



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 414

[CMS-1674-P]

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: Proposed rule.

SUMMARY: This rule proposes to update and make revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2018, as well as to update the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). This rule also proposes to set forth requirements for the ESRD Quality Incentive Program (QIP), including for payment years (PYs) 2019 through 2021.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. August 28, 2017.

ADDRESSES: In commenting, please refer to file code CMS-1674-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

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

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1674-P,

P.O. Box 8010,

Baltimore, MD 21244-8010.

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

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

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1674-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,
Washington, DC 20201

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

b. For delivery in Baltimore, MD--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1810.

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

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

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

FOR FURTHER INFORMATION CONTACT:

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.

SUPPLEMENTARY INFORMATION:

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

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

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Acronyms

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

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
ATRA	American Taxpayer Relief Act of 2012
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
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
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
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
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
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 proposes to update and make 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 proposes to set forth 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 proposed CY 2018 ESRD PPS base rate is \$233.31. This amount reflects a reduced market basket increase as required by section 1881(b)(14)(F)(i)(I) of the Act (0.7 percent), and application of the wage index budget-neutrality adjustment factor (1.000605), equaling \$233.31 ($\$231.55 \times 1.007 \times 1.000605 = \233.31).

- 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 are not proposing any changes to the application of the wage index floor and we propose to continue to apply the current wage index floor (0.4000) to areas with wage index values below the floor.

- Update to the outlier policy: Consistent with our proposal to annually update the outlier policy using the most current data, we are proposing to update the outlier services fixed-dollar loss (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 \$49.55 and the MAP amount would decrease from \$38.29 to \$38.25, as compared to CY 2017 values. For adult beneficiaries, the FDL amount would increase from \$82.92 to \$83.12 and the MAP amount would decrease from \$45.00 to \$42.70. 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 would 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 proposing 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 proposing to update the AKI payment rate for CY 2018. The proposed CY 2018 payment rate is \$233.31, which is the same base rate proposed under the ESRD PPS.

3. ESRD QIP

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

- Updating the Performance Score Certificate Beginning in PY 2019: In section IV.C of this proposed rule, we set forth the updates we are proposing to make to the Performance Score Certificate (PSC) beginning in PY 2019. Specifically, in response to feedback from stakeholders about the length and complexity of the PSC, and in an effort to make the document more effective and understandable for the community, we propose to shorten and simplify the PSC. Specifically, we are proposing to shorten the PSC by removing some of the information we had previously finalized would be included in the document. We are proposing that the revised 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 and information showing how the facility's TPS

compared to the national average TPS for that specific payment year. We are not making any proposals to change the other requirements associated with this document. Facilities would still be required to post their PSC in a public location in both English and Spanish (77 FR 67517).

- Proposed Changes to the Extraordinary Circumstances Exception (ECE) Policy: In section IV.D.2 of this proposed rule, we set forth the updates we are proposing to the Extraordinary Circumstances Exception (ECE) Policy for the ESRD QIP. In an effort to bring our policy into alignment with other quality reporting and value based purchasing programs, we are proposing to (1) allow facilities to submit a form signed by the facility's CEO or designated personnel; (2) expand the reasons for which an ECE can be requested by a facility or granted by CMS of its own accord 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, in this case, would be one which did not allow the facility to submit data by the data submission deadline and one which was unable to be resolved with a work-around); 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. We are also clarifying that our intent is to notify a facility of our decision on a facility's ECE request within 90 days of the date that we receive it.

- Proposed PY 2021 Measure Set: As discussed in section IV.E.1 of this proposed rule, in the CY 2017 ESRD PPS final rule (81 FR 77834 through 77969), we previously finalized 16 measures to be included in the PY 2020 ESRD QIP. For PY 2021, we are proposing to update the Standardized Transfusion Ratio (STrR) Clinical Measure to bring the measure into alignment with the National Quality Forum (NQF)-endorsed specifications, and replace the two existing Vascular Access Type (VAT) measures with newly endorsed vascular access measures that

address long-held concerns of the community. Specifically, we are proposing to replace the VAT measures with the Proposed Hemodialysis Vascular Access: Standardized Fistula Rate Clinical Measure and the Proposed Hemodialysis Vascular Access: Long-Term Catheter Rate Clinical Measure. There would be no increase in burden associated with the proposed measure changes.

- Data Validation: In section IV.D.7 of this proposed rule, we set forth the updates we are proposing to make to the data validation program in the ESRD QIP. For PY 2020, we are proposing to continue the pilot validation study for validation of Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) data. Under this continued validation study, we are proposing to continue using the same methodology used for the PY 2018 and PY 2019 ESRD QIP. Under this methodology, we would sample approximately 10 records per facility from 300 facilities during CY 2018.

For PY 2020, we are proposing to continue a National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) Data Validation study similar to the one that we finalized in the CY 2017 ESRD PPS final rule. Under that methodology, we would select 35 facilities to participate in an NHSN dialysis event validation study for two quarters of data reported in CY 2018. The CMS data validation contractor would then send these facilities requests for medical records for all patients with “candidate events” during the evaluation period, as well as randomly selected patient records. Each facility selected would be required to submit 10 records total to the CMS validation contractor. The CMS contractor would utilize a methodology for reviewing and validating the candidate events that is consistent with the Centers for Disease Control and Prevention’s (CDC’s) validation protocol, and analyze those records to determine whether the facility reported dialysis events for those patients in accordance with the NHSN Dialysis Event

Protocol. Information from the validation study would be used to develop a methodology to score facilities based on the accuracy of their reporting of the NHSN BSI Clinical Measure.

C. Summary of Costs and Benefits

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

1. Impacts of the Proposed ESRD PPS

The impact chart in section IX of this proposed 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 0.8 percent increase in payments. Hospital-based ESRD facilities have an estimated 1.0 percent increase in payments compared with freestanding facilities with an estimated 0.8 percent increase.

We estimate that the aggregate ESRD PPS expenditures would increase by approximately \$100 million from CY 2017 to CY 2018. This reflects a \$90 million increase from the payment rate update and a \$10 million increase due to the updates to the outlier threshold amounts. As a result of the projected 0.8 percent overall payment increase, we estimate that there would be an increase in beneficiary co-insurance payments of 0.8 percent in CY 2018, which translates to approximately \$20 million.

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

We anticipate an estimated \$2.0 million would 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.

3. Impacts of the Proposed ESRD QIP

We estimate that the overall economic impact of the ESRD QIP would be approximately \$113 million in PY 2020 and \$113 million in PY 2021. The \$113 million figure for PY 2020 includes costs associated with the collection of information requirements, which we estimate would be approximately \$91 million.¹ For PY 2021, we estimate that ESRD facilities would experience an aggregate impact of approximately \$120 million as a result of the PY 2021 ESRD QIP. For PY 2021, these estimates have not significantly changed because we are not proposing to add any new measures to the program which would require an increased burden associated with the collection of information requirements. We are proposing to replace two existing measures but no new burdens are being proposed. Similarly, we are not proposing to increase the size of either of the Data Validation Studies proposed for PY 2020 so facilities would not experience an increase in burden with respect to being selected to participate in either of those two studies. Therefore, the overall economic impact of the ESRD QIP would be similar in PY 2021 to what it was in PY 2020.

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

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

¹ We note that the aggregate impact of the PY 2020 ESRD QIP was included in the CY 2017 ESRD PPS Final Rule (81 FR 77957). The previously finalized aggregate impact of \$113 million reflects the PY 2020 estimated payment reductions and the collection of information requirements finalized in the PY 2020 ESRD QIP Final Rule.

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

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112-240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014 to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule we finalized \$29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. And section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions

to those adjustments.

On April 1, 2014, 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. 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 adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, four co-morbidity categories, and pediatric patient-level adjusters consisting of two age categories and two dialysis modalities (42 CFR 413.235(a) and (b)).

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

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

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 (42 CFR 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 (42 CFR 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. Provisions of the Proposed Rule

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 MAP amount for ESRD outlier services furnished to a beneficiary exceeds the predicted ESRD outlier services MAP amount for outlier services plus the FDL amount, as specified in § 413.237(b). In the CY 2011 ESRD PPS final rule (75 FR 49134 through 49147), we discuss the details of establishing the outlier policy under the ESRD PPS, including determining eligibility for outlier payments. We discuss the proposed CY 2018 updates to the outlier policy in section II.B.2.c of this proposed rule.

Under 42 CFR § 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 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

website, 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, as discussed above, 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 will continue to use the ASP methodology, including any modifications finalized in the Physician Fee Schedule (PFS) final rules, to compute outlier MAP amounts. (We referred to the PFS 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, 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 under the ESRD PPS drug designation process. Specifically, we proposed that any new injectable or intravenous product that fits into one of the ESRD functional categories would be considered included in the ESRD PPS and would count toward the calculation of an outlier payment. We further explained that in calculating the outlier payment, we price drugs using the ASP methodology, which is currently ASP + 6 percent (80 FR 37831). In addition, we proposed that for a new injectable or intravenous product that is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or intravenous product would be eligible for the TDAPA if it meets specific criteria (80 FR 37831 through 37832). We further proposed that we would base the TDAPA on the ASP methodology and pay this amount during the utilization data collection time period (80 FR 37832 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 PFS final rule (77 FR 69140 through 69141), 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 PFS final rule (75 FR 73461 through 73462).

d. Proposal for 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 there is no longer a Medicare program need for a drug to remain on the ASP fee schedule, or when drugs or biologicals are new to market and manufacturers have not yet reported ASP data. However, based on CMS' experience with determining Part B drug payment limits under section 1847A of the Act, we believe there are limited situations in which ASP data would not be available for drugs or biologicals that could qualify for the 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.

In this proposed rule, we propose 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 explained above, 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 (42 CFR 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 believe that using the pricing methodologies under section 1847A of the Act is consistent with the ESRD PPS drug designation process and how covered drugs and biologicals

are paid under Medicare Part B. We believe that 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 on the ESRD claim with the AY modifier; and therefore facilities would be able to predict outlier payments. We are proposing 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. In situations where 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 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 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 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 propose 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 are soliciting 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 are also soliciting 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.

2. Proposed CY 2018 ESRD PPS Update

a. ESRD Bundled Market Basket

i. Proposed CY 2018 ESRD Market Basket Update, Productivity Adjustment, and Labor-Related Share for ESRD PPS

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. The statute also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services.

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

by section 1881(b)(14)(F)(i)(I) of the Act, and will further reduce it by the productivity adjustment.

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

We propose to use the CY 2012-based ESRDB market basket as finalized and described in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136) to compute the CY 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 IHS Global Inc.’s (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.

Using this methodology and the IGI forecast for the first quarter of 2017 of the CY 2012-based ESRDB market basket (with historical data through the fourth quarter of 2016), and consistent with our historical practice of estimating market basket increases based on the best available data, the proposed CY 2018 ESRDB market basket increase factor is 2.2 percent. As required by section 1881(b)(14)(F)(I)(i) of the Act as amended by section 217(b)(2) of PAMA,

we must reduce the amount of the market basket increase factor by 1.0 percent, resulting in a proposed CY 2018 ESRDB market basket percentage increase factor of 1.2 percent.

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

Using IGI's first quarter 2017 forecast, the MFP adjustment for CY 2018 (the 10-year moving average of MFP for the period ending CY 2018) is projected to be 0.5 percent.

For the CY 2018 ESRD payment update, we propose to continue using a labor-related share of 50.673 percent for the ESRD PPS payment, which was finalized in the CY 2015 ESRD PPS final rule (79 FR 66136).

ii. Proposed CY 2018 ESRDB Market Basket Update, Adjusted for Multifactor Productivity (MFP)

Under section 1881(b)(14)(F) of the Act, beginning in CY 2012, ESRD PPS payment amounts shall be annually increased by an ESRD market basket percentage increase factor reduced by the productivity adjustment. For CY 2018, section 1881(b)(14)(F)(i)(I) of the Act, as amended by section 217(b)(2)(A)(ii) of PAMA, requires the Secretary to implement a 1.0

percentage point reduction to the ESRDB market basket increase factor in addition to the productivity adjustment.

As a result of these provisions, the proposed CY 2018 ESRD market basket increase is 0.7 percent. This market basket increase is 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 MFP adjustment (the 10-year moving average of MFP for the period ending CY 2018) of 0.5 percent. As is our general practice, if more recent data are subsequently available (for example, a more recent estimate of the market basket or MFP adjustment), we will use such data to determine the CY 2018 market basket update and MFP adjustment in the CY 2018 ESRD PPS final rule.

b. The Proposed 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 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 would update 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 proposed CY 2018 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the proposed 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 as established in the CY 2014 ESRD PPS final rule (78 FR 72172) (0.9611) to American Samoa and the Northern Mariana Islands. We

apply the statewide urban average based on the average of all urban areas within the state (78 FR 72173) (0.8478) 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.

In the CY 2011 ESRD PPS final rule (75 FR 49116 through 49117), we finalized that we would continue to reduce the wage index floor by 0.05 for each of the remaining years of the ESRD PPS transition, that is, until CY 2014. In the CY 2012 ESRD PPS final rule (76 FR 70241), we finalized the 0.05 reduction to the wage index floor for CYs 2012 and 2013, resulting in a wage index floor of 0.5500 and 0.5000, respectively. We continued to apply and to reduce the wage index floor by 0.05 in the CY 2013 ESRD PPS final rule (77 FR 67459 through 67461). Although our intention initially was to provide a wage index floor only through the 4-year transition to 100 percent implementation of the ESRD PPS (75 FR 49116 through 49117; 76 FR 70240 through 70241), in the CY 2014 ESRD PPS final rule (78 FR 72173), we continued to apply the wage index floor and continued to reduce the floor by 0.05 per year for CY 2014 and for CY 2015.

In the CY 2016 ESRD PPS final rule (80 FR 69006 through 69008), we finalized the continuation of the application of the wage index floor of 0.4000 to areas with wage index values below the floor, rather than reducing the floor by 0.05. We stated in that rule that we needed more time to study the wage indices that are reported for Puerto Rico to assess the

appropriateness of discontinuing the wage index floor. Also, in that rule a commenter provided three alternative wage indices for Puerto Rico for the CY 2016 ESRD PPS final rule: (1) Utilize our policy for areas that do not have reliable hospital data by applying the wage index for Guam as we did in implementing the ESRD PPS in the Northern Marianas and American Samoa; (2) use the U.S. Virgin Islands as a proxy for Puerto Rico, given the geographic proximity and its “non-mainland” or “island” nature; or (3) reestablish the wage index floor in effect in 2010 when Puerto Rico became the only location with wage areas subject to the floor, that is, 0.65.

In the CY 2017 proposed rule (81 FR 42817), we presented the findings from analyses of ESRD facility cost report and claims data submitted by facilities located in Puerto Rico and mainland facilities. We solicited public comments on the wage index for CBSAs in Puerto Rico as part of our continuing effort to determine an appropriate course of action. We did not propose to change the wage index floor for CBSAs in Puerto Rico, but we requested public comments in which stakeholders can provide useful input for consideration in future decision-making. Specifically, we solicited comment on the useful suggestions that were submitted in the CY 2016 ESRD PPS final rule (80 FR 69007). After considering the public comments we received regarding the wage index floor, we finalized the wage index floor of 0.4000 in the CY 2017 ESRD PPS final rule (81 FR 77858).

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

We continue 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 will continue to monitor and analyze ESRD facility cost reports and projected impacts to guide future rulemaking with regard to the wage index floor.

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 erythropoiesis stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty, obesity, and comorbidities, such as cancer. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy in our regulations at 42 CFR 413.237. The policy provides the following ESRD outlier items and services are included in the ESRD PPS bundle: (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 also identify through our monitoring efforts items and services that are either incorrectly being identified as eligible outlier services or any new items and

services that may require an update to the list of renal dialysis items and services that qualify as outlier services, which are made through administrative issuances.

Our regulations at 42 CFR 413.237 specify the methodology used to calculate outlier payments. An ESRD facility is eligible for an outlier payment if its actual or imputed MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus the fixed-dollar loss (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 would use the existing methodology for determining outlier payments by applying outlier services payment multipliers that were developed for the CY 2016 ESRD PPS final rule (80 FR 68993-68994, 69002). We used these outlier services payment multipliers to calculate the predicted outlier service MAP amounts and projected outlier payments for CY 2018.

For CY 2018, we propose that the outlier services MAP amounts and FDL amounts would be derived from claims data from CY 2016. Because we believe that any adjustments made to the MAP amounts under the ESRD PPS should be based upon the most recent data year available in order to best predict any future outlier payments, we propose the outlier thresholds for CY 2018 would be based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2016. 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. For this proposed rule, as discussed below, CY 2016 claims data show outlier payments represented approximately 0.78 percent of total payments. We believe 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.

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 from 2015 Q3 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 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 are not proposing any change to the methodology used to compute the MAP or FDL amounts. Rather, we will continue to update the outlier services MAP amounts and FDL amounts to reflect the utilization of outlier services reported on 2016 claims. For this proposed rule, the outlier services MAP amounts and FDL amounts were updated using 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 proposed estimates for this rule. The estimates for the proposed

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 Proposed 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	\$38.20	\$44.52
Adjustments				
Standardization for outlier services	1.0078	0.9770	1.0218	0.9788
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	\$38.29	\$45.00	\$38.25	\$42.70
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	\$68.49	\$82.92	\$49.55	\$83.12
Patient-months qualifying for outlier payment	4.6%	6.7%	7.4%	6.3%

*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; \$83.12) is higher than that used for the CY 2017 outlier policy (Column I; \$82.92). The higher threshold is accompanied by a decrease in the adjusted average MAP for outlier services from \$45.00 to \$42.70. For pediatric patients, there is a decrease in the FDL amount from \$68.49 to \$49.55. There is a slight decrease in the adjusted average MAP for outlier services among pediatric patients, from \$38.29 to \$38.25.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2018 will be 6.3 percent for adult patients and 7.4 percent for pediatric patients, based on the 2016 claims data. The pediatric outlier MAP and FDL amounts continue to be lower

for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of ESAs and other injectable drugs).

ii. Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081), 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, slightly 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 would 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 proposed rule would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments, but would increase payments to ESRD facilities for beneficiaries with renal dialysis items and services that are eligible for outlier payments. Therefore, beneficiary co-insurance obligations would also increase for renal dialysis services eligible for outlier payments.

d. Proposed 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 § 413.220 and § 413.230. The CY 2011 ESRD PPS final rule also provides a

detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment 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, or transitional drug add-on payments.

ii. Annual Payment Rate Update for CY 2018

We are proposing an ESRD PPS base rate for CY 2018 of \$233.31. This update reflects several factors, described in more detail as follows:

- 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 2.2 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 $2.2 - 1.0 = 1.2$ percent. This amount is then reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. The proposed MFP adjustment for CY 2018 is 0.5 percent, thus yielding a proposed update to the base rate of

0.7 percent for CY 2018 ($1.2 - 0.5 = 0.7$ percent). Therefore, the proposed ESRD PPS base rate for CY 2018 before application of the wage index budget-neutrality adjustment factor would be \$233.17 ($\$231.55 \times 1.007 = \233.17).

- 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 are not proposing 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 CY 2018 proposed wage index budget-neutrality adjustment factor is 1.000605. This application would yield a CY 2018 ESRD PPS proposed base rate of \$233.31 ($\$233.17 \times 1.000605 = \233.31).

In summary, we are proposing a CY 2018 ESRD PPS base rate of \$233.31. This amount reflects a market basket increase of 0.7 percent and the CY 2018 wage index budget-neutrality adjustment factor of 1.000605.

III. 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 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 ESRD 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 (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 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 § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in 42 CFR 413.372.

B. Annual Payment Rate Update for CY 2018

1. 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 section II.B.2.d of this proposed rule, the CY 2018 proposed ESRD PPS base rate is \$233.31, which reflects the ESRD bundled market basket and multifactor productivity adjustment. Accordingly, we are proposing a CY 2018 per treatment payment rate of \$233.31 for renal dialysis services furnished by ESRD facilities to individuals with AKI.

2. 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 section II.B.2.d of this proposed rule. 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. As stated above, we are proposing a CY 2018 AKI dialysis payment rate of \$233.31, adjusted by the ESRD facility’s wage index.

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) are reduced by up to 2 percent if the facility does not meet or exceed the total performance score 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.

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

The CY 2013 ESRD PPS final rule (77 FR 67450), published in the **Federal Register** on November 9, 2012, set forth requirements for the ESRD QIP, including for payment year 2015 and beyond. In that rule, CMS added several new measures to the ESRD QIP’s measure set and expanded the scope of some of the existing measures. CMS 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.

The CY 2014 ESRD PPS final rule (78 FR 72156), published in the **Federal Register** on December 2, 2013, set forth requirements for the ESRD QIP, including for PY 2016 and beyond. In that rule, CMS 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.

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

The CY 2016 ESRD PPS final rule (80 FR 68968), published in the **Federal Register** on November 6, 2015, set forth requirements for the ESRD QIP, including for PYs 2017 through 2019. In that rule, CMS finalized the PY 2019 Measure Set, reinstated the ICH CAHPS Attestation beginning with PY 2017, and revised the Small Facility Adjuster (SFA) beginning with PY 2017.

The CY 2017 ESRD PPS final rule (81 FR 77834), published in the **Federal Register** on November 4, 2016, set forth new requirements for the ESRD QIP, including the inclusion of new quality measures beginning with PYs 2019 and 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). This proposed rule discusses each of these elements and our proposals for their application to the ESRD QIP.

B. Accounting for Social Risk Factors in the ESRD QIP Program

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 excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE)² 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 considering 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

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-medicare-value-based-purchasing-programs>.

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.³ 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.⁴

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) has undertaken a 2-year trial period in which certain new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period can be assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. This trial entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. At the conclusion of the trial, NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for these quality measures, and we will closely review its findings.

As we continue to consider the analyses and recommendations from these reports and await the results of the NQF trial on risk adjustment for quality measures, we are continuing to work with stakeholders in this process. As we have previously communicated, we are concerned about holding facilities to different standards for the outcomes of their patients with social risk

³ 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>.

⁴ National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

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, while we sought input on this topic previously, we 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 methods include: 1) adjustment of the payment adjustment methodology under the ESRD QIP; 2) adjustment of provider performance scores (for instance, stratifying facilities based on the proportion of their patients who are dual eligible); 3) confidential reporting of stratified measure rates to facilities; public reporting of stratified measure rates; 4) risk adjustment of a particular measure as appropriate based on data and evidence; and 5) redesigning payment incentives (for instance, rewarding improvement for facilities caring for patients with social risk factors or incentivizing facilities to achieve health equity).

We note that in section V.I.9 of the FY 2018 IPPS proposed rule (82 FR 19796), we discuss considerations 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 (Cures Act). We refer readers to that rule for a detailed discussion of these alternatives; while this discussion and corresponding proposal are specific to the Hospital Readmissions Reduction Program, they reflect 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 the ESRD QIP. While we consider whether and to what extent we currently have statutory authority to implement one or more of the above-described methods, we are seeking comments 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.

In addition, we are seeking 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 are seeking 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 the Medicare programs. Implementing any of the above methods would be taken into consideration in the context of how this and other Medicare programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others). We also welcome comment on operational considerations. CMS is committed to ensuring that its beneficiaries have access to and receive excellent care, and that the quality of care furnished by facilities is assessed fairly in the Medicare programs.

C. Proposed Change to the Performance Score Certificate Beginning with the Payment Year (PY) 2019 ESRD QIP

In a final rule, which published in the **Federal Register** on January 5, 2011, we finalized a policy for informing the public of facility performance through facility-posted certificates (76

FR 637). We finalized that these Performance Score Certificates (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, in an effort to make the PSC a more effective and understandable document for the community, we are proposing to shorten the PSC by removing some of the information we had previously finalized would be included in the document. We propose that beginning in PY 2019 and continuing in future years, the PSC will 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 (name, address, etc.). Additionally, we are proposing to include on the PSC information showing how the facility's TPS compared to the national average TPS for that specific payment year.

We are not proposing any other changes to the requirements we previously finalized for the PSC.

We seek comments on this proposal, and we are 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.

D. Proposed Requirements Beginning with the PY 2020 ESRD QIP

1. Proposal to Clarify 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 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, and we are proposing the intended application of this policy for PY 2020 in this proposed rule. We are not proposing 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 displays the proposed patient minimum requirements for each of the measures finalized for PY 2020, as well as the proposed CCN Open Dates after which a facility would not be eligible to receive a score on a reporting measure.

TABLE 2–PROPOSED MINIMUM DATA REQUIREMENTS FOR THE PY 2020 ESRD QIP

Measure	Minimum Data Requirements	CCN Open Date	Small Facility Adjuster
Dialysis Adequacy (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Vascular Access Type: Catheter (Clinical).	11 qualifying patients	N/A	11-25 qualifying patients
Vascular Access Type: Fistula (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients

Measure	Minimum Data Requirements	CCN Open Date	Small Facility Adjuster
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	11-25 qualifying patients
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Clinical)	10 patient-years at risk	N/A	10-21 patient years at risk
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 welcome comments on this proposal.

2. Proposed 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 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 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 CMS Certification Number (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 are proposing 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. 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 are proposing that these policies would apply beginning with the PY 2020 ESRD QIP program, as related to extraordinary circumstance events that occur on or after January 1, 2018.

We note 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 recognize 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 will 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 believe 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 are proposing to address these situations in one of two ways. In some cases, CMS may issue a blanket exemption 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 waiver to the affected facilities using routine communication channels. In other cases,

CMS may not issue a blanket exemption 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 believe 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 transparency of our process, we believe it is appropriate to specify that we will strive to complete our review of each request within 90 days of receipt.

We seek comments on these proposals.

3. 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 section 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 NHSN BSI Clinical and Reporting Measures⁵. However, we now have the authority to collect data on this patient population and believe that it is vitally

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

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 are seeking 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.

4. 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). At this time, we do not have the necessary data to assign numerical values to those performance standards, achievement thresholds, and benchmarks because we do not yet have complete data from CY 2016. Nevertheless, we are able to estimate these numerical values based on the most recent data available. For the VAT, Hypercalcemia, NHSN BSI, In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS), Standardized Readmission Ratio (SRR), and Standardized Transfusion Ratio (STrR) clinical measures, this data comes from the period of January through December 2015. In Table 3, we have provided the estimated numerical values for all finalized PY 2020 ESRD QIP clinical measures. We will publish updated values for the clinical measures, using data from the first part of CY 2017, in the CY 2018 ESRD PPS final rule.

TABLE 3 – Estimated Numerical Values for the Performance Standards for the PY 2020 ESRD QIP Clinical Measures Using the Most Recently Available Data

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.

In previous rulemaking, we have finalized 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 would substitute the previous year's performance standard, achievement threshold, and/or benchmark for that measure. We finalized this policy because we believe that the ESRD QIP should not have lower performance standards than in previous years. In 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 on the basis of 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 propose to continue use of this policy for the reasons explained above. Therefore, for PY 2020, with the exception of the NHSN BSI Clinical Measure, we will 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. Based upon the estimated values shown above, we do not anticipate needing to substitute the performance standards from PY 2019 for any measures included in the PY 2020 ESRD QIP.

Although we are not proposing any changes to this policy, we are seeking comments on whether we should continue to use this policy in the future.

5. 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 Program, 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 4 shows the weights finalized for PY 2020 for the Clinical Measure Domain.

TABLE 4: FINALIZED CLINICAL MEASURE DOMAIN WEIGHTING FOR THE PY 2020 ESRD QIP

Measures/Measure Topics by Subdomain	Measure Weight in the Clinical Domain Score	Measure Weight as Percent of TPS (Updated)
Patient and Family Engagement/Care Coordination Subdomain	40%	
ICH CAHPS measure	25%	18.75%

Measures/Measure Topics by Subdomain	Measure Weight in the Clinical Domain Score	Measure Weight as Percent of TPS (Updated)
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 are not proposing any changes to these weights finalized in the CY 2017 ESRD PPS final rule at 81 FR 77918.

6. Proposed Payment Reductions for the PY 2020 ESRD QIP

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the 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 were not yet able to calculate the performance standards for each of the clinical measures. We therefore stated that we would publish the minimum TPS for the PY 2020

ESRD QIP in the CY 2018 ESRD PPS final rule (81 FR 77927).

Based on the estimated performance standards listed above, we estimate that a facility must meet or exceed a minimum TPS of 61 for PY 2020. For all of the clinical measures, these data come from CY 2015. We are proposing that a facility failing to meet the minimum TPS, which we will finalize in the CY 2018 ESRD PPS final rule, will receive a payment reduction based on the estimated TPS ranges indicated in Table 5.

Table 5 – Estimated Payment Reduction Scale for PY 2020 based on the Most Recently Available Data

Total Performance Score	Reduction
100-61	0%
60-51	0.5%
50-41	1.0%
40-31	1.5%
30-21	2.0%

7. 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 CROWNWeb under the pilot data validation program. That methodology was fully developed and adopted through the rulemaking process. For the PY 2016 ESRD QIP (78 FR 72223 through 72224), we finalized a requirement to sample approximately 10 records from 300 randomly selected facilities; these facilities had 60 days to comply once they received requests for records. We continued this pilot for the PY 2017, PY 2018 and PY 2019 ESRD QIP, and propose 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 in order 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 program. 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 propose to deduct 10 points from the facility's TPS.

In the CY 2015 ESRD PPS final rule (79 FR 66120 through 66265), we also finalized that there would be a feasibility study for validating data reported to 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 propose 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 CDC, the CMS contractor would utilize a methodology for reviewing and validating records from selected patients, in order to determine whether the facility reported dialysis events for those patients in accordance with the NHSN Dialysis Event Protocol. If a facility is selected to participate in the validation study but does not provide CMS with the requisite lists of information or medical records within 60 calendar days of receiving a request, then we propose to deduct 10 points from the facility’s TPS. Information from the validation study may be used in future years of the program to inform our consideration of future policies that would incorporate NHSN data accuracy into the scoring process. 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.

E. Proposed Requirements for the PY 2021 ESRD QIP

1. Proposed 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. In accordance with our policy to continue using measures unless we propose to remove or replace them, (77 FR 67477), we will continue to use all but 2 of these measures in the PY 2021 ESRD QIP. These measures are summarized in Table 6 below. We are proposing to replace the two VAT Clinical Measures with the proposed Hemodialysis Vascular Access: Standardized Fistula Rate Clinical Measure and the proposed Hemodialysis Vascular Access: Long-Term Catheter Rate Clinical Measure beginning with PY 2021.

TABLE 6 – PY 2020 ESRD QIP MEASURES BEING CONTINUED IN PY 2021

NQF #	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

NQF #	Measure Title and Description
	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.

2. Proposed 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).

Subsequent to the publication of the CY 2017 ESRD PPS final rule, we evaluated the

finalized PY 2020 ESRD QIP measures that would be continued in PY 2021 against all of 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 7.

As Table 7 illustrates, the distributions of the PY 2020 clinical measures were assessed in order to determine if any measures were “topped out.” In order 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 ($SD_{\text{truncated}}/Mean_{\text{truncated}}$). The TCV was then converted to a decimal by dividing the TCV by 100.

Measures evaluated included the combined Kt/V (that is, a measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume measure), Fistula, Catheter, Hypercalcemia, NHSN Standardized Infection Ratio (SIR), SRR, STrR, SHR, and the six individual CAHPS clinical measures. Medicare claims data from 2015 were used in

Fistula and Catheter calculations. CROWNWeb data from 2015 was 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 7 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.

Table 7: 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	97.8 ^a	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

^aTruncated mean for percentage is reversed (100 percent - truncated mean) for measures where lower score = better performance.

As the information in Table 7 indicates, none of these clinical measures are currently topped-out

in the ESRD QIP. Accordingly, we are not proposing to remove any of these measures from the ESRD QIP for PY 2021 because they are topped out.

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 are proposing 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. As discussed more fully below, we are proposing to replace the VAT measures with the Proposed Hemodialysis Vascular Access: Standardized Fistula Rate Clinical Measure (NQF #2977) and the Proposed Hemodialysis Vascular Access: Long-Term Catheter Rate Clinical Measure (NQF #2978). These proposed measures will address the methodological concerns the community has shared regarding the existing measures. Additionally, they have both been endorsed by the NQF and are supported by the Measures Application Partnership. Both of the proposed measures are being considered for reporting on Dialysis Facility Compare

and in the Dialysis Facility Compare Star Ratings for 2018 and both measures can be calculated using data that facilities are already required to report in CROWNWeb in order to meet 42 CFR 494.180(h) of the 2008 updated 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 seek comments on our proposal to remove the current VAT measures from the ESRD QIP measure set beginning with the PY 2021 program year.

3. Proposed 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 US 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, 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 particular 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 change we are proposing 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).

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>.

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 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 feasible⁸. 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.

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

⁸ <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452>.

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 MAP'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 publications⁹. Under this definition, transfusion events are included in the measure

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.

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 believe the revision to the STrR measure should be reflected in the ESRD QIP, and beginning with the PY 2021 program year, we propose to use the updated

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).

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.

We note that the complete list of ICD-10 codes that would be included in the measure is included in the Technical Report for the measure, provided at the link listed above.

We seek comments on this proposal.

4. Proposed New Vascular Access Measures Beginning with the PY 2021 ESRD QIP

As discussed in sections IV.E.4, IV.E.4.a, and IV.E.4.b of this proposed rule, for PY 2021, we propose 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 are proposing 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), 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. A number of 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 Initiative¹⁰, 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 (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 (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. By incorporating additional exclusion criteria to account for such patients, this measure avoids setting a quality standard that may penalize facilities for providing appropriate vascular access.

In 2015, we convened a Technical Expert Panel (TEP) to review the existing vascular

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

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.

a. Proposed 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 propose 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 seek comments on this proposal.

b. Proposed 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 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 propose 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 seek comments on this proposal.

5. Proposed Performance Period for the PY 2021 ESRD QIP

We are proposing 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 are proposing 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 seek comments on these proposals.

6. Proposed 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.

a. Proposed 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 are proposing 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 seek comments on our proposal to continue this policy for PY 2021.

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

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

c. Proposed 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 are proposing to continue use of these performance standards for the Reporting Measures included in the PY 2021 ESRD QIP.

7. Proposal for Scoring the PY 2021 ESRD QIP

a. Scoring Facility Performance on Clinical Measures Based on Achievement

In the CY 2014 ESRD PPS final rule, we finalized a policy for scoring performance on clinical measures based on achievement (78 FR 72215). Under this methodology, facilities receive points along an achievement range based on their performance during the performance period for each measure, which we define as a scale between the achievement threshold and the benchmark. In determining a facility's achievement score for each clinical measure under the PY 2021 ESRD QIP, we propose to continue using this methodology for all clinical measures.

We also propose to use this same methodology for scoring the two new Vascular Access measures proposed in sections IV.E.4.a and IV.E.4.b.

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

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

We also propose to use this same methodology for scoring the two new Vascular Access measures proposed in sections IV.E.4.a and IV.E.b.

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

c. Scoring the ICH CAHPS Clinical Measure

In the CY 2015 ESRD PPS final rule, we finalized a policy for scoring performance on the ICH CAHPS clinical measure based on both achievement and improvement (79 FR 66209 through 66210). We are proposing 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 seek comments on this proposal.

d. Proposal for 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 are proposing to use the same methodology described in the CY 2013 ESRD PPS to calculate the VAT Measure Topic Score.

We seek comments on this proposal.

e. Proposal for Calculating Facility Performance on Reporting Measures

In the CY 2013 ESRD PPS final rule, we finalized policies for scoring performance on the Anemia Management and Mineral Metabolism reporting measures in the ESRD QIP (77 FR 67506). 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 propose to continue use of these policies for the PY 2021 ESRD QIP.

8. Proposal for Weighting the Clinical Measure Domain, and Weighting the TPS

a. Proposal for Weighting the Clinical Measure Domain 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 propose to weight the following measures in the following subdomains of the clinical measure domain (see Table 8):

TABLE 8: 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%
NHSN HCP 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

Specifically, for PY 2021 we are proposing 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). Additionally, as discussed above, although we are not proposing to change the total number of measures in the ESRD QIP's measure set for PY 2021, we are proposing 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 are therefore not proposing any changes to the weights finalized for PY 2020 in the CY 2017 ESRD PPS final rule. 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 increased NHSN Data Validation Study.

We seek comments on these proposals.

b. Proposal for Weighting the Domains Used to Calculate the TPS

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 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 are not proposing any changes to this and are proposing to apply it to the PY 2021 program year.

In the CY 2017 ESRD PPS final rule, we 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 are not proposing any changes to this policy for the PY 2021 ESRD QIP.

We seek comments on the continued use of these policies.

9. Example of the Proposed PY 2021 ESRD QIP Scoring Methodology

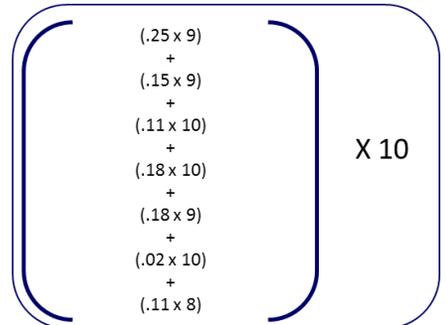
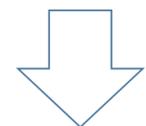
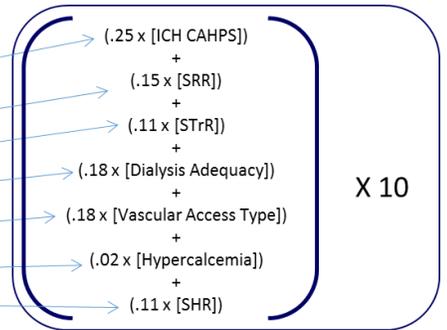
In this section, we provide an example to illustrate the proposed scoring methodology for PY 2021. Figures 1 through 4 illustrate how to calculate the Clinical Measure Domain score, the Reporting Measure Domain score, the Safety Measure Domain score, and the TPS. Figure 5 illustrates the full proposed scoring methodology for PY 2021. Note that for this example, Facility A, a hypothetical facility, has performed very well.

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

FIGURE 1:

Clinical Measure Domain: Facility A

Clinical Measure	Measure Score
ICH CAHPS	9
SRR	9
STrR	10
Dialysis Adequacy	10
Vascular Access Type	9
Hypercalcemia	10
SHR	8



Clinical Measure Scoring Domain = 92

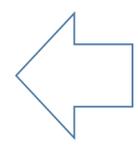
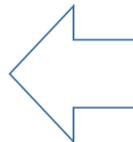
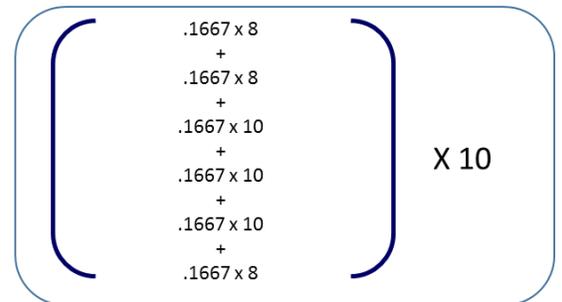
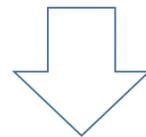
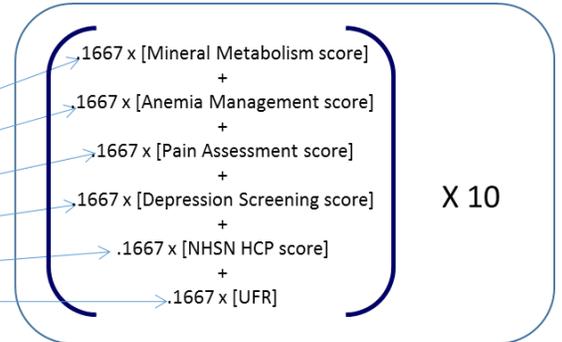


Figure 2 illustrates the general methodology for calculating the Reporting Measure Domain score for Facility A.

FIGURE 2:

Reporting Measure Domain: Facility A

Reporting Measure	Measure Score
Serum Phosphorus	8
Anemia Management	8
Pain Assessment and Follow-Up	10
Clinical Depression Screening and Follow-Up	10
NHSN Healthcare Personnel Influenza Vaccination	10
Ultrafiltration Rate	8



Reporting Measure Scoring Domain = 90

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

FIGURE 3:

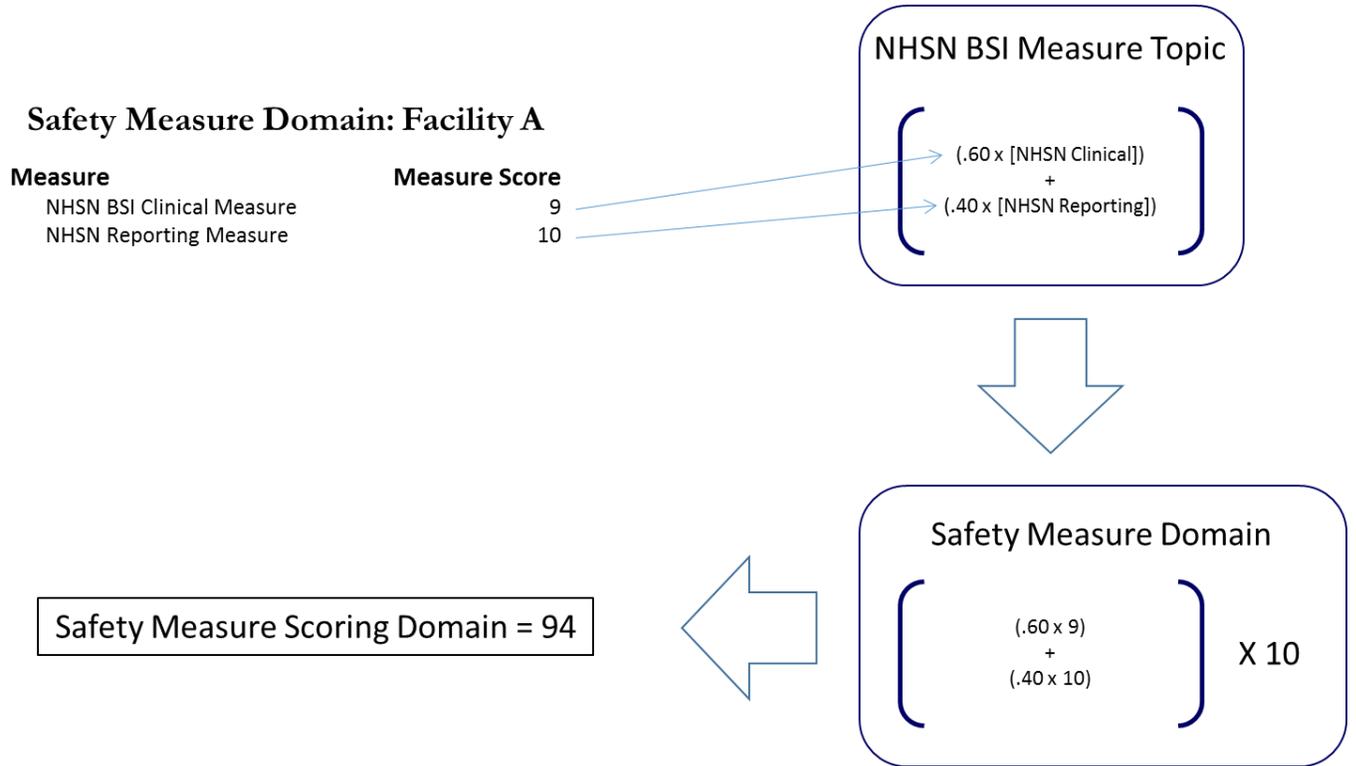


Figure 4 illustrates the methodology used to calculate the TPS for Facility A.

FIGURE 4:

Total Performance Score: Facility A

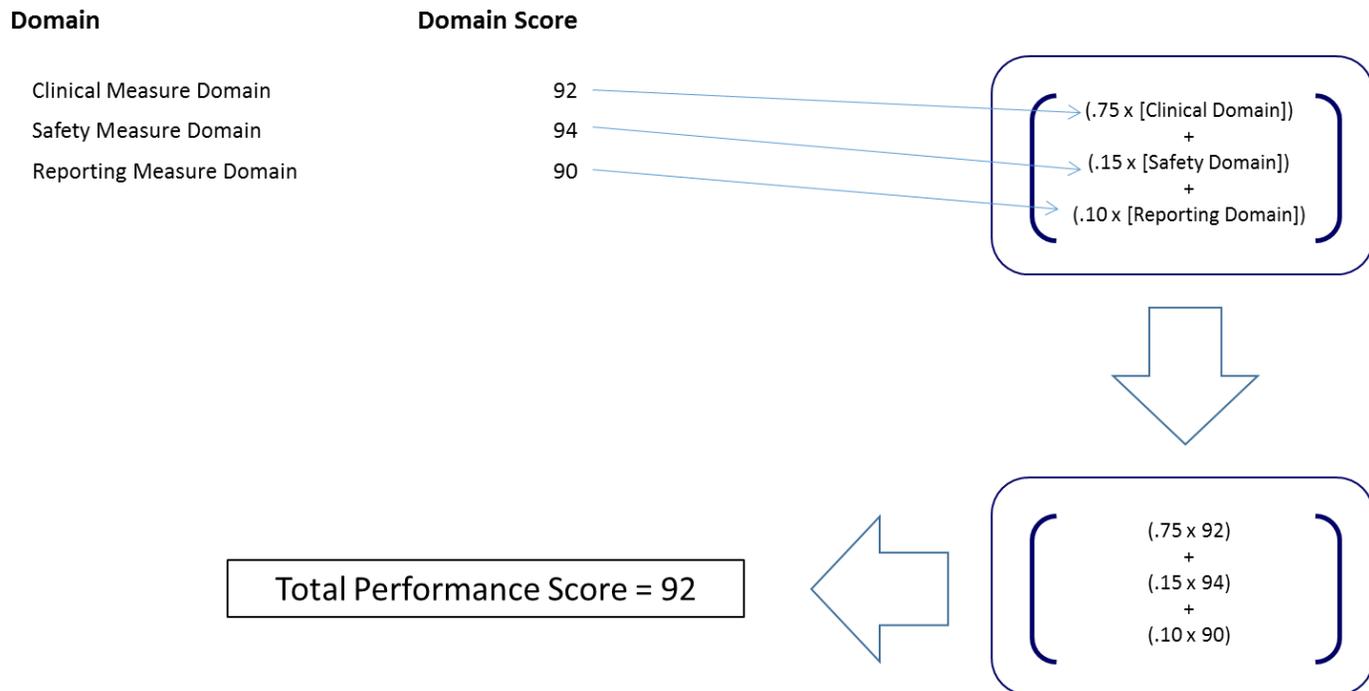
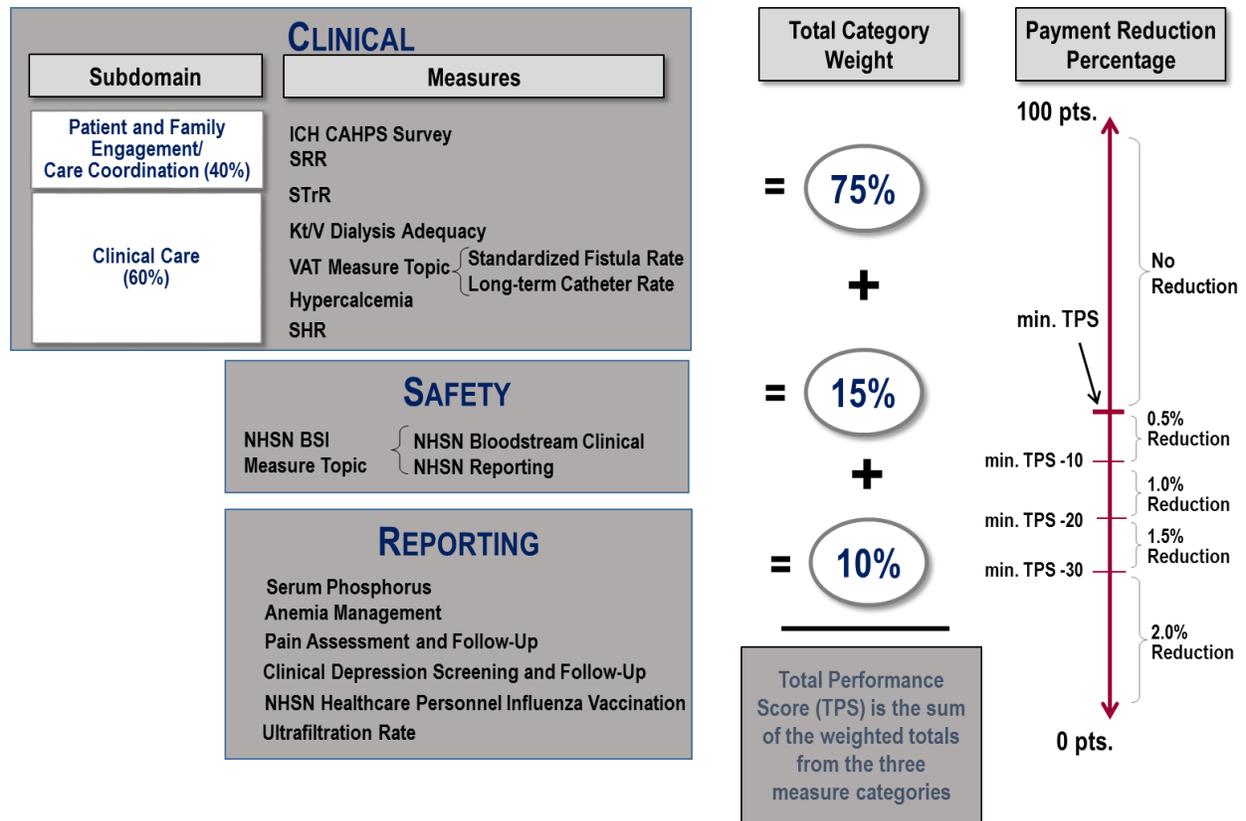


Figure 5 illustrates the full scoring methodology for PY 2021.

FIGURE 5:



10. Proposed 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 propose to continue use of these minimum data policies for the measures that we have proposed to continue including in the PY 2021 ESRD QIP measure set. Additionally, we propose to use these same minimum data policies for the proposed Vascular Access Measures discussed above.

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 section IV.D.1 of the preamble, we proposed clarifications to our CCN Open Date Policy and to the patient minimum requirements for each of the measures finalized for the PY 2020 ESRD QIP. 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 propose to continue applying these CCN open date policies to the measures proposed for PY 2021.

Table 9 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 the majority of the measures shown in the table below is a long-standing policy in the ESRD QIP.

TABLE 9 – 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: Standardized 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

Measure	Minimum Data Requirements	CCN Open Date	Small Facility Adjuster
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.

11. Proposed 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 propose 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 note this proposed policy for PY 2021 is identical to the policy finalized for PY 2020.

We recognize that we are not proposing a policy regarding the inclusion of measures for which we are not able to establish a numerical value for the performance standard through the rulemaking process before the beginning of the performance period in the PY 2020 minimum TPS. We have not proposed 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 publish that value once we have calculated final measure scores for the PY 2019 program.

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

We are not proposing any changes to these policies.

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, 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 a common set of electronic clinical information at the nationwide level by the end of 2017. Moreover, the vision described in the Roadmap significantly expands the types of electronic health information, information sources, and information users well beyond clinical information derived from electronic health records.

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.

VI. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

B. Requirements in Regulation Text

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

C. Additional Information Collection Requirements

This proposed rule does not impose any new information collection requirements in the regulation text, as specified above. However, there are changes in some currently approved information collections. 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 data¹¹, 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

¹¹ <https://www.bls.gov/oes/current/oes292071.htm>.

¹² <https://www.bls.gov/oes/current/oes291141.htm>.

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 Proposed Reporting Requirements

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

c. Data Validation Requirements for the PY 2020 ESRD QIP

Section IV.D.7 of this proposed rule outlines our data validation proposals for PY 2020. Specifically, for the CROWNWeb validation, we propose to continue randomly sampling records from 300 facilities as part of our continuing pilot data-validation program. Each sampled facility would be required to produce approximately 10 records, and the sampled facilities will be reimbursed by our validation contractor for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimate that it will take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities will be 750 hours (300 facilities x 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit this data, we estimate that the aggregate cost of the CROWNWeb data validation would be approximately \$29,895 (750 hours x \$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 proposed continued data validation study for validating data reported to the NHSN Dialysis Event Module, we are proposing to continue using the methodology finalized in the CY 2017 ESRD PPS final rule, however we have proposed a modification to our sampling methodology (81 FR 77956). A CMS contractor would 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 would 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 would be 35 hours (35 facilities x 1 hour). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit this data, we estimate that the aggregate cost of the NHSN data validation would be \$1,395.10 (35 hours x \$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-NEW).

To determine the burden associated with new 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 proposing to replace two existing measures for PY 2021. We believe replacing the two existing measures would 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. Request for Information on Medicare Flexibilities and Efficiencies

CMS is committed to transforming the health care delivery system—and the Medicare program—by putting an additional focus on patient-centered care and working with providers, physicians, and patients to improve outcomes. We seek to reduce burdens for hospitals, physicians, and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. These are the reasons we are including this Request for Information in this proposed rule.

As we work to maintain flexibility and efficiency throughout the Medicare program, we would like to start a national conversation about improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families. We aim to increase quality of care, lower costs, improve program integrity, and make the health care system more effective, simple and accessible.

We would like to take this opportunity to invite the public to submit their ideas for regulatory, subregulatory, policy, practice, and procedural changes to better accomplish these

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).

goals. Ideas could include payment system redesign, elimination or streamlining of reporting, monitoring and documentation requirements, aligning Medicare requirements and processes with those from Medicaid and other payers, operational flexibility, feedback mechanisms and data sharing that would enhance patient care, support of the physician-patient relationship in care delivery, and facilitation of individual preferences. Responses to this Request for Information could also include recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, physicians, providers, and suppliers. Where practicable, data and specific examples would be helpful. If the proposals involve novel legal questions, analysis regarding CMS' authority is welcome for CMS' consideration. We are particularly interested in ideas for incentivizing organizations and the full range of relevant professionals and paraprofessionals to provide screening, assessment and evidence-based treatment for individuals with opioid use disorder and other substance use disorders, including reimbursement methodologies, care coordination, systems and services integration, use of paraprofessionals including community paramedics and other strategies. We are requesting commenters to provide clear and concise proposals that include data and specific examples that could be implemented within the law.

We note that this is a Request for Information only. Respondents are encouraged to provide complete but concise responses. This Request for Information is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This Request for Information does not commit the United States Government to contract for any supplies or services or make a grant award.

Further, CMS is not seeking proposals through this Request for Information and will not accept unsolicited proposals. Responders are advised that the United States Government will not

pay for any information or administrative costs incurred in response to this Request for Information; all costs associated with responding to this Request for Information will be solely at the interested party's expense. We note that not responding to this Request for Information does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this Request for Information announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this Request for Information. CMS will not respond to comment submissions in response to this Request for Information in the CY 2018 ESRD PPS final rule. Rather, CMS will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. CMS may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this Request for Information. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this Request for Information may be used by the Government for program planning on a nonattribution basis. Respondents should not include any information that might be considered proprietary or confidential. This Request for Information should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become United States Government property and will not be returned. CMS may publicly post the public comments received, or a summary of those public comments.

VIII. Response to Comments

Because of the large number of public comments we normally receive on Federal Register documents, we are not able to acknowledge or respond to them individually. We will

consider all comments we receive by the date and time specified in the “DATES” section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IX. 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 economically significant within the meaning of section 3(f)(1) of the Executive Order, since it meets the \$100 million threshold. Additionally, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact. We solicit comments on the regulatory impact analysis provided.

2. Statement of Need

This rule proposes a number of routine updates and one policy change to the ESRD PPS in CY 2018. The proposed routine updates include the CY 2018 wage index values, the wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. The proposed policy change involves an update to the outlier pricing policy. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2018 for renal dialysis services furnished to ESRD patients.

This rule proposes routine updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this proposed 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 proposes to implement requirements for the ESRD QIP, including a proposal to

adopt a measure set for the PY 2021 program, as directed by section 1881(h) of the Act. Failure to propose requirements for the PY 2021 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2020. In addition, proposing requirements for the PY 2021 ESRD QIP provides facilities with more time to review and fully understand new measures before their implementation in the ESRD QIP.

3. Overall Impact

We estimate that the proposed revisions to the ESRD PPS will result in an increase of approximately \$100 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 \$2 million that would now be paid to ESRD facilities for dialysis treatments provided to AKI beneficiaries.

For PY 2021, we estimate that the proposed 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 proposed rule, we should 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 proposed 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 welcome any

comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

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 proposed rule. For each ESRD facility that reviews the rule, the estimated cost is \$131.25 (1.25 hours x \$105.00). Therefore, we estimate that the total cost of reviewing this regulation is \$19,162.50 (\$131.25 x 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 proposed rule, we used CY 2016 data from the Part A and B Common Working Files, as of February 17, 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 proposed rule. Table 10 shows the impact of the estimated CY 2018 ESRD payments compared to estimated payments to ESRD facilities in CY 2017.

Table 10 – Impact of Proposed Changes in Payment to ESRD Facilities for CY 2018
Proposed Rule

Facility Type	Number of Facilities A	Number of Treatments (in millions) B	Effect of 2018 Changes in Outlier Policy C	Effect of 2018 Changes in Wage Indices and Wage Floor D	Effect of 2018 Changes in payment rate update E	Effect of Total 2018 Proposed Changes F
All Facilities	6,754	44.3	0.1%	0.0%	0.7%	0.8%
Type						
Freestanding	6,325	41.9	0.1%	0.0%	0.7%	0.8%
Hospital based	429	2.4	0.2%	0.1%	0.7%	1.0%
Ownership Type						
Large dialysis organization	5,001	33.3	0.1%	0.0%	0.7%	0.8%
Regional chain	881	5.9	0.1%	0.1%	0.7%	1.0%
Independent	502	3.2	0.1%	0.0%	0.7%	0.8%
Hospital based ¹	368	2.0	0.2%	0.1%	0.7%	1.1%
Unknown	2	0.0	0.1%	-0.8%	0.7%	-0.1%
Geographic Location						
Rural	1,235	6.4	0.1%	-0.2%	0.7%	0.6%
Urban	5,519	37.9	0.1%	0.0%	0.7%	0.8%
Census Region						
East North Central	1,094	6.2	0.1%	-0.1%	0.7%	0.8%
East South Central	546	3.3	0.1%	-0.1%	0.7%	0.7%
Middle Atlantic	732	5.4	0.1%	0.1%	0.7%	0.9%
Mountain	380	2.2	0.1%	-0.2%	0.7%	0.6%
New England	190	1.5	0.1%	-0.1%	0.7%	0.8%
Pacific ²	800	6.3	0.1%	0.0%	0.7%	0.8%
Puerto Rico and Virgin Islands	50	0.4	0.1%	0.1%	0.7%	0.8%
South Atlantic	1,556	10.3	0.1%	-0.1%	0.7%	0.7%
West North Central	482	2.2	0.1%	0.2%	0.7%	1.1%
West South Central	924	6.5	0.1%	0.2%	0.7%	1.0%
Facility Size						
Less than 4,000 treatments	1,272	3.6	0.1%	-0.1%	0.7%	0.7%
4,000 to 9,999 treatments	2,372	10.9	0.1%	-0.1%	0.7%	0.8%
10,000 or more treatments	2,860	28.6	0.1%	0.0%	0.7%	0.8%
Unknown	250	1.2	0.2%	0.2%	0.7%	1.1%
Percentage of Pediatric Patients						
Less than 2%	6,650	44.0	0.1%	0.0%	0.7%	0.8%
Between 2% and 19%	39	0.3	0.1%	0.1%	0.7%	1.0%
Between 20% and 49%	12	0.0	0.2%	-0.4%	0.7%	0.5%
More than 50%	53	0.0	0.3%	0.3%	0.7%	1.2%

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

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

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall

effect of the proposed changes to the outlier payment policy described in section II.B.2.c of this proposed 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 0.1 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 proposed outlier policy changes.

Column D shows the effect of the proposed 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 0.8 percent decrease to a 0.3 percent increase due to these proposed updates in the wage indices.

Column E shows the effect of the proposed CY 2018 ESRD PPS payment rate update. The proposed ESRD PPS payment rate update is 0.7 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2018 of 2.2 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 0.5 percent.

Column F reflects the overall impact, that is, the effects of the proposed outlier policy changes, the proposed wage index floor, and payment rate update. We expect that overall ESRD facilities would experience a 0.8 percent increase in estimated payments in CY 2018. The categories of types of facilities in the impact table show impacts ranging from a decrease of 0.1 percent to an increase of 1.2 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 proposed ESRD PPS would have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2018 would be approximately \$10.0 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 1.8 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 0.8 percent overall increase in the proposed CY 2018 ESRD PPS payment amounts, we estimate that there will be an increase in beneficiary co-insurance payments of 0.8 percent in CY 2018, which translates to approximately \$20 million. The \$20 million is based on 20 percent of CY 2018 estimated total payment increase of \$100 million.

e. Alternatives Considered

In section II.B.2.b of this proposed rule, we propose maintaining the wage index floor at 0.4000. We considered increasing the wage index floor to 0.5000 as well as increasing the wage index floor to 0.6000 and determined that maintaining the wage index floor at 0.4000 provided the appropriate adjustment related to the cost of furnishing dialysis in areas with a wage index less than 0.4000.

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

a. Effects on ESRD Facilities

We analyzed CY 2016 hospital outpatient claims to identify the number of treatments

furnished historically for AKI patients. We identified 8,900 outpatient treatments with AKI that also had dialysis treatments that were furnished in CY 2016. We then inflated the 8,900 treatments to 2018 values using estimated population growth for fee-for service non-ESRD beneficiaries. This results in an estimated 9,170 treatments that would now be paid to ESRD facilities for furnishing dialysis to beneficiaries with AKI. Using the proposed CY 2018 ESRD base rate of \$233.31 and an average wage index multiplier, we are estimating approximately \$2 million that would now be paid to ESRD facilities for dialysis treatments provided to AKI beneficiaries.

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

b. Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are proposing to update the 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 his or her physician. Therefore, this proposal will have zero impact on other Medicare providers.

c. Effects on the Medicare Program

We estimate approximately \$2 million would be paid to ESRD facilities in CY 2018 as a result of AKI patients receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting.

d. Effects on Medicare Beneficiaries

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

e. Alternatives Considered

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. We will monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring will assist us in developing knowledgeable, data-driven proposals.

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 ESRD dialysis facility services provided to beneficiaries as a result of payment changes under the ESRD PPS. The methodology that we are proposing to use to determine a facility's TPS for the PY 2021 ESRD QIP is described in section IV.E.8 of this proposed 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 11 shows the overall estimated distribution of payment reductions resulting from the PY 2021 ESRD QIP.

TABLE 11: Estimated Distribution of PY 2021 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities
0.0%	3469	57.6%
0.5%	1507	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 12.

TABLE 12: 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 proposals outlined in section IV.E.8 of this proposed 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 13 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2021. The table details the distribution of ESRD facilities by facility size (both among facilities considered to be small entities and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital based/freestanding facilities). Given that the time periods used for these calculations will differ from those we propose to use for the PY 2021 ESRD QIP, the actual impact of the PY 2021 ESRD QIP may vary significantly from the values provided here.

TABLE 13: Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2021

	<i>Number of Facilities</i>	<i>Number of Treatments 2015 (in millions)</i>	<i>Number of Facilities with QIP Score</i>	<i>Number of Facilities Expected to Receive a Payment Reduction</i>	<i>Payment Reduction (percent change in total ESRD payments)</i>
<i>All Facilities</i>	6,453	40.0	6,020	2,551	-0.32%
<i>Facility Type:</i>					
<i>Freestanding</i>	6,022	37.8	5,852	2,502	-0.33%
<i>Hospital-based</i>	431	2.2	168	49	-0.20%
<i>Ownership Type:</i>					
<i>Large Dialysis</i>	4,541	28.6	4,432	1,910	-0.32%
<i>Regional Chain</i>	989	6.2	929	316	-0.26%
<i>Independent</i>	568	3.5	536	282	-0.50%
<i>Hospital-based (non-chain)</i>	354	1.8	123	43	-0.25%
<i>Unknown</i>	1	0.0	0	0	-
<i>Facility Size:</i>					
<i>Large Entities</i>	5,530	34.8	5,361	2,226	-0.31%
<i>Small Entities¹</i>	922	5.2	659	325	-0.45%
<i>Unknown</i>	1	0.0	0	0	-
<i>Rural Status:</i>					
1) <i>Yes</i>	1,260	6.0	1,146	325	-0.19%
2) <i>No</i>	5,193	34.0	4,874	2,226	-0.35%
<i>Census Region:</i>					
<i>Northeast</i>	879	6.2	786	340	-0.32%
<i>Midwest</i>	1,511	7.6	1,356	557	-0.31%
<i>South</i>	2,852	18.2	2,743	1,276	-0.36%
<i>West</i>	1,142	7.6	1,084	341	-0.22%
<i>US Territories²</i>	69	0.4	51	37	-0.56%

	<i>Number of Facilities</i>	<i>Number of Treatments 2015 (in millions)</i>	<i>Number of Facilities with QIP Score</i>	<i>Number of Facilities Expected to Receive a Payment Reduction</i>	<i>Payment Reduction (percent change in total ESRD payments)</i>
<i>Census Division:</i>					
<i>Unknown</i>	1	0.0	0	0	-
<i>East North Central</i>	1,045	5.5	951	443	-0.36%
<i>East South Central</i>	522	3.0	515	202	-0.30%
<i>Middle Atlantic</i>	702	4.9	623	300	-0.37%
<i>Mountain</i>	368	2.0	336	86	-0.17%
<i>New England</i>	182	1.3	164	40	-0.14%
<i>Pacific</i>	782	5.7	753	257	-0.24%
<i>South Atlantic</i>	1,458	9.4	1,388	719	-0.41%
<i>West North Central</i>	469	2.1	406	115	-0.19%
<i>West South Central</i>	875	5.8	841	355	-0.33%
<i>US Territories²</i>	49	0.3	43	34	-0.62%
<i>Facility Size (# of total treatments)</i>					
<i>Less than 4,000 treatments</i>	1,211	2.7	1,006	357	-0.30%
<i>4,000-9,999 treatments</i>	2,401	11.0	2,324	880	-0.29%
<i>Over 10,000 treatments</i>	2,680	26.1	2,603	1,256	-0.35%
<i>Unknown</i>	161	0.2	87	58	-0.66%

b. Effects on Other Providers

The ESRD QIP is applicable to outpatient dialysis facilities. Therefore, this proposal will have zero impact on other Medicare providers. We are aware that several of our measures do impact other 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 outpatient 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 14 shows the payment reductions achieved by the ESRD QIP program for PYs 2016 through 2021.

Table 14: 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 outpatient 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 addition of new measures to the program and 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 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 15 below, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule.

TABLE 15 Accounting Statement: Classification of Estimated Transfers and Costs/Savings	
ESRD PPS and AKI	
Category	Transfers
Annualized Monetized Transfers	\$80 million
From Whom to Whom	Federal government to ESRD providers
Category	Transfers
Increased Beneficiary Co-insurance Payments	\$20 million
From Whom to Whom	Beneficiaries to ESRD providers
ESRD QIP for PY 2021	
Category	Transfers
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 proposed rule was reviewed by the Office of Management and Budget.

X. 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 13 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 13 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 10. Using the definitions in this ownership category, we consider the 502 facilities that are independent and the 368 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 would have total revenues of more than \$38.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS updates proposed in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of dialysis facility) is estimated to receive a 1.1 percent increase in payments for CY 2018. An independent facility (as defined by ownership type) is also estimated to receive a 0.8 percent increase in payments for CY 2018.

For AKI dialysis, we are unable to estimate whether patients will go to ESRD facilities, however, we have estimated there is a potential for \$2.0 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

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 11 (“Estimated Distribution of PY 2021 ESRD QIP Payment Reductions”) and Table 13 (“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.

Therefore, the Secretary has determined that this proposed rule would 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. We solicit comment on the RFA analysis provided.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Any such regulatory impact analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 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 0.7 percent decrease in payments. As a result, this proposed rule is not estimated to have a significant impact on small rural hospitals.

Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

XI. 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 proposed rule does not include any mandates that would impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of \$141 million. 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.

XII. Federalism Analysis

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

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

XIII. 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 proposed rule is not expected to be subject to the requirements of E.O. 13771 because, if finalized as proposed, it is expected to result in no more than de minimis costs.

XIV. Congressional Review Act

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

XV. Files Available to the Public via the Internet

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

CMS-1674-P

Dated: June 27, 2017

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: June 27, 2017

Thomas E. Price,

Secretary,

Department of Health and Human Services.

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