or biological will not have an ASP or WAC, they indicated that it is important to ensure that payment policies do not disincentivize the use of drugs and biologicals. Another commenter stated patients who require outlier drugs should not be denied the individualized care they need and deserve due to revisions to the pricing methodology.

Response: We appreciate the commenters' support for our outlier proposal. We also agree with the importance of beneficiary access to new therapies when they come to market and, as discussed more fully below, we believe the policy we are finalizing ensures that every drug and biological within an ESRD PPS functional category, except for drugs that are eligible for the TDAPA, is included in the outlier calculation.

Comment: Several commenters expressed concern about the availability of an outlier payment in the event there is no pricing data available for drugs and biologicals. The commenters offered alternative pricing approaches that would be applied when no price is available using the methods described in section 1847A of the Act to ensure that all drugs and biologicals could be priced for the outlier calculation. Several commenters urged CMS to rely upon contract pricing rather than not include a new drug in the outlier calculation. One commenter asked that CMS provide an analysis of the proposal to clarify the impact on the ESRD PPS.

Another commenter recommended pricing the drug or biological by the hospital's cost-to-charge ratio for Cost Center 7300, Drugs Charged to Patients, for hospital-based ESRD facilities or the hospital-specific Reasonable Cost Factor that is currently used for payment of vaccines and blood products on ESRD claims from hospital-based facilities. Since this Reasonable Cost Factor is already used in the ESRD PPS, the commenter stated that applying it to this category of drugs and biologicals should be relatively easy administratively. The commenter indicated that adding an additional last resort pricing method would allow for hospital-based ESRD facilities to receive outlier payments or payments for non-ESRD related services (meaning, we believe, separately billable items and services reported with the AY modifier) that reflect the costs of drugs or biologicals for which no other pricing method is possible.

Response: We agree with the commenters that all eligible drugs and biologicals should be counted in the outlier calculation, to maintain consistency in the policies under the ESRD PPS and to ensure patient access to necessary medications. Also, while we appreciate the commenters' suggestions for alternative pricing methodologies, none of the suggestions fall under the pricing methodologies in section 1847A of the Act. Since our goal is to ensure all eligible drugs and biologicals are counted in the outlier calculation, while maintaining consistency with the drug pricing policies under the ESRD PPS, we believe adopting any of the suggested alternatives would make drug pricing policies under the ESRD PPS inconsistent.

As we stated in the CY 2018 ESRD PPS proposed rule (82 FR 31196), we believe that using the pricing

methodologies under section 1847A of the Act is consistent with the ESRD PPS drug designation process for new injectable and intravenous drugs, and how covered drugs and biologicals are paid under Medicare Part B. We continue to believe that consistency with Medicare Part B payment for drugs and biologicals is beneficial to ESRD facilities because, as mentioned above, this is the way CMS pays for injectable drugs and biologicals on the ESRD claim with the AY modifier; and therefore, facilities would be able to predict outlier payments. We continue to believe it is preferable to have one pricing policy for Part B drugs and biologicals under the ESRD PPS applicable to both the drug designation process, including TDAPA, and outlier policy. Therefore, we are not adopting the commenters' suggestions at this time.

Upon further review and discussion, while we believe the ASP and WAC pricing methodologies under section 1847A of the Act are sufficient to price most eligible drugs and biologicals for the purposes of outlier payment, we note that Medicare Administrative Contractors are authorized to use invoice pricing in scenarios in which neither ASP nor WAC data is available. This is consistent with chapter 17, section 20.1.3 of the Medicare Claims Processing Manual, which directs the Medicare Administrative Contractors to develop payment allowance limits for covered drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified Pricing File based on the published WAC or invoice pricing. Invoice pricing is not as robust a measure of actual sales price as ASP, but it is nearly universally available. Therefore, as we now believe the pricing methodologies under section 1847A of the Act and related guidance are sufficiently comprehensive, we are not finalizing the proposal to not count certain drugs and biologicals toward the outlier calculation when pricing methodologies are not available under section 1847A of the Act.

We intend to analyze the utilization of drugs and biologicals and how they are priced on a consistent basis to monitor the use of those methodologies described in section 1847A of the Act.

With regard to the comment that we provide an analysis of the impact of this proposal, currently we are aware of only 2 drugs with low utilization that were unable to be priced using ASP for outlier purposes. Those particular drugs had WAC prices and thus could be priced using the pricing methods under section 1847A of the Act; therefore, we believe the impact is negligible.

Comment: MedPAC commented that CMS should rely on ASP data when pricing drugs and biologics under the ESRD PPS outlier policy and drug designation process, including TDAPA, with one exception: New, single-source drugs and biologics, and the first biosimilar to reference a biologic (that lacks ASP data). MedPAC recommended that new single-source drugs and biologics, and the first biosimilar to a reference biologic (that lack ASP data), should be priced using WAC data only for 2 to 3 calendar quarters to permit time for manufacturers to report sales data to CMS and for the agency to calculate an ASP. If at the end of 2 to 3 calendar quarters, ASP data are not available, MedPAC recommended CMS should not use WAC for purposes of calculating outlier payments.

MedPAC referred to its June 2017 report to the Congress, entitled ''Medicare and the Health Care Delivery System,'' which raised concerns about the accuracy of WAC data. MedPAC stated that unlike an ASP, a product's WAC does not incorporate prompt-pay or other discounts. If discounts are available, then a product's WAC price would be greater than it otherwise would be under the ASP-based formula. Consequently, MedPAC noted that using WAC data to determine payments under the outlier policy could result in higher spending for beneficiaries and taxpayers.

MedPAC further commented that, to reduce the need to use less accurate prices, such as WAC, and to improve the accuracy of ASP data, it recommended in the June 2017 report that Congress improve ASP data reporting by requiring all manufacturers of Part B drugs and biologics to report ASP and impose civil monetary penalties for failure to report. As noted by MedPAC, under current policy, not all manufacturers of Part B drugs are required to submit their ASP data. Section 1927(b)(3) of the Act requires only manufacturers with Medicaid drug rebate agreements in place to report their sales data to calculate ASP for each of their Part B drugs.

Response: Our intent for the outlier proposal was to have a consistent drug pricing policy under the ESRD PPS with respect to Part B drugs and to protect beneficiary access to renal dialysis services. We believe that our proposal achieves those goals. We further believe that a change as substantial as relying only on ASP data for TDAPA pricing, as suggested by MedPAC, is out of scope for this rulemaking because we did not propose any changes to the TDAPA. Therefore, we are not adopting the MedPAC recommendation for TDAPA in this final rule. We share MedPAC's concern that ongoing reliance on the use of WAC pricing under the ESRD PPS could result in higher payments and will consider limiting the use of the other non-ASP pricing methods available under section 1847A of the Act in the future if our monitoring indicates they are used for an extended period of time and manufacturers are not reporting ASP data.

Final Rule Action: We are finalizing our proposal to use the pricing methodologies in section 1847A of the Act, as appropriate, to price drugs and biologicals for the outlier calculation when ASP pricing data is not available. We are not finalizing the proposal to not count certain drugs and biologicals toward the outlier calculation when pricing methodologies are not available under section 1847A of the Act.

2. CY 2018 ESRD PPS Update

a. CY 2018 ESRD Bundled 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 2018, we proposed to reduce the amount of the market basket percentage increase by 1.0 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 2018 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 Inc. (IGI) 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 2017 of the CY 2012-based ESRDB market basket (with historical data through the 4th quarter of 2016), the proposed CY 2018 ESRD market basket increase was 0.7 percent. This market basket increase was calculated by starting with the proposed CY 2018 ESRDB market basket percentage increase factor of 2.2 percent, reducing it by the mandated legislative adjustment of 1.0 percent (required by section 1881(b)(14)(F)(I)(i) of the Act), and reducing it further by the multifactor productivity (MFP) adjustment (the 10-year moving average of MFP for the period ending CY 2018) 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 2018 market basket update and MFP adjustment in the CY 2018 ESRD PPS final rule.

The IGI 3rd quarter 2017 forecast of the CY 2018 ESRDB market basket update is 1.9 percent. The decrease from the 1st quarter 2017 forecast (2.2 percent) to the 3rd quarter 2017 forecast (1.9 percent) is mostly attributable to a decrease in the projected growth of the series ''Producer Price Index: Commodity Data—Biological products excluding diagnostic, for human use.'' This series is used as the price proxy to estimate the ''erythropoiesis-stimulating agent (ESAs)'' cost category. The IGI 3rd quarter 2017 forecast of the MFP adjustment is 0.6 percent. The increase from the 1st quarter 2017 MFP forecast (0.5 percent) to the 3rd quarter 2017 MFP forecast (0.6) is mainly attributable to the incorporation of upward revisions of historical data by the Bureau of Labor Statistics (BLS), as well as slower projected labor input growth and capital input growth. Slower growth in labor and capital inputs result in a faster growth in topline MFP since MFP is measured as the change in outputs divided by the change in inputs.

For the CY 2018 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 PPS final rule (79 FR 66136).

We did not receive any comments on the proposed CY 2018 market basket update, MFP adjustment, or labor-related share.

Final Rule Action: As noted above, the final CY 2018 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 IGI 3rd quarter 2017 forecast with historical data through the 2nd quarter 2017, the final CY 2018 ESRDB update is 0.3 percent. This is based on a 1.9 percent market basket update, less a 1.0 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 0.6 percent MFP update.

b. Final CY 2018 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's) CBSAs-based geographic area designations to define urban and rural areas and their corresponding wage index values. OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The latest bulletin, as well as subsequent bulletins, is available online at *https://www.whitehouse.gov/omb/information-for-agencies/bulletins*.

For CY 2018, 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 2018 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 sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. The final CY 2018 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the final CY 2018 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 (0.9611) to American Samoa and the Northern Mariana Islands as established in the CY 2014 ESRD PPS final rule (78 FR 72172). We apply the statewide urban average based on the average of all urban areas within the state (78 FR 72173) (0.8472) 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 instead of the calculated wage index values below the floor in making payment for renal dialysis services under the ESRD PPS. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico. However, the wage index floor value is applicable for any area that may fall below the floor. A detailed description of the history of the wage index floor under the ESRD PPS can be found in the CY 2018 ESRD PPS proposed rule (82 FR 31198).

In the proposed rule, for CY 2018 and subsequent years, we proposed to maintain the current wage index floor of 0.4000 for CBSAs that have wage index values that fall below the floor. We stated that the cost report analyses that we have conducted over the years are inconclusive and have not convinced us that an increase in the wage index floor is warranted at this time. We explained that we continued to believe maintaining the current wage index

floor value of 0.4000 is appropriate as it continues to provide additional payment support to the lowest wage areas and avoids the need for an additional budget-neutrality adjustment that would reduce the ESRD PPS base rate, beyond the adjustment needed to reflect updated hospital wage data, in order to maintain budget neutrality for wage index updates. We noted that we would continue to monitor and analyze ESRD facility cost reports and projected impacts to guide future rulemaking with regard to the wage index floor (82 FR 31198).

The comments and our responses to the comments on our wage index proposals are set forth below.

Comment: A national dialysis organization and a large dialysis organization support the methodology for determining the wage indices and the continued application of the wage index floor. However, they asked that CMS consider how the current policy could be modified to adjust wage index values to account for laws requiring wage increases. They noted that under the current methodology for determining the wage indices for ESRD facilities, there can be a lag of several years with the wage index recognizing these changes.

Response: We agree with commenters that there is a data lag that occurs when a State changes its minimum wage or staffing requirements and when it is reflected in the hospital-reported wage data. We also believe it is more prudent to base the wage index on actual reported data rather than anticipated changes and the uncertainty of what may or may not be reported. For this reason, we are retaining the current methodology for determining wage indices.

Comment: Although we did not propose to change the wage index floor, we received comments from the major dialysis providers in Puerto Rico and a coalition of healthcare stakeholders in Puerto Rico. The commenters described the economic and healthcare crisis in Puerto Rico and recommended that CMS should use the United States Virgin Islands wage index for payment rate calculations in Puerto Rico as a proxy for CY 2018, given disadvantages recognized by CMS analysis, the unreliability of hospital-reported data in Puerto Rico and the inconsistencies with the wage indices used for other Territories. One commenter indicated that making this change for CY 2018 is similar to the CMS policy established in the CY 2017 Physician Fee Schedule final rule (81 FR 80261 through 80265) about the applicable geographic practice cost index (GPCI) factors and would be a natural ''outgrowth'' policy to define as a temporary measure derived from analysis and language presented in the CY 2017 ESRD PPS final rule and the CY 2018 ESRD PPS proposed rule, as well as from other previous regulatory cycles.

Commenters indicated that the primary issue is that Puerto Rico hospitals report comparatively lower wages that are not adjusted for occupational mix and, as CMS indicates in the CY 2017 ESRD PPS proposed rule (81 FR 42817), in Puerto Rico, only registered nurses (RNs) can provide dialysis therapy in the outpatient setting. This staffing variable artificially lowers the reportable index values even though the actual costs of dialysis service wages in Puerto Rico are much higher than the data CMS is relying upon. In addition, several commenters stated that non-labor costs, including utilities and shipping costs and the CY 2015 change in the labor-share based on the rebased and revised ESRDB market basket compound the issue even further. One organization stated that it does not believe maintaining the current wage index for Puerto Rico for CY 2018 is enough to offset the poor economic conditions, high operational costs and epidemiologic burden of ESRD on the island.

Response: We did not propose to change the wage index floor or otherwise change the wage indexes for Puerto Rico and will maintain the current wage index floor of 0.4000 for CY 2018. We note that the current wage index floor and labor-related share have been in effect since CY 2015 and neither the floor nor the labor share has been reduced since then. More importantly, the wage index is solely intended to reflect differences in labor costs and not to account for non-labor cost differences, such as utilities or shipping costs.

With regard to staffing in Puerto Rico facilities, we have learned that ESRD facilities there utilize RNs similarly to ESRD facilities on the mainland, that is, facilities utilize dialysis technicians and aides to provide dialysis services with oversight by an RN. In addition, hourly wages for RNs and dialysis support staff were approximately half of those salaries in mainland ESRD facilities. For these reasons, we do not agree that the hospital-reported data is unreliable, and we believe using that data is more appropriate than applying the wage index value for the Virgin Islands where salaries are considerably higher.

Final Rule Action: After considering the public comments we received regarding the wage index, we are finalizing the CY 2018 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 the labor-related share of 50.673 percent, which is based on the 2012-based ESRDB market basket. Thus, for CY 2018, the labor-related share to which a facility's wage index would be applied is 50.673 percent.

c. CY 2018 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 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: (1) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (3) 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 (4) renal dialysis services drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including ESRD related oral-only drugs effective January 1, 2025.

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 Medicare Part D for outlier eligibility purposes and in order to provide unit prices for calculating imputed outlier services. In addition, we 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 FDL 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 FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL 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 2018 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 through 68994, 69002). We used these outlier services payment multipliers to calculate the predicted outlier service MAP amounts and projected outlier payments for CY 2018.

For CY 2018, we proposed that the outlier services MAP amounts and FDL amounts would be derived from claims data from CY 2016. As we stated in the CY 2018 ESRD PPS proposed rule, 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. Therefore, we proposed the outlier thresholds for CY 2018 would be based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2016. We stated that 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 FDL amounts every year under the ESRD PPS.

In the CY 2017 ESRD PPS final rule (81 FR 77860), we stated that based on the CY 2015 claims data, outlier payments represented approximately 0.93 percent of total payments. In the CY 2018 ESRD PPS proposed rule (82 FR 31199), we discussed that the CY 2016 claims data show outlier payments represented approximately 0.78 percent of total payments. We explained that data indicates that trends in the utilization of the ESAs could be a reason for the decrease. Beginning in 2015 and continuing into 2016, there were large shifts in the composition of the utilization of ESA drugs. Specifically, utilization of Epoetin (EPO) alfa decreased and utilization of the longer-acting ESA drugs, darbepoetin and EPO beta, increased, based on estimates of average ESA utilization per session. As EPO alfa is measured in different units than both darbepoetin and EPO beta, it is difficult to compare the overall utilization of ESAs between 2014 and 2016 by units alone.

As we stated in the CY 2018 ESRD PPS proposed rule, in examining the claims data, we find that compositional shift away from use of EPO alfa to the longer acting darbepoetin and EPO beta was a significant factor in the decrease in total ESA costs in 2016. We first calculated the actual cost for ESAs administered during 2016. We then calculated the projected cost of ESAs that was used for the CY 2016 ESRD PPS final rule, using total utilization from 2014 and drug prices the from 3rd quarter 2015 inflated to 2016 prices. The actual costs of ESAs administered in 2016 were roughly 20 percent lower than the value projected in the CY 2016 ESRD PPS final rule. We then calculated the projected cost of ESAs assuming that the utilization of various ESAs per dialysis session in 2014 and 2016 were similar and also used the prices and total dialysis session count from 2016. The projected costs from these two scenarios were similar and suggest that compositional change in ESA utilization was likely a significant factor in the decrease in the total cost of ESAs between 2014 and 2016. We noted that we continue to believe that the decline is leveling off and that 1.0 percent is an appropriate threshold for outlier payments.

i. CY 2018 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2018, we did not propose any changes to the methodology used to compute the MAP or FDL amounts. Rather, we proposed to update the outlier services MAP amounts and FDL amounts to reflect the utilization of outlier services reported on 2016 claims. For this final rule, the outlier services MAP amounts and FDL amounts were updated using the latest available 2016 claims data. The impact of this update is shown in Table 1, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2017 with the updated estimates for this rule. The estimates for the CY 2018 outlier policy, which are included in Column II of Table 1, were inflation-adjusted to reflect projected 2018 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 2017 (based on 2015 data, price inflated to 2017) *		Column II final outlier policy for CY 2018 (based on 2016 data, price inflated to 2018)	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	$38.77	$47.00	$37.41	$44.27
Adjustments	.....	.....	.....	.....
Standardization for outlier services	1.0078	0.9770	1.0177	0.9774
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$38.29	$45.00	$37.31	$42.41
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$68.49	$82.92	$47.79	$77.54
Patient-months qualifying for outlier payment	4.6%	6.7%	9.0%	7.4%

* Note that Column I was obtained from Column II of Table 1 from the CY 2017 ESRD PPS final rule.

As demonstrated in Table 1, the estimated FDL amount per treatment that determines the CY 2018 outlier threshold amount for adults (Column II; $77.54) is lower than that used for the CY 2017 outlier policy (Column I; $82.92). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $45.00 to $42.41. For pediatric patients, there is a decrease in the FDL amount from $68.49 to $47.79. There is a slight decrease in the adjusted average MAP for outlier services among pediatric patients, from $38.29 to $37.31.

We estimate that the percentage of patient-months qualifying for outlier payments in CY 2018 will be 7.4 percent for adult patients and 9.0 percent for pediatric patients, based on the 2016 claims data. The pediatric outlier MAP amount continues 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), under § 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 as described in § 413.237. Based on the 2016 claims, outlier payments represented approximately 0.78 percent of total payments, below the 1 percent target due to small overall declines in the use of outlier services. Recalibration of the thresholds using 2016 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2018. We believe the update to the outlier MAP and FDL amounts for CY 2018 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 FDL amounts in this final rule will 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 will increase payments to ESRD facilities for beneficiaries with renal dialysis items and services that are eligible for outlier payments. Therefore, beneficiary coinsurance obligations will also increase for renal dialysis services eligible for outlier payments.

The comments and our responses to the comments on the proposal to update the outlier thresholds using CY 2016 data are set forth below:

Comment: A national dialysis organization and a large dialysis organization expressed concern about the statement made in the CY 2018 ESRD PPS proposed rule (82 FR 31199) that ESAs administered in 2016 were roughly 20 percent lower than the value we projected in the CY 2016 ESRD PPS final rule. They do not disagree with the conclusion that there should be no change in the threshold for outlier payments. However, they indicated that understanding the cost and utilization of drugs generally, and ESAs in particular, is important to understanding the adequacy of the payment system. They expressed concern that the preamble of the CY 2018 ESRD PPS proposed rule does not describe how CMS determined this value and it seems inconsistent with trends that some ESRD facilities see in their own data.

Response: In the CY 2017 ESRD PPS final rule (81 FR 77860), we stated that based on the CY 2015 claims data, outlier payments represented approximately 0.93 percent of total payments. For this final rule, CY 2016 claims data show outlier payments representing approximately 0.78 percent of total payments. To address the commenters' concern regarding how we determined that the actual costs of ESAs administered in 2016 were roughly 20 percent lower than the value projected in the CY 2016 ESRD PPS final rule, we have included more detail of the analysis here. As we discussed above, beginning in 2015 and continuing into 2016, there were large shifts in the composition of the utilization of ESA drugs in the claims data. Specifically, estimates of average ESA utilization of EPO alfa (Healthcare Common Procedure Coding System (HCPCS) Q4081) per dialysis session decreased from 28.54 units in 2014 to 13.73 units in 2016, and utilization of the longer-acting ESA drugs, darbepoetin (HCPCS J0886) and EPO beta (HCPCS Q9972/J0887), increased, from 0.75 and 0.001 mcg in 2014 to 2.13 and 3.01 mcg in 2016, respectively. As EPO alfa is measured in different units than both darbepoetin and EPO beta, it is difficult to compare the overall utilization of ESAs between 2014 and 2016 by units alone.

In examining the claims data, we continue to find that the compositional shift away from use of EPO alfa to the longer acting darbepoetin and EPO beta was a significant factor in explaining why total ESA costs actually incurred in 2016 were lower than the total ESA costs projected for 2016 using 2014 data. We first calculated the actual cost for ESAs administered during 2014 and 2016. We found shifts in the composition of costs per dialysis session associated with each ESA that were proportional to changes in utilization per session. Specifically, estimates of average ESA cost of EPO alfa per dialysis session decreased from $32.50 in 2014 to $17.19 in 2016, and average cost per session of darbepoetin and EPO beta increased from $2.79 and $0.00 in 2014 to $8.53 and $5.08 in 2016, respectively. Total calculated costs of ESAs in 2014 and 2016 were $1.6 billion and $1.4 billion. We then

calculated the projected cost of ESAs that was used for the CY 2016 ESRD PPS final rule, using total utilization from 2014 and drug prices from the 3rd quarter 2015 inflated to 2016 prices, to be $1.7 billion. The actual costs of ESAs administered in 2016 were roughly 20 percent lower than this value projected in the CY 2016 ESRD PPS final rule (80 FR 68974).

In order to understand the reason for this difference, we created a projected 2016 value using an alternative scenario. In this scenario, we calculated the projected cost of ESAs assuming that the utilization of various ESAs per dialysis session in 2016 was equivalent to that in 2014, but instead we used the prices and total dialysis session count from 2016. The projected costs from these two scenarios were similar and suggest that neither the difference in the projected (3rd quarter 2015 prices inflated to 2016) versus actual ESA prices for 2016 nor changes in the number of dialysis sessions between 2014 and 2016 explain the difference between the projected and actual cost of ESAs in 2016. Therefore, the residual factor indicates that compositional changes in ESA utilization were the most likely factor in the decrease in the total cost of ESAs between 2014 and 2016. We continue to believe that the decline is leveling off and that 1.0 percent is an appropriate target for outlier payments.

Comment: Although we did not propose changes to the outlier target percentage or update methodology, we received many comments regarding the difference between estimated outlier payments and the 1.0 percent outlier target. A national kidney organization and a large dialysis organization expressed support for CMS' proposal to refine the outlier pool so that the dollars paid out more closely align with the estimated amount used to create the outlier pool. However, they expressed concern that CMS has not yet addressed the fact that the outlier pool is consistently paying out less than the amount removed from the base rate. Both organizations referenced an analysis that estimated the outlier pool underpaid $0.46 per treatment in 2016 and that, cumulatively since 2011, $4.97 has been removed by the underpayment of the outlier pool. They asked that CMS further refine the outlier policy so that it is more consistent with how outlier policies in other Medicare payment systems work.

A patient advocacy organization expressed strong support for CMS having an outlier payment policy as the organization believes it is a helpful policy for ensuring that costlier patients receive the care they need. However, the organization recommended that CMS revisit the calculation and application of the outlier payment policy to ensure that total amount of payments withheld are paid back to facilities for patient care.

An organization representing non-profit facilities and a large dialysis organization urged CMS to reconsider the 1 percent outlier policy first implemented in 2011, stating that while an outlier adjustment is required under the statute, a 0.5 percent outlier target percentage would reduce the offset to the base payment and still provide for payment in the case of extraordinary costs.

A large dialysis organization stated that despite CMS's efforts to equalize payment made into and out of the outlier pool, limited progress toward that goal has been achieved. The commenter recommended that CMS should address this problem by paying out any remaining outlier pool dollars to providers in the subsequent year. A professional association agreed, expressing concern about the ongoing leakage of funds withheld, but not paid out as outlier payments. Although the professional association agreed the rationale provided for the anticipated increase in outlier payments may be accurate, it noted that in calculating these estimates, CMS is adjusting for input costs but not for changes in provider behavior, including a substantial shift to other ESAs that are similarly expensive. The commenter stated that in a fixed bundled payment environment, there is an incentive to continually find ways to reduce costly practices—an unaccounted-for factor that will likely contribute to the continued under-projection of outlier payouts.

The professional association offered two alternate paths to addressing the gap between outlier withholds and outlier payments for CMS' consideration: (1) Revise the withhold on an annual basis so that only the exact necessary amount is withheld to meet payouts (likely, retrospectively); or (2) reinvest the difference between actual outlier costs incurred and the funds withheld to support research and other patient-focused initiatives within CMS' scope, such as: Analyzing data to better understand aspects of dialysis care related to improved patient outcomes; developing a demonstration project or pilot focused on covering the cost of care for vascular access payment in the first 90 days prior to new ESRD patient eligibility; or supporting other initiatives to improve the value of ESRD care provided, in partnership with the kidney community.

Response: We appreciate the continued support for the outlier policy and the suggestions provided. We continue to believe that 1.0 percent is an appropriate target for outlier payments given that using more recent claims data to update the outlier MAP and FDL amounts for CY 2018 will increase outlier payments for ESRD beneficiaries. A 1.0 percent outlier target percentage is a modest amount in comparison to other Medicare prospective payment systems and helps to ensure that high cost patients receive the individualized services they need. We will, however, take the commenters' views into consideration as we explore ways to enhance and update the outlier policy in future rulemaking.

Comment: A professional association noted the decreases in the pediatric MAP and FDL amounts to reflect the utilization of services in 2016 and expressed concern about the greater than 25 percent decrease in the pediatric FDL amount. While the commenter recognizes that this is the first proposed decrease in several years, the commenter believes that it could negatively impact the delivery of care in pediatric facilities.

Response: The reduction in the pediatric outlier threshold amounts indicates that the cost of caring for pediatric ESRD patients was lower in 2016 than in 2015. The decrease in the pediatric FDL amount makes exceeding the amount for pediatric facilities easier to achieve. Therefore, we believe this update will improve payments to facilities serving pediatric patients and will not negatively impact the delivery of care.

Final Rule Action: After considering the public comments, we are finalizing the updated outlier thresholds based on CY 2016 data.

d. Final Impacts to the CY 2018 ESRD PPS Base Rate

i. ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), we discussed the development of the ESRD PPS per treatment base rate that is codified in the Medicare regulations at 42 CFR 413.220 and 42 CFR 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 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, training add-on payments, and transitional drug add-on payment adjustments.

ii. Annual Payment Rate Update for CY 2018

The ESRD PPS base rate for CY 2018 is $232.37. This update reflects several factors, described in more detail as follows:

• *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 2018, we did not propose any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). The final CY 2018 wage index budget-neutrality adjustment factor is 1.000531, based on the updated wage index data. Therefore, the final ESRD PPS base rate for CY 2018 before application of the payment rate update is $232.24 ($231.55 × 1.000531 = $231.67).

• *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 2018 projection for the ESRDB market basket is 1.9 percent. In CY 2018, this amount must be reduced by 1.0 percentage point 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 1.9 − 1.0 = 0.9 percent. This amount is then reduced by the MFP 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 MFP adjustment for CY 2018 is 0.6 percent, thus yielding a final update to the base rate of 0.3 percent for CY 2018 (0.9 − 0.6 = 0.3 percent). This application yields a CY 2018 ESRD PPS final base rate of $232.37 ($231.67 × 1.003 = $232.37).

The comments and our responses to the comments on our proposals to update the payment rate for CY 2018 are set forth below.

Comment: One commenter expressed concern about the application of section 1877 of the Act (the physician self-referral law) to dialysis facilities that, under the TDAPA policy, would furnish and be reimbursed for outpatient dialysis-related drugs that are not yet considered ''part of the bundle.'' The commenter noted that outpatient prescription drugs are designated health services for purposes of the physician self-referral law and urged us to add outpatient dialysis-related drugs furnished by a dialysis facility under the TDAPA policy to the list of codes that are eligible for the exception for EPO and other dialysis-related drugs furnished by an ESRD facility (42 CFR 411.355(g)), which would avoid the application of the physician self-referral law to the referral of and billing for such drugs. The commenter also urged us to confirm that any new drugs added to the ''bundle'' (such as calcimimetics after the TDAPA period) would fall within the exclusion from the definition of ''designated health services'' for outpatient prescription drugs reimbursed as part of a composite rate. The commenter suggested that these steps would help avoid confusion in the provider community and remove any potential barriers to beneficiary access to dialysis drugs that might otherwise occur in an environment in which there are perceived uncertainties about compliance with the physician self-referral law.

Response: As the commenter noted, under section 1877 of the Act and our regulations at 42 CFR 411.351, outpatient prescription drugs are designated health services. However, services that are reimbursed by Medicare as part of a ''composite rate'' are not included in the definition of ''designated health services'' (unless the services are specifically identified in § 411.351 and are themselves payable through a composite rate, such as inpatient and outpatient hospital services). For purposes of the physician self-referral law, ''composite rate'' refers to payments made under a distinct payment methodology (66 FR 868). With respect to ESRD services, for purposes of the physician self-referral law, we interpret the ''composite rate'' as the per-treatment payment amount. As described in our TDAPA implementation guidance issued August 4, 2017, available on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R1889OTN.pdf*, the methodology used to calculate the per-treatment payment amount incorporates the cost of the drugs that are paid for using a TDAPA. Thus, the commenter incorrectly presumes that outpatient prescription drugs furnished and reimbursed under the TDAPA policy are not considered part of the ESRD ''composite rate'' for purposes of the physician self-referral law when, in fact, they are included in this ''composite rate.'' As requested by the commenter, we confirm that, after the TDAPA period under § 413.234(c)(2), calcimimetics will be part of the ESRD PPS ''composite rate'' for purposes of the physician self-referral law.

We note that the payment methodology for calculating the ESRD PPS per-treatment amount is unique to ESRD services, and our determination regarding outpatient prescription drugs furnished and reimbursed under the TDAPA policy does not apply to ambulatory surgical center services, hospice services, skilled nursing facility Part A services, or any other services that are reimbursed by Medicare as part of a composite rate. We also note that our treatment of TDAPA drugs as part of the ESRD PPS ''composite rate'' is consistent with our treatment of EPO and other dialysis-related outpatient prescription drugs as excluded from the ESRD PPS ''composite rate'' prior to January 1, 2011. In our January 4, 2001 rulemaking interpreting section 1877 of the Act (Phase I), we defined ''designated health services'' to exclude services that are reimbursed by Medicare as part of a composite rate (66 FR 924). In contrast to drugs that are paid for using a TDAPA, at the time of our Phase I rulemaking, EPO and other dialysis-related outpatient drugs were not included in the methodology used to calculate the per-treatment payment amount; that is, for purposes of the physician self-referral law, they were not paid as part of the ESRD PPS ''composite rate'' and remained ''designated health services.'' Therefore, a physician owner of an ESRD facility that did not qualify as a ''rural provider'' (for purposes of the physician self-referral law) would have been precluded from ordering EPO and other dialysis-related outpatient prescription drugs for his or her Medicare patients and the ESRD facility would have been precluded from submitting claims to Medicare for the drugs ordered by the physician owner. Because of our belief that the Congress did not intend to preclude physician ownership of ESRD facilities when enacting section 1877 of the Act, we established a separate exception to the physician self-referral

law at § 411.355(g) for EPO and other dialysis-related outpatient prescription drugs (66 FR 938). As of January 1, 2011, EPO and other anemia management outpatient prescription drugs (as well as access management, bone and mineral metabolism, cellular management, antiemetic, anti-infectives, antipruritic, anxiolytic, excess fluid management, fluid and electrolyte management including volume expanders, and pain management outpatient prescription drugs) are included in the ESRD PPS ''composite rate'' (that is, the ESRD per-treatment payment amount) and no longer qualify as ''designated health services'' for purposes of the physician self-referral law. Because drugs that are paid for using a TDAPA are included in the ESRD PPS ''composite rate'' and not considered ''designated health services,'' they need not be included on the list of Current Procedural Terminology (CPT)/HCPCS codes that are eligible for use with the exception at § 411.355(g).

Comment: Several organizations expressed support for the proposed increase to the ESRD PPS base rate and for the consistent and the predictable approach to updating the base rate.

An organization representing dialysis patients expressed appreciation that this year's ESRD PPS rulemaking extends a period of relative stability in Federal support for dialysis; however, that organization and a large dialysis organization indicated that the success of the ESRD PPS depends, by design, on cross subsidization from private coverage and that any action that constrains private coverage for ESRD patients will exacerbate policies that have resulted in consistent ESRD PPS underpayments and destabilize the nation's care delivery system for all ESRD patients. Given CMS's role in overseeing the ESRD PPS and the Health Insurance Marketplaces, they urged CMS to work to preserve the long-standing public-private ESRD partnership and work with the kidney care community to address policies that have resulted in chronic underpayments through the ESRD PPS.

A professional association noted MedPAC's previous findings that the margins in Medicare dialysis care are extremely thin or negative and asked CMS to bear in mind, to the extent possible, when determining the overall base rate that many aspects of care that dialysis facilities provide are not covered by the elements used to calculate the base rate. The professional association stated that this means that any new unfunded mandates (for example, requirements to use pre-filled syringes and follow more time-consuming disinfection processes) must be offset elsewhere in the context of the fixed payment environment. While these new mandates could have patient benefits, they also may come at the expense of other activities that also have patient benefits. The professional association urged CMS to move cautiously and transparently in implementing such new policies, both to promote community understanding and buy-in and to avoid the unintended consequence of effectively mandating new actions that might adversely impact care elsewhere. The professional association stated that any new requirements selected must provide the greatest value to patients in the context of a fixed, bundled payment environment.

Response: We appreciate the commenters' support for the increase to the ESRD PPS base rate and will take into consideration the concerns regarding ESRD facility profit margins.

Final Rule Action: We are finalizing a CY 2018 ESRD PPS base rate of $232.37.

C. Miscellaneous Comments

We received many comments from beneficiaries, physicians, professional organizations, renal organizations, and manufacturers related to issues that were not specifically addressed in the CY 2018 ESRD PPS proposed rule. These comments are discussed below.

Comment: A national kidney organization and a patient advocacy organization requested that the rate setting file released with each proposed and final ESRD PPS rule include specific flags for each payment adjuster that is applied and all modifiers on claims, particularly the ''AY'' modifier which is used for billing items and services that are not furnished for the treatment of ESRD and are therefore separately payable. They noted that the outpatient prospective payment system rate setting file format that is the template for the ESRD PPS rate setting file normally includes all modifiers, and there are a number of ways that adjuster variable flags could be added to that file. These data are necessary to engage in a timely discussion of the impact of the adjusters on accurate estimates of payment and impact analyses.

Response: We appreciate the commenter's thoughts with regard to the rate setting file and we will consider this suggestion for future updates.

Comment: A national kidney organization and a national dialysis provider organization thanked CMS for eliminating the medical director fee limitation that had been a policy left over from before dialysis facilities were paid on a prospective payment system basis. However, they expressed concern that some of the contractors overseeing the cost report submissions are requiring facilities to submit detailed physician logs describing the hours worked and tasks performed and still applying the limitation. The commenters stated there may be confusion because the most recent edition of the Medicare Claims Processing Manual, Chapter 8, section 40.6.C.2, updated November 10, 2016 continues to include instructions that do not reflect the policy changes made in previous rulemakings.

Therefore, they requested that CMS revise the instructions in the Medicare Claims Processing Manual to align with the policy finalized in previous rulemaking that eliminates the limitation on medical director fees. They also requested that we clarify that detailed physician logs not be required, consistent with the elimination of the limitation and the requirements (such as providing an invoice) applied to other health care providers and suppliers with regard to establishing medical director fees.

A dialysis organization requested more information related to items included in the ESRD PPS bundle and requested that CMS create separate lists of what they can include on Medicare claims, which items and services are subject to consolidated billing and whether or not they can bill for these items and services, as well as what is not included in the bundle.

Response: We appreciate the commenter's suggestions regarding claims processing guidance and we will consider them for future updates.

Comment: Although we did not include any proposals regarding the TDAPA, we received many comments from dialysis provider and patient advocacy organizations, professional associations and drug manufacturers covering payment, coverage, and clinical issues surrounding the implementation of the two new HCPCS J-codes for oral and IV calcimimetics that will become renal dialysis services and paid for using a TDAPA beginning on January 1, 2018.

There were several comments regarding timing, including comments expressing that implementation on January 1, 2018 took CMS too long and other comments indicating that this is a complex change for ESRD facilities and they will need time after CMS issues guidance to incorporate that guidance into their billing systems and care planning. In addition, commenters urged us to coordinate with Medicare Advantage as well as Part D to ensure

a seamless conversion of calcimimetics from Part D to Part B. Commenters requested that we closely monitor patient access and outcomes related to calcimimetics, and expressed concern about coinsurance and the need to support innovation, especially for new drugs within the existing ESRD PPS functional categories. They also raised issues regarding refills, CMS reimbursing for shipping and dispensing costs, and reporting the drug dispensed rather than the amount used by patients. Lastly, a national dialysis provider association commented that nephrologists have voiced concerns about the potential implications of CMS reimbursement policies relating to calcimimetics under the physician self-referral law.

Response: We plan to issue guidance soon that will address the issues raised by commenters. We do not understand some of the commenters' concerns because oral equivalents of IV medications currently in the ESRD PPS bundled payment and other oral medications used for the treatment of ESRD (that is, oral drugs that fit into the established ESRD PPS functional categories) have been covered under the ESRD PPS since 2011 when the ESRD PPS bundled system was first implemented. Because of this, we believe that ESRD facilities would have existing relationships with pharmacies that could provide oral drugs to ESRD patients and these pharmacies could also furnish the oral calcimimetics.

Comment: MedPAC commented that section 217(e) of PAMA required the Secretary to conduct audits of Medicare cost reports beginning in 2012 for a representative sample of freestanding and hospital-based facilities furnishing dialysis services. To support this effort, the law authorized the Secretary to transfer $18 million (in fiscal year 2014) from the Federal Supplementary Medical Insurance Trust Fund to CMS's program management. In September 2015, CMS awarded a contract to conduct the audit. MedPAC strongly encouraged CMS to accelerate the audit's completion and release its final results, and emphasized the importance of auditing the cost reports that dialysis facilities submit to CMS to ensure the data are accurate.

An organization of small and independent dialysis facilities agreed, stating that standardized cost reports can improve payment accuracy in the ESRD PPS and thus the organization seeks to partner with CMS to develop standardized cost reports and reporting guidance for ESRD facilities. The organization indicated that the current reporting structure lacks the detail necessary to assist providers in proper cost allocation, and leads to significant inconsistency in cost reporting.

In addition, a patient advocacy organization noted that CMS previously stated that it would review cost reports to better understand the costs of home dialysis training. The organization inquired about CMS's progress towards this goal.

Response: We appreciate the commenters' thoughts and suggestions on the CMS cost reports and audits. The audit process is underway, but not complete at this time. We will take commenters' views into consideration for future cost report updates.

Comment: Although CMS did not propose any changes to the case-mix and facility-level adjustments under the ESRD PPS, we received many comments from national dialysis provider organizations, large dialysis organizations, and patient advocacy organizations expressing concern about the payment adjustments under the ESRD PPS, specifically the use of cost reports for patient-level adjustments. They recommended that CMS update the standardization factor using the most current data available.

The commenters stated that they have recommended several steps that CMS should take to address shortcomings with the case-mix adjusters' validity and accuracy. Until those steps are taken, the organizations asserted that CMS should not apply the case-mix adjustments and restore the dollars historically removed from the base rate to reflect the frequency and size of the revised adjusters. They also recommended that CMS have an independent, third-party perform a peer review of the research methodology employed within the ESRD PPS and asked that CMS consider the comments regarding methodology submitted by the public and provide substantive responses on the record to address concerns. Commenters also asked that CMS provide more detailed data to allow for a complete analysis of the ESRD PPS. For example, commenters requested a comprehensive list of variables, descriptions, and analyses that could resolve the variances identified in the dialysis industry's analysis of the ESRD PPS methodology. They also stated that a more comprehensive list of data elements would clarify the CMS contractor's conclusions and allow them to better address the underpayment of the ESRD PPS.

Response: We appreciate the commenters' thoughts with regard to the ESRD PPS case-mix adjustments and research methodology and will consider the suggestions for future updates.

Comment: We received many other comments that were beyond the scope of the CY 2018 ESRD PPS proposed rule including the following suggestions: Develop a renal-specific productivity factor; require the sharing of dialysis patient information with the treating ESRD facility after a hospitalization to promote health information technology initiatives; allow ESRD facilities to include the 50 cents per treatment Network Fee on their cost reports; encourage home dialysis by consistently covering the costs of home training and more frequent treatments by home patients; and preserve the public-private partnership for ESRD care and ensure that private insurers are incentivized to cover 30 months of dialysis or transplantation services as well as preventive care for patients with diabetes and hypertension to slow the progression of chronic kidney disease to ESRD.

Response: We appreciate receiving these comments so that we are aware of issues impacting ESRD facilities and beneficiaries. However, we did not include any proposals regarding these topics in the CY 2018 ESRD PPS proposed rule, and therefore we consider these suggestions to be beyond the scope of this rule.

Comment: A national dialysis provider association and a national dialysis organization recommended clarification regarding patients with AKI who do not recover kidney function and transition to become ESRD patients. Specifically, these commenters requested guidance related to Medicare eligibility, transplant wait list, and incident patient modifier.

Response: We appreciate the feedback on this issue and we will consider this topic for future guidance.

III. Calendar Year (CY) 2018 Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

A. Background

On June 29, 2015, the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted. In the TPEA, the Congress amended the Social Security Act (the Act) to include coverage and provide for payment for dialysis furnished by an ESRD facility to an individual with acute kidney injury (AKI). Specifically, section 808(a) of the 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) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) to the Act. Subsection (r)(1) of section 1834 of the Act provides for payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the end-stage renal disease (ESRD) prospective payment system (PPS) base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and may be adjusted by the Secretary of the Department of Health and Human Services (the Secretary) (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act.

In the calendar year (CY) 2017 ESRD PPS final rule, we finalized several coverage and 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, including the payment rate for AKI dialysis (81 FR 77866 through 77872). We interpret section 1834(r)(1) of the Act to mean the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for such year under the ESRD base rate as set forth in 42 CFR 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in 42 CFR 413.196(d)(1), adjusted for wages as set forth in 42 CFR 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under 42 CFR 413.373. We codified this policy in § 413.372.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on CY 2018 Payment for Renal Dialysis Services Furnished to Individuals With AKI

The proposed rule, entitled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program'' (82 FR 31190 through 31233), hereinafter referred to as the CY 2018 ESRD PPS proposed rule, was published in the **Federal Register** on July 5, 2017, with a comment period that ended on August 28, 2017. In that proposed rule, we proposed to update the AKI dialysis payment rate. We received approximately 9 public comments on our proposal, 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 the proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for CY 2018 payment for renal dialysis services furnished to individuals with AKI.

1. Annual Payment Rate Update for CY 2018

a. CY 2018 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate. We note that ESRD facilities 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.

As discussed in the CY 2018 ESRD PPS proposed rule (82 FR 31201), the CY 2018 proposed ESRD PPS base rate was $233.31, which reflected the proposed ESRD bundled market basket and multifactor productivity adjustment. Therefore, we proposed a CY 2018 per treatment payment rate of $233.31 for renal dialysis services furnished by ESRD facilities to individuals with AKI.

b. 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 subparagraph (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 apply the same wage index that is used under the ESRD PPS, as discussed in the CY 2018 ESRD PPS proposed rule (82 FR 31201). In the CY 2017 ESRD PPS final rule (81 FR 77868), we finalized that the AKI dialysis payment rate will be adjusted for wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted for wage index for that facility. Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. We proposed a CY 2018 AKI dialysis payment rate of $233.31, adjusted by the ESRD facility's wage index.

The comments and our responses to the comments on this AKI payment proposal are set forth below.

Comment: We received a comment from MedPAC stating that the AKI payment policy should be site-neutral for all settings, including hospital outpatient departments and ESRD facilities. MedPAC stated that this policy would lower spending for beneficiaries and taxpayers and reduce incentives to provide service in a higher paid sector since payment rates should be based on the setting where beneficiaries have adequate access to good quality care at the lowest cost to beneficiaries and the program, adjusting for differences in patient severity. MedPAC suggested that the Centers for Medicare & Medicaid Services (CMS) should pursue legislative authority to implement such a policy.

Response: We appreciate MedPAC's comment with regard to site-neutrality and pursuing legislative authority. We did not propose any specific changes to our AKI payment policies in the CY 2018 ESRD PPS proposed rule, and therefore we consider this comment to be outside the scope of this rule. As we noted in the CY 2017 ESRD PPS final rule (81 FR 77868), section 808(b) of TPEA did not address payments to hospital outpatient departments for dialysis services furnished to beneficiaries with AKI.

Comment: Two national dialysis organizations and a large dialysis organization asked that we affirm the distinction between AKI patients and ESRD beneficiaries, ensure sufficient funds are available to meet the utilization of AKI services by Medicare beneficiaries since the Congress did not mandate that CMS implement the provisions of TPEA in a budget-neutral manner, and also affirm that the ESRD Network fee does not apply to AKI treatments. The commenters noted that the ESRD Networks are charged with focusing on patients with ESRD, and therefore, the Network fee should not be applied to AKI payments.

A professional association, clinician's group, and a national dialysis provider association commented that CMS did not fully reflect the nuances of the distinctly different needs of AKI patients from ESRD patients in the AKI coverage and payment policy implemented in the CY 2017 ESRD PPS final rule. Specifically, the association noted the time and cost of educating staff about AKI dialysis and extra attention required by AKI patients and

more frequent laboratory monitoring of blood and urine. The commenters urged CMS to closely track utilization of items and services that are included in the ESRD PPS bundled payment to ensure that payment is appropriate for AKI dialysis.

The provider association also stated that as we learn more about the provision of services to these patients, it may become apparent that an *AKI adjustment* to the payment rate is necessary to address the differences in the services provided to AKI patients. The commenter was pleased that CMS recognized in the CY 2017 ESRD PPS final rule that adjustments may be necessary in the future, as well as the need to bill certain services separately.

Response: We agree with the commenters that care for AKI patients is different from the care provided to individuals with ESRD. With respect to the comment about ensuring sufficient funds are available for AKI payments, we note that AKI treatments administered in an ESRD facility represent a shift in service from the hospital outpatient department to the ESRD facility and therefore represent a savings to the Medicare Trust Fund, since reimbursement for services provided in an ESRD facility is lower than services provided in a hospital setting. As we stated in the CY 2017 ESRD PPS final rule (81 FR 77867), we believe the definition of an individual with AKI set forth in TPEA provides an appropriate way to distinguish patients with AKI from patients with ESRD. Additionally, the TPEA did not mandate implementation on a budget-neutral basis.

As we discussed in the CY 2017 ESRD PPS final rule (81 FR 77868), we finalized a policy that the AKI dialysis payment rate is the final ESRD PPS base rate adjusted by the wage index that is used under the ESRD PPS. We stated that we are not adjusting the payment amount by any other factors at this time, but may do so in future years. To address the higher costs associated with AKI patients as compared to ESRD patients, we finalized a policy of paying for all AKI dialysis treatments provided to a patient, without applying the monthly treatment limits applicable under the ESRD PPS. We also finalized a policy to pay separately for all items and services that are not part of the ESRD PPS base rate. We have created the ability through our claims processing systems to identify individuals with AKI in order to track the utilization of services and their health outcomes to ensure these patients are receiving the care they require. 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.

Finally, regarding the comment about the applicability of the ESRD Network fee to AKI treatments, we note that we discussed that issue in detail in the CY 2017 ESRD PPS final rule (81 FR 77867 through 77678). We explained that after considering comments and reviewing the applicable statutory provision, we will not apply the ESRD Network fee to the AKI dialysis payment rate.

Comment: We received comments from national provider organizations, large dialysis organizations, and a drug manufacturer providing evidence that the AKI utilization estimates included in the CY 2018 ESRD PPS proposed rule may be inaccurate. These organizations indicated that the outpatient data used to estimate the shift in services from the outpatient hospital setting to the ESRD facility may underestimate the number of beneficiaries that received treatment for AKI. The organizations stated this underestimation could be due to hospitals not consistently billing for dialysis treatments administered to beneficiaries with AKI.

Response: We agree that the estimates used in the CY 2018 ESRD PPS proposed rule underestimated the number of beneficiaries receiving treatments for AKI. When the CY 2018 ESRD PPS proposed rule was developed, we used the best available information, which was information regarding treatments provided in a hospital outpatient setting. In the time between the publication of the CY 2018 ESRD PPS proposed rule and the CY 2018 ESRD PPS final rule, data regarding actual ESRD facility utilization of treatments provided to beneficiaries with AKI has become available. As a result, CMS has revised the impact analysis for AKI payment from $2 million to $20 million for CY 2018.

Comment: National provider organizations, a large dialysis organization, and a patient advocacy organization requested that CMS explain the AKI monitoring program and the transparent provision of data related to the program. These commenters noted that historic utilization may not be representative of the actual prevalence of AKI patients requiring dialysis due to operational models used by hospital outpatient departments and suggested that current data be used to develop an AKI adjustment as necessary to address the differences in the services provided to AKI patients.

Response: We appreciate the feedback on historic utilization and agree that current data is the most appropriate for use with regard to the AKI population. The AKI monitoring program will include current data and will be used to inform future payment policy, including any potential adjustments to the AKI payment rate. As we stated in the CY 2017 ESRD PPS final rule (81 FR 77871), we will develop public use files for the utilization of these services, but we do not anticipate that this data will be available until we have at least 1 full year of claims data. If stakeholders have additional clinical data regarding utilization and the treatments administered to AKI patients, we would welcome the receipt of that data in de-identified form.

Comment: National provider organizations suggested that an AKI specific modifier should be identified for laboratory tests and drugs used by AKI patients and should allow separate payment. Commenters suggested that CMS issue guidance defining the utilization of this modifier, for example, for laboratory tests repeated more frequently for AKI patients than for ESRD patients. These organizations also believe that the AY modifier should not be used on AKI claims. Rather, they recommended that CMS identify a new AKI-specific modifier, which would allow CMS and providers to track utilization of key products and services by AKI patients to better inform policy in future rulemaking. One commenter asked that such modifiers be appropriately flagged in both the rate setting and standard analytic data files to ensure transparency to the public for the purpose of analysis.

Another dialysis organization stated that with regard to AKI and billing, it is still not clear which claim modifiers are required for Medicare claims for AKI patients. They requested that CMS provide specific clarification on this issue.

Response: We appreciate the feedback on the operationalization of AKI claim submission. As we noted in the CY 2017 ESRD PPS final rule (81 FR 77867), the TPEA requires that we pay ESRD facilities for renal dialysis services furnished to beneficiaries with AKI in the amount of the wage-adjusted ESRD PPS base rate. In addition, we stated there is no weekly limit on the number of treatments that will be paid. ESRD facilities will receive payment based on the applicable Part B fee schedules for other items and services that are not considered to be renal dialysis services. As we stated in the CY 2017 ESRD PPS final rule, we continue to believe that these payment considerations are

sufficient for Medicare payment of renal dialysis services furnished to beneficiaries with AKI. As these services evolve in ESRD facilities, we can address any changes in future rulemaking. We will also provide billing guidance as necessary to address updates to modifier rules and claims submission.

Comment: A software vendor requested that we clarify whether the TDAPA applies to AKI services.

Response: We will issue additional program guidance that will address the application of the TDAPA to AKI services and other billing guidance. If we determine that it is appropriate for the TDAPA to apply to AKI services, we would consider that to be a substantive payment policy which would be established through notice and comment rulemaking.

Comment: A health system and a provider organization commented that including AKI treatments in the count to determine eligibility for the low-volume payment adjustment (LVPA) is inappropriate. The commenters believe that including these treatments in that count could discourage facilities from accepting AKI patients if their treatment jeopardizes their low volume status. The commenters also believe that including AKI treatments in the LVPA count, but not applying the LVPA to those treatments, is an inconsistent application of the LVPA policy.

An industry organization urged CMS to include the rural adjustment in the AKI payment to reflect the increased cost necessary to provide high-quality care since rural facilities face all of the same challenges in the providing dialysis treatment to AKI patients as they do to ESRD patients.

Response: We appreciate the commenters' feedback on the application of the LVPA to AKI dialysis treatments as well as their inclusion toward a facility's eligibility. Since the policy regarding eligibility for the LVPA is based on all treatments provided by a facility, including non-Medicare treatments, we determined that the policy should also include AKI dialysis treatments, not just ESRD treatments at this time (81 FR 77869). In the CY 2017 ESRD PPS final rule (81 FR 77868), we discussed not applying the case-mix adjusters to the payment for AKI treatments because those adjusters were developed based on ESRD treatments, and we continue to believe this is the most appropriate policy. As we continue to monitor data, we will review the efficacy of our LVPA and rural policies to determine if modification is required.

Comment: A patient advocacy organization expressed support for our proposal to adjust the AKI payment rate by only the geographic and wage indices. This commenter further noted that, for some patients, peritoneal dialysis (PD) is the most appropriate modality. Additionally, some AKI patients can safely dialyze at home and have their urine and blood tests performed for the assessment of kidney function in a location closer to home. The commenter recommended that home training be paid separately, without dollars removed from the base rate.

Response: We appreciate the commenter's support for our AKI payment rate proposal. With regard to PD, we agree that it is an appropriate modality for some beneficiaries, however, in the CY 2017 ESRD PPS final rule, we stated that we do not expect that AKI beneficiaries will dialyze at home (81 FR 77870 through 77871). We continue to believe that this is a population that requires close medical supervision by qualified staff during their dialysis treatment. We affirm in this final rule that payment will only be made for in-center PD or hemodialysis treatments for AKI beneficiaries. We will monitor this policy to determine if changes are necessary in the future, understanding that there may be a subset of patients for whom AKI dialysis at home is an appropriate treatment. We appreciate the commenter's insight on the home training add-on payment.

Comment: One industry organization urged CMS to adopt a pediatric adjustment for facilities that treat pediatric AKI patients, while another industry organization recognized that pediatric patients are only covered for ESRD and expressed support for our payment policy and appreciation that CMS recognizes the treatment differences in the ESRD and AKI populations.

Response: We appreciate the support and comments with regard to our AKI payment policy, especially for pediatric patients. As we evaluate and monitor the payments for AKI treatments, we will continue to evaluate the appropriateness of the ESRD case-mix adjustments, including the pediatric adjustment. The current clinical literature (*Walters, Scott & Porter, Craig & Brophy, Patrick. (2008). Dialysis and pediatric acute kidney injury: Choice of renal support Modality. Pediatric nephrology (Berlin, Germany). 24. 37–48. 10.1007/s00467–008–0826–x*) indicates that pediatric treatment for AKI is most commonly done in an intensive care unit, not an ESRD facility due to access site difficulties and fluid overload. In a review of data, we have found very few claims for pediatric AKI patients.

Comment: A national dialysis provider association and a national dialysis organization recommended modifying cost reports to separately capture certain AKI costs. Specifically, they recommended that new rows should be added to Worksheet D for AKI hemodialysis treatments and PD treatments. They stated the instructions should explain that AKI treatments are to be reported separately from all other ESRD dialysis treatments.

Response: We agree that updates will need to be made to the dialysis facility cost report in order to differentiate costs of AKI dialysis treatments from treatments provided for the treatment of ESRD. We are currently developing the transmittal that will update the cost report to allow for the differentiation between AKI treatments and treatments for ESRD.

Final Rule Action: We are finalizing the AKI payment rate as proposed, that is, based on the finalized ESRD PPS base rate. Specifically, the final CY 2018 ESRD PPS base rate is $232.37. Accordingly, we are finalizing a CY 2018 payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI as $232.37.

IV. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for Payment Year (PY) 2021

A. Background

For over 30 years, monitoring the quality of care provided to end-stage renal disease (ESRD) patients by dialysis providers or facilities (hereinafter referred to collectively as ''facility'' or ''facilities'') has been an important component of the Medicare ESRD payment system. The ESRD quality incentive program (QIP) is the most recent step in fostering improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by the Centers for Medicare & Medicaid Services (CMS).

Under the ESRD QIP, payments made to a dialysis facility by Medicare under section 1881(b)(14) of the Social Security Act (the Act) for a year are reduced by up to 2 percent if the facility does not meet or exceed the total performance score (TPS) with respect to performance standards established by the Secretary of the Department of Health and Human Services (the Secretary) with respect to certain specified measures.

In the calendar year (CY) 2012 ESRD PPS final rule (76 FR 70228), published in the **Federal Register** on November 10, 2011, we set forth certain requirements for the ESRD QIP for payment years (PYs) 2013 and 2014.

In the CY 2013 ESRD PPS final rule (77 FR 67450), published in the **Federal Register** on November 9, 2012, we set forth requirements for the ESRD QIP, including for payment year 2015 and beyond. In that rule, we added several new measures to the ESRD QIP's measure set and expanded the scope of some of the existing measures. We also established CY 2013 as the performance period for the PY 2015 ESRD QIP, established performance standards and adopted scoring and payment methodologies similar to those finalized for the PY 2014 ESRD QIP.

In the CY 2014 ESRD PPS final rule (78 FR 72156), published in the **Federal Register** on December 2, 2013, we set forth requirements for the ESRD QIP, including for PY 2016 and beyond. In that rule, we added several new measures to the ESRD QIP's measure set, established the performance period for the PY 2016 ESRD QIP, established performance standards for the PY 2016 measures, and adopted scoring and payment reduction methodologies that were similar to those finalized for the PY 2015 ESRD QIP.

In the CY 2015 ESRD PPS final rule (79 FR 66120), published in the **Federal Register** on November 6, 2014, we finalized requirements for the ESRD QIP, including for PYs 2017 and 2018. In that rule, we finalized the measure set for both PY 2017 and PY 2018, revised the In-Center Hemodialysis Consumer Assessment of Healthcare Providers System (ICH CAHPS) Reporting Measure, revised the Mineral Metabolism Reporting Measure, finalized the Extraordinary Circumstances Exemption (ECE) policy, and finalized a new scoring methodology beginning with PY 2018.

In the CY 2016 ESRD PPS final rule (80 FR 68968), published in the **Federal Register** on November 6, 2015, we set forth requirements for the ESRD QIP, including for PY 2017 through PY 2019. In that rule, we finalized the PY 2019 measure set, reinstated the ICH CAHPS Reporting Measure attestation beginning with PY 2017, and revised the small facility adjuster (SFA) beginning with PY 2017.

In the CY 2017 ESRD PPS final rule (81 FR 77834), published in the **Federal Register** on November 4, 2016, we set forth new requirements for the ESRD QIP, including new quality measures beginning with PY 2019 and PY 2020, and updated other policies for the program.

The ESRD QIP is authorized by section 1881(h) of the Act, which was added by section 153(c) of Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 1881(h) of the Act requires the Secretary to establish an ESRD QIP by (1) selecting measures; (2) establishing the performance standards that apply to the individual measures; (3) specifying a performance period with respect to a year; (4) developing a methodology for assessing the total performance of each facility based on the performance standards with respect to the measures for a performance period; and (5) applying an appropriate payment reduction to facilities that do not meet or exceed the established Total Performance Score (TPS).

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

The proposed rule, entitled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program'' (82 FR 31190 through 31233), hereinafter referred to as the CY 2018 ESRD PPS proposed rule, was published in the **Federal Register** on July 5, 2017, with a comment period that ended on August 28, 2017. In that proposed rule, we proposed updates to the ESRD QIP, including for PY 2019 through PY 2021. We received approximately 58 public comments on our proposals, including comments from large dialysis organizations, renal dialysis 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, including for PYs 2019 through 2021.

1. Accounting for Social Risk Factors in the ESRD QIP.

In the CY 2018 ESRD PPS proposed rule (82 FR 31202), we discussed the issue of accounting for social risk factors in the ESRD QIP. We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status factors or socio-demographic status factors), play a major role in health. One of our core objectives is to improve beneficiary outcomes, including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by facilities is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to high quality care.

We have reviewed reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) [1] and the National Academies of Sciences, Engineering, and Medicine on the issue of accounting for social risk factors in CMS' value-based purchasing and quality reporting programs, and considered options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors in Medicare beneficiaries on quality measures and measures of resource use that are used in one or more of nine Medicare value-based purchasing programs, including the ESRD QIP.[2] The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by The National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.[3]

As noted in the fiscal year (FY) 2017 Inpatient Prospective Payment System/ Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) final rule (81 FR 56762 through 57345), the National Quality Forum (NQF) undertook a 2-year trial period in which

[1] Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[2] Office of the Assistant Secretary for Planning and Evaluation. 2016. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[3] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

certain new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period could be assessed to determine whether risk adjustment for selected social risk factors would be appropriate for these measures. This trial entailed temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. Recently, the NQF concluded this trial (*http://www.qualityforum.org/Publications/2017/07/Social_Risk_Trial_Final_Report.aspx*), and based on its findings, the NQF will continue its work to evaluate the impact of social risk factor adjustment on intermediate outcome and outcome measures for an additional 3 years. The extension of this work will allow the NQF to determine further how to effectively account for social risk factors through risk adjustment and other strategies in quality measurement.

As we consider the analyses and recommendations from the ASPE report and the NQF trial on risk adjustment for quality measures, we are continuing to work with stakeholders. As we have previously communicated, we are concerned about holding facilities to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, we will continue to seek public comment on whether we should account for social risk factors in the ESRD QIP, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of potential methods include: Adjustment of the payment adjustment methodology under the ESRD QIP; adjustment of provider performance scores (for instance, stratifying facilities based on the proportion of their patients who are dual eligible); confidential reporting of stratified measure rates to facilities; public reporting of stratified measure rates; risk adjustment of a particular measure as appropriate based on data and evidence; and redesigning payment incentives (for instance, rewarding improvement for facilities caring for patients with social risk factors or incentivizing facilities to achieve health equity). In the CY 2018 ESRD PPS proposed rule (82 FR 31202 through 31203), we requested comment on whether any of these methods should be considered, and if so, which of these methods or combination of methods would best account for social risk factors in the ESRD QIP.

We note that in section V.I.9 of the FY 2018 IPPS/LTCH PPS final rule (82 FR 38229 through 38231), we finalized an approach for stratifying hospitals into peer groups for purposes of assessing payment adjustments under the Hospital Readmissions Reduction Program, as required under the 21st Century Cures Act of 2016 (Pub. L. 114–255). We refer readers to that section for a detailed discussion of the final policy; while this discussion is specific to the Hospital Readmissions Reduction Program, it reflects the level of analysis we would undertake when evaluating methods and combinations of methods for accounting for social risk factors in CMS' other value-based purchasing programs, such as ESRD QIP. In addition, in the CY 2018 ESRD PPS proposed rule (82 FR 31202), we requested public comment on which social risk factors might be most appropriate for stratifying measure scores and/or potential risk-adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We also requested comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the ESRD QIP. We note that any such changes would be proposed through future notice-and-comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the above methods would be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), so we also welcomed comment on operational considerations. CMS is committed to ensuring beneficiaries have access to and receive high quality care, and the quality of care furnished by providers and suppliers is assessed fairly in CMS programs.

We requested comments on accounting for social risk factors in the ESRD QIP. The comments and our responses are set forth below.

Comment: Many commenters expressed appreciation to CMS for requesting comments on how to account for social risk factors in the ESRD QIP. They argued that beneficiaries with ESRD are disproportionately affected by social risk factors and stressed that in considering factors, CMS must strike the correct balance to ensure it meets the goals of assessing providers and suppliers in a fair manner while not masking disparities or dis-incentivizing the provision of care to more medically complex patients. Commenters added that CMS should continue to support further research to examine the costs of caring for beneficiaries with social risk factors and to determine whether current payments adequately account for these differences in care needs. Some of the factors commenters recommended for consideration by CMS include: (1) Functional status, because there is evidence that those from lower socioeconomic and minority groups have poorer functional status and that this affects both their medical care and quality of life; (2) poverty and education, because dialysis facilities take care of a higher number of patients in poverty with lower levels of education and these patients tend to be less adherent to medications, diet and fluid restrictions; (3) geography, because regional variation in transplantation access is significant, as is regional differences in waitlist times, which ultimately could change the percentage of patients on the waitlist and impact a performance measure score; (4) family support; (5) ability to adhere to medication regimens; (6) capacity for follow-up; (7) insurance status; (8) income; (9) race and ethnicity; (10) disability; and (11) community resources.

One commenter pointed out the importance of accounting for risk factors that affect both pediatric patients and those caring for pediatric patients because some of these risk factors, in particular those present among the parents and caregivers of pediatric patients, may affect their ability to properly care for those patients. Commenters urged CMS to consider a more robust set of social risk factors to meet the needs of the pediatric patient population. They added that there must be an accounting not only of race and ethnicity, insurance status, and other socioeconomic factors, but also their school attendance and performance, and peer interactions. Factors to consider for parents and other primary caregivers include their employment status, fatigue, and financial strains among others. One commenter argued that dual-eligible status is the most consistent of all social risk factors in

predicting which patients will have the worst outcomes.

A few commenters expressed concerns with our desire to look at social risk factor adjustments. One commenter expressed concerns that there is already an issue with small sample sizes in the QIP, which would likely be aggravated by dividing the measure population into smaller subsets. The same commenter stated that small sample sizes disproportionately affect facilities that only furnish ESRD care to patients in their homes or those that care for a small number of pediatric ESRD patients because those facilities tend to be small and are often scored only on a few measures. To collect this data, one commenter argued that it should be straightforward for CMS to use its data to identify dual eligibility/low-income subsidy data, as well as geographic area of residence. Another commenter added that it could be difficult to collect race/ethnicity data but that patient self-reporting may be the most appropriate way to collect such data.

Response: We appreciate all the comments and interest in this topic. As we have previously stated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors, because we do not want to mask potential disparities or minimize incentives to improve outcomes for disadvantaged populations. We believe that the path forward should incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have access to excellent care. We intend to consider all suggestions as we continue to assess each measure and the overall program. We appreciate that some commenters recommended risk adjustment as a strategy to account for social risk factors, while others stated a concern that risk adjustment could minimize incentives and reduce efforts to address disparities for patients with social risk factors. We intend to conduct further analyses on the impact of strategies such as measure-level risk adjustment and stratifying performance scoring to account for social risk factors. In addition, we appreciate the recommendations from the commenters about consideration of specific social risk factor variables and will examine these variables and the feasibility of collecting one or more of these patient-level variables. As we consider the feasibility of collecting patient-level data and the impact of strategies to account for social risk factors through further analysis, we will continue to evaluate the reporting burden on providers. Future proposals would follow further research and continued stakeholder engagement.

2. Changes to the Performance Score Certificate (PSC) Beginning With the PY 2019 ESRD QIP

In the ESRD QIP final rule, which published in the **Federal Register** on January 5, 2011 (76 FR 628 through 646), we finalized a policy for informing the public of facility performance through facility-posted certificates (76 FR 637). Specifically, we finalized that these PSCs would include the following information: (1) The TPS achieved by the facility under the ESRD QIP with respect to the payment year involved; (2) comparative data that shows how well the facility's TPS compares to the national TPS; (3) the performance result that the facility achieved on each individual measure with respect to the year involved; and (4) comparative data that shows how well the facility's individual quality measure performance scores compare to the national performance result for each quality measure (76 FR 637). As the ESRD QIP has become more complex over the years and as new measures have been added to the program, the PSC has become a lengthy document that facilities are required to print and post in both English and Spanish for their patients to view (77 FR 67517). We have received feedback from the community about the difficulty patients and their families have with interpreting and understanding the information contained on the PSC due to its sheer volume and complexity.

Section 1881(h)(6)(c) of the Act only requires that the PSC indicate the TPS achieved by the facility with respect to a program year. Therefore, to make the PSC a more effective and understandable document for the community, we proposed to shorten the PSC by removing some of the information that is currently included on it. We proposed that beginning in PY 2019, and continuing in future years, the PSC would indicate the facility's TPS, as required under section 1881(h)(6)(C) of the Act, as well as information sufficient to identify the facility (for example, name, address, etc.). Additionally, we proposed to include information showing how the facility's TPS compared to the national average TPS for that specific payment year. We did not propose any other changes to the requirements we previously finalized for the PSC.

We requested comments on this proposal, and were particularly interested in comments on whether the reduced amount of information on the PSC would both benefit facilities and enhance the public's understanding of the TPS.

Comment: Several commenters supported CMS's proposed simplification of the PSC and agreed that the changes would make it easier for patients to understand the facility's performance score. One commenter recommended that CMS review the white papers commissioned by Agency for Healthcare Research and Quality on ''Best Practices in Public Reporting,'' which the commenter believes provide a good overview of principles for presenting health care quality information to consumers.

Response: We thank the commenters for their support. Our proposal was intended, in part, to address feedback we obtained during two patient engagement sessions that were open to the public.[4] The majority of patients who took part in these sessions reported that they felt overwhelmed by the amount of information that we currently include on the PSC, did not understand all of the information, and that they focused mainly on specific data such as the facility scores or the comparison of facility scores with the national median. Patients also requested that the information be simplified and translated into plain language. We believe that our changes to the PSC will make it easier for patients and their caregivers to understand how facilities perform under the ESRD QIP.

We will review the recommended reports and determine the feasibility of incorporating some of these suggestions.

Comment: Several commenters did not support CMS's proposals to simplify the PSC, stating that the PSC should provide more rather than fewer details and that the current PSC helps patients make informed decisions about their care. One commenter pointed out that section 1881(h)(6)(C) of the Act only refers to the TPS, but that section 1881(h)(6)(A) of the Act calls upon the Secretary to make information available to the public including the total score, comparisons to the national average, and performance on individual measures.

Response: We thank commenters for sharing their concerns. Our proposal was intended to make the PSC easier to understand while still conveying important information about facility performance under the ESRD QIP. However, we agree that the data we are

[4] ''Executive Summary of the December 13 DFC–ESRD QIP Patient Listening Session at the CMS Quality Conference,'' December 20, 2016.

''Dialysis Facility Compare Patient Engagement Session Debrief,'' April 3, 2017, NORC at the University of Chicago.

removing, as well as other ESRD QIP related data, should continue to be publicly available. We intend to report these data on Dialysis Facility Compare (DFC) and cms.gov.

Comment: A patient advocacy organization recommended that the PSC be simplified by including just a simple cumulative number, such as the TPS, because it believed that this number would be most useful, and would be something that most people would likely look at. This organization also believed that it is potentially confusing to have the national average presented along with the national median given that very few people understand what a median is. The organization additionally thought that the phrases for each row would be more understandable and helpful if they were worded in a simpler manner, decimals and percentages should be presented consistently, and that the language around scores could be simplified.

Response: We thank the commenter for sharing these recommendations for ways to improve the PSC. We believe the revised PSC will address the commenter's recommendations. The revised PSC contains a more simply displayed TPS for each facility as well as the national average, but no national median. We are excluding the national median because it does not increase understanding of facility performance and may cause unnecessary confusion. The new PSC also does not contain decimals or percentages unless the average is a decimal, and it directs those viewing the document to review additional information on the *CMS.gov* Web site and on Dialysis Facility Compare. We are still considering the best format for display and we intend to make the explanations on the PSC as plan language as possible to increase understanding of the document.

Final Rule Action: After careful consideration of the comments received, we are finalizing our proposal, as proposed, to update the PSC. We believe these changes will help make the document more easily readable and understandable by the community. The information being removed from the PSC will still be available in other locations and we encourage beneficiaries and their families to use all the resources currently available to them to make informed decisions about the care they receive.

3. Requirements Beginning With the PY 2020 ESRD QIP

a. Clarification of the Minimum Data Policy for Scoring Measures Finalized for the PY 2020 ESRD QIP

Under our current policy, we begin counting the number of months in which a facility is open on the first day of the month after the facility's CMS certification number (CCN) Open Date. In the CY 2017 ESRD PPS final rule (81 FR 77926), we inadvertently made errors in finalizing how we intended this policy to apply to a number of measures in the PY 2020 ESRD QIP.

Table 19 finalized in the CY 2017 ESRD PPS final rule (81 FR 77926) has been duplicated here, as Table 2(a):

TABLE 2(a)—PREVIOUSLY FINALIZED 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.

In the CY 2018 ESRD PPS proposed rule (82 FR 31203), we proposed the intended application of this policy for PY 2020. We did not propose to make any changes to the methodology we use to count the number of months for which a facility is open for purposes of scoring facilities on clinical and reporting measures, or to the minimum number of cases (qualifying patients, survey-eligible patients, index discharges, or patient-years at risk) that

applies to each measure. Table 2(b) displays the proposed revised patient minimum requirements for each of the measures finalized for PY 2020, as well as the proposed revised CCN Open Dates after which a facility would not be eligible to receive a score on a reporting measure.

TABLE 2(b)—PROPOSED REVISED 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	Before January 1, 2018	11–25 qualifying patients.
NHSN Dialysis Event (Reporting).	11 qualifying patients	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.	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, 2018	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 requested comments on this proposal.

Comment: Commenters were appreciative of the clarification CMS provided on the minimum number of cases.

Response: We thank commenters for their support.

Comment: Several commenters expressed concern with using sample sizes as small as 11 and argued that the small sample size exposes the ESRD QIP scores to random results that are not fully compensated by the SFA. One commenter urged CMS to adopt a minimum sample size of 26 patients and to eliminate the SFA altogether. The commenters suggested that there are many ways in which small facilities can be included while avoiding random results.

Response: We appreciate the commenters' concerns. However, because we did not propose to change the minimum number of cases that apply to each measure, or to revisit the SFA, we consider these comments to be outside the scope of the proposed rule and are not addressing them in this final rule.

Final Rule Action: Based on the comments received, we are finalizing the proposed minimum data requirements for the PY 2020 ESRD QIP, as described in Table 2(b) above.

b. Changes to the Extraordinary Circumstances Exception (ECE) Policy

Many of our quality reporting and value-based purchasing programs share a common process for requesting an exception from program reporting due to an extraordinary circumstance not within a facility's control. The Hospital Inpatient Quality Reporting, Hospital Outpatient Quality Reporting, Inpatient Psychiatric Facility Quality Reporting, Ambulatory Surgical Center Quality Reporting, PPS-Exempt Cancer Hospital Quality Reporting, the Hospital Acquired Condition Reduction Program, and the Hospital Readmissions Reduction Program all share common processes for Extraordinary Circumstances Exception (ECE) requests. In reviewing the policies for these programs, we recognized that there are five areas in which these programs have variance in comparison to the policy within the ESRD QIP regarding ECE requests. These are: (1) Allowing the facilities or hospitals to submit a form signed by the facility's or hospital's chief executive officer (CEO) versus CEO or designated personnel; (2) requiring the form be submitted within 30 days following the date that the extraordinary circumstance occurred, versus within 90 days following the date the extraordinary circumstance occurred; (3) inconsistency regarding specification of a timeline for us to provide our response notifying the facility or hospital of our decision; (4) inconsistency regarding whether we would grant ECEs based on a facility's inability to timely and completely report data due to CMS data system issues; and (5) referring to this policy as ''extraordinary extensions/exemptions'' versus as ''extraordinary circumstances exceptions''. We believe that aligning the way the ECE policy is implemented in our program, with the way it is implemented in the programs listed

above, can improve the overall administrative efficiencies for affected facilities or hospitals.

In the CY 2015 ESRD PPS final rule (79 FR 66120 through 66265), we finalized that to receive consideration for an exception from the ESRD QIP requirements in effect during the time period that a facility is affected by an extraordinary circumstance, facilities would need to be closed and provide CMS with a CMS Disaster Extension/Exception Request Form within 90 calendar days of the date of the disaster or extraordinary circumstance (79 FR 66190). We finalized that the facility would need to provide the following information on the form:

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

We also finalized that we would consider granting an ECE to facilities absent a request, if we determine that an extraordinary circumstance affected an entire region or locale (79 FR 66190).

We proposed to update these policies by: (1) Allowing the facility to submit a form signed by the facility's CEO or designated personnel; (2) expanding the reasons for which an ECE can be requested to include an unresolved issue with a CMS data system, which affected the ability of the facility to submit data (an unresolved data system issue would be one which did not allow the facility to submit data by the data submission deadline and which was unable to be resolved with a work-around), and (3) specifying that a facility does not need to be closed in order to request and receive consideration for an ECE, as long as the facility can demonstrate that its normal operations have been significantly affected by an extraordinary circumstance outside of its control. We stated that these proposed policies generally align with policies in the Hospital Inpatient Quality Reporting Program (76 FR 51651 through 51652), (78 FR 50836 through 50837) and (81 FR 57181 through 57182), Hospital Outpatient Quality Reporting Program (77 FR 68489 and 81 FR 79795), as well as ECE policies we have finalized for other quality reporting and value-based purchasing programs. We proposed that these policies would apply beginning with the PY 2020 ESRD QIP, as related to extraordinary circumstance events that occur on or after January 1, 2018.

We also noted that there may be circumstances in which it is not feasible for a facility's CEO to sign the ECE request form. In these circumstances, we believe that facilities affected by such circumstances should be able to submit an ECE request regardless of the CEO's availability to sign. This proposed change would allow facilities to designate an appropriate, non-CEO contact for this purpose. We would accept ECE forms which have been signed by designated personnel.

Although we do not anticipate that unresolved issues with CMS data systems will happen on a regular basis, we also stated that we recognized that there may be times when CMS experiences issues with its data systems that inhibits facilities' ability to submit data. We are often able to resolve such issues and allow facilities an extended period of time to report the data. However, in the case that the issue inhibits the complete reporting of data (even under an extended deadline), we stated that we believed it would be inequitable to take the absence of such unreported data into account when computing a facility's TPS for a payment year. Therefore, we proposed to address these situations in one of two ways. In some cases, CMS would issue a blanket exception to facilities that have been affected by an unresolved technical issue. In such cases, facilities would not be required to submit an ECE request to CMS, and CMS would send communications about the blanket exception to the affected facilities using routine communication channels. In other cases, CMS would not issue a blanket exception to facilities. In these cases, facilities would be required to submit an ECE request to CMS using the regular ECE request process, and would need to indicate how they were directly affected by the technical issue.

Furthermore, we stated our belief that it is important for facilities to receive timely feedback regarding the status of ECE requests. We strive to complete our review of each ECE request as quickly as possible. However, we recognize that the number of requests we receive, and the complexity of the information provided impacts the actual timeframe to make ECE determinations. To improve the transparency of our process, we stated that we would strive to complete our review of each request within 90 days of receipt.

We requested comments on these proposals.

Comment: Commenters supported CMS's proposed modifications to the ECE policy in the ESRD QIP, and urged CMS to finalize the proposal. One commenter requested that CMS issue clear guidance on the criteria used to deny or approve an ECE to ensure that approvals and denials are made consistently, uniformly, and in a manner that ensures that dialysis facilities can rely on such guidance from CMS as they make determinations about whether to submit an ECE request.

Response: We thank commenters for their support of our proposals to update the ECE policy in the ESRD QIP. When considering ECE requests that we receive from facilities, we consider all information provided by the facility. We consider whether the facility submitted the request in a timely manner and included all required information on its ECE request form. We consider the reason for the closure and the strength of the supporting documentation provided. We take each request under consideration and decide based on all the evidence provided.

Comment: One commenter recommended that CMS add a separate exclusion for dialysis camps, given their very limited operating schedules. Another commenter recommended that CMS grant ECEs to camps that request them. According to these commenters, these camps, which operate for short, well-defined periods during the year, make it possible for ESRD pediatric patients to have a traditional camp experience but are often penalized under the ESRD QIP.

Response: We appreciate commenter's concerns. However, the camps referred to by the commenters furnish renal dialysis services (as defined in section 1881(b)(14)(B)) and, for that reason, we have no discretion to exclude them from the ESRD QIP, if they otherwise meet the program's eligibility requirements (such as the minimum data requirements, CCN open date, etc.). We also see no basis to grant ECEs to facilities that otherwise meet the program's eligibility requirements simply because they are not open for the entire year. The ECE policy was designed to provide relief to renal dialysis facilities that experience extraordinary circumstances outside of their control. Although we recognize the role that these camps may play in improving the quality of life for pediatric ESRD patients, we do not view their partial year operating status as a circumstance outside of their control. We also see no reason for not holding these facilities accountable to the same quality standards of care that apply to other facilities under the ESRD QIP.

Comment: One commenter requested clarification of the term ''designated personnel'', and asked for information about how someone would be designated as such.

Response: We expect that each facility will have its own process for designating personnel with appropriate authority to sign an ECE request on behalf of the facility, and we will accept an ECE request signed either by the facility's CEO or such designated personnel.

Final Rule Action: After careful consideration of the comments received, we are finalizing the updates to the ECE policy as proposed.

c. Solicitation of Comments on the Inclusion of Acute Kidney Injury (AKI) Patients in the ESRD QIP

The services for which quality is measured under the ESRD QIP are renal dialysis services defined in section 1881(b)(14)(B) of the Act. Prior to January 1, 2017, these services could only be covered and reimbursed under Medicare if they were furnished to individuals with ESRD, but they are now also covered and reimbursed if they are furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with acute kidney injury (AKI) (see sections 1861(s)(2)(F) and 1834(r) of the Act).

We currently do not require facilities to report AKI patient data for any of our measures in the ESRD QIP, including the National Healthcare Safety Network (NHSN) Bloodstream infection (BSI) Clinical and Reporting Measures.[5] However, we now have the authority to collect data on this patient population and believe that it is vitally important to monitor and measure the quality of care furnished to these patients.

In the future, we intend to require facilities to report data on AKI patients under the ESRD QIP. We requested comments on whether and how to adapt any of our current measures to include this population, as well as the type of measures that might be appropriate to develop for future inclusion in the program that would address the unique needs of beneficiaries with AKI.

Comment: Several commenters supported the inclusion of those with AKI into the ESRD QIP. One commenter stated that because the incidence of AKI is increasing, and is estimated to double over the next decade, it's important to collect data on this population and to include them in performance calculations.

Response: We agree that the quality of care afforded to AKI patients by dialysis facilities is an emergent issue in dialysis care, and collecting data on that care is important. Including AKI patients in the ESRD QIP will require careful consideration of the clinical appropriateness of including them in each measure.

Comment: Many commenters did not support the inclusion of AKI patients in the ESRD QIP. They stressed that CMS should continue to gather and evaluate AKI data before proposing to include AKI patient outcomes in any QIP measure and expressed concerns regarding the appropriateness of including AKI patients in any of the measures currently included in the program. Several commenters made measure-specific recommendations about why AKI patients should not be included in the NHSN BSI measures, the Vascular Access measures, and the Dialysis Adequacy measures. Many commenters stressed that if AKI patients are included in the QIP, then the program should use quality measures based solely on data from AKI patients, which are supported by AKI care guidelines.

Response: We thank the commenters for sharing their concerns regarding the inclusion of AKI patients in the ESRD QIP generally, and for their recommendations regarding the inclusion of AKI patients in specific quality measures. We intend to systematically evaluate the appropriateness of including AKI patients in our existing quality measures through our measure maintenance process, and in new measures that could be focused specifically on that subset of patients treated by facilities. In considering the inclusion of AKI patients in our measures, we intend to apply the same standards that we use to determine the applicability of our measures to specific patient populations, which include seeking input from clinical experts and other stakeholders. We would also consider the clinical differences between ESRD dialysis patients and AKI patients, as well as the relatively small number of AKI patients currently being treated by dialysis facilities.

Comment: A few commenters argued that while monitoring AKI patients is important and supported CMS' efforts to do so, CMS only has statutory authority to apply the QIP to beneficiaries with ESRD. Commenters argued that the statute establishing and governing the ESRD QIP is limited to ''individuals who have been determined to have end-stage renal disease as determined in section 226A of the Act,'' and that this limitation excludes AKI patients from the ESRD benefit and programs. Commenters pointed out that the ESRD QIP statutory language further defines the quality incentive as avoiding a payment reduction to the rates paid under section 1881(b)(14) of the Act and noted that facilities that provide services to AKI patients are paid under section 1834(r) of the Act.

Response: We continue to believe that we have authority to collect data on the AKI patient population from facilities under the ESRD QIP and that it is important to hold facilities accountable for the quality of renal dialysis services furnished to those patients. We appreciate the feedback we received on this issue and we will take it into account as we consider whether to make proposals related to this population in future rulemaking.

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

In the CY 2017 ESRD PPS final rule (81 FR 77834 through 77969), we finalized that for PY 2020, 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 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 (81 FR 77915). We stated in the CY 2018 ESRD PPS proposed rule that we did not have the necessary data to assign numerical values to those performance standards, achievement thresholds, and benchmarks because we did not yet have complete data from CY 2016. Nevertheless, we could estimate these numerical values based on the most recent data available at the time we issued the CY 2018 ESRD PPS proposed rule, and we have since updated those values based on more recently available data. For the vascular access type (VAT), Hypercalcemia, NHSN BSI, In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS), Standardized Readmission Ratio (SRR), Standardized Hospitalization Ratio (SHR), Kt/V Dialysis Adequacy, and Standardized Transfusion Ratio (STrR) clinical measures, this data came from the period of January through December 2015. In Table 3, we provided the

[5] To the extent that the CDC requests facilities to report AKI patient data under its own, separate, statutory authority, data on these patients are not shared with CMS or used in the calculation of any ESRD QIP measures, including the NHSN Clinical and Reporting Measures.

estimated numerical values for all finalized PY 2020 ESRD QIP clinical measures (these are the values we estimated in the proposed rule). In Table 4, we have provided updated values for the clinical measures, using data from the first part of CY 2017.

TABLE 3—ESTIMATED NUMERICAL VALUES FOR THE PERFORMANCE STANDARDS FOR THE PY 2020 ESRD QIP CLINICAL MEASURES

Measure	Achievement threshold	Benchmark	Performance standard
VAT:	.....	.....	.....
%Fistula	53.66%	79.62%	65.93%
%Catheter	17.20%	2.95%	9.19%
Kt/V Dialysis Adequacy Comprehensive	87.37%	97.74%	93.20%
Hypercalcemia	4.24%	0.32%	1.85%
STrR	1.488	0.421	0.901
SRR	1.271	0.624	0.998
NHSN BSI	1.738	0	0.797
Standardized Hospitalization Ratio measure (SHR)	1.244	0.672	0.970
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%

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

Our current policy generally is that if final numerical values for the performance standard, achievement threshold, and/or benchmark are worse than they were for that measure in the previous year of the ESRD QIP, then we will substitute the previous year's performance standard, achievement threshold, and/or benchmark for that measure. We adopted this policy because we believe that the ESRD QIP should not have lower performance standards than in previous years. In the CY 2017 ESRD PPS final rule, we finalized an update to that policy because in certain cases, it may be appropriate to re-baseline the NHSN BSI Clinical Measure, such that expected infection rates are calculated based on a more recent year's data (81 FR 77886). In such cases, numerical values assigned to performance standards may appear to decline, even though they represent higher standards for infection prevention. For PY 2020 and future payment years, we proposed to continue use of this policy for the reasons explained above. Under that policy, except for the NHSN BSI Clinical Measure, we would substitute the PY 2019 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 2019 ESRD QIP. We would also substitute the PY 2019 values for two CAHPS measures: (1) ICH CAHPS: Overall Rating of Nephrologists and (2) ICH CAHPS: Overall Rating of Dialysis Center Staff because the final numerical values for those measures were worse for PY 2020 than they were for PY 2019.

Final Rule Action: We did not receive comments on our proposal to continue our policies for substituting the performance standard, achievement threshold and benchmark in appropriate cases. We are therefore, finalizing our proposal to continue use of these policies for PY 2020 and future payment years, as proposed. We are also updating the performance standards, achievement thresholds, and benchmarks for the finalized PY 2020 ESRD QIP clinical measures as shown in Table 4, using the most recently available data.

TABLE 4—FINALIZED PERFORMANCE STANDARDS FOR THE PY 2020 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

Measure	Achievement threshold	Benchmark	Performance standard
Vascular Access Type (VAT):			
%Fistula	53.95%	79.90%	65.98%
%Catheter	17.22%	3.11%	9.40%
Kt/V Dialysis Adequacy Comprehensive	91.09%	98.56%	95.64%
Hypercalcemia	2.41%	0.00%	0.86%
Standardized Transfusion Ratio (STrR)	1.444	0.429	0.889
Standardized Readmission Ratio (SRR)	1.273	0.629	0.998
NHSN Bloodstream Infection	1.598	0	0.740
Standardized Hospitalization Ratio measure (SHR)	1.249	0.670	0.967
ICH CAHPS: Nephrologists' Communication and Caring	57.36%	78.09%	67.04%
ICH CAHPS: Quality of Dialysis Center Care and Operations	53.14%	71.52%	61.22%
ICH CAHPS: Providing Information to Patients	73.31%	86.83%	79.79%
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%

TABLE 4—FINALIZED PERFORMANCE STANDARDS FOR THE PY 2020 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA—Continued

Measure	Achievement threshold	Benchmark	Performance standard
ICH CAHPS: Overall Rating of the Dialysis Facility	52.24%	82.48%	66.82%

Data sources: VAT measures: 2016 CROWNWeb; SRR, STrR, SHR: 2016 Medicare claims; Kt/V: 2016 CROWNWeb; Hypercalcemia: 2016 CROWNWeb; NHSN: 2016 CDC, ICH CAHPS: CMS 2016.

e. Policy for Weighting the Clinical Measure Domain for PY 2020

In the CY 2017 ESRD PPS final rule, we finalized our policy for weighting the Clinical Measure Domain for PY 2020. With the addition of the Safety Measure Domain to the ESRD QIP, we finalized that the Clinical Measure Domain would comprise 75 percent of the TPS, the Safety Measure Domain would comprise 15 percent of the TPS and the Reporting Measure Domain would comprise 10 percent of the TPS. Table 5 shows the weights finalized for PY 2020 for the Clinical Measure Domain.

TABLE 5—FINALIZED CLINICAL MEASURE DOMAIN WEIGHTING FOR THE PY 2020 ESRD QIP

Measures/measure topics by subdomain	Measure weight in the clinical domain score (percent)	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
VAT measure topic	18	13.5
Hypercalcemia measure	2	1.5
SHR measure	11	8.25
Total	100% (of Clinical Measure Domain)	75% (of TPS)

Note: The percentages listed in this Table represent the measure weight as a percent of the Clinical Domain Score for PY 2020.

We did not propose any changes to these weights, but we received a few comments.

Comment: Some commenters recommended that we increase the weight of the VAT Catheter Measure and decrease the weight of the VAT Fistula Measure to emphasize the clinical benefits of eliminating catheters. Additionally, a commenter recommended that CMS adopt a set of global exclusions that would consistently apply to all measures, which would be automatically applied unless there is a specific clinical or operational reason they should not be.

Response: We appreciate the commenters' recommendations. However, because we did not make any proposals related to these specific policy areas, we consider these comments to be out of the scope of the proposed rule. Therefore, we have not addressed them in this final rule.

f. 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 ESRD QIP scoring methodology results in an appropriate distribution of payment reductions across facilities, such that facilities achieving the lowest TPS receive the largest payment reductions. In the CY 2017 ESRD PPS final rule, we finalized our proposal for calculating the minimum TPS for PY 2020 and future payment years (81 FR 77927). 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: (1) It performs at the performance standard for each clinical measure; and (2) it receives 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 (81 FR 77927).

We were unable to calculate a minimum TPS for PY 2020 in the CY 2017 ESRD PPS final rule because we did not yet have the data to calculate the performance standards for each of the clinical measures. We therefore stated that we would publish the minimum TPS for the PY 2020 ESRD QIP in the CY 2018 ESRD PPS final rule (81 FR 77927). We estimated the minimum TPS for PY 2020, along with the updated payment reduction scale, in Table 5 in the proposed rule (renumbered as Table 6 in this final rule). Based on the estimated performance standards which we provided in the CY 2018 ESRD PPS proposed rule (82 FR 31207) and listed above, we estimated that a facility would need to meet or exceed a minimum TPS of 61 for PY 2020. For all the clinical measures, these data came from CY 2015. We proposed that a facility failing to meet the minimum TPS, would receive a payment reduction based on the estimated TPS ranges indicated in Table 6.

TABLE 6—ESTIMATED PAYMENT REDUCTION SCALE FOR PY 2020

Total performance score	Reduction (%)
100–61	0
60–51	0.5
50–41	1.0
40–31	1.5
30–21	2.0

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

Comment: One commenter asked CMS to fix an error in the CY 2018 ESRD PPS proposed rule, Table 5 (Table

6 in this final rule), titled ''Estimated Payment Reduction Scale for PY 2020 Based on the Most Recently Available Data,'' stating that the last line should be corrected to read ''30–0''. The commenter stated that the table, as published in the proposed rule, does not include the TPS range between 0 and 20.

Response: We thank the commenter for pointing out this error. We inadvertently neglected to include in Table 5 (Table 6 in this final rule) of the proposed rule that the payment reduction would be 2.0 percent for facilities that achieve a TPS between 30–0. We have included the final TPS ranges in Table 7 based on the most recently available data.

Final Rule Action: After consideration of the comments received and an analysis of the most recently available data, we are finalizing that the minimum TPS for PY 2020 will be 59. We are also finalizing the payment reduction scale shown in Table 7.

TABLE 7—FINALIZED PAYMENT REDUCTION SCALE FOR PY 2020 BASED ON THE MOST RECENTLY AVAILABLE DATA

Total performance score	Reduction (%)
100–59	0
58–49	0.5
48–39	1.0
38–29	1.5
28–0	2.0

g. Data Validation

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. We began a pilot data validation program in CY 2013 for the ESRD QIP, and procured the services of a data validation contractor that was tasked with validating a national sample of facilities' records as reported to CROWNWeb. For validation of CY 2014 data, our priority was to develop a methodology for validating data submitted to Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) under the pilot data validation program. In the CY 2014 ESRD PPS final rule (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, PY 2018 and PY 2019 ESRD QIP, and proposed to continue doing so for the PY 2020 ESRD QIP. Using the data collected thus far, we are exploring options for refining the methodology used to improve the effectiveness and reliability of the data collected. For future payment years, we will consider whether this validation effort should continue in pilot status or as a permanent feature of the ESRD QIP. Under the continued validation study, we will sample the same number of records (approximately 10 per facility) from the same number of facilities, which totaled 300 facilities during CY 2018. 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 proposed to deduct 10 points from the facility's TPS.

In the CY 2015 ESRD PPS final rule (79 FR 66120 through 66265), we finalized a feasibility study for validating data reported to the CDC's NHSN Dialysis Event Module for the NHSN BSI Clinical Measure (OMB #0938–NEW). Healthcare-acquired infections 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 2020 ESRD QIP, we proposed to continue conducting the same NHSN dialysis event validation study, that we finalized in the CY 2017 ESRD PPS final rule for PY 2019 (81 FR 77894). For PY 2020, we would continue to 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 2018. However, for PY 2020, the sampling method used to select the 35 facilities would be adjusted such that a more representative sample of facility data can be analyzed, including data from high performing facilities as well as facilities identified as being at risk of underreporting. A CMS contractor would send these facilities requests for medical records for all patients with ''candidate events'' during the evaluation period; that is, 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 would have 60 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 would send a request for additional, randomly selected patient records from the facility. The facility would have 60 calendar days from the date of the letter to respond to the request. With input from the CDC, the CMS contractor would use a methodology for reviewing and validating records from selected patients, 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 information or medical records within 60 calendar days of receiving a request, then we proposed to deduct 10 points from the facility's TPS. We stated that 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. In future years of the program we may also look to improve the NHSN dialysis event validation study by validating records from a greater number of facilities or by validating a larger sample of records from each facility participating in the study.

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

Comment: Several commenters supported CMS's efforts to continue the NHSN BSI Data Validation Study and supported the efforts of CDC around BSI prevention. One commenter specifically supported CMS's efforts to include both high performing facilities and those at risk of under-reporting. Another commenter expressed that a larger, more representative sample is needed for validation. A few commenters applauded CMS for working with CDC on the proposed methodology for data validation and recommended that the sample size of facilities be increased to 5 percent, consistent with the dialysis facility validation sample size for CROWNWeb data. One commenter pointed out that CMS should include a diverse group of facilities to ensure that the major providers are not over-represented in the sample. The commenter encouraged CMS to use lessons learned from the CY 2017 data validation study when conducting the CY 2018 validation survey.

Response: We thank the commenters for sharing their recommendations, and we appreciate their support. We agree that it's important to monitor and prevent infections and that it's important to continue conducting validation to ensure that the data received on infections is accurate and complete so that CMS and CDC can continue in their efforts to help facilities with infection prevention. We also agree that an increase in the sample size of the NHSN validation study will allow us to more comprehensively validate the BSI data. We are currently working closely with CDC to determine whether we should propose in future rulemaking to change the current sample size, and as part of that analysis, we are considering how to best ensure that the sample size includes a diverse group of facilities that does not over or under-represent any particular type of facilities.

Comment: One commenter expressed concerns with the accuracy of NHSN Data and recommended that CMS mandate reporting of culture results to NHSN by the lab processing the specimen, and when Regional Health Information Exchanges become operational in all communities, mandate participation in an Exchange by all laboratories processing blood cultures. The commenter also recommended that there should be an ongoing auditing of at least 10 percent of facilities to provide an incentive for diligent data collection and honest and accurate reporting. Additionally, the commenter recommended that the NHSN BSI Clinical Measure remain in the program as a reporting measure only until such an ongoing audit can be put in place.

Response: We thank the commenter for their recommendations and will continue working with CDC to identify ways to assess and strengthen the overall accuracy of NSHN BSI data. We remind commenters that the overall purpose of the validation under the ESRD QIP is to ensure that renal dialysis facilities are reporting accurate and complete information to CMS for purposes of calculating their TPSs. While we agree that one way to encourage all facilities to report accurate BSI data would be to require a larger number of facilities to participate in a given year, we are also examining whether we can achieve the same goal of accurate reporting in other ways that may be less burdensome and more cost-efficient.

Comment: One commenter requested that CMS make the results of the CROWNWeb validation publicly available. Another commenter questioned whether CMS has not released any validation results because those results would show that CROWNWeb is not a reliable data collection tool and that the NHSN BSI Measure is not valid.

Response: We thank the commenter for sharing this recommendation. However, one of our main goals for validation is to give feedback that the selected facility can use to make internal improvements to its reporting processes, and we do not think it would be beneficial to make this feedback public. Further, given the small sample size, we are concerned that publicly releasing the information would threaten the confidentiality and privacy of facilities that are chosen to participate in the validation study. To date, our validation studies have not shown any concerns with the reliability of data reported to CROWNWeb or NHSN. In fact, our most recent CROWNWeb Validation Study found an overall error rate of 3.4 percent (95 percent confidence interval of 1.3 percent to 5.5 percent) for the CROWNWeb system. Given stakeholders continued concerns, we will consider providing a national summary report, validation fact sheet, or similar document that summarizes high-level aggregate results from each validation study.

Comment: Several commenters expressed concerns that the Data Validation Study is actually an audit and suggested that a true audit process would provide appropriate due process, including the right to appeal adverse decisions. One commenter argued that the timeframe for response is inadequate and that the penalty for failing to comply with it is disproportionately severe when compared to the problem being identified. The same commenter also recommended that while the validation ''study'' is taking place, CMS should not reduce a facility's ESRD QIP score because the purpose of the study is to assess future policies to ensure the accuracy of NHSN data. One commenter asked CMS to clearly state in the final rule the reason why the validation studies are necessary and, if the purpose is to audit facilities, the commenter asked that CMS provide appropriate due process. Another commenter acknowledged that CMS has an interest in auditing quality data submissions to ensure their accuracy at the individual facility level, but questioned why CMS continues to refer in the ESRD QIP to a ''validation study'' rather than an audit program of CROWNWeb data submissions and the NHSN BSI Clinical Measure.

Response: We thank commenters for sharing their concerns. As we stated in the CY 2016 ESRD PPS final rule (80 FR 69049), the data validation studies are not designed to be an audit, but rather to assess the capacity of renal dialysis facilities to provide accurate and complete data on performance measures, and to find ways to assist them in improving their data reporting. It is meant to be a collaborative effort between CMS and the facilities selected for validation with the goal of determining ways to improve the process for all facilities. An audit, by contrast, would be a more directed search for errors and punitive in nature. We are also using the validation data to improve the integrity of data reported to CROWNWeb and NHSN; whereas we would use the data collected through an audit to detect inaccuracies in reported data and reconcile those differences. Additionally, information gathered from the validation studies is used to develop training and/or education modules to assist facilities that may be having trouble with reporting complete and accurate data to CROWNWeb or NHSN.

Final Rule Action: After carefully considering the comments received, we are finalizing our data validation studies for PY 2020 as proposed.

4. Requirements for the PY 2021 ESRD QIP

a. Measures for the PY 2021 ESRD QIP

We previously finalized 16 measures in the CY 2017 ESRD PPS final rule for the PY 2020 ESRD QIP. Our policy is to continue using measures unless we propose to remove or replace them, (77 FR 67477), therefore, we will continue to use all but two of these measures in the PY 2021 ESRD QIP. In the CY 2018 ESRD PPS proposed rule, we proposed to replace the two VAT Clinical Measures with the Hemodialysis Vascular Access: Standardized Fistula Rate Clinical Measure and the Hemodialysis Vascular Access: Long-Term Catheter Rate Clinical Measure beginning with PY 2021. The measures being continued in PY 2021 are summarized in Table 8.

TABLE 8—PY 2020 ESRD QIP MEASURES BEING CONTINUED IN PY 2021

NQF Number	Measure title and description
0258	ICH CAHPS Survey Administration, a clinical measure. Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple testing tools.
2496	SRR, a clinical measure. Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
2979	STrR, 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.
N/A	Kt/V Dialysis Adequacy Comprehensive, a clinical measure. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
1454	Hypercalcemia, a clinical measure. Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463*	SHR, a clinical measure. Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
0255	Serum Phosphorus, a reporting measure. Percentage of all adult (≥18 years of age) peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum or plasma phosphorus measured at least once within month.
N/A	Anemia Management Reporting, a reporting measure. Number of months for which facility reports erythropoiesis-stimulating agent (ESA) dosage (as applicable) and hemoglobin/hematocrit for each Medicare patient, at least once per month.
Based on NQF #0420	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.
Based on NQF #0418	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.
Based on NQF #0431	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	Ultrafiltration Rate, a reporting measure. Number of months for which a facility reports elements required for ultrafiltration rates for each qualifying patient.
Based on NQF #1460	NHSN BSI in Hemodialysis Patients, a clinical measure. The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event Reporting Measure. Number of months for which facility reports NHSN Dialysis Event data to CDC.

*We note that the complete lists of ICD–10 codes associated with the Standardized Readmission Ratio Clinical Measure and the Standardized Hospitalization Ratio Clinical Measure included in the ESRD QIP for PY 2020 are included in the Measure Technical Reports, available here: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html*.

We did not propose any changes to the measures previously finalized and continuing for PY 2021, however we received two comments requesting clarification on measures continuing in PY2021 and a number of comments on ways to improve those measures in the ESRD QIP. Those comments and our responses are set forth below.

Comment: One commenter asked why CMS removed transient patients from the set of exclusions for the Serum Phosphorus Reporting Measure.

Response: The measure specification language was changed from excluding transient patients to needing to be in the facility for the entire month as an inclusion criterion. This was done to clarify how we identify eligible patients for the measure, and aligns the measure more closely with how CROWNWeb (the data source) attributes patients to a facility. There is essentially no difference in application between the previous and updated specification. The updated specification also makes the Serum Phosphorus Reporting Measure that we use in the ESRD QIP more consistent with the specifications for the Serum Phosphorus Reporting Measure that is endorsed by the NQF (NQF #0255), and which evaluates the extent to which facilities monitor and report patient phosphorus levels.

Comment: One commenter asked about the Standardized Readmission Ratio (SRR) Clinical Measure, inquiring why CMS removed amputation status and added functional disability to the list of past-year comorbidity adjustments in the risk model.

Response: We used the term ''functional disability'' in a measure methodology report that lists the coefficients for the past year comorbidity adjustments but defined that term to mean hierarchical condition groupers (177 and 178) which describe amputation status (the measure Methodology report is available here: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html*). Moving forward, we will use the term ''Amputation,'' because that term more correctly describes the comorbidity being risk adjusted under the measure.

Comment: Regarding the Serum Phosphorus Reporting Measure, one commenter expressed concerns that requiring facilities to report phosphorus results from the first month that a patient is on home hemodialysis represents a barrier to home dialysis. We understood this to be a reference to concerns about the complexity of transitioning into home hemodialysis as a treatment modality, and the timing of obtaining the blood draw necessary for the data.

Regarding the Comprehensive Dialysis Adequacy measure, commenters expressed concerns that Kt/V is an outdated measure of dialysis adequacy and shared that there are other tests which would indicate optimal dialysis such as the Beta-2 microglobulin or a 24-hour urine test. One commenter stressed that it's important to include a measure of residual kidney function, particularly for peritoneal dialysis patients.

Regarding the ICH CAHPS measure, commenters argued that the measure should be included in the program as a reporting measure rather than as a clinical measure, that the survey should only be conducted once a year because twice-yearly administration leads to patient fatigue, limiting feedback on patient experiences, and that the survey should be split into three separate and independently tested sections rather than requiring the entire survey twice a year. Commenters also stressed the need for a separate survey for home hemodialysis patients.

Regarding the NHSN BSI Clinical and Reporting Measures, commenters pointed out flaws with the measures, including the fact that dialysis facilities cannot report information if they are not receiving infection information from hospitals. Several commenters urged CMS to include only the NHSN Dialysis Event reporting measure and to remove the NHSN BSI clinical measure from the program. Two other concerns were that blood cultures obtained in hospitals are not systematically captured in the Reporting Measure and that there is incomplete antibiotic susceptibility data in NHSN.

Regarding the Standardized Hospitalization Ratio Clinical Measure, one commenter argued that the SHR should not be included in the program until its reliability at the facility size used in the measure has been demonstrated because for small facilities, more than half of a facility's score is due to random noise and is not an accurate signal of quality. Another commenter asked CMS to include an exclusion in the measure for hospitalizations that occur within 29 days of the index discharge because this would avoid a readmission being captured as a hospitalization by the SHR but it would still be captured as a readmission by the SRR.

Regarding the Ultrafiltration Rate (UFR) Reporting measure, several commenters recommended that CMS require January 2018 UFR rates to be reported on or before March 31, 2018 rather than February 28, 2018, to align with the reporting of other clinical values for January 2018. Another commenter recommended that CMS define ''treatment week'' or ''collection period'' for the UFR measure in a way that takes into consideration operational details such as lab draws early in the month or the unavailability of a UFR prior to the Kt/V draw for other reasons. Alternatively, the commenter suggested that any three contiguous UFRs should provide an accurate estimate of UFR to accomplish the measure goals and asked CMS to adopt this position and define the collection period as ''any three contiguous UFRs during a calendar month.'' Several commenters expressed concerns about the measure specifications for the measure, including that a treatment preceding the Kt/V but that falls within the prior calendar month may not meet the reporting requirement. These commenters requested that CMS revise the measure specifications so that the UFR reporting requirement can be independent of the Kt/V measurement because, they argued, there is no rationale for tying the two measures to one another.

Regarding the Anemia Management Measure, one commenter urged CMS to restore a measure establishing a minimal standard for anemia management and another requested a separate anemia management measure for home dialysis patients.

One commenter requested that CMS differentiate within the Pain Measure between chronic and immediate pain, and another commenter requested that a pain assessment be required at every treatment rather than merely twice a year. A few commenters recommended that CMS develop a standardized ESRD-specific tool for depression.

Regarding the Hypercalcemia Clinical measure, one commenter asked CMS to remove the measure from the program entirely because it's challenging for patients who continue to experience difficulties with access to medications and the health outcomes related to surgery for hyperparathyroidism and hypercalcemia.

Response: We appreciate commenters' thoughtful comments about the measures continuing for PY 2021. However, as we did not propose any changes to these measures which were previously finalized and are continuing into PY 2021, we consider these comments to be outside the scope of the CY 2018 ESRD PPS proposed rule. We continue to believe that the measures previously finalized for inclusion in the program represent the most appropriate way to assess quality of care in dialysis facilities. As we continue to assess the existing measures in the program, we will take these recommendations into consideration. However as mentioned above, we are not making updates to these measures at this time. For a more thorough discussion of the concerns raised at the time we introduced each of these measures into the ESRD QIP, please review the following rules where each of these measures was finalized: ICH CAHPS (77 FR 67480 through 67481, and 78 FR 72193), NHSN Dialysis Event Reporting Measure (77 FR 67484), NHSN BSI Clinical Measure (78 FR 72204), Anemia Management Reporting Measure (77 FR 67491 through 67495, and 78 FR 72198), Comprehensive Dialysis Adequacy Clinical Measure (80 FR 69043–69057), Ultrafiltration Rate Reporting Measure (81 FR 77912 through 77915), Standardized Hospitalization Rate Reporting Measure (81 FR 77906 through 77911), Serum Phosphorus Reporting Measure (81 FR 77911 through 77912), Mineral Metabolism Reporting Measure (78 FR 72197), Hypercalcemia Clinical Measure (78 FR 72203).

Comment: Commenters made several recommendations regarding measures we should consider for future inclusion in the program. Commenters recommended a measure for referrals for transplantation, more measures that focus on pediatric patients, an advanced care planning measure, and a standardized mortality ratio measure.

Response: We thank commenters for these recommendations and we will consider them as we continue to assess measures for future inclusion in the ESRD QIP.

b. Replacement of the Vascular Access Type (VAT) Clinical Measures Beginning With the PY 2021 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 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 set would address the unique needs of a specific subset of the ESRD population (79 FR 66174).

After publication of the CY 2017 ESRD PPS final rule (81 FR 77834 through 77969), we evaluated the finalized PY 2020 ESRD QIP measures that would be continued in PY 2021 against these criteria. We determined that none of these measures met criterion (1), (2), (3), (4), (5) or (7). As part of this evaluation for criterion one, we performed a statistical analysis of the PY 2020 measures we plan to continue using for PY 2021 and future payment years 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 9.

As Table 9 illustrates, the distributions of the PY 2020 clinical measures were assessed to determine if any measures were ''topped out.'' For a measure to be considered topped out, two conditions had to be met. First, a measure was considered topped out if the 75th percentile, or 25th percentile for measures where lower percentiles indicate better performance, was statistically indistinguishable from the 90th (or 10th) percentile, and second, the truncated coefficient of variation (TCV) was less than or equal to 10 percent, or 0.10. We note that the percentiles were considered statistically indistinguishable if the 75th/25th percentile was within two standard errors of the 90th/10th percentile. Additionally, for each measure the TCV was calculated by first removing the lower and upper 5th percentiles, then dividing the standard deviation by the mean of this truncated distribution ($SD_{truncated}/Mean_{truncated}$). The TCV was then converted to a decimal by dividing the TCV by 100.

The measures we evaluated were the comprehensive Dialysis Adequacy measure, Hypercalcemia (referred to in the table as ''Serum Calcium >10.2''), NHSN Standardized Infection Ratio (SIR), SRR, STrR, and SHR clinical measures, and 6 individual components of the CAHPS clinical measure. The Vascular Access measures were not included in this evaluation because they will not be continuing from PY 2020 to PY 2021. CROWNWeb data from 2015 were used for Hypercalcemia, the combination of 2015 CROWNWeb data and 2015 Medicare claims data were used for Kt/V measure, and the SRR, STrR, and SHR measures were based on both combination of 2014 CROWNWeb data and 2014 Medicare claims data. The NHSN BSI Clinical Measure was calculated using the CY 2015 NHSN data from the CDC, and the six components of the ICH–CAHPS measure were calculated using the CY 2015 ICH–CAHPS data.

Table 9 presents the percentiles, standard error, and TCV for each measure. In this analysis, all facilities with the minimum eligible patient requirement per measure were included. The results indicate none of the PY 2020 clinical measures met both ''topped out'' conditions. Therefore, we did not propose to remove any of these measures from the ESRD QIP for PY 2021 for being topped out.

TABLE 9—PY 2020 CLINICAL MEASURES CONTINUING IN PY 2021 INCLUDING FACILITIES WITH MINIMUM ELIGIBLE PATIENT REQUIREMENT PER MEASURE

Measure	N	75th/25th percentile	90th/10th percentile	Std error	Statistically indistinguishable	Truncated mean	Truncated SD	TCV	TCV ≤0.10
Kt/V delivered dose above minimum (%)	6101	96.0	97.7	0.084	No	92.6	3.88	0.04	Yes
Serum Calcium >10.2	6258	0.91	0.32	0.050	No	[a] 97.8	1.49	<0.01	Yes
ICH–CAHPS: Nephrologists Communication and Caring (%)	3349	71.8	77.1	0.159	No	65.7	7.11	0.11	No
ICH–CAHPS: Quality of Dialysis Center Care and Operations (%)	3349	66.2	71.2	0.134	No	60.9	6.20	0.10	No
ICH–CAHPS: Providing Information to Patients (%)	3349	82.4	85.6	0.101	No	78.4	4.61	0.06	Yes
ICH–CAHPS: Percent, Rating of Nephrologist	3349	69.9	76.6	0.204	No	62.0	9.29	0.15	No
ICH–CAHPS: Percent, Rating of Dialysis Facility Staff	3349	70.9	77.4	0.215	No	62.0	9.92	0.16	No
ICH–CAHPS: Percent, Rating of Dialysis Center	3349	73.8	80.6	0.221	No	64.8	10.18	0.16	No
NHSN-SIR	5805	0.40	0.00	0.011	No	0.964	0.57	<0.01	Yes
SRR	6178	0.78	0.63	0.003	No	0.969	0.21	<0.01	Yes
STrR	5742	0.63	0.42	0.007	No	0.955	0.39	<0.01	Yes
SHR	6298	0.81	0.67	0.004	No	0.978	0.20	<0.01	Yes

[a] Truncated mean for percentage is reversed (100 percent-truncated mean) for measures where lower score = better performance.

Over the past few years, we have received numerous public comments regarding the two VAT measures included in the ESRD QIP's measure set. Specifically, commenters have recommended that CMS adjust the weights of the VAT measures to place more emphasis on reducing catheters to encourage the use of fistulas and grafts (81 FR 77904). Another commenter specifically supported CMS' submission of new VAT Measures to the NQF Renal Standing Committee to address the small number of patients for whom a catheter may be the most appropriate vascular access type when life expectancy is limited (81 FR 77905). We also note that the VAT measures currently used in the ESRD QIP measure set are calculated using claims data. This limits the applicability of the measures to Medicare Fee-For-Service (FFS) patients, while excluding all others.

Although there is no evidence to suggest that the current VAT measures are leading to negative or unintended consequences, we proposed to remove both from the ESRD QIP measure set beginning with the PY 2021 program based on criterion (6) listed earlier because measures that are more strongly associated with desired patient outcomes for the particular topic are now available. We proposed to replace the VAT measures with the Hemodialysis Vascular Access: Standardized Fistula Rate Clinical Measure (NQF #2977) and the Hemodialysis Vascular Access: Long-Term Catheter Rate Clinical Measure (NQF #2978). We believe these

measures will address the methodological concerns the community has shared regarding the existing measures. Additionally, both measures have been endorsed by the NQF, are supported by the Measures Application Partnership, and can be calculated using data that facilities are already required to report in CROWNWeb to meet 42 CFR 494.180(h) of the Conditions for Coverage for ESRD Dialysis Facilities. Because CROWNWeb collects data on all patients, we believe that the adoption of these measures will enable us to more accurately assess the quality of care furnished by facilities.

We requested comments on our proposal to remove the current VAT measures from the ESRD QIP measure set beginning with the PY 2021 program year. The comments and our responses are set forth below.

Comment: Commenters were generally supportive of CMS's proposed replacement of the VAT measures with the proposed Hemodialysis Vascular Access measures, pointing out that the new fistula measure adds adjustment for factors associated with illness severity and comorbid conditions, while the catheter measure excludes patients who may be more appropriately treated with a catheter. Commenters also appreciated efforts made by CMS over the last few years to convene a Technical Expert Panel (TEP) and to assess best practices in Vascular Access. They added that CMS should continue reviewing and revisiting these measures when necessary to account for factors that may warrant further refinement.

Response: We appreciate commenters' support for our efforts to ensure our measures reflect best practices in providing quality care to ESRD dialysis patients. We believe that the new Hemodialysis Vascular Access measures have several advantages: (1) They address long-standing concerns with the previous VAT measures that were included in the program, (2) they take into consideration the important clinical differences between patients, and (3) they are reflective of the importance of patient choice in their own clinical care.

c. Revision of the Standardized Transfusion Ratio (STrR) Clinical Measure Beginning With the PY 2021 Program Year

We believe that changes during the past several years to the way ESRD services are reimbursed under Medicare, as well as changes to how ESRD care is measured under the ESRD QIP and through other quality reporting initiatives, may have impacted how anemia is clinically managed. Some of these changes include the identification of safety concerns associated with aggressive erythropoiesis-stimulating agent (ESA) use, the expansion of the ESRD PPS bundled payment methodology to include ESAs, and the continued growth and expansion of the ESRD QIP. There are concerns that these changes could result in the underutilization of ESAs, with lower achieved hemoglobin values that may increase the frequency of red blood cell transfusion in the United States chronic dialysis population.

Excessive rates of blood transfusion may be an indicator for underutilization of clinical treatments to increase endogenous red blood cell production (for example, ESA and iron). Dialysis patients who are eligible for kidney transplant and have received transfusions are at increased risk of becoming sensitized to the donor pool thereby making transplant more difficult to accomplish. Blood transfusions carry a small risk of transmitting blood borne infections and/or the development of a transfusion reaction, and using infusion centers or hospitals to transfuse patients is expensive, inconvenient, and could compromise future vascular access.[6]

Monitoring the risk-adjusted transfusion rate at the dialysis facility level, relative to national standards, allows for detection of treatment patterns in dialysis-related anemia management. This is of importance due to recommendations by the Food and Drug Administration regarding more conservative ESA dosing.[7] As providers use less ESAs in an effort to minimize the risks associated with aggressive anemia treatment, it becomes more important to monitor for an overreliance on transfusions. Beginning with PY 2017, we adopted the STrR to address gaps in the quality of anemia management. We also submitted that measure to the NQF for consensus endorsement, but the Renal Standing Committee did not recommend it for endorsement, in part due to concerns that variability in hospital coding practices with respect to the use of 038 and 039 revenue codes might unduly bias the measure rates. Upon reviewing the committee's feedback, we revised the STrR measure to address these concerns. Following this revision, we resubmitted the STrR (NQF #2979) to NQF for consensus endorsement, and the NQF endorsed it in 2016. The proposed change to the STrR beginning with the PY 2021 ESRD QIP will align the measure specifications we use for the ESRD QIP with the measure specifications that the NQF endorsed in 2016 (NQF #2979).

Summary of Change

The proposed updated specifications to the STrR measure contain a more restricted definition of transfusion events than is used in the current STrR measure. Specifically, the revised definition excludes inpatient transfusion events for claims that include only 038 or 039 revenue codes without an accompanying International Classification of Diseases–9 (ICD–9) or ICD–10 procedure code or value code. As a result of requiring that all inpatient transfusion events include an appropriate ICD–9 or ICD–10 procedure code or value code, the measure will identify transfusion events more specifically and with less bias related to regional coding variation. As a result, it will assess a smaller number of events as well as a smaller range of total events.

2016 Measures Application Partnership Review

We determined that the proposed revision to the STrR (NQF #2979) constituted a substantive change to the measure, and we submitted that revision to the Measures Application Partnership for consideration as part of the pre-rulemaking process. The Measures Application Partnership recommended that this measure be refined and resubmitted due to concerns that measuring transfusions in dialysis facilities may not be feasible.[8] The Measures Application Partnership also expressed concern that the decision to administer a blood transfusion may be outside of the dialysis facility's control because in general, clinicians in hospitals make the decisions about blood transfusions. The Measures Application Partnership also expressed concern that variability in blood transfusion coding practices could inadvertently affect a dialysis facility's performance on this measure.

[6] FDA Drug Safety Communication: Modified dosing recommendations to improve the safe use of Erythropoiesis-Stimulating Agents (ESAs) in chronic kidney disease. *http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm.*

Kidney Disease: Improving Global Outcome (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney inter., Suppl. 2012; 2: 279–335. *http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO-Anemia%20GL.pdf.*

Obrador and Macdougall. Effect of Red Cell Transfusions on Future Kidney Transplantation. Clin J Am Soc Nephrol 8: 852–860, 2013.

Ibrahim, et al. Blood transfusions in kidney transplant candidates are common and associated with adverse outcomes. Clin Transplant 2011: 25: 653–659.

[7] *https://www.fda.gov/Drugs/DrugSafety/ucm259639.htm.*

[8] *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452.*

Although we acknowledge that the Measures Application Partnership recommended that we refine and resubmit the updated version of the STrR measure, we note that the Measures Application Partnership's recommendation is at odds with the earlier conclusion of the NQF to endorse this change. On the issue of whether it is feasible to measure transfusions in dialysis facilities, the NQF concluded that these events can be identified using the same Medicare claims code algorithm that we use to identify transfusion events in other outpatient settings. The STrR measure identifies transfusion events during at-risk periods for patients cared for in a dialysis facility.

With respect to the Measures Application Partnership's concern that the decision to administer a blood transfusion might be outside of the dialysis facility's control, we note that the issue of whether anemia management practices in a dialysis facility can be linked to transfusion risk was specifically considered by the NQF during the endorsement process.

The NQF Renal Standing Committee concluded that this transfusion avoidance measure would incentivize facilities to properly manage anemia, with the result of lowering the patient's transfusion risk. The NQF Renal Standing Committee also found that although the decision to transfuse might ultimately be made by a hospital, the need to do so is dictated not only by clinical circumstances observed by the hospital, but also by the way the patient's anemia was managed by the facility.

Although the Measures Application Partnership was concerned that variability in blood transfusion coding practices could inadvertently affect a dialysis facility's performance on this measure, we note that the definition of transfusion events used in the revised STrR measure is consistent with the definition used in numerous scientific publications, including several peer reviewed publications.[9] Under this definition, transfusion events are included in the measure only if they are coded with specific transfusion procedure or value codes. We believe this coding requirement reduces the potential for inadvertently capturing non-transfusion events in the measure. In addition, the exclusion of revenue code only transfusion events from the measure decreases the potential that the measure results would be influenced by differences in hospital coding practices.

We agree with the NQF Standing Committee's assessment that the STrR (NQF #2979) is an appropriate measure of quality for dialysis facilities. We further believe that the measure is appropriate for the ESRD QIP because the measure (1) Demonstrates variation in performance among facilities, (2) is an outcome of care that is modifiable by dialysis providers through effective management of anemia in patients, and (3) is a valid and reliable indicator of quality at the facility level. Proper management of anemia is an important quality of care issue for dialysis patients, and a topic for which the ESRD QIP must include measures (see section 1881(h)(2)(A)(i)).

For these reasons, we proposed the revision to the STrR measure be reflected in the ESRD QIP, and beginning with the PY 2021 program year, we proposed to use the updated version of the STrR (NQF #2979). Full measure specifications and testing data are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html*. The complete list of ICD–10 codes that would be included in the measure is included in the Technical Report for the measure and can also be found in that link.

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

Comment: Several commenters supported CMS's proposal to update the STrR measure because they support CMS's efforts to ensure that the QIP measures remain current with NQF standards.

Response: We thank the commenters for their support and we agree that in general it is best to maintain the QIP measures current with NQF standards.

Comment: One commenter generally supported the concept of a transfusion measure, but suggested possible adjustments, which the commenter believes will improve the proposed standardized transfusion ratio measure. The commenter added that the goal of comparing transfusion rates across facilities is to identify those facilities that are systematically allowing hemoglobin values to fall, presumably by limiting ESA administration. However, transfusions occur in two situations: (1) In the setting of chronically low hemoglobin values which the facility could arguably have influenced, and (2) in the setting of an acutely low hemoglobin value, over which the facility has little control. To distinguish these two situations, the commenter recommended that CMS look at the last outpatient hemoglobin value reported on an ESRD claim before the transfusion, or at the 3-month rolling average. According to the commenter, if the hemoglobin value was greater than a set cutoff value, the transfusion would be included in the measure. In addition, the commenter stated that the measure could exclude conditions other than cancers not amenable to ESA based anemia treatment correction.

Response: We thank the commenter for these suggested improvements to the STrR. The STrR measure evaluates risk-adjusted blood transfusion ratios at the dialysis facility level, comparing dialysis facilities' relative success in transfusion avoidance. Its goal is not limited to reducing transfusion risk associated with chronic severe anemia as suggested by the commenter. Several dialysis facility practices can influence patient risk for transfusion, including anemia management decisions, as well as dialysis prescription and delivery practices. Furthermore, the consequences of these practices can result in acute increased transfusion risk or chronic increased risk for transfusion, depending on the clinical situation. Limiting identification of transfusion events to only those scenarios associated with chronic anemia and transfusion risk would inappropriately result in a less impactful transfusion avoidance measure. For these reasons, we believe that it is appropriate not to limit our assessment of transfusions to those with a prior hemoglobin level reported to CROWNWeb.

Comment: One commenter expressed concern that the STrR measure has inappropriately low reliability and pointed out that when the measure was considered for NQF endorsement, it was

[9] Hirth, Turenne, Wilk et al. Blood transfusion practices in dialysis patients in a dynamic regulatory environment. Am J Kidney Dis. 2014 Oct;64(4):616–21. Doi: 10.1053/j.ajkd.2014.01.011. Epub 2014 Feb 19.

Gilbertson, Monda, Bradbury & Collins. RBC Transfusions Among Hemodialysis Patients (1999–2010): Influence of Hemoglobin Concentrations Below 10 g/dL. Am J Kidney Dis. 2013; Volume 62, Issue 5, 919–928.

Collins et al. Effect of Facility-Level Hemoglobin Concentration on Dialysis Patient Risk of Transfusion. Am J Kidney Dis. 2014; 63(6):997–1006.

Cappell et al. Red blood cell (RBC) transfusion rates among US chronic dialysis patients during changes to Medicare end-stage renal disease (ESRD) reimbursement systems and erythropoiesis stimulating agent (ESA) labels. BMC Nephrology 2014, 15:116.

Ibrahim, et al. Blood transfusions in kidney transplant candidates are common and associated with adverse outcomes. Clin Transplant 2011: 25: 653–659.

Molony, et al. Effects of epoetin alfa titration practices, implemented after changes to product labeling, on hemoglobin levels, transfusion use, and hospitalization rates. Am J Kidney Dis 2016: epub before print (published online March 12, 2016).

found to have very low reliability, particularly for small facilities. Another commenter pointed to an analysis, which suggested that longer look-back periods would result in a significant increase in reliability for both the SHR and the STrR measures. The commenter stated that for small facilities, the inter-unit reliability (IUR) for the 1-year measures is low, and that for small facilities in the STrR measure, the 1-year IUR for 0.36 means that nearly two-thirds of the variance in the measure is due to random noise rather than real differences between facilities. Commenter added that with a 4-year look-back period, the IURs for small facilities are similar to the IURs for large facilities in the 1-year look-back period. According to the commenter, these results suggest, that with a 4-year look-back period, a minimum of two-thirds of the variance in both measures in all three subgroups would be due to actual differences between facilities. Additionally, the commenter believed that using a 4-year look-back period would align these measures with the Standardized Mortality Ratio measure used in the DFC program, creating consistency across the measures used in the ESRD QIP and DFC.

Another commenter pointed out that 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 and not underlying performance. The commenter stated that IURs increase as a function of sample size. Therefore, commenter argued, smaller samples would be associated with lower IURs. Based on the NQF documentation submitted by CMS, the commenter stated that one would expect the vast majority of STrR variation to be due to random variation across the 10–21 patient-years at risk that CMS has proposed for the small facility adjustment for STrR. While the small facility adjustment would raise scores for small facilities, the commenter argued that it would not adequately offset the substantial effect of random variation for small sample sizes. The commenter recommended that CMS set the minimum data requirement for each measure at the sample size at which the IUR reaches 0.70, the value commonly used at NQF. That is, the minimum sample size would be set at the point where at least 70 percent of the observed result would be driven by actual performance. Anything below that, commenter argued, means that too high a proportion of the observed result is simply due to chance.

Response: We thank commenters for sharing these concerns regarding the reliability of the STrR. Given the established effect of sample size on IUR calculations, we generally expect, based on statistical modeling, that large facilities will have higher IUR values and small facilities will have lower IUR values for any given measure. Reliability is fundamentally associated with the size of a facility: A larger denominator leads to more precise assessments. Regardless of a measure's IUR, it will be higher for larger facilities and lower for smaller facilities. The dependence of reliability on facility size is understood when IUR is considered as a standard of reliability by NQF.

In response to commenter's suggestion above about requiring an IUR of 0.70, we are not aware of any formal and prescriptive NQF guideline or standard that sets or requires this test result value as a minimum threshold for passing reliability. Additionally, there is no formal required threshold set 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. The STrR and SHR 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 (#0229 Heart failure measure, ICC: 0.55; #0468 Pneumonia mortality measure, Intraclass Correlation Coefficient: 0.79; #1893 Chronic Obstructive Pulmonary Disease mortality measure, ICC: 0.51; #2558 Coronary Artery Bypass Grafting mortality measure, ICC: 0.32). The 2013 NQF Task Force on Evaluating Evidence and Testing also acknowledged that although the ''Consensus Standards Approval Committee and subcommittee would like to have provided some guidance regarding minimum thresholds, they repeatedly noted the difficulties in determining such thresholds and the need for steering committees to have flexibility to make judgments.'' (Page 13; Review and Update of Guidance for Evaluating Evidence and Measure Testing. Technical Report. Approved by CSAC on October 8, 2013: *http://www.qualityforum.org/Publications/2013/10/Review_and_Update_of_Guidance_for_Evaluating_Evidence_and_Measure_Testing_-_Technical_Report.aspx*).

Aside from considering the appropriateness of limiting assessment as the commenters suggested, we believe setting a sample size threshold to reach 0.7 IUR for each measure is not feasible. As has been shown, large facilities tend to obtain IUR of 0.7 or greater. Setting the range for the SFA based on this approach would result in: (1) Applying the SFA for a larger portion of facilities, depending on the measure; or (2) potentially excluding those facilities, and limiting the value of the measure to the program. Finally, setting consistent minimum data requirements and ranges would be challenging because the frequency of events varies in these measures (for example, hospitalizations are more frequent than transfusion events). Incorporating multiple years of data also has potential consequences for implementation. As a practical matter, it would be difficult to provide performance standards in advance of 4-year performance period. Doing so would also limit the degree to which providers could be assessed on improvement from year to year, since only one quarter of the data would change from payment year to payment year.

Comment: One commenter did not support the proposed modifications to the STrR measure because it differs from the NQF-endorsed version (#2979). Commenter argued that since the statute requires CMS to use NQF-endorsed measures if available, CMS should comply with the statutory requirement and use the actual NQF-endorsed measure.

Response: The modifications to the STrR proposed for PY 2021 of the ERSD QIP will align the measure used in the ESRD QIP with the NQF-endorsed version of that measure.

Comment: One commenter recommended that CMS adopt true risk-standardized rate measures, which would be more transparent and useable by all stakeholders. The commenter added that risk standardized rates are easier to understand and that 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. Rather than continuing to use a confusing set of measures, the commenter urged CMS to replace the standardized ratio measures with the year-over-year difference between normalized (per 100 patient years) rates (for example, for hospitalization) currently available from Dialysis Facility Reports until they can be replaced by true risk-standardized rate measures.

Another commenter noted that moving to rates, while an important step forward, would also create issues that CMS would need to carefully address. The commenter believed that choosing a methodology to convert ratios to rates

would be a challenge and did not believe that a conversion approach would produce a true risk-standardized rate measure. The commenter believed that under a conversion approach, the use of the national median rate as the conversion factor for ratios may be misleading in regions of the country where typical performance varies significantly from the national rate. According to this commenter, the goal of using rates instead of ratios is to make the measure results more meaningful to patients, providers, and other stakeholders by expressing measure results in terms that are both valid and have intrinsic meaning, rather than the abstract meaning expressed by ratios.

Response: The risk-adjustment approach currently used for the StrR measure is based on indirect standardization which also forms the basis of many measures implemented in the ESRD QIP and other CMS quality reporting and value-based purchasing programs, and we believe that this approach leads naturally to a standardized ratio. This ratio compares the rate for this facility with the national rate, having adjusted for the patient mix and as such is relatively straightforward. We are unclear on why the commenter believes that rates are more easily understood than ratios. Similarly to ratios, risk-adjusted rates are not the same as actual rates and require a consideration of the patient mix adjustment for interpretation. We do agree that any conversion to rates would require careful consideration of the measure methodology and implications for assessing facility performance prior to implementation.

Final Rule Action: After carefully considering the comments received, we are finalizing the changes to the Standardized Transfusion Ratio Clinical Measure as proposed.

d. New Vascular Access Measures Beginning With the PY 2021 ESRD QIP

As discussed in the CY 2018 ESRD PPS proposed rule (82 FR 31212), for PY 2021, we proposed to remove the two VAT measures from the ESRD QIP and to replace them with two Vascular Access measures that were recently endorsed by the NQF. We proposed to score these measures the same way that we score the current VAT measures, and to include them within the Vascular Access Measure Topic.

Background

Beginning with the PY 2015 ESRD QIP, we adopted the Minimizing Catheter Use as Chronic Dialysis Access (NQF #0256) and Maximizing Placement of Arterial Venous (AV) Fistula (NQF #0257) measures, which are paired measures of the rate of catheter and fistula placement for chronic dialysis access, respectively, for the ESRD QIP (77 FR 67479). These measures were developed in accordance with the National Kidney Foundation Kidney Disease Outcomes Quality Initiative Guidelines that state the following: (1) AV fistulas have the lowest rate of thrombosis and require the fewest interventions, (2) cost of AV fistula use and maintenance is the lowest, (3) fistulas have the lowest rates of infection, and (4) fistulas are associated with the highest survival and lowest hospitalization rates. Several epidemiologic studies consistently demonstrate the reduced morbidity and mortality associated with greater use of AV fistulas for vascular access in maintenance hemodialysis.

Based upon data we collected during the CMS Fistula First/Catheter Last Initiative,[10] a gradual trend towards lower catheter use has been observed among prevalent maintenance hemodialysis patients in the United States, declining from approximately 28 percent in 2006 to approximately 18 percent by August 2015. Furthermore, the percentage of maintenance HD patients using a catheter for at least 3 months has declined during this time period from nearly 12 percent to 10.8 percent. Continued monitoring of chronic catheter use is needed to sustain this trend.

Since the Maximizing Placement of AV Fistula Measure (NQF #0257) was first implemented, we have received public comments expressing concerns that in certain cases, such as patients with a low life expectancy, placement of a fistula may not be appropriate. A growing number of studies report that creating AV fistulas in some patients is less likely to be successful in the presence of certain comorbidities. In addition, certain patient groups may have less incremental benefit from an AV fistula relative to an AV graft.

Since the implementation of Minimizing Catheter Use as Chronic Dialysis Access Measure (NQF #0256), we have received comments from stakeholders raising concerns about its inability to account for patients with a limited life expectancy, for whom a fistula, with its extended maturation period, may not represent an improved quality of life.

In 2015, we convened a TEP to review the existing vascular access measures to consider how best to address these concerns. A copy of the summary TEP report is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html*. The TEP made the following recommendations:

- The fistula measure should be risk-adjusted for factors that are associated with decreased likelihood of AV fistula success, including:
  - ++ Diabetes.
  - ++ Heart diseases.
  - ++ Peripheral vascular disease.
  - ++ Cerebrovascular disease.
  - ++ Chronic obstructive pulmonary disease.
  - ++ Anemia (unrelated to ESRD/Chronic Kidney Disease).
  - ++ Non-Vascular Access-Related Infections.
  - ++ Drug Dependence.
- The measures should include all eligible hemodialysis patients, not just Medicare beneficiaries.
- The measures should include patients in the first 90 days of dialysis because this is a critical time for access planning/placement.
- The measures should include in the numerator only patients with an AV fistula using 2 needles (or an approved single needle device).
- The measures should exclude conditions associated with a limited life expectancy where an AV fistula may not be the appropriate choice for access (for example, hospice, metastatic cancer, end stage liver disease, and coma/brain injury).

We responded to the TEP's recommendations by developing two new VAT measures intended to be jointly reported to assess the placement of vascular access among ESRD dialysis patients. These two vascular access quality measures, when used together, consider AV fistula use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients have exhausted options for an AV fistula or have comorbidities that may limit the success of AV fistula creation, joint reporting of the measures accounts for all three vascular access options. This paired incentive structure that relies on both measures (standardized fistula rate and long-term catheter rate) reflects consensus-based best practice, and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last Project over the last decade.

We received general comments on our proposal to include two new Vascular Access measures in the ESRD QIP beginning in PY 2021. The comments and our responses are set forth below:

[10] Fistula First Catheter Last Dashboard August 2015 *http://fistulafirst.esrdncc.org/ffcl/for-ffcl-professionals/archive/*.

Comment: Several commenters recommended that CMS combine the fistula and catheter rates into a single quality measure to avoid double counting. Specifically, these commenters argued that if fistulas and grafts are both counted, then using the catheter rate as a quality measure is virtually a duplication of the fistula/graft rate as a quality measure since the catheter percentage would equal 100 percent less the total of fistulas and grafts. Even if grafts are not included, commenters argued, there is still a large overlap of the fistula and catheter rates, giving a double penalizing effect of using both the fistula and catheter rates as two quality measures.

Response: The two vascular access measures, when used together, consider AV fistula use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients have exhausted options for an arteriovenous fistula, or have comorbidities that may limit the success of AV fistula creation, pairing the measures accounts for all three vascular access options. The standardized fistula rate measure includes risk adjustment for patient factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option. This paired incentive structure that relies on both measures reflects consensus best practice, and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last Project over the last decade. Additionally, the fistula and catheter measures apply exclusions for certain conditions recognizing that catheter placement may be the only means of vascular access for these patient sub-populations. Specifically, both measures exclude patients with a catheter that have limited life expectancy defined as being under hospice care in the current reporting month, or with metastatic cancer, end stage liver disease, coma or anoxic brain injury in the past 12 months. In this way, the combination of risk adjustment for the standardized fistula rate measure and the application of the exclusions to both measures does not result in doubly penalizing facilities and instead is intended to incentivize best practices for vascular access. Finally, the standardized fistula rate measure is a risk adjusted standardized rate, and contains exclusions, therefore the standardized fistula rate cannot be directly added/subtracted from a raw percentage of grafts and catheters.

Comment: One commenter expressed concerns about CMS's proposal to use CROWNWeb as the data source for the proposed Vascular Access measures and added that it is not clear how ''life expectancy'' will be calculated. Commenter recommended that based on the proposal to use CROWNWeb as the primary data source for numerator and denominator, CMS should consider delaying the implementation of these two measures until CROWNWeb can be shown to be a reliable data source.

Another commenter noted that for the two vascular access measures, there are patient-level exclusions for patients with a catheter but with limited life expectancy, and asked for clarification regarding the 4 criteria used to determine limited life expectancy and how this information is intended to be documented.

Response: Collection of vascular access data through CROWNWeb has been ongoing for 5 years. When analyzing the concordance of CROWNWeb vascular access data with that of Medicare claims, which have been used in the ESRD QIP VAT measures since PY 2015, we found a high level of agreement for the AV fistula (kappa = .89) and catheter (kappa = .73) data. We believe the data fidelity is sufficient to merit the use of CROWNWeb data for measurement in the ESRD QIP.

Regarding life expectancy, both the standardized fistula rate and the catheter measures exclude patients with a catheter as their vascular access and who meet one of the following conditions below that are identified through Medicare claims. No additional documentation (that is, attestation) is required from the facility. Specifically, limited life expectancy is defined as follows:

- Patients under hospice care in the current reporting month.
- Patients with metastatic cancer in the past 12 months.
- Patients with end-stage liver disease in the past 12 months.
- Patients with coma or anoxic brain injury in the past 12 months.

These conditions were reviewed and supported by the 2015 Vascular Access TEP and all of them are associated with a very high mortality rate in the 6-month period after they first appear in Medicare claims.

Comment: Many commenters supported the inclusion of the new Vascular Access measures as endorsed by NQF in the QIP because this ensures patient safety while recognizing the needs of the individual patient. One commenter noted that CMS indicated in the proposed rule that it concurred with the recommendation of the 2015 Vascular Access TEP that the fistula measure under development specify that the AV fistula must use 2 needles (or an approved single-needle device). The commenter noted that this revision is reflected in the methodology report, but not in the specifications. Another commenter was pleased to see that the flowchart in the methodology report specifies AV fistula only with 2 needles or an approved single-needle device, but recommended that the numerator specifications should also explicitly state that the patient must be on maintenance HD ''using an AV fistula with 2 needles and without a dialysis catheter present'' to emphasize clarity and avoid ambiguity. The commenter also recommended that the specifications address how a patient with a co-existing AV graft should be handled. Given that removal of an AV graft is complex and not without risk of complications, the commenter stated that the presence of a graft is acceptable even when using a fistula. As this is not the case when a catheter is present, the commenter agreed that the continued presence of a catheter when a fistula is being used should not constitute success on the measure. Finally, a commenter recommended that CMS redefine the denominator as it mistakenly uses the construction ''patients'' when it should use the term ''patient-months'' to be consistent with the numerator.

Response: Both the flowchart and the numerator details in the NQF measure specifications include language for the use of 2 needles or an approved single-needle device. We intend to provide clarifying language in the published technical specifications to make this clear. Regarding the revision recommended by commenter to specify in the measure technical specifications how a patient with a co-existing AV graft should be handled, we thank commenter for their recommendation and we will make any necessary updates to the measure technical specifications as necessary to ensure clarity. With regard to the recommendation that the technical specifications explicitly state that the patient must be on maintenance HD ''using an AV fistula with 2 needles and without a dialysis catheter present'' to emphasize clarity and avoid ambiguity, CROWNWeb did not support this level of granularity during the development of this measure, and so it is not reflected in the NQF-endorsed measure specifications. We agree that this is an appropriate enhancement to consider for future measure maintenance and system development. We confirm that

the denominator is constructed using patient-months, which is consistent with the NQF-endorsed specifications.

Comment: One commenter agreed with the proposed exclusion from the Vascular Measures of conditions associated with a limited life expectancy where an AV fistula may not be the appropriate choice for access, but argued that any exclusions or risk-adjustments that are calculated based on Medicare claims will not capture patients who do not have Medicare. These commenters urged CMS to clarify whether the proposed new vascular access measures would accurately measure the care furnished to the facility's total ESRD population (including Medicare beneficiaries and patients with other payers).

Response: We will calculate the comorbidity risk adjustment using ICD diagnostic codes reported on Medicare claims or, if the patient is not a Medicare beneficiary, information in incident comorbidities reported on the CMS Form 2728. This provides a method for application of comorbidity risk adjustment to patients that do not have Medicare claims and allows the measure to be applied to all patients regardless of payer type.

The additional exclusion criteria for the proposed vascular access measures are captured using Medicare claims data only. These measures were recommended by the Vascular Access TEP in 2015 with the expectation that considering the exclusions is appropriate. We conducted sensitivity analyses regarding the application of these measures and found that the exclusions are relatively rare and do not substantially bias the measure assessment.

Comment: Commenter recommended that rather than using fistulas alone, CMS should consider including arteriovenous grafts with AV fistula for several reasons: (1) While overall fistulas are slightly superior to grafts, there is virtually no difference in the elderly, (2) grafts are as long-lasting as fistulas if primary failures are included, (3) grafts may be placed shortly before dialysis to avoid unnecessary fistulas that aren't used, (4) grafts are more successful than fistulas as a second access, (5) grafts help avoid catheters, and (6) inclusion of both fistulas and grafts may minimize or eliminate the need for a complex adjustment in the fistula rate as is proposed.

Response: We thank the commenter for its comments on the vascular access measures. The two vascular access measures, when used together, consider AV fistula use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients have exhausted options for an arteriovenous fistula, or have comorbidities that may limit the success of AV fistula creation, pairing the measures accounts for all three vascular access options. The standardized fistula rate measure includes risk adjustment for patient factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option. This paired incentive structure that relies on both measures reflects consensus best practice, and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last Project over the last decade. Additionally, the fistula and catheter measures apply exclusions for certain conditions recognizing catheter may be the only means of vascular access for these patient sub-populations. Specifically, both measures exclude patients with a catheter that have limited life expectancy defined as being under hospice care in the current reporting month, or with metastatic cancer, end stage liver disease, coma or anoxic brain injury in the past 12 months.

i. New Hemodialysis Vascular Access: Standardized Fistula Rate Clinical Measure (NQF #2977)

Summary of Changes

This proposed measure replaces NQF #0257, Maximizing Placement of AV fistula, and it incorporates changes that reflect input from the 2015 Vascular Access TEP:

- Risk Adjustment for the following conditions that affect the success of fistula placement:
  - ++ Diabetes.
  - ++ Heart diseases.
  - ++ Peripheral vascular disease.
  - ++ Cerebrovascular disease.
  - ++ Chronic obstructive pulmonary disease.
  - ++ Anemia (unrelated to ESRD/Chronic Kidney Disease).
  - ++ Non-Vascular Access-Related Infections.
  - ++ Drug Dependence.
- Inclusion of all eligible hemodialysis patients, not just Medicare beneficiaries.
- Inclusion of patients in the first 90 days of dialysis because this is a critical time for access planning/placement.
- Inclusion in the numerator of only patients with an AV fistula using 2 needles (or an approved single needle device).
- Exclusion of conditions associated with a limited life expectancy where an AV fistula may not be the appropriate choice for access (for example, hospice, metastatic cancer, end-stage liver disease, and coma/brain injury).

Data Sources

CROWNWeb, Medicare claims and the CMS Medical Evidence form 2728 (OMB No. 0938–0046) are used as the data sources for establishing the denominator. CROWNWeb is the data source for establishing the numerator. Medicare claims and the CMS Medical Evidence form 2728 are data sources for the risk adjustment factors. Medicare claims and CROWNWeb are used for the exclusion criteria. Using CROWNWeb as the primary data source allows us to expand the Standardized Fistula Rate to include all ESRD dialysis patients, rather than only Medicare FFS patients, providing a more complete quality assessment for dialysis facilities. This was a key consideration by the TEP that recommended the development of this measure.

Outcome

The outcome of the Standardized Fistula Rate is the use of an AV fistula as the sole means of vascular access as of the last hemodialysis treatment session of the month.

Cohort

The cohort includes adult ESRD dialysis patients who are determined to be maintenance hemodialysis patients (in-center or home) for the entire reporting month at the same facility.

Inclusion and Exclusion Criteria

The Standardized Fistula Rate excludes pediatric patients (<18 years old), patients on peritoneal dialysis, and patient-months where the patient was not on hemodialysis (in-center or home) at the same facility for the entire reporting month. The measure additionally excludes patients with a catheter who have a limited life expectancy.

Risk Adjustment

The Standardized Fistula Rate is a directly standardized percentage, with each facility's percentage of fistula use adjusted by a series of risk factors, including patient demographic and clinical characteristics based on a logistic regression model. The demographic and clinical characteristics were chosen in order to adjust for factors outside the control of a facility that are associated with a decreased likelihood of AV fistula success.

We submitted the measure to NQF, where the Renal Standing Committee recommended it for consensus

endorsement, and the NQF endorsed the measure in December 2016. The Standardized Fistula Rate (NQF #2977) was submitted to the Measure Applications Partnership in 2016, which supported the measure for implementation in the ESRD QIP.

We proposed implementing Hemodialysis Vascular Access: Standardized Fistula Rate (NQF #2977) beginning with the PY 2021 program year. Detailed measure specifications and testing data are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html*. We requested comments on these proposals.

Comment: One commenter recommended that CMS expand the exclusion criteria for the Vascular Access measures to include the following: (1) Steal syndrome that required ligation of AV fistula or arteriovenous graft, (2) Patients who have had multiple failed AV fistula or arteriovenous graft attempts and have no suitable sites left to create AV fistula or arteriovenous graft, and (3) Patients who have medical contraindications to AV fistula surgery including severe congestive heart failure, and high output cardiac failure from previous AV fistula.

Commenter also recommended that if patients choose to have neither a fistula nor a graft placed, after adequate education by their physician, then the patients should be excluded from the denominator. Commenter added that while overall, fistulas are slightly superior to grafts, there is virtually no difference in the elderly. The commenter also added that some of the benefits of grafts are that they are as long-lasting as fistulas if primary failures are included, they may be placed shortly before dialysis to avoid unnecessary fistulas that aren't used, they are more successful than fistulas as a second access, they help to avoid central venous catheters, and they may minimize or eliminate the need for a complex risk adjustment in the fistula rate as is proposed.

Response: The TEP that developed this measure in 2015 discussed at length the proposed exclusion for patients who have exhausted anatomic options for permanent access. The TEP agreed that this was an important exclusion, but they also recognized that it would be difficult to implement. A major concern was also that there are not currently data sources or infrastructure in place that would allow identification of patients who have no further surgical options for vascular access. There would also need to be strong consensus on what determines whether patients do not meet criteria for successful fistula placement. We intend to evaluate this criterion and data availability to determine feasibility of adding this exclusion in a future iteration of this measure.

Many of the exclusion criteria based on comorbidities suggested by commenters are either associated with shortened life expectancy or low likelihood of successful fistula placement. In some situations, the severity of the underlying diagnosis is difficult to ascertain from claims data, although like heart failure, we anticipate this will improve over time with the change to and availability of ICD–10 codes. Therefore, other comorbidities will be evaluated as part of future measure maintenance. Lastly, multiple prior failed vascular access attempts were considered by the TEP as an exclusion criterion to address the exhaustion of vascular sites or failed attempts to create a fistula or graft, however consensus was not reached within the TEP on how best to implement this exclusion. At the present time, historical vascular access data in CROWNWeb are limited, but this exclusion criterion will be evaluated when more historical vascular access data are available.

The two vascular access measures, when used together, consider AV fistula use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients have exhausted options for an arteriovenous fistula, or have comorbidities that may limit the success of AV fistula creation, pairing the measures accounts for all three vascular access options. The standardized fistula measure adjusts for patient factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option. This paired incentive structure that relies on both measures reflects consensus best practice, and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last Project over the last decade. Finally, it would be difficult to ascertain what constitutes adequate education by a nephrologist from the patient's perspective as well as how to validate informed patient choice not to have an AV fistula or arteriovenous graft, and this may be particularly a concern for vulnerable patients.

Final Rule Action: After consideration of the comments received, we are finalizing our proposal to include the Hemodialysis Vascular Access: Standardized Fistula Rate Clinical Measure in the ESRD QIP measure set beginning with the PY 2021 program.

ii. New Hemodialysis Vascular Access: Long-Term Catheter Rate (NQF #2978) Beginning With the PY 2021 ESRD QIP

Summary of Changes

This proposed measure replaces NQF #0256, Minimizing Use of Catheters as Chronic Dialysis Access, and it incorporates the following changes that reflect input from the 2015 Vascular Access TEP:

- Inclusion of all eligible hemodialysis patients, not just Medicare beneficiaries, since the measure is now specified to be calculated from CROWNWeb.
- Patients using a catheter continuously for 3 months or longer, even if combined with an AV fistula (or graft), are now counted in the numerator. The current measure does not count patients in the numerator if they have a catheter combined with an AV fistula or graft.
- Patients with missing VAT are counted in both the denominator and the numerator. That is, ''missing'' access type is considered a ''failure'' and therefore counts against the facility.
- Exclusion criteria have been added to the measure for conditions associated with a limited life expectancy where a catheter may be an appropriate choice for access. These are the same exclusions applied to the Standardized Fistula Rate measure (for example, hospice, metastatic cancer, end stage liver disease, and coma/brain injury).

Data Sources

CROWNWeb, Medicare Claims and the CMS Medical Evidence form 2728 are used as the data sources for establishing the denominator. CROWNWeb is the data source for establishing the numerator. Medicare claims and CROWNWeb are used for the exclusion criteria. Medicare claims and the CMS Medical Evidence Form 2728 are used for risk adjustment. Using CROWNWeb as the primary data source allows us to expand the Long-Term Catheter Rate to include all ESRD dialysis patients, rather than only Medicare FFS patients, providing a more complete quality assessment for dialysis facilities. This was a key consideration by the TEP that recommended the development of this measure.

Outcome

The outcome of the Long-Term Catheter Rate is the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.

Cohort

The cohort includes adult ESRD dialysis patients who are determined to be maintenance hemodialysis patients (in-center or home) for the entire reporting month at the same facility.

Inclusion and Exclusion Criteria

The Long-Term Catheter Rate excludes pediatric patients (<18 years old), patients on peritoneal dialysis, and patient-months not on hemodialysis (in-center or home) for the entire reporting month at the same facility. The measure additionally excludes patients with a catheter who have a limited life expectancy.

We submitted the Long-Term Catheter Rate (NQF #2978) to NQF, where the Renal Standing Committee recommended it for consensus endorsement, and the NQF endorsed the measure in December 2016. The measure was submitted to the Measure Application Partnership in 2016, which supported it for implementation in the ESRD QIP.

We proposed to introduce the Long-Term Catheter Rate (NQF #2978) into the ESRD QIP beginning with the PY 2021 program year. Full measure specifications and testing data are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html*.

We requested comments on this proposal.

Comment: One commenter supported the inclusion of the NQF-endorsed catheter measure in the program but asked that CMS provide some additional clarifications. The commenter asked that CMS clarify how data with missing access type will be handled.

Response: We thank commenter for its support. The NQF-endorsed measure specifications we have adopted for the measure state that the measure counts patient-months with missing vascular access type in both the denominator and the numerator. Therefore, missing vascular access type is counted as a catheter.

Comment: Two commenters recommended that the catheter rate be adjusted for the following: (1) Arterial steal syndromes or other medical contraindications to a fistula or graft, for example, severe congestive heart failure; (2) extensive arm swilling from a fistula or graft; (3) co-morbidities with short predicted survivals and patients over 90 years old; (4) exhausted vascular sites or multiple failed attempts to create a fistula or graft; (5) prolonged access hemorrhaging post-dialysis from a fistula or graft (over 30 minutes on average) that decreases patient quality of life enough for access ligation; and (6) patient preference. If patient preference cannot be fully considered by CMS, commenter recommended that an adjustment be included at least for those patients on hemodialysis 4–6 times per week or with needle phobia. A patient preference adjustment or exception, the commenter suggested, could be evaluated by signed patient forms and statistics with inspections of outlier facilities. Commenter further argued that for most of the patients with these conditions, a catheter is the appropriate vascular access and facilities should not be penalized for those patients. The commenter stated that there are some dialysis facilities that don't accept patients with catheters in an effort to avoid CMS penalties and this ''cherry-picking'' concern would be eliminated by including an exception for patient preferences.

Commenter suggested that while these additional exclusion criteria could open the door to gaming the system, signed patient forms and statistics with inspections of outlier facilities could handle that issue. If a patient chooses to have long-term catheter after adequate education from their Nephrologist and care team, then the commenter believes that the patient should be excluded. Commenter added that most patients with these conditions have a catheter that is clinically appropriate. If the catheter is the best medical access for that patient, then the commenter believes that the facility should not be penalized.

Response: Many of the comorbidities suggested by commenters are either associated with shortened life expectancy or low likelihood of successful fistula placement. In some situations, the severity of the underlying diagnosis is difficult to ascertain from claims data, although like heart failure, we anticipate this will improve over time with the change to and availability of ICD–10 codes. Therefore, we anticipate other comorbidities will be evaluated as part of future measure maintenance. Regarding the 4th suggestion of commenter, regarding ''exhausted vascular sites or multiple failed attempts to create a fistula or graft,'' multiple prior failed vascular access attempts were considered by the TEP as an exclusion criterion, however consensus was not reached within the TEP on how best to implement this exclusion. At the present time, historical vascular access data in CROWNWeb are limited, but we anticipate evaluating this exclusion criterion when more historical vascular access data are available. Finally, as the commenter stated, applying patient consent could be subject to gaming and would be difficult to validate, particularly for vulnerable patients.

Comment: One commenter argued that without including AV Grafts in the measure, there's a portion of the patient population being excluded. Also, if the facility does not meet the AV fistula threshold, then the commenter believes that the long-term catheter rate is directly impacted and facilities are at risk for losing points in two measures. The proposed risk adjustments for the standardized fistula rate, commenter argued, should also be applied to the long-term catheter rate. Also, the commenter stated that the exclusion criteria for this measure should be expanded to incorporate patient choice, and those appropriate medical and surgical exclusions, so that this measure reflects the quality of care being delivered at the facility. Even with the addition of the proposed exclusion criteria, the commenter stated that it's still possible for the QIP score to penalize facilities for recommending the most clinically appropriate access for their patients.

Response: The fistula and catheter measures apply exclusions for certain conditions recognizing that catheter placement may be the only means of vascular access for these patient sub-populations. Specifically, both measures exclude patients with a catheter that have limited life expectancy defined as being under hospice care in the current reporting month, or with metastatic cancer, end stage liver disease, coma or anoxic brain injury in the past 12 months. In this way, the combination of risk adjustment for the SFR and the application of the exclusions to both measures does not result in doubly penalizing facilities and instead is intended to incentivize best practices for vascular access.

Final Rule Action: After consideration of the comments received, we are finalizing our proposal to include the Hemodialysis Vascular Access: Long-Term Catheter Rate Clinical Measure in the ESRD QIP measure set beginning with the PY 2021 program.

e. Performance Period for the PY 2021 ESRD QIP

We proposed to establish CY 2019 as the performance period for the PY 2021 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, 2018 through March 31, 2019, because this period spans the length of the 2018–2019 influenza season.

We requested comments on these proposals.

Comment: Two commenters supported setting CY 2019 as the performance period for PY 2021 generally but did not support the proposed performance period for the NHSN Healthcare Personnel Influenza Vaccination Reporting Measure as being from October 1, 2018 through March 31, 2019. They argued that the dates of vaccine availability do not coincide with the dates for the measure and encouraged CMS to modify the measure to align with the CDC's guidelines for immunization, which define the performance period as October 1 or ''whenever the vaccine became available.''

Response: We thank the commenters for sharing their concerns, however as we have explained in previous rules, the performance period for this measure defines the flu season during which healthcare personnel must be protected against influenza. The performance period is only used to identify personnel who have physically worked at the facility for at least 1 day between October 1 and March 31. These are employees that are considered eligible for inclusion in the measure denominator. The performance period does not indicate when the influenza vaccination should be administered. Therefore, any personnel who are employed for at least 1 day during the flu season, may be vaccinated as soon as the vaccine becomes available for that respective season. Facilities should report influenza vaccinations given to all healthcare personnel whether they are vaccinated prior to or during the denominator reporting period to receive full credit for the measure; therefore, there is no penalty for early vaccination built into the NHSN measure (81 FR 77901).

Comment: One commenter supported the influenza vaccination reporting measure performance period of October 1 through March 31 because it is consistent with other quality reporting and value-based purchasing programs.

Response: We thank commenter for their support of the proposed performance period for the Healthcare Personnel Influenza Vaccination Reporting Measure.

Final Rule Action: After consideration of the comments received, we are finalizing the performance period for the PY 2021 ESRD QIP as proposed.

f. Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2021 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.

i. Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures in the PY 2021 ESRD QIP

For the same reasons stated in the CY 2013 ESRD PPS final rule (77 FR 67500 through 76502), we proposed for PY 2021 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 2017, because this will give us enough time to calculate and assign numerical values to the proposed performance standards for the PY 2021 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 requested comments on our proposal to continue this policy for PY 2021. The comments and our responses are set forth below.

Comment: One commenter stated that it supports CMS's reliance on the same basic methodology year-over-year for the ESRD QIP and therefore supports the continuation of the previous policy of setting the performance standard, achievement threshold, and benchmark at the 50th, 15th, and 90th percentiles respectively, in PY 2021. The commenter also stated that it supports the policy for determining payment reductions, including the process for setting the minimum TPS.

Response: We thank the commenter for their support and we agree that consistency in program implementation is an important consideration in selecting a methodology for scoring performance under the ESRD QIP.

Final Rule Action: After consideration of the comments received, we are finalizing our proposal to continue our methodology for setting the performance standards, achievement thresholds, and benchmarks for the PY 2021 ESRD QIP.

ii. Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures Proposed for the PY 2021 ESRD QIP

We do not currently 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 2017 or the first portion of CY 2018. We will publish values for the clinical measures, using data from CY 2017 and the first portion of CY 2018 in the CY 2019 ESRD PPS final rule.

iii. Performance Standards for the PY 2021 Reporting Measures

In the CY 2014 ESRD PPS final rule, we finalized performance standards for the Anemia Management and Mineral Metabolism reporting measures (78 FR 72213). In the CY 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). In the CY 2017 ESRD PPS final rule, we finalized performance standards for the Ultrafiltration Rate Reporting Measure (81 FR 77916), the Serum Phosphorus Reporting measure (81 FR 77916), and the NHSN Dialysis Event Reporting measure (81 FR 77916).

We proposed to continue use of these performance standards for the Reporting Measures included in the PY 2021 ESRD QIP.

We did not receive any comments on our proposed use of these performance standards for the Reporting Measures included in the PY 2021 ESRD QIP and we are therefore finalizing these standards as proposed.

g. Scoring the PY 2021 ESRD QIP

i. 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 2021 ESRD QIP, we proposed to continue using this methodology for all clinical measures.

We also proposed to use this same methodology for scoring the two new Vascular Access measures.

Aside from the proposed addition of the two Vascular Access measures, we did not propose any changes to this policy. We proposed to continue use of this policy for the PY 2021 ESRD QIP.

We did not receive any comments on our continued use of this policy for PY 2021. Accordingly, we are finalizing this policy as proposed.

ii. 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 2021 ESRD QIP, we proposed to continue using this methodology for all clinical measures. Under this methodology, facilities receive points along an improvement range, defined as a scale running between the improvement threshold and the benchmark. We proposed to define the improvement threshold as the facility's performance on the measure during CY 2018. The facility's improvement score would be calculated by comparing its performance on the measure during CY 2019 (the performance period) to the improvement threshold and benchmark.

We also proposed to use this same methodology for scoring the two new Vascular Access measures.

Aside from the proposed addition of the two new Vascular Access measures, we did not propose any other changes to this policy. We proposed to continue use of this policy for the PY 2021 ESRD QIP.

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

Comment: Commenters expressed concerns with the current policy for scoring the ESRD QIP and suggested that it could be a barrier to home dialysis uptake at small facilities or stand-alone ''home only'' programs because a small sample size can put a facility at risk for a payment reduction due to one or two low scores on a measure.

Regarding the clinical measure domain score, which is worth 75 percent of the TPS and only comprises 2–3 measures for most home programs, commenter suggested that one way to mitigate this effect would be to apply the current low volume scoring adjustment to a facility's home dialysis population, should they meet the rest of the criteria. The commenter stated that this adjustment was originally designed to be applied facility-wide to facilities having only 11–25 eligible cases for a given clinical measure, and the commenter was unsure whether this approach would adequately compensate for the disadvantage of being scored on a small number of measures.

Another commenter argued that the measures should reflect the unique nature of each modality and should be developed based on data specific to that modality, recommending that CMS improve Peritoneal Dialysis adequacy scoring within the scoring methodology because PD therapy is inherently different from Hemodialysis and outcomes should be measured accordingly. According to the commenter, many PD patients experience residual renal function, which is not captured by the QIP and this is a particularly significant scoring limitation with respect to the pediatric PD population. Commenter urged CMS to revise the dialysis adequacy targets downward to more accurately capture and reflect the actual experiences of PD patients.

Response: We thank commenters for sharing their concerns. While we recognize there are differences in the achievement of adequate dialysis by modality and age, all ESRD dialysis patients require adequate dialysis, and it is reasonable to expect providers to provide adequate dialysis to all patients, regardless of modality or age. CMS continues to believe that facilities should strive to provide the best quality care, regardless of a patient's modality or age. We will consider these concerns and evaluate the issue further.

Comment: One commenter supported the proposal to use the existing methodology for scoring in PY 2021.

Response: We appreciate the support.

Final Rule Action: After consideration of the comments received, we are finalizing our proposals for scoring facilities on clinical measures based on the improvement and achievement methodologies as proposed for the PY 2021 ESRD QIP.

iii. 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 proposed to use this scoring methodology for the PY 2021 ESRD QIP. 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 2021, 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 2019 falls, relative to the achievement threshold and benchmark for that measure and rating based on CY 2017 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 2019 to its performance rates on these items during CY 2018.

We requested comments on this proposal. We did not receive any comments on this proposal. We are therefore finalizing this policy as proposed.

iv. Scoring the Proposed Hemodialysis Vascular Access: Standardized Fistula Rate and Long-Term Catheter Rate Measures and the Vascular Access Measure Topic

In the CY 2013 ESRD PPS final rule we established a methodology for deriving the overall scores for measure topics (77 FR 67507). We proposed to use the same methodology described in the CY 2013 ESRD PPS to calculate the VAT Measure Topic Score.

We requested comments on this proposal. We did not receive any comments on this proposal. We are therefore finalizing this policy as proposed.

v. 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). 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). In the CY 2017 ESRD PPS final rule, we finalized policies for scoring performance on the

Ultrafiltration Rate, Serum Phosphorus, and NHSN Dialysis Event reporting measures (81 FR 77917).

We proposed to continue use of these policies for the PY 2021 ESRD QIP.

We did not receive any comments on this proposal. We are therefore finalizing these policies as proposed.

h. Weighting the Measure Domains, and Weighting the TPS for PY 2021

In the CY 2017 ESRD PPS final rule, we discussed our policy priorities for quality improvement for patients with ESRD (81 FR 77887). These priorities have not changed since that time.

Accordingly, in an effort to remain consistent in the weighting of measures included in the program, we proposed to weight the following measures in the following subdomains of the three individual measure domains (see Table 10):

TABLE 10—PROPOSED MEASURE DOMAIN WEIGHTING FOR THE PY 2021 ESRD QIP

Measures/measure topics by subdomain	Measure weight within the domain (proposed for PY 2021)	Measure weight as percent of TPS (proposed for PY 2021)
Clinical Measure Domain		
Patient and Family Engagement/Care Coordination Subdomain	40%	30.
ICH CAHPS Measure	25%	18.75.
SRR Measure	15%	11.25.
Clinical Care Subdomain	60%	45.
STrR measure	11%	8.25.
Kt/V Dialysis Adequacy Comprehensive Measure	18%	13.5.
Vascular Access Type Measure Topic	18%	13.5.
Hypercalcemia measure	2%	1.5.
SHR Measure	11%	8.25.
Total: Clinical Measure Domain	100% of Clinical Measure Domain.	75% of Total Performance Score.
Reporting Measure Domain		
Serum Phosphorus reporting measure	20%	2.
Anemia Management reporting measure	20%	2.
Pain Assessment and Follow-Up reporting measure	20%	2.
Clinical Depression Screening and Follow-Up reporting measure	20%	2.
Healthcare Personnel Influenza Vaccination reporting measure	20%	2.
Total: Reporting Measure Domain	100% of Reporting Measure Domain.	10% of Total Performance Score.
Safety Measure Domain		
NHSN BSI Clinical Measure	60%	9.
NHSN Dialysis Event Reporting Measure	40%	6.
Total: Safety Measure Domain	100% of Safety Measure Domain.	15% of Total Performance Score.

For PY 2021 we proposed to maintain the weight of the Safety Measure Domain at 15 percent of a facility's TPS without raising it further, in light of validation concerns discussed in the CY 2017 ESRD PPS final rule (81 FR 77887). Specifically, we identified two distinct types of accidental or intentional under-reporting. First, there is a belief that many facilities do not consistently report monthly dialysis event data for the full 12-month performance period. Second, even with respect to the facilities that do report monthly dialysis event data, there is a concern that many of those facilities do not consistently report all of the dialysis events that they should be reporting (81 FR 77879). Although we did not propose to change the total number of measures in the ESRD QIP's measure set for PY 2021, we proposed to replace the existing Vascular Access measures with the proposed Standardized Fistula and Catheter Clinical measures. We believe these measures hold the same importance and value as the measures they are replacing and therefore did not propose any changes to the weights finalized for PY 2020 in the CY 2017 ESRD PPS final rule (81 FR 77887). We stated that we may, in future years of the program, 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 recently updated NHSN Data Validation Study.

We continue to believe that while the reporting measures are valuable, the clinical measures assess facility performance on actual patient care processes and outcomes, and therefore, justify a higher combined weight (78 FR 72217). In the CY 2017 ESRD PPS final rule, we finalized that for PY 2020, the weight of the Safety Measure Domain would be 15 percent of a facility's TPS, the weight of the Clinical Measure Domain would be 75 percent of a facility's TPS and the weight of the Reporting Measure Domain would be 10 percent of a facility's TPS. We did not propose any changes to the weights assigned to these domains and proposed to apply the same weights to the three scoring domains for the PY 2021 program year.

In the CY 2017 ESRD PPS final rule, we also finalized that, 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 did not propose

any changes to this policy for the PY 2021 ESRD QIP.

We requested comments on these proposals.

Comment: Commenters urged CMS to re-weight the Vascular Access measures within the Clinical Measure Domain, assigning ⅔ of the weight of that measure topic to the Catheter Measure and ⅓ to the Fistula. Commenters argued that with a differential weighting of the two measures, a facility that scores especially well on the catheter measure (that is, low numbers of catheters) compared to the fistula measure could achieve an increase of about 2 points in its TPS. Conversely, these commenters stated that a facility that scores especially well on the fistula measure but still has high numbers of catheters could see its TPS decrease by approximately 2 points. Commenters argued that these differences could be meaningful for facilities that are near the TPS cut-off points for payment reduction levels. Commenters also stated that facilities that score about the same on the two measures would not see a notable change in their TPS.

Response: We conducted an analysis to determine how the Vascular Access Measure Topic Scores, TPS, and estimated payment reductions would be impacted if we were to assign ⅔ of the weight of the measure topic to the Catheter Measure, and ⅓ of the weight of the measure topic to the Fistula Measure. Results (shown in Table 11), suggest that although some facilities would benefit from this policy change, a larger percentage would not.

TABLE 11—ANALYSIS OF THE EFFECTS OF RE-WEIGHTING THE VASCULAR ACCESS MEASURES

	N	%
Difference in Payment Reduction		
Lower Payment Reduction	328	5.82
Higher Payment Reduction	417	7.40
No Change	4890	86.78
Difference in TPS		
Lower TPS	2373	42.10
Higher TPS	2004	35.56
No Change	1258	22.30

As shown in Table 11, under this re-weighting approach for the Vascular Access Measures, approximately 36 percent of facilities would receive a higher VAT Topic Score and TPS, but 42 percent would receive lower scores. Additionally, under this weighting policy recommended by commenters, 5.8 percent would receive a lower payment reduction, but 7.4 percent would receive a higher payment reduction. While the recommendation to re-weight the VAT Measure topic fits with the overall goal of the ESRD QIP to increase performance on the catheter measure, we believe that some facilities would be adversely impacted were we to adopt this weighting structure.

Comment: One commenter requested clarification on the weight of the Ultrafiltration Rate Reporting Measure for PY 2021 because no weight was included for that measure in the proposed rule.

Response: We thank the commenter for pointing out the error. Although we inadvertently did not include the proposed numerical weight for the UFR Reporting Measure for PY 2021 in Table 8 of the proposed rule, we proposed to weight the reporting measures and the Reporting Measure Domain consistent with how we have weighted them in previous years of the program (79 FR 66217, 79 FR 66219). Under that weighting scheme, which is reflected in Table 8 of the proposed rule, each reporting measure is weighted equally within the Reporting Domain, and the Reporting Domain, as a whole, comprises 10 percent of the TPS. Application of that policy to the PY 2021 reporting measures, which includes the UFR Reporting Measure, results in each measure being weighted at 16.66 percent of the Reporting Measure Domain, or 1.66 percent of the TPS. Table 12 reflects these values.

Final Rule Action: After considering the comments we received, we are finalizing our domain weighting policy for PY 2021. The final weights are reflected in Table 12.

TABLE 12—FINALIZED MEASURE DOMAIN WEIGHTING FOR THE PY 2021 ESRD QIP

Measures/measure topics by subdomain	Measure weight within the domain (proposed for PY 2021)	Measure weight as percent of TPS (proposed for PY 2021)
Clinical Measure Domain		
Patient and Family Engagement/Care Coordination Subdomain	40%	30.
ICH CAHPS Measure	25%	18.75.
SRR Measure	15%	11.25.
Clinical Care Subdomain	60%	45.
STrR measure	11%	8.25.
Kt/V Dialysis Adequacy Comprehensive Measure	18%	13.5.
Vascular Access Type Measure Topic	18%	13.5.
Hypercalcemia measure	2%	1.5.
SHR Measure	11%	8.25.
Total: Clinical Measure Domain	100% of Clinical Measure Domain.	75% of Total Performance Score.
Reporting Measure Domain		
Serum Phosphorus reporting measure	16.66%	1.66.
Anemia Management reporting measure	16.66%	1.66.
Pain Assessment and Follow-Up reporting measure	16.66%	1.66.
Clinical Depression Screening and Follow-Up reporting measure	16.66%	1.66.
Healthcare Personnel Influenza Vaccination reporting measure	16.66%	1.66.
Ultrafiltration Rate Reporting Measures	16.66%	1.66.
Total: Reporting Measure Domain	100% of Reporting Measure Domain.	10% of Total Performance Score.

TABLE 12—FINALIZED MEASURE DOMAIN WEIGHTING FOR THE PY 2021 ESRD QIP—Continued

Measures/measure topics by subdomain	Measure weight within the domain (proposed for PY 2021)	Measure weight as percent of TPS (proposed for PY 2021)
Safety Measure Domain		
NHSN BSI Clinical Measure	60%	9.
NHSN Dialysis Event Reporting Measure	40%	6.
Total: Safety Measure Domain	100% of Safety Measure Domain.	15% of Total Performance Score.

i. Example of the PY 2021 ESRD QIP Scoring Methodology

In this section, we provide an example to illustrate the scoring methodology for PY 2021. 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 scoring methodology for PY 2021. Note that for this example, Facility A, a hypothetical facility, has performed very well.

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

FIGURE 1:

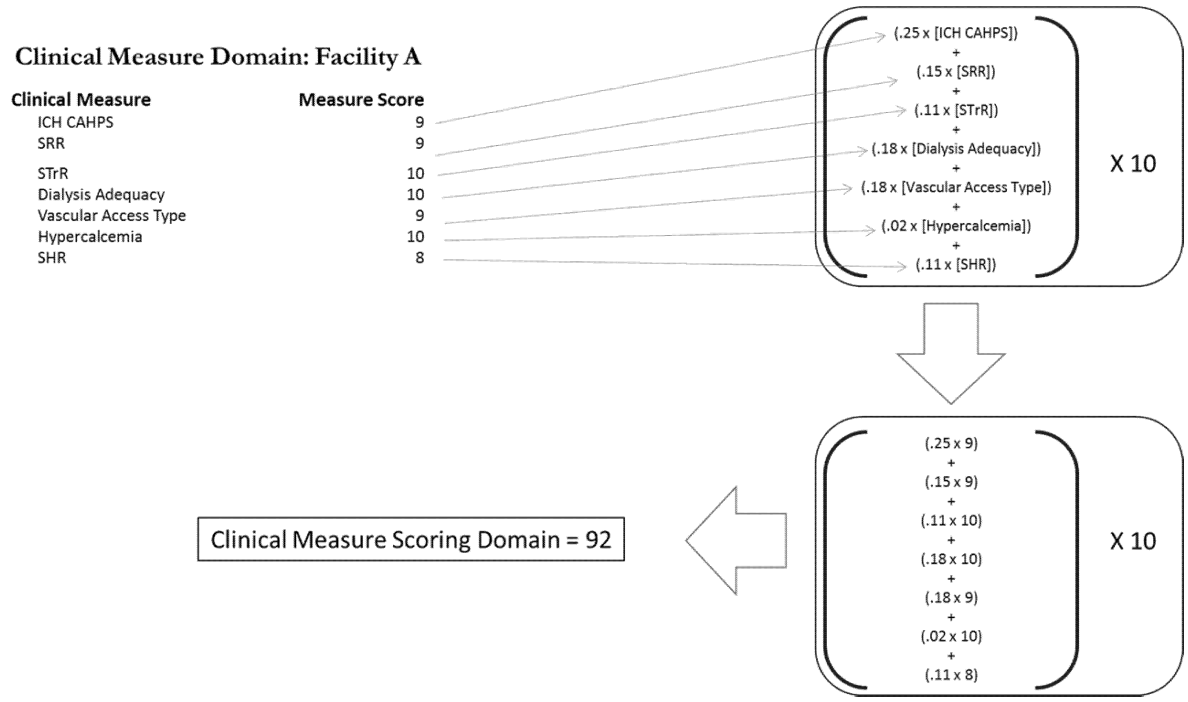


Figure 2 illustrates the general methodology for calculating the Reporting Measure Domain score for Facility A.

FIGURE 2:

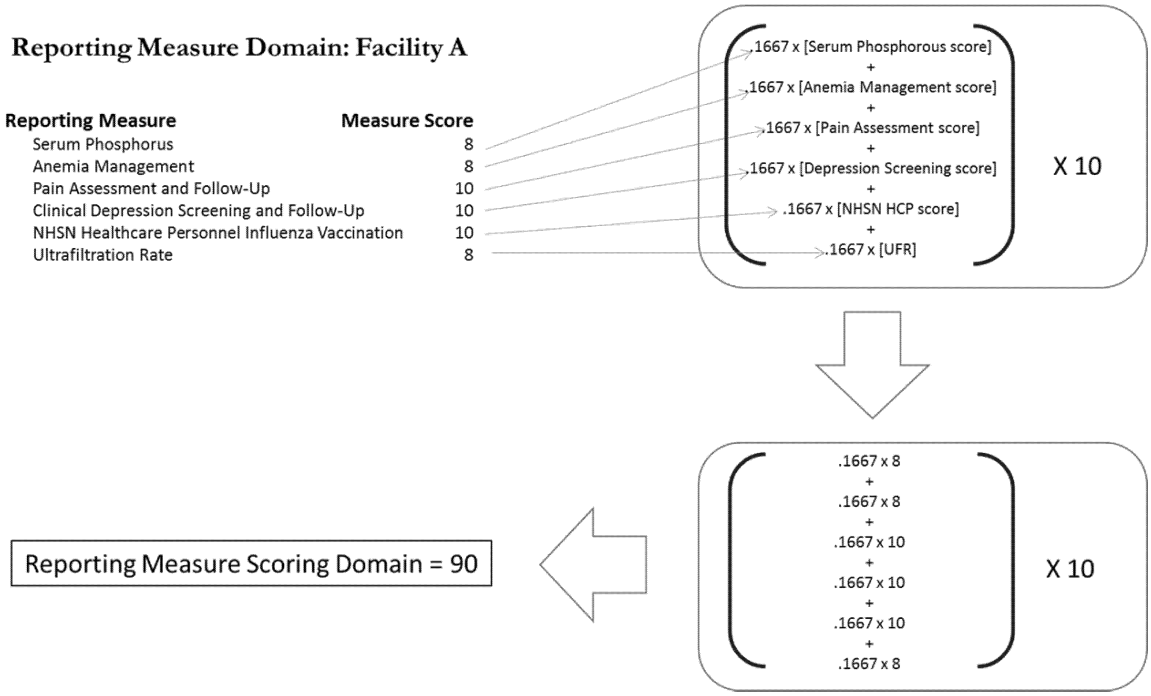


Figure 3 illustrates the methodology used for calculating the Safety Measure Domain score for Facility A.

FIGURE 3:

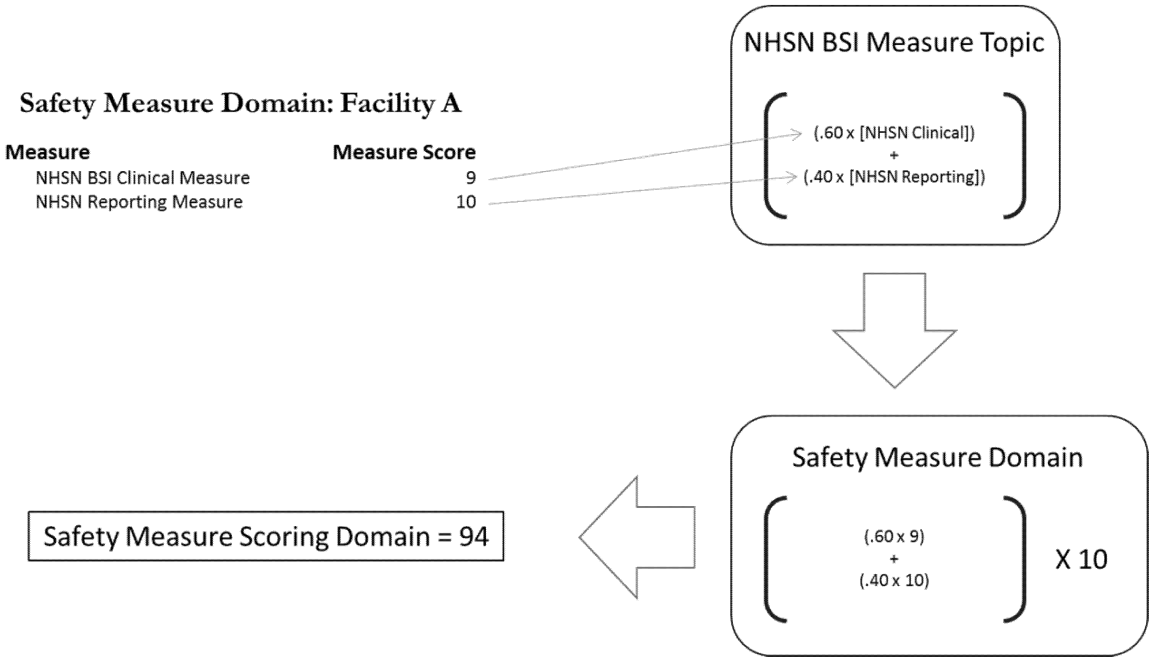


Figure 4 illustrates the methodology used to calculate the TPS for Facility A.

FIGURE 4:

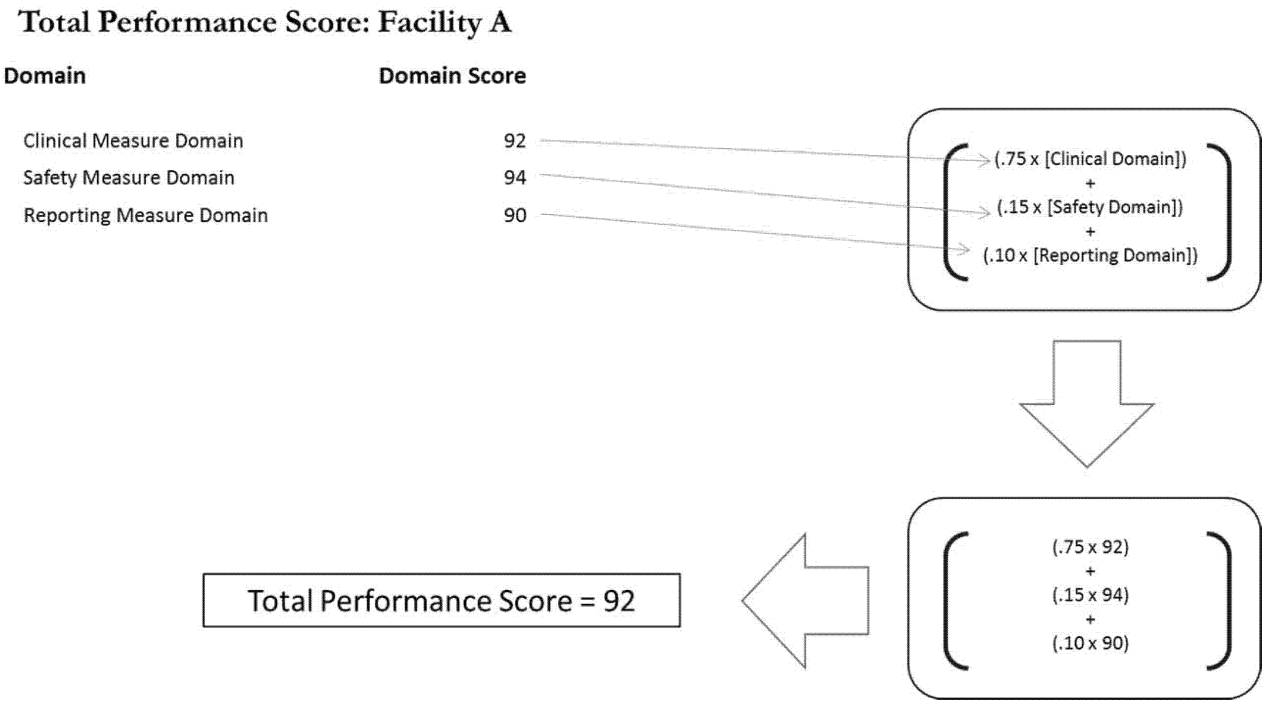
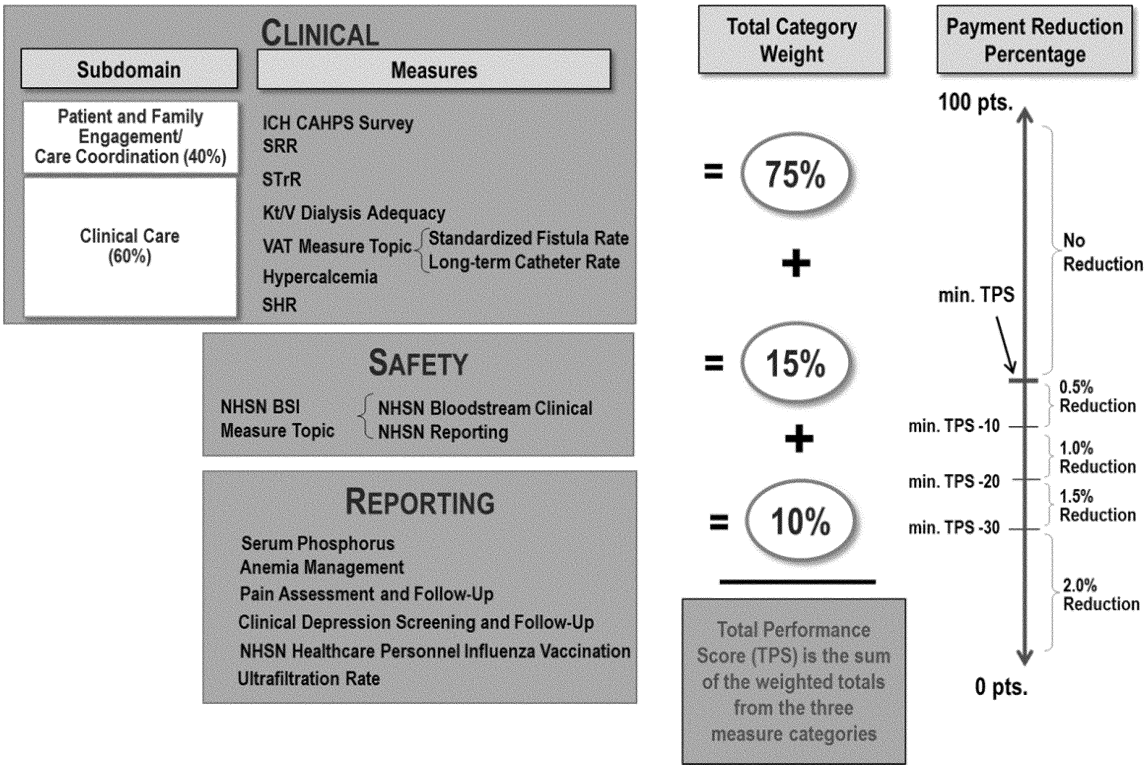


Figure 5 illustrates the full scoring methodology for PY 2021.

FIGURE 5:



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j. Minimum Data for Scoring Measures for the PY 2021 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, NHSN Healthcare Personnel Influenza Vaccination, 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. The NHSN Healthcare Personnel Influenza Vaccination measure does not assess patient-level data and therefore does not have a minimum qualifying patient count. 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 proposed to continue use of these minimum data policies for the measures that we proposed to continue including in the PY 2021 ESRD QIP measure set. We also proposed to use these same minimum data policies for the proposed Vascular Access Measures.

Under our current policy, we begin counting the number of months for which a facility is open on the first day of the month after the facility's CMS Certification Number (CCN) Open Date. In the CY 2018 ESRD PPS proposed rule (81 FR 31203), we discussed our proposed clarifications, which we are finalizing in this final rule (see Table 2b), to our CCN open date policy and to the patient minimum requirements for each of the measures finalized for the PY 2020 ESRD QIP. Similarly, for the PY 2021 ESRD QIP, only facilities with a CCN Open Date before July 1, 2019 would be eligible to be scored on the Anemia Management, Serum Phosphorous, Ultrafiltration Rate, Pain Assessment and Follow-Up, Clinical Depression Screening and Follow-Up reporting measures, and only facilities with a CCN Open Date before January 1, 2019 would be eligible to be scored on the NHSN BSI Clinical and Reporting Measures, the ICH CAHPS Clinical Measure, and the NHSN Healthcare Personnel Influenza Vaccination reporting measure. We proposed to continue applying these CCN open date policies to the measures proposed for PY 2021.

Table 13 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. We note that the 11 qualifying patient minimum used for most of the measures shown in the Table 13 is a long-standing policy in the ERSD QIP.

TABLE 13—PROPOSED MINIMUM DATA REQUIREMENTS FOR THE PY 2021 ESRD QIP

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Dialysis Adequacy (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients.
Hemodialysis Vascular Access: Standardized Fistula Rate (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Hemodialysis Vascular Access: Long-Term Catheter Rate (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients.
NHSN BSI (Clinical)	11 qualifying patients *	Before January 1, 2019	11–25 qualifying patients.
NHSN Dialysis Event (Reporting)	11 qualifying patients *	Before January 1, 2019	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 CY preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period.	Before January 1, 2019	N/A.
Anemia Management (Reporting)	11 qualifying patients	Before July 1, 2019	N/A.
Serum Phosphorus (Reporting)	11 qualifying patients	Before July 1, 2019	N/A.
Depression Screening and Follow-Up (Reporting).	11 qualifying patients	Before July 1, 2019	N/A.
Pain Assessment and Follow-Up (Reporting).	11 qualifying patients	Before July 1, 2019	N/A.
NHSN Healthcare Personnel Influenza Vaccination (Reporting).	N/A	Before January 1, 2019	N/A.
Ultrafiltration Rate (Reporting)	11 qualifying patients	Before July 1, 2019	N/A.

* For the NHSN BSI Clinical Measure and the NHSN Dialysis Event Reporting Measure, qualifying patients include only in-center hemodialysis patients. Inpatient hemodialysis patients and home hemodialysis or peritoneal dialysis patients are excluded from this measure.

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

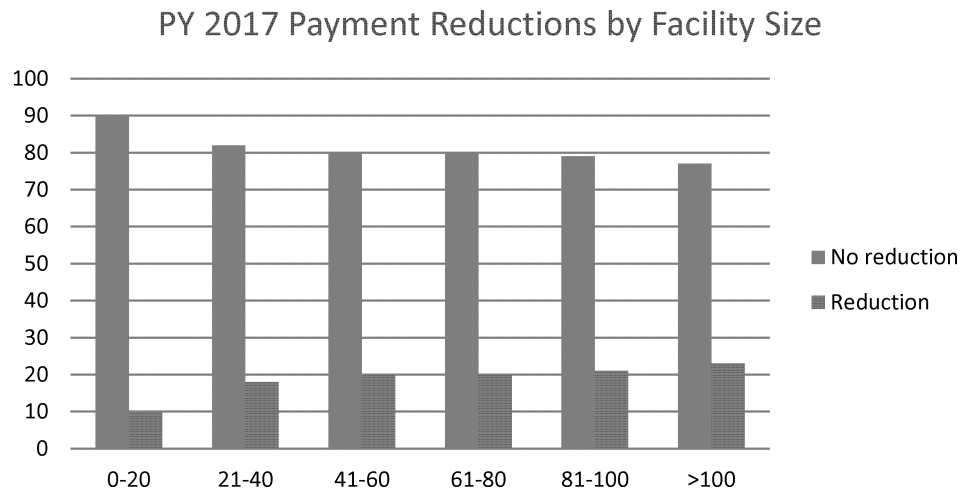
Comment: One commenter argued that the use of the 11-case minimum, while meant to ensure the privacy of individuals, is not ensuring the integrity of the data being reported. The commenter believes that CMS has introduced randomness into the process of scoring quality measures and that this randomness leads to facilities being unable to predict how their actions will impact outcomes and therefore makes measures meaningless in terms of improving quality. The commenter added that the minimum data threshold makes the outcome of these measures

meaningless to patients because the small number of patients drives the outcome rather than the actual care being provided. The commenter recommended that CMS eliminate the small facility adjuster and adopt instead a minimum sample size of 26 patients for scoring measures.

Response: We thank the commenter for their comments. While it is true that smaller facilities will most likely have more variability in measure scores, our analysis of the PY 2017 results suggest smaller facilities received fewer payment reductions (see figure 6 below). Reliability analyses have been used to determine upper thresholds for the small facility adjustment. These reliability analyses were published when the small facility adjuster was first introduced into the ESRD QIP (78 FR 72222), and are available here: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Small-Facility-Adjustment-Proposal-for-the-ESRD-QIP.pdf*.

These reliability analyses were performed for all measures, including the ratio measures (which have different thresholds).

FIGURE 6. Payment Year 2017 Payment Reductions by Facility Size



Final Rule Action: After considering the comments received, we are finalizing the minimum data policy for the PY 20201 ESRD QIP as proposed.

k. Payment Reductions for the PY 2021 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 2021 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.
- It received the number of points for each reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2019 reporting measures.

We noted in the proposed rule that this proposed policy for PY 2021 is identical to the policy finalized for PY 2020.

We stated in the proposed rule 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 for PY 2020. We did not propose such a policy because no measures in the proposed PY 2021 measure set meet this criterion. However, should we choose to adopt a clinical measure in future rulemaking without the baseline data required to calculate a performance standard before the beginning of the performance period, we will propose a criterion accounting for that measure in the minimum TPS for the applicable payment year at that time.

The PY 2019 program is the most recent year for which we will have calculated final measure scores before the beginning of the proposed performance period for PY 2021 (that is, CY 2019). Because we have not yet calculated final measure scores, we are unable to determine the 50th percentile of facility performance on the PY 2019 reporting measures. We will propose that value in the CY 2019 ESRD PPS proposed rule once we have calculated final measure scores for the PY 2019 program, and will finalize those values in the CY 2019 ESRD PPS final rule using the most updated data available at the time of publication.

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 2021 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 propose a minimum TPS, based on data from CY 2017 and the first part of CY 2018, in the CY 2019 ESRD PPS proposed rule.

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

Comment: Several commenters expressed concerns with the significant increase in the number of facilities projected to receive a payment reduction from PY 2017 to PYs 2020 and 2021. They found no changes in the methodology or measures that would explain such a substantial fluctuation. One commenter stated that changes in the minimum TPS do not predict the change that the addition of any single measure is unlikely to drive a major shift in payment reductions and there are no significant changes in the measure thresholds that would explain the large shift. The commenter therefore urged CMS to adjust the QIP payment reduction parameters to maintain more consistent payment levels from one year to the next and asked that CMS work with the community to consider a policy to adjust the payment reduction thresholds to generate more predictable payment outcomes. Another commenter asked CMS to explain how it determined the percentage of penalties and why there appears to be such a significant change, to provide for greater transparency.

Response: Though we did not propose a minimum TPS for PY 2021, we were able to provide simulations. We estimated the minimum TPS for PY 2021 for the analyses provided in the CY 2018 ESRD PPS proposed rule using the available data. For simulations, we use the performance standards from the prior year to calculate the minimum TPS. We do this so that we are simulating what is actually done when we calculate final sores. However, we have found that it does not make a big difference which performance standards are used to conduct our simulations—results do not change drastically.

Our policies for determining payment reductions have not changed from year to year and are consistent with the methodology described in several of our previous rules (see for example, 80 FR 69046 and 81 FR 77893). We believe the increases in simulated payment reductions are due to the inclusion of the ICH CAHPS and SHR measures in the PY 2020 simulation, whereas they were not included in the PY 2019 simulation because data was not available at that time. It is also due to a decrease in performance for the SRR, STrR, VAT, and Hypercalcemia measures among a subset of facilities. Finally, we note that as the ESRD QIP increases the number of measures included in the TPS, this also increases the chance that a facility will score poorly on one or more measures, which can result in increased payment reductions.

Final Rule Action: After consideration of the comments received, we are finalizing our policy for determining payment reductions for the PY 2021 ESRD QIP as proposed.

C. Miscellaneous Comments

We received several general comments on the ESRD QIP. The comments and our responses are set forth below.

Comment: Several commenters supported the general goals of the ESRD QIP and supported our efforts to develop a quality incentive program that promotes high quality patient care for patients with ESRD.

Response: We appreciate commenters' support of the ESRD QIP and welcome the opportunity to collaborate with the community to ensure that the program continues to promote high quality patient care in renal dialysis facilities.

Comment: Several commenters expressed concerns about the burden associated with the program, arguing that adding new measures to the program only increases the burden for providers and for CMS.

Response: We thank commenters for sharing their concerns. We are constantly reviewing our program and are always looking for ways to balance minimizing burden with employing a comprehensive quality performance assessment. One way in which we try to achieve this balance is, when feasible, to calculate measures using Medicare claims and other administrative data so that facilities do not need to report additional data. Doing so allows us to assess key clinical care outcomes while minimizing additional burden on dialysis facilities.

Comment: Several commenters encouraged CMS to abstain from creating new measures and to instead focus on ensuring that the current set of measures is evidence-based, promotes the delivery of high-quality care, and improves patient outcomes. One commenter recommended a detailed set of criteria for prioritizing ESRD quality measures. In addition to more closely examining the measures that are added to the program, several commenters also recommended that CMS look carefully at the existing measures to determine whether any can be retired, especially as they become ''topped out.'' Commenters expressed concern that having too large a number of measures in the measure set dilutes the impact of individual measures.

Response: We thank commenters for sharing their concerns. We are constantly re-examining the measures that are included in the program to ensure that they are capturing a wide variety of information about the care that patients receive, and we carefully consider whether measures should be retired from the program using a set of criteria previously finalized through rulemaking (81 FR 77896 through 77897). We agree that new measures implemented in the QIP should be evidence-based, promote the delivery of high-quality care, and improve patient outcomes. We also consider how our measures are weighted within the TPS in an effort to ensure that measures with greater clinical significance receive greater weight and emphasis. Additionally, through our measurement development process and consideration of which measures to include in the program, we seek to implement NQF-endorsed outcomes-based measures to the extent feasible and, as part of that analysis, examine the reporting burden associated with those measures.

V. 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. Health IT facilitates the secure, efficient, and effective sharing and use of health-related information when and where it is needed, and is an important tool for settings across the continuum of care, including ESRD facilities. Health IT plays an important role in developing care plans to manage dialysis related care and co-morbid conditions for patients with ESRD, as well as enabling electronic coordination and communication among multidisciplinary teams. Such tools can promote quality improvement, improve efficiencies and reduce unnecessary costs.

HHS continues to make important strides promoting the availability of technology tools to support providers, including those in ESRD settings. For instance, in 2015 the Office of the National Coordinator for Health Information Technology (ONC) 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 priority data domains 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.

In addition, ONC has released the 2017 Interoperability Standards Advisory (available at *https://www.healthit.gov/standards-advisory*), a coordinated catalog of standards and implementation specifications to enable priority health information exchange functions. Providers, payers, and vendors are encouraged to take these health IT 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.

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

Comment: Several commenters noted the recent focus on leveraging health IT to improve provider communication but noted that dialysis facilities often do not receive discharge information needed for continuity of care. Commenters indicated that patients often do not disclose information about recent hospitalizations and dialysis facilities face challenges when requesting discharge instructions and summaries on behalf of the patient. Commenters recommended that CMS require hospitals, particularly those using certified health IT, to send the following information to providers involved in the patient's care: (1) The discharge instructions and discharge summary within 48 hours; (2) pending test results within 72 hours of their availability; and (3) all other necessary information specified in the ''transfer to another facility'' requirements.

Response: We agree with commenters' support for the use of health IT to facilitate improved communication and coordination across care settings. We appreciate commenters' concerns that discharge information is often not sent to dialysis facilities following a hospitalization or may not be sent in a timely manner for continuity of care. While out of scope for this rulemaking, several policies currently address this issue. Under Medicare's Conditions of Participation in 42 CFR 482.43(d), hospitals transferring or referring a patient are already required to send necessary medical information to appropriate facilities and outpatient services as needed for follow-up care. We also note that eligible hospitals and critical access hospitals participating in Stage 2 and Stage 3 of the Medicare and Medicaid Electronic Health Record Incentives Programs are measured on their ability to electronically send summary of care information for transitions of care or referrals to another setting or provider of care, which may include dialysis facilities. With respect to recommendations regarding timing requirements for the sending of discharge information, we will take these comments under consideration as we continue to revise and build on these policies in the future.

VI. 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. We solicited comments in the notice of proposed rulemaking that published in the **Federal Register** on July 5, 2017 (82 FR 31190). For the purpose of transparency, we are republishing the discussion of the information collection requirements. All of the requirements discussed in this section are already accounted for in OMB approved information collection requests.

B. Requirements in Regulation Text

We are not finalizing changes to the regulatory text for the ESRD PPS or for AKI dialysis payment in CY 2018.

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

To derive wage estimates, we used data from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and 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,[11] 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.[12] The mean hourly wage of a Medical Records and Health Information Technician is $19.93 per hour. Fringe benefit is calculated at 100 percent. Therefore, using these assumptions, we estimate an hourly labor cost of $39.86 as the basis of the wage estimates for all collection of information calculations in the ESRD QIP. We have adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. These are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that these are reasonable estimation methods.

b. Time Required To Submit Data Based on Reporting Requirements for PY 2020

In the CY 2016 ESRD PPS final rule (80 FR 69070), we estimated that the time required to submit measure data for Payment Year 2019 using CROWNWeb is 2.5 minutes per data element submitted, which takes into account the small percentage of data

[11] *https://www.bls.gov/oes/current/oes292071.htm.*

[12] *https://www.bls.gov/oes/current/oes291141.htm.*

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. Since then, these estimates of the time required to submit data have not changed and we are therefore continuing to rely upon them in our burden calculations for PY 2020 and future payment years.

c. Data Validation Requirements for the PY 2020 ESRD QIP

Section IV.B.3.g of this final rule outlines our data validation policies for PY 2020. Specifically, for the CROWNWeb validation, we will continue randomly sampling records from 300 facilities as part of our continuing pilot data validation program. Each sampled facility will 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 $29,895 (750 hours × $39.86/hour), or a total of approximately $93 ($29,895/300 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 continuing data validation study for validating data reported to the NHSN Dialysis Event Module, we will continue using the methodology finalized in the CY 2017 ESRD PPS final rule, however we are adopting a modification to our sampling methodology, which we described at section IV.B.3.g of this final rule. 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 would 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 will submit this data, we estimate that the aggregate cost of the NHSN data validation will be $1,395.10 (35 hours × $39.86/hour), or a total of $39.86 ($1,395.10/35 facilities) per facility in the sample. The burden associated with these requirements is captured in an information collection request (OMB control number 0938–1340).

To determine the burden associated with the collection of information requirements, we look at each of these elements together: The total number of patients nationally, the number of elements per patient-year required for each measure, the amount of time required for data entry, and the estimated wage plus benefits of the individuals within facilities who are most likely to be entering data into CROWNWeb. Therefore, based on this methodology, in the CY 2017 ESRD PPS final rule, we anticipated the burden associated with the new collection of information requirements was approximately $91 million for the PY 2020 ESRD QIP (81 FR 77957).[13] We are not changing our data collection methodology for PY 2021; however, we are replacing two existing measures for PY 2021. We believe replacing the two existing measures will have a de minimis effect on the overall burden associated with collection of information requirements in PY 2021. Accordingly, the PY 2021 burden estimate remains the same at $91 million. The net incremental burden from PY 2020 to PY 2021 is $0.

VII. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as economically significant); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule is not economically significant within the meaning of section 3(f)(1) of the Executive Order. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) and 3(f)(3) of the Executive Order. Therefore, OMB has reviewed this final rule, and the Departments have provided the following assessment of their impact. We solicited comments on the regulatory impact analysis provided and no comments were received.

2. Statement of Need

This rule finalizes a number of routine updates and one policy change to the ESRD PPS in CY 2018. The finalized routine updates include the CY 2018 wage index values, the wage

[13] We note that the aggregate impact of the PY 2020 ESRD QIP was included in the CY 2017 ESRD PPS final rule (81 FR 77834 through 77969). The previously finalized aggregate impact of $113 million reflects the PY 2020 estimated payment reductions and the collection of information requirements for the Ultrafiltration Rate Reporting Measure, finalized in the CY 2017 ESRD PPS final rule (81 FR 77915).

index budget-neutrality adjustment factor, and outlier payment threshold amounts. The finalized policy change involves an update to the outlier pricing policy. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2018 for renal dialysis services furnished to ESRD patients.

This rule finalizes routine updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2018 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

This rule finalizes requirements for the ESRD QIP, including the adoption of a measure set for the PY 2021 program, as directed by section 1881(h) of the Act. Failure to finalize requirements for the PY 2021 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2020. In addition, finalizing requirements for the PY 2021 ESRD QIP provides facilities with more time to review and fully understand new measures before they are scored on them in the ESRD QIP.

3. Overall Impact

We estimate that the final revisions to the ESRD PPS will result in an increase of approximately $60 million in payments to ESRD facilities in CY 2018, which includes the amount associated with updates to the outlier thresholds, outlier policy, and updates to the wage index. We are estimating approximately $20 million that would now be paid to ESRD facilities for dialysis treatments provided to AKI beneficiaries.

We note that the impacts for the ESRD PPS and AKI payments in the proposed rule are substantially different from what we are finalizing. The proposed ESRD PPS impact was $100 million based on the proposed update factor of 0.7. The final update factor was calculated as 0.3 percent, and that change resulted in the lower impact amount included in this final rule.

The proposed impact for AKI payments was $2 million. The increase from the proposed rule to the final rule is based on actual preliminary claims data that became available after publication of the proposed rule, which allowed us to make a more accurate estimation of the utilization of services.

For PY 2021, we estimate that the final revisions to the ESRD QIP will result in a savings of $29 million, which includes a zero incremental burden due to collection of information requirements and $29 million in estimated payment reductions across all facilities.

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We requested comments on the approach in estimating the number of entities which will review the proposed rule and no comments were received.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We requested comments on this assumption, however, no comments were received.

Using the wage information from the BLS (*https://www.bls.gov/oes/2015/may/naics4_621100.htm*) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $105.00 per hour, including overhead and fringe benefits. Assuming an average reading speed, we estimate that it would take approximately 1.25 hours for the staff to review half of this final rule. For each ESRD facility that reviews the rule, the estimated cost is $131.25 (1.25 hours × $105.00). Therefore, we estimated that the total cost of reviewing this regulation is $19,162.50 ($131.25 × 146 reviewers).

B. Detailed Economic Analysis

1. CY 2018 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 2017 to estimated payments in CY 2018. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2017 and CY 2018 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 CY 2016 data from the Part A and B Common Working Files, as of August 4, 2017, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2016 claims to 2017 and 2018 using various updates. The updates to the ESRD PPS base rate are described in section II.B.2.d of this final rule. Table 14 shows the impact of the estimated CY 2018 ESRD payments compared to estimated payments to ESRD facilities in CY 2017.

TABLE 14—IMPACT OF CHANGES IN PAYMENT TO ESRD FACILITIES FOR CY 2018 FINAL RULE [1]

Facility type	Number of facilities	Number of treatments (in millions)	Effect of 2018 changes in outlier policy	Effect of 2018 changes in wage indexes	Effect of 2018 changes in payment rate update	Effect of total 2018 proposed changes (outlier, wage indexes, routine updates to the payment rate)
	A	B	C(%)	D(%)	E(%)	F(%)
All Facilities	6,814	45.1	0.2	0.0	0.3	0.5

TABLE 14—IMPACT OF CHANGES IN PAYMENT TO ESRD FACILITIES FOR CY 2018 FINAL RULE [1]—Continued

Facility type	Number of facilities	Number of treatments (in millions)	Effect of 2018 changes in outlier policy	Effect of 2018 changes in wage indexes	Effect of 2018 changes in payment rate update	Effect of total 2018 proposed changes (outlier, wage indexes, routine updates to the payment rate)
	A	B	C(%)	D(%)	E(%)	F(%)
Type						
Freestanding	6,383	42.7	0.2	0.0	0.3	0.5
Hospital based	431	2.4	0.3	0.1	0.3	0.7
Ownership Type						
Large dialysis organization	5,110	34.3	0.2	0.0	0.3	0.4
Regional chain	871	5.8	0.2	0.1	0.3	0.6
Independent	487	3.1	0.2	0.0	0.3	0.5
Hospital based [2]	341	1.8	0.3	0.1	0.3	0.8
Unknown	5	0.0	0.0	0.2	0.3	0.5
Geographic Location						
Rural	1,243	6.5	0.2	-0.2	0.3	0.3
Urban	5,571	38.6	0.2	0.0	0.3	0.5
Census Region						
East North Central	1,109	6.4	0.2	0.0	0.3	0.4
East South Central	551	3.4	0.2	−0.1	0.3	0.4
Middle Atlantic	742	5.5	0.2	0.1	0.3	0.6
Mountain	382	2.2	0.1	−0.1	0.3	0.3
New England	191	1.5	0.2	−0.1	0.3	0.4
Pacific [3]	808	6.4	0.2	0.0	0.3	0.5
Puerto Rico and Virgin Islands	50	0.4	0.1	0.0	0.3	0.5
South Atlantic	1,572	10.5	0.2	−0.1	0.3	0.4
West North Central	484	2.3	0.2	0.2	0.3	0.7
West South Central	925	6.5	0.2	0.2	0.3	0.7
Facility Size						
Less than 4,000 treatments	1,158	2.0	0.2	0.0	0.3	0.4
4,000 to 9,999 treatments	2,542	11.7	0.2	−0.1	0.3	0.4
10,000 or more treatments	3,036	31.0	0.2	0.0	0.3	0.5
Unknown	78	0.4	0.3	0.5	0.3	1.1
Percentage of Pediatric Patients						
Less than 2%	6,706	44.7	0.2	0.0	0.3	0.5
Between 2% and19%	43	0.3	0.2	0.2	0.3	0.8
Between 20% and 49%	11	0.0	0.3	−0.6	0.3	0.0
More than 50%	54	0.1	0.3	0.2	0.3	0.9

[1] Sensipar will be paid under the transitional drug add-on payment adjustment for CY 2018. In CY 2016 there was approximately $840 million in spending for Sensipar under Part D.
[2] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Island.
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.2.c of this rule is shown in column C. For CY 2018, the impact on all ESRD facilities as a result of the changes to the outlier payment policy would be a 0.2 percent increase in estimated payments. Nearly all ESRD facilities are anticipated to experience a positive effect in their estimated CY 2018 payments as a result of the finalized outlier policy changes.

Column D shows the effect of the finalized CY 2018 wage indices and the wage index floor of 0.4000. The categories of types of facilities in the impact table show changes in estimated payments ranging from a −0.6 percent decrease to a 0.5 percent increase due to these finalized updates in the wage indices.

Column E shows the effect of the finalized CY 2018 ESRD PPS payment rate update. The finalized ESRD PPS payment rate update is 0.3 percent,

which reflects the finalized ESRDB market basket percentage increase factor for CY 2018 of 1.9 percent, the 1.0 percent reduction as required by the section 1881(b)(14)(F)(i)(I) of the Act, and the MFP adjustment of 0.6 percent.

Column F reflects the overall impact, that is, the effects of the finalized outlier policy changes, the finalized wage index floor, and payment rate update. We expect that overall ESRD facilities would experience a 0.5 percent increase in estimated payments in CY 2018. The categories of types of facilities in the impact table show impacts ranging from 0.0 percent to an increase of 1.1 percent in their CY 2018 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 2018, we estimate that the finalized 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 2018 would be approximately $9.8 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 1.6 percent in CY 2018.

d. Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 0.5 percent overall increase in the finalized CY 2018 ESRD PPS payment amounts, we estimate that there will be an increase in beneficiary co-insurance payments of 0.5 percent in CY 2018, which translates to approximately $10 million a figure which is rounded to the nearest $10 million. The rounded $10 million is based on 20 percent of CY 2018 estimated total payment increase of $60 million. There are roughly 400,000 ESRD beneficiaries, so this increase represents a $25 increase per beneficiary.

e. Alternatives Considered

In section II.B.1.d of this final rule, we finalized a policy to price eligible outlier drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B using any of the methodologies available under section 1847A of the Act. We considered not making any change to the outlier pricing policy and also potentially requiring manufacturers to submit ASP data in order to be eligible for outlier payment or payment under the TDAPA.

2. CY 2018 Payment for Renal Dialysis Services Furnished to Individuals With AKI

a. Effects on ESRD Facilities

We analyzed CY 2017 hospital outpatient claims to identify the number of treatments furnished historically for AKI patients. We identified 32,433 AKI dialysis treatments that were furnished in the first four months of CY 2017. We then inflated the 32,433 treatments to account for the whole year of 2017. We further inflated to 2018 values using estimated population growth for fee-for service non-ESRD beneficiaries. This results in an estimated 98,900 treatments that would now be paid to ESRD facilities for furnishing dialysis to beneficiaries with AKI. Using the CY 2018 final ESRD base rate of $232.37 and an average wage index multiplier, we are estimating approximately $20 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. However, because we have no way to project how many patients with AKI requiring dialysis will choose to have dialysis treatments at an ESRD facility, we are unable to provide a table at this time.

b. Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are 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 provision will have zero impact on other Medicare providers.

c. Effects on the Medicare Program

We anticipate paying an estimated $20 million to ESRD facilities in CY 2018 as a result of AKI patients receiving renal dialysis services in the ESRD facility.

d. Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent coinsurance 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 coinsurance. 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 $50 less coinsurance when AKI dialysis is furnished by ESRD facilities.

e. Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients and as such, including those policies and adjustment would be inappropriate.

3. ESRD QIP

a. Effects of the PY 2021 ESRD QIP on ESRD Facilities

The ESRD QIP provisions are intended to prevent possible reductions in the quality of renal dialysis services provided to beneficiaries. The methodology that we are using to determine a facility's TPS for the PY 2021 ESRD QIP is described in section IV.B.4.g of this final rule. Any reductions in ESRD PPS payments as a result of a facility's performance under the PY 2021 ESRD QIP would apply to ESRD PPS payments made to the facility in CY 2021.

For the PY 2021 ESRD QIP, we estimate that, of the 6,453 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 40 percent or 2,551 of the facilities would receive a payment reduction in PY 2021. The total payment reduction for all of the 2,551 facilities expected to receive a reduction is approximately $29 million ($29,017,218). Facilities that do not receive a TPS are not eligible for a payment reduction.

Table 15 shows the overall estimated distribution of payment reductions resulting from the PY 2021 ESRD QIP.

TABLE 15—ESTIMATED DISTRIBUTION OF PY 2021 ESRD QIP PAYMENT REDUCTIONS

Payment Reduction (%)	Number of facilities	Percent of facilities
0.0	3,469	57.6
0.5	1,507	25.0
1.0	754	12.5
1.5	228	3.8
2.0	62	1.0

Note: This table excludes 433 facilities that we estimate will not receive a payment reduction because they will not report enough data to receive a TPS.

To estimate whether or not a facility would receive a payment reduction in PY 2021, 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 16.

TABLE 16—DATA USED TO ESTIMATE PY 2021 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, performance standards, benchmarks, and improvement thresholds	Performance period
VAT		
Standardized Fistula Ratio	Jan 2014–Dec 2014	Jan 2015–Dec 2015.
%Catheter	Jan 2014–Dec 2014	Jan 2015–Dec 2015.
Kt/V Dialysis Adequacy Comprehensive	Jan 2014–Dec 2014	Jan 2015–Dec 2015.
Hypercalcemia	Jan 2014–Dec 2014	Jan 2015–Dec 2015.
STrR	Jan 2014–Dec 2014	Jan 2014–Dec 2014.
ICH CAHPS Survey	Jan 2015–Dec 2015	Jan 2015–Dec 2015.
SRR	Jan 2014–Dec 2014	Jan 2015–Dec 2015.
NHSN BSI	Jan 2014–Dec 2014	Jan 2015–Dec 2015.
SHR	Jan 2014–Dec 2014	Jan 2015–Dec 2015.

For all measures except STrR and SHR, clinical measure topic areas with less than 11 cases for a facility were not included in that facility's TPS. For SHR and STrR, facilities were required to have at least 5 and 10 patient-years at risk, respectively, in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated minimum TPS and an estimated payment reduction table that were consistent with the final policies outlined in section IV.B.4.g of this final rule. Facility reporting measure scores were estimated using available data from CY 2014 and 2015. Facilities were required to have a score on at least one clinical and one reporting measure to receive a TPS.

To estimate the total payment reductions in PY 2021 for each facility resulting from this 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.

Table 17 shows the estimated impact of the finalized ESRD QIP payment reductions to all facilities for PY 2021. The table details the distribution of 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 differ from those we are using for the PY 2021 ESRD QIP, the actual impact of the PY 2021 ESRD QIP may vary significantly from the values provided here.

TABLE 17—ESTIMATED IMPACT OF QIP PAYMENT REDUCTIONS TO FACILITIES FOR PY 2021

	Number of facilities	Number of treatments 2015 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments) (%)
All Facilities	6,453	40.0	6,020	2,551	−0.32
Facility Type:					
Freestanding	6,022	37.8	5,852	2,502	−0.33
Hospital-based	431	2.2	168	49	−0.20

TABLE 17—ESTIMATED IMPACT OF QIP PAYMENT REDUCTIONS TO FACILITIES FOR PY 2021—Continued

	Number of facilities	Number of treatments 2015 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments) (%)
Ownership Type:					
Large Dialysis	4,541	28.6	4,432	1,910	−0.32
Regional Chain	989	6.2	929	316	−0.26
Independent	568	3.5	536	282	−0.50
Hospital-based (non-chain)	354	1.8	123	43	−0.25
Unknown	1	0.0	0	0	
Facility Size:					
Large Entities	5,530	34.8	5,361	2,226	−0.31
Small Entities[1]	922	5.2	659	325	−0.45
Unknown	1	0.0	0	0	
Rural Status:					
(1) Yes	1,260	6.0	1,146	325	−0.19
(2) No	5,193	34.0	4,874	2,226	−0.35
Census Region:					
Northeast	879	6.2	786	340	−0.32
Midwest	1,511	7.6	1,356	557	−0.31
South	2,852	18.2	2,743	1,276	−0.36
West	1,142	7.6	1,084	341	−0.22
US Territories[2]	69	0.4	51	37	−0.56
Census Division:					
Unknown	1	0.0	0	0	
East North Central	1,045	5.5	951	443	−0.36
East South Central	522	3.0	515	202	−0.30
Middle Atlantic	702	4.9	623	300	−0.37
Mountain	368	2.0	336	86	−0.17
New England	182	1.3	164	40	−0.14
Pacific	782	5.7	753	257	−0.24
South Atlantic	1,458	9.4	1,388	719	−0.41
West North Central	469	2.1	406	115	−0.19
West South Central	875	5.8	841	355	−0.33
US Territories[2]	49	0.3	43	34	−0.62
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,211	2.7	1,006	357	−0.30
4,000–9,999 treatments	2,401	11.0	2,324	880	−0.29
Over 10,000 treatments	2,680	26.1	2,603	1,256	−0.35
Unknown	161	0.2	87	58	−0.66

b. Effects on Other Providers

The ESRD QIP is applicable to dialysis facilities. We are aware that several of our measures finalized for PY 2021 may impact other Medicare providers. For example, with the introduction of the Standardized Readmission Ratio Clinical measure in PY 2017 and the Standardized Hospitalization Ratio Clinical Measure in PY 2020, we anticipate that hospitals may experience financial savings as dialysis facilities work to reduce the number of unplanned readmissions and hospitalizations. We are actively exploring various methods to assess the impact these measures have on hospitals and other types of providers and facilities.

c. Effects on the Medicare Program

For PY 2021, we estimate that ESRD QIP will contribute approximately $29 million ($29,017,218) in Medicare savings. For comparison, Table 18 shows the payment reductions achieved by the ESRD QIP program for PYs 2016 through 2021 totals nearly $115 million ($114,736,974).

TABLE 18—PAYMENT REDUCTIONS PAYMENT YEAR 2016 THROUGH 2021

Payment year	Estimated payment reductions (citation)
PY 2021	$29,017,218.
PY 2020	$31,581,441 (81 FR 77960).
PY 2019	$15,470,309 (80 FR 69074).
PY 2018	$11,576,214 (79 FR 66257).
PY 2017	$11,954,631 (79 FR 66255).
PY 2016	$15,137,161 (78 FR 72247).

d. Effects on Medicare Beneficiaries

The ESRD QIP is applicable to dialysis facilities. Since the program's inception, there is evidence of improved performance on ESRD QIP measures. As we stated in the CY 2017 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (81 FR 77873). 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 (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. To date we have been unable to examine the impact of the ESRD QIP on Medicare beneficiaries including the financial impact of the program or the impact on the health outcomes of beneficiaries. However, in future years we are interested in examining these impacts through the analysis of available data from our existing measures.

e. Alternatives Considered

In an effort to reduce administrative and financial burden on dialysis facilities, we considered the burden associated with each of the measures included in the ESRD QIP to determine whether any of the measures could feasibly be removed from the program at this time. The Ultrafiltration Rate Reporting measure, finalized for inclusion in the program beginning with PY 2020, adds a significant burden to facilities because of the number of data elements required to be entered for each patient treated by the facility. We carefully considered whether this measure could be removed from the program in an effort to reduce burden for facilities, but as we noted in the CY 2017 ESRD PPS final rule, this measure is extremely valuable from a clinical perspective. Studies [14] suggest that higher ultrafiltration rates are associated with higher mortality and higher odds of an ''unstable'' dialysis session, 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 (81 FR 77912). Therefore we continue to believe that, despite the high burden associated with this measure, it is clinically valuable and important to continue including this measure in the ESRD QIP's measure set and that the clinical benefits outweigh the burden associated with the measure.

C. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 19 below, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this final rule.

TABLE 19—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS

Category	Transfers
ESRD PPS and AKI	
Annualized Monetized Transfers	$70 million.
From Whom to Whom	Federal government to ESRD providers.
Increased Beneficiary Co-insurance Payments	$10 million.
From Whom to Whom	Beneficiaries to ESRD providers.
ESRD QIP for PY 2021	
Annualized Monetized Transfers	$-29 million.
From Whom to Whom	Federal government to ESRD providers (payment reductions).
Category	Costs
Annualized Monetized ESRD Provider Costs	$0.

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

VIII. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354) (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 12 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 12 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 14. Using the definitions in this ownership category, we consider the 487 facilities that are independent and the 341 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by large dialysis organizations (LDOs) and regional chains will 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 finalized in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of dialysis facility) is estimated to receive a 0.8 percent increase in payments for CY 2018. An independent facility (as defined by ownership type) is also estimated to receive a 0.5 percent increase in payments for CY 2018.

[14] Flythe JE, Kimmel SE, Brunelli SM. Rapid fluid removal during dialysis is associated with cardiovascular morbidity and mortality. Kidney International (2011) Jan; 79(2):250–7. PMID: 20927040.

Flythe JE, Curhan GC, Brunelli SM. Disentangling the Ultrafiltration Rate–Mortality Association: The Respective Roles of Session Length and Weight Gain. Clin J Am Soc Nephrol. 2013 Jul;8(7):1151–61.

Movilli, Ezio, et al. ''Association between high ultrafiltration rates and mortality in uraemic patients on regular haemodialysis. A 5-year prospective observational multicenter study.'' Nephrology Dialysis Transplantation 22.12(2007): 3547–3552.

For AKI dialysis, we are unable to estimate whether patients will go to ESRD facilities, however, we have estimated there is a potential for $20 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

We estimate that of the 2,551 ESRD facilities expected to receive a payment reduction in the PY 2021 ESRD QIP, 325 are ESRD small entity facilities. We present these findings in Table 15 (''Estimated Distribution of PY 2021 ESRD QIP Payment Reductions'') and Table 17 (''Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2021'') above. We estimate that the payment reductions will average approximately $11,375 per facility across the 2,551 facilities receiving a payment reduction, and $13,885 for each small entity facility. Using our estimates of facility performance, we also estimated the impact of payment reductions on ESRD small entity facilities by comparing the total estimated payment reductions for 922 small entity facilities with the aggregate ESRD payments to all small entity facilities. We estimate that there are a total of 922 small entity facilities, and that the aggregate ESRD PPS payments to these facilities would decrease 0.45 percent in PY 2021.

The Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs.

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 132 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 132 rural hospital-based dialysis facilities will experience an estimated 0.4 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 will not have a significant impact on the operations of a substantial number of small rural hospitals.

IX. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2017, that is approximately $148 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 $148 million. Moreover, HHS interprets UMRA as applying only to unfunded mandates. We do not interpret Medicare payment rules as being unfunded mandates, but simply as conditions for the receipt of payments from the Federal government for providing services that meet federal standards. This interpretation applies whether the facilities or providers are private, State, local, or tribal.

X. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this 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.

XI. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. This final rule is not expected to be subject to the requirements of Executive Order 13771 because it is expected to result in no more than de minimis costs.

XII. 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.

XIII. Files Available to the Public via the Internet

The Addenda for the annual ESRD PPS proposed and final rulemakings will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the Internet and is posted on the CMS Web site at *http://www.cms.gov/ESRDPayment/PAY/list.asp*. In addition to the Addenda, limited data set (LDS) files are available for purchase at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.html*. Readers who experience any problems accessing the Addenda or LDS files, should contact *ESRDPayment@cms.hhs.gov*.

Dated: October 23, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 24, 2017.

Eric D. Hargan,

Acting Secretary, Department of Health and Human Services.

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