DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 512

[CMS–1749–F]

RIN 0938–AU39

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

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

ACTION: Final rule.

SUMMARY: This final rule updates the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2022. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). In addition, this rule updates requirements for the ESRD Quality Incentive Program (QIP), including a measure suppression policy for the duration of the coronavirus disease 2019 (COVID–19) public health emergency (PHE) as well as suppression of individual ESRD QIP measures for Payment Year (PY) 2022 under the measure suppression policy. This rule also finalizes that CMS will not score facilities or reduce payment to any facility under the ESRD QIP in PY 2022. Further, this rule finalizes changes to the ESRD Treatment Choices (ETC) Model, which is a mandatory payment model that is focused on encouraging greater use of home dialysis and kidney transplants, to reduce Medicare expenditures while preserving or enhancing the quality of care furnished to Medicare beneficiaries.

DATES: These regulations are effective on January 1, 2022.

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.

ESRDApplications@cms.hhs.gov, for issues related to the Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES).

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

ETC-CMMI@cms.hhs.gov, for issues related to the ESRD Treatment Choices (ETC) Model.

SUPPLEMENTARY INFORMATION: *Current Procedural Terminology (CPT) Copyright Notice:* Throughout this final rule, we use CPT® codes and descriptions to refer to a variety of services. We note that CPT® codes and descriptions are copyright 2020 American Medical Association (AMA). All Rights Reserved. CPT® is a registered trademark of the AMA. Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

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I. Executive Summary

A. Purpose

This rule finalizes changes related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), the ESRD Quality Incentive Program (QIP), and the ESRD Treatment Choices (ETC) Model.

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 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 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. This rule updates the ESRD PPS for CY 2022.

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 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 acute kidney injury (AKI). Section 808(b) of the 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. This rule updates the AKI payment rate for CY 2022.

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

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act. The Program fosters improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by the Centers for Medicare & Medicaid Services (CMS). This rule finalizes our proposals to suppress the use of certain ESRD QIP measure data for scoring and payment adjustment purposes in the PY 2022 ESRD QIP because we have determined that circumstances caused by the Public Health Emergency (PHE) for the coronavirus disease 2019 (COVID–19) pandemic have significantly affected the validity and reliability of the measures and resulting performance scores, as well as special scoring and payment policies for PY 2022. We are also finalizing our proposal to update the specifications for the SHR clinical measure beginning with the PY 2024 ESRD QIP. We are also finalizing our proposal to use CY 2019 data to calculate the PY 2024 ESRD QIP performance standards. This final rule further describes policies that will apply for PY 2025. Finally, this final rule describes several requests for information that also appeared in the CY 2022 ESRD PPS proposed rule. These requests for information solicited stakeholder feedback on several important topics, including strategies that we can use to address the gap in existing health inequities, the addition of COVID–19 vaccination measures in future rulemaking, and the use of digital quality measurement.

4. End-Stage Renal Disease Treatment Choices (ETC) Model

This rule finalizes changes to the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC) Model, a mandatory Medicare payment model tested under the authority of section 1115A of the Act. The ETC Model is operated by the Center for Medicare and Medicaid Innovation (Innovation Center), and tests the use of payment adjustments to encourage greater utilization of home dialysis and kidney transplants, in order to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures. The ETC Model includes ESRD facilities and certain clinicians caring for beneficiaries with ESRD—or Managing Clinicians—located in Selected Geographic Areas as participants.

The ETC Model was finalized as part of a final rule published in the **Federal Register** on September 29, 2020, titled, ''Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' (85 FR 61114), referred to herein as the ''Specialty Care Models final rule.'' The ETC Model is designed to test the effectiveness of adjusting certain Medicare payments to ETC Participants (ESRD facilities and Managing Clinicians—clinicians who furnish and bill the Monthly Capitation Payment (MCP) for managing ESRD Beneficiaries—who have been selected to participate in the ETC Model) to encourage greater utilization of home dialysis and kidney transplantation, support beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. In the Specialty Care Models final rule, we established that the ETC Model adjusts payments for home dialysis and home dialysis-related claims with claim service dates from January 1, 2021 through December 31, 2023 through the Home Dialysis Payment Adjustment (HDPA). We are assessing the rates of home dialysis and of kidney transplant waitlisting and living donor transplantation, among beneficiaries attributed to ETC Participants during the period beginning January 1, 2021, and ending June 30, 2026. Based on those rates, we are applying the Performance Payment Adjustment (PPA) to claims for dialysis and dialysis-related services with claim service dates beginning July 1, 2022, and ending June 30, 2027. We codified these provisions in a new subpart of the Code of Federal Regulations (CFR) 42 CFR part 512, subpart C.

This final rule includes modifications to the ETC Model, including changes to the home dialysis rate and transplant rate, the PPA achievement benchmarking methodology, and the PPA improvement benchmarking and scoring methodology. We are also adding processes and requirements for ETC Participants to receive certain data from CMS and including certain additional waivers and flexibilities as part of the ETC Model test.

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the ESRD PPS base rate for CY 2022:* The final CY 2022 ESRD PPS base rate is $257.90. This amount reflects the application of the wage index budget-neutrality adjustment factor (0.99985) and a productivity-adjusted market basket increase of 1.9 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $257.90 (($253.13 × 0.99985) × 1.019 = $257.90).
- *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 2022, we are updating the wage index values based on the latest available data and continuing the 2-year transition to the Office of Management and Budget (OMB) delineations as described in the September 14, 2018 OMB Bulletin No. 18–04.
- *Update to the outlier policy:* We are updating the outlier policy using the most current data, as well as updating the outlier services fixed-dollar loss (FDL) amounts for adult and pediatric patients and Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2022 using CY 2020 claims data. Based on the use of the latest available data, the final FDL amount for pediatric beneficiaries will decrease from $44.78 to $26.02, and the MAP amount will decrease from $30.88 to $27.15, as compared to CY 2021 values. For adult beneficiaries, the final FDL amount will decrease from $122.49 to $75.39, and the MAP amount will decrease from $50.92 to $42.75. The 1.0 percent target for outlier payments was not achieved in CY 2020. Outlier payments represented approximately 0.6 percent of total payments rather than 1.0 percent.
- *Update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2022:* The

final CY 2022 average per treatment offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for capital-related assets that are home dialysis machines is $9.50. This offset amount reflects the application of the productivity-adjusted market basket increase of 1.9 percent ($9.32 × 1.019 = $9.50).

• *TPNIES applications received for CY 2022:* In this final rule, we announce our determination on the one TPNIES application under consideration for the TPNIES for CY 2022 payment.

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

We are updating the AKI payment rate for CY 2022. The final CY 2022 payment rate is $257.90, which is the same as the base rate finalized under the ESRD PPS for CY 2022.

3. ESRD QIP

We are adopting a measure suppression policy for the duration of the COVID–19 PHE that enables us to suppress the use of one or more measures in the ESRD QIP for scoring and payment adjustment purposes if we determine that circumstances caused by the COVID–19 PHE have significantly affected the measures and resulting performance scores. We are also finalizing our proposal to suppress the Standardized Hospitalization Ratio (SHR) clinical measure, the Standardized Readmission Ratio (SRR) clinical measure, the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) clinical measure, and the Long-Term Catheter Rate clinical measure for PY 2022 under the measure suppression policy. We are also finalizing our proposal to not score or reduce payment to any facility in PY 2022. We are finalizing our proposal to update the specifications for the SHR clinical measure beginning with the PY 2024 ESRD QIP. We are also finalizing our proposal for the PY 2024 ESRD QIP to use CY 2019 data to calculate the performance standards for that payment year. This final rule also announces the performance standards and estimated payment reductions that will apply for PY 2024. This final rule describes several policies continuing for PY 2025, but does not include any new requirements beginning with the PY 2025 ESRD QIP.

This final rule includes public comments received in response to requests for information that appeared in the CY 2022 ESRD PPS proposed rule. In those requests for information, we solicited stakeholder feedback on several important topics, including closing the gap in health equity, adding a COVID–19 vaccination measure for health care personnel (HCP) to the ESRD QIP measure set in future rulemaking, adding a COVID–19 vaccination measure for ESRD patients to the ESRD QIP measure set in future rulemaking, and potential actions and priority areas that would enable us to continue moving toward a greater digital capture of data and use of the Fast Healthcare Interoperability Resources (FHIR®) standard in quality measurement.

4. ETC Model

We are implementing the following changes to the ETC Model beginning for the third Measurement Year (MY3) of the Model, which begins January 1, 2022.

• *Beneficiary Attribution for Living Kidney Donor Transplants:* To better reflect the care relationship between beneficiaries who receive pre-emptive living donor transplants (LDT) and the Managing Clinicians who provide their care, we are modifying the methodology for attributing Pre-emptive LDT Beneficiaries to Managing Clinicians, such that a Pre-emptive LDT Beneficiary will be attributed to the Managing Clinician who submitted the most claims for services furnished to the beneficiary during the 365 days prior to the transplant date.

• *Home Dialysis Rate Calculation:* To incentivize additional alternative renal replacement modalities under the ETC Model, we are adding nocturnal in-center dialysis to the calculation of the home dialysis rate for ESRD facilities and Managing Clinicians.

• *Transplant Rate Beneficiary Exclusion:* To better align with common reasons transplant centers do not place patients on the transplant waitlist, we are excluding beneficiaries with a diagnosis of, and who are receiving treatment with chemotherapy or radiation for, vital solid organ cancers from the calculation of the transplant rate.

• *Performance Payment Adjustment Achievement Benchmarking Methodology:* When we originally finalized the ETC Model, we stated our intent to increase achievement benchmarks above rates observed in Comparison Geographic Areas for future model years. As such, we will increase achievement benchmarks by 10 percent over rates observed in Comparison Geographic Areas every two MYs, beginning in MY3 (2022). We also will stratify achievement benchmarks based on the proportion of attributed beneficiaries who are dually-eligible for Medicare and Medicaid or receive the Low Income Subsidy (LIS) during the MY, in recognition that beneficiaries with lower socioeconomic status have lower rates of home dialysis and transplant than those with higher socioeconomic status.

• *Performance Payment Adjustment Improvement Benchmarking and Scoring:* In conjunction with the stratification of the achievement benchmarks based on the proportion of beneficiaries who are dual-eligible or LIS recipients, we will introduce the Health Equity Incentive to the improvement scoring methodology used in calculating the PPA. CMS expects that the Health Equity Incentive will encourage ETC Participants to decrease disparities in renal replacement modality choice among beneficiaries with lower socioeconomic status by rewarding ETC Participants that demonstrate significant improvement in the home dialysis rate or transplant rate among their attributed beneficiaries who are dual-eligible or LIS recipients. We also will adjust the improvement scoring calculation to avoid the scenario where an ETC Participant cannot receive an improvement score because its home dialysis rate or transplant rate was zero during the Benchmark Year.

• *Performance Payment Adjustment Reports and Related Data Sharing:* To ensure that ETC Participants have timely access to ETC Model reports, we are establishing a process under which CMS will share certain model data with ETC Participants.

• *Medicare Waivers:* We are including an additional programmatic waiver to provide Managing Clinicians who are ETC Participants additional flexibility in furnishing the kidney disease patient education services described in § 410.48, namely a waiver of certain telehealth requirements as necessary solely for purposes of allowing ETC Participants to furnish kidney disease patient education services via telehealth under the ETC Model to take effect at the end of the COVID–19 PHE.

• *Kidney Disease Patient Education Services Coinsurance Waivers:* We will permit Managing Clinicians who are ETC Participants to reduce or waive the beneficiary coinsurance for kidney disease patient education services, subject to certain requirements. We have made the determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)), will be available to protect the reduction or elimination of coinsurance that is made in compliance with our policy.

C. Summary of Costs and Benefits

In section VIII.C.5 of this final rule, we set forth a detailed analysis of the impacts that the changes will have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact table in section VIII.C.5.a of this final rule displays the estimated change in payments to ESRD facilities in CY 2022 compared to estimated payments in CY 2021. The overall impact of the CY 2022 changes is projected to be a 2.5 percent increase in payments. Hospital-based ESRD facilities have an estimated 3.3 percent increase in payments compared with freestanding facilities with an estimated 2.5 percent increase. We estimate that the aggregate ESRD PPS expenditures will increase by approximately $290 million in CY 2022 compared to CY 2021. This reflects a $220 million increase from the payment rate update, a $70 million increase due to the updates to the outlier threshold amounts, and approximately $2.5 million in estimated TPNIES payment amounts, as further described in the next paragraph. Because of the projected 2.5 percent overall payment increase, we estimate there will be an increase in beneficiary coinsurance payments of 2.5 percent in CY 2022, which translates to approximately $60 million.

Section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. Under this authority, CMS implemented § 413.236 to establish the TPNIES, a transitional add-on payment adjustment for new and innovative equipment and supplies, which is not budget neutral. As discussed in section II.C.1.a. of this final rule, we have determined that the Tablo® System, a hemodialysis machine that has FDA authorization for home use, has met the criteria for the TPNIES for CY 2022 payment. We estimate that the overall TPNIES payment amounts in CY 2022 would be approximately $2.5 million, of which, approximately $490,000 would be attributed to beneficiary coinsurance amounts.

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

The impact table in section VIII.C.5.b of this final rule displays the estimated change in payments to ESRD facilities in CY 2022 compared to estimated payments in CY 2021. The overall impact of the CY 2022 changes is projected to be a 1.9 percent increase in payments for individuals with AKI. Hospital-based ESRD facilities have an estimated 2.0 percent increase in payments compared with freestanding ESRD facilities with an estimated 1.9 percent increase. The overall impact reflects the effects of the updated wage index and the final payment rate update. We estimate that the aggregate payments made to ESRD facilities for renal dialysis services furnished to patients with AKI, at the final CY 2022 ESRD PPS base rate, will increase by $1 million in CY 2022 compared to CY 2021.

3. Impacts of the ESRD QIP

Our finalized policy to suppress measures for the PY 2022 ESRD QIP and to revise the scoring and payment methodology such that no facility will receive a payment reduction necessitated a modification to our previous estimated overall economic impact of the PY 2022 ESRD QIP (84 FR 60651). In the CY 2020 ESRD PPS final rule, we estimated that the overall economic impact of the PY 2022 ESRD QIP would be approximately $229 million as a result of the policies we had finalized at that time. The $229 million figure for PY 2022 included costs associated with the collection of information requirements, which we estimated would be approximately $211 million, and $18 million in estimated payment reductions across all facilities. However, as a result of the policies we are finalizing in this final rule for the PY 2022 ESRD QIP, we are modifying our previous estimate for PY 2022. We estimate that the new overall economic impact of the PY 2022 ESRD QIP will be approximately $215 million. The $215 million figure for PY 2022 only includes the costs associated with the collection of information requirements because there will be no payment reductions in PY 2022. We estimate that the overall economic impact of the PY 2024 ESRD QIP will be approximately $232 million, of which $215 million is associated with the collection of information requirements and $17 million is associated with the estimated payment reductions across all facilities. We also estimate that the overall economic impact of the PY 2025 ESRD QIP will be approximately $232 million.

4. Impacts of Changes to the ETC Model

The impact estimate in section VIII.B.4 of this final rule describes the estimated change in anticipated Medicare program savings arising from the ETC Model over the duration of the ETC Model as a result of the changes in this final rule. We estimate that the ETC Model will result in $28 million in net savings over the 6.5-year duration of the ETC Model. We also estimate that $5 million of the estimated $28 million in net savings will be attributable to changes in this final rule.

II. Calendar Year (CY) 2022 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, the Centers for Medicare & Medicaid Services (CMS) implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). 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), established that beginning with 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. 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 CY 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 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 definition of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies. 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, and four comorbidity categories (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, myelodysplastic syndrome). A different set of case-mix adjusters are applied for the pediatric population. Pediatric patient-level adjusters include two age categories (under age 22, or age 22–26) and two dialysis modalities (that is, peritoneal or hemodialysis) (§ 413.235(a) and (b)).

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

There are four additional payment adjustments under the ESRD PPS. The ESRD PPS provides adjustments, when applicable, for: (1) A training add-on for home and self-dialysis modalities (§ 413.235(c)); (2) an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care (§ 413.237); (3) a transitional drug add-on payment adjustment (TDAPA) for certain new renal dialysis drugs and biological products (§ 413.234(c)); and (4) a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for certain qualifying, new and innovative renal dialysis equipment and supplies (§ 413.236(d)).

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 9, 2020, we published a final rule in the **Federal Register** titled, ''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,'' referred to herein as the ''CY 2021 ESRD PPS final rule''. In that rule, we updated the ESRD PPS base rate, wage index, and outlier policy, for CY 2021. We also finalized an update to the ESRD PPS wage index to adopt the 2018 OMB delineations with a transition period, changes to the eligibility criteria and determination process for the TPNIES, an expansion of the TPNIES to include certain new and innovative capital-related assets that are home dialysis machines, an addition to the ESRD PPS base rate to include calcimimetics in the ESRD PPS bundled payment, and a change to the low-volume payment adjustment eligibility criteria and attestation requirement to account for the coronavirus disease 2019 (COVID–19) Public Health Emergency (PHE). For further detailed information regarding these updates, see 85 FR 71398.

B. Provisions of the Proposed Rule, Public Comments, and Responses to the Comments on the CY 2022 ESRD PPS

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'' (86 FR 36322 through 36437), referred to as the ''CY 2022 ESRD PPS proposed rule,'' was published in the **Federal Register** on July 9, 2021, with a comment period that ended on August 31, 2021. In that proposed rule, we proposed to make a number of annual updates for CY 2022, including updates to the ESRD PPS base rate, wage index, outlier policy, and the offset amount for TPNIES for capital-related assets that are home dialysis machines used in the home. The proposed rule presented a summary of the two CY 2022 TPNIES applications that we received by the February 1, 2021 deadline and our analysis of the applicants' claims related to substantial clinical improvement (SCI) and other eligibility criteria for the TPNIES.

We received 286 public comments on our proposals, including comments from kidney and dialysis organizations, such as large and small dialysis organizations, for-profit and non-profit ESRD facilities, ESRD networks, and a dialysis coalition. We also received comments from patients; healthcare providers for adult and pediatric ESRD beneficiaries; home dialysis services and advocacy organizations; provider and legal advocacy organizations; administrators and insurance groups; a non-profit dialysis association, a professional association, and alliances for kidney care and home dialysis stakeholders; drug and device manufacturers; health care systems; a

health solutions company; and the Medicare Payment Advisory Commission (MedPAC).

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the CY 2022 ESRD PPS.

1. CY 2022 ESRD PPS Update

a. CY 2022 ESRD Bundled (ESRDB) Market Basket Update, Productivity Adjustment, and Labor-Related Share

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 percent 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.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD Bundled (ESRDB) input price index (75 FR 49151 through 49162). In the CY 2015 ESRD PPS final rule, we rebased and revised the ESRDB input price index to reflect a 2012 base year (79 FR 66129 through 66136). Subsequently, in the CY 2019 ESRD PPS final rule, we finalized a rebased ESRDB input price index to reflect a 2016 base year (83 FR 56951 through 56962).

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 proposed to use the CY 2016-based ESRDB market basket as finalized and described in the CY 2019 ESRD PPS final rule (83 FR 56951 through 56962) to compute the CY 2022 ESRDB market basket increase factor based on the best available data. Consistent with historical practice, we proposed to estimate the ESRDB market basket update based on IHS Global Inc.'s (IGI's) forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm with which we contract to forecast the components of the market baskets. Using this methodology and the IGI first quarter 2021 forecast of the CY 2016-based ESRDB market basket (with historical data through the fourth quarter of 2020), the proposed CY 2022 ESRDB market basket increase factor was 1.6 percent.

Under section 1881(b)(14)(F)(i) of the 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 productivity adjustment is calculated using a projection of multifactor productivity (MFP), which is derived by subtracting the contribution of labor and capital input growth from output growth. We finalized the detailed methodology for deriving the projection of MFP 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 *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/MFPMethodology.pdf.* We noted in the CY 2022 ESRD PPS proposed rule that for CY 2022 and beyond, we are changing the name of this adjustment to refer to it as the productivity adjustment, which is the term used in sections 1881(b)(14)(F)(i) and 1886(b)(3)(B)(xi)(II) of the Act, rather than the multifactor productivity or MFP adjustment. This is not a change in policy, as we will continue to use the same methodology for deriving the adjustment and rely on the same underlying data. Using this methodology and the IGI first quarter 2021 forecast, the proposed productivity adjustment for CY 2022 (the 10-year moving average of MFP for the period ending CY 2022) was 0.6 percent.

As a result of these provisions, the proposed CY 2022 ESRD market basket increase factor reduced by the productivity adjustment was 1.0 percent. The proposed market basket increase factor is calculated by starting with the proposed CY 2022 ESRDB market basket percentage increase factor of 1.6 percent and reducing it by the proposed productivity adjustment (the 10-year moving average of MFP for the period ending CY 2022) of 0.6 percent.

As is our general practice, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the CY 2016-based ESRD market basket increase factor or productivity adjustment), we would use such data, if appropriate, to determine the final CY 2022 market basket update and productivity adjustment in this final rule (85 FR 36327).

We invited public comment on our proposals for the CY 2022 ESRD market basket update and productivity adjustment. The following is a summary of the public comments received on these proposals and our responses.

Comment: Several commenters encouraged CMS to examine the data sources and other elements to ensure that the market basket update reflects ESRD facilities' current experience. The commenters stated that while they understand CMS must follow the statutory framework for the annual market basket update, they believe that the proposed CY 2022 market basket update appears low given inflation and rising expenses including rent and labor. Several commenters expressed that they support the proposed ESRD PPS annual payment rate update for CY 2022 and support the use of more recent data for the market basket update and productivity adjustment, if available, to determine the final update factors for CY 2022. MedPAC commented that while it recognizes that CMS must provide the statutorily mandated payment update of the market basket minus the productivity adjustment, the Commission has concluded that this increase is not warranted based on their analysis of payment adequacy, which includes an assessment of beneficiary access, supply of ESRD facilities, and ESRD facilities' access to capital, quality, and financial indicators for the sector. MedPAC further recommended that Congress should eliminate the update to the ESRD PPS base rate for CY 2022.

Response: We acknowledge the concerns of some of the commenters and appreciate the support of some of the commenters regarding the proposed ESRD PPS annual payment rate update and use of more recent data to determine the market basket and productivity adjustment in determination of the final update factor. We also appreciate MedPAC's comments but note that the ESRD market basket increase factor is mandated by statute. For this final rule, we have incorporated more current historical data and revised forecasts provided by IGI that factor in expected price and wage pressures. By incorporating the most recent estimates available of the market basket update

and productivity adjustment, we believe these data reflect the best available projection of input price inflation faced by ESRD facilities for CY 2022, adjusted for economy-wide productivity, which is required by statute. As stated previously in this section of the final rule, consistent with our proposal to use more recent data, the CY 2022 ESRD market basket increase factor is 1.9 percent based on the more recent IGI third quarter 2021 forecast.

Comment: A few commenters noted that while they understand that the productivity adjustment is statutorily required, they believe that the experience of ESRD facilities argues against the idea that productivity can be improved year-over-year.

Response: We acknowledge the commenters' concerns regarding productivity growth at the economy-wide level and its application to ESRD facilities. As the commenter acknowledges, however, section 1881(b)(14)(F)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the ESRD PPS market basket increase factor for 2012 and subsequent years. We will continue to monitor the impact of the payment updates, including the effects of the productivity adjustment, on ESRD provider margins as well as beneficiary access to care as reported by MedPAC.

Comment: One commenter recommended CMS replace the current price proxy for the non-Erythropoietin Stimulating Agents (ESA) Pharmaceutical cost weight in the 2016-based ESRD market basket Producer Price Index (PPI)—Commodity—Vitamin, nutrient, and hematinic preparations) with BLS PPI Commodity Data for Chemicals and Allied Products-Drugs and Pharmaceuticals, seasonally adjusted (BLS Series ID: WPS063 Series). The commenter further stated that they do not believe that the current proxy appropriately captures the price of drugs that fall within this category as they are not over-the-counter vitamins but prescription-only, synthesized hormones. The commenter also noted that there are new drugs under development currently that likely will be added to the ESRD PPS bundled payment during the next few years. The commenter asserted that an alternative proxy for the non-ESA drugs should be based on prescription drugs rather than the current proxy.

Response: We appreciate the commenter's suggestion and share the commenter's desire to use the most appropriate price proxy for non-ESA drugs in the ESRD market basket. As described in the CY 2019 ESRD PPS final rule (83 FR 56960 through 56961), and in the CY 2021 ESRD PPS final rule (85 FR 71428), we believe the PPI for Vitamins, Nutrients, and Hematinic Preparation (VNHP) is the most appropriate price proxy for non-ESA drugs and analysis of the Average Sales Price (ASP) data for Non-ESA drugs in the ESRD PPS bundled payment suggests the trends in the PPI VNHP trends are reasonable. We appreciate the commenter's concern about the potential shifts in the mix of drugs within the ESRD PPS bundled payment as new drugs enter the market. We will continue to monitor the impact that these changes have on the relative cost share weights and the mix of Non-ESA drugs included in the ESRD PPS bundled payment in the ESRDB market basket, and propose changes if appropriate in future rulemaking.

Final Rule Action: After considering the public comments, consistent with our historical practice and our proposal, we are estimating the market basket increase and the productivity adjustment based on IGI's forecast using the most recent available data. Based on IGI's third quarter 2021 forecast of the 2016-based ESRDB market basket with historical data through the second quarter of 2021, the 2016-based ESRDB market basket update for CY 2022 is 2.4 percent. IGI's 2021 third quarter forecast reflects a higher CY 2022 inflationary outlook compared to IGI's 2021 first quarter forecast, which is resulting in a notable upward revision to the CY 2022 ESRD market basket update for the CY 2022 ESRD PPS final rule (2.4 percent) compared to the CY 2022 ESRD PPS proposed rule (1.6 percent). As the economic impacts of the COVID–19 pandemic ease, the relatively higher inflation is resulting in relatively higher projected growth in wage, medical materials and supplies, and capital prices.

Based on the more recent data available from IGI's third quarter 2021 forecast, the current estimate of the productivity adjustment for CY 2022 (the 10-year moving average of MFP for the period ending CY 2021) is 0.5 percentage point. Therefore, the final CY 2022 ESRD market basket adjusted for the productivity adjustment is projected to be 1.9 percent (2.4 percent market basket update reduced by 0.5 percentage point productivity adjustment).

For the CY 2022 ESRD PPS payment update, we proposed to continue using a labor-related share of 52.3 percent for the ESRD PPS payment, which was finalized in the CY 2019 ESRD PPS final rule (83 FR 56963). We invited public comment on the proposed labor-related share for CY 2022. We did not receive any comments on the proposal to continue using a labor-related share of 52.3 percent for CY 2022 and, therefore, are finalizing the continued use of a 52.3 percent labor-related share as proposed.

b. CY 2022 ESRD PPS Wage Indices

(1) Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. We use OMB's CBSA-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The bulletins are available online at *https://www.whitehouse.gov/omb/information-for-agencies/bulletins/*.

For CY 2022, we proposed to update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. 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 prefloor hospital data that are unadjusted for occupational mix. For CY 2022, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2017, and before October 1, 2018 (fiscal year [FY] 2018 cost report data).

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For a full discussion, see CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the State to serve as a reasonable

proxy for the wage index of that urban CBSA, that is, we 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 statewide urban average based on the average of all urban areas within the State to Hinesville-Fort Stewart, Georgia (78 FR 72173), and we apply the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172).

A wage index floor value (0.5000) is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico. However, the wage index floor value is applicable for any area that may fall below the floor. A description of the history of the wage index floor under the ESRD PPS can be found in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967).

An ESRD facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2019 ESRD PPS final rule (83 FR 56963), we finalized a labor-related share of 52.3 percent, which is based on the 2016-based ESRDB market basket. In the CY 2021 ESRD PPS final rule (85 FR 71436), we updated the OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, beginning with the CY 2021 ESRD PPS wage index. In addition, we finalized the application of a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. We finalized that the transition would be phased in over 2 years, such that the reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022. Thus, for CY 2022, the labor-related share to which a facility's wage index would be applied is 52.3 percent.

The comments received on the proposed CY 2022 ESRD PPS wage index and our responses to the comments are set forth below.

Comment: A coalition of dialysis organizations and a professional association acknowledged and supported the final phase-in of the updated OMB delineations for CY 2022. These commenters, along with another large dialysis organization, suggested that CMS consider ways to better tailor the ESRD PPS wage index, including using additional data beyond the hospital wage data. Another small dialysis organization expressed concerns that the ESRD PPS wage index does not keep pace with the hospital wage index, and identified several potential changes to align the ESRD PPS wage index with the hospital wage index, including the application of a statewide rural floor on wage indices, the application of different labor-related share percentages for areas with wage indices above and below 1, and allowing ESRD facilities to reclassify to a different geographic area. Another commenter, a non-profit kidney care alliance, expressed similar concerns and urged CMS to promptly address these disparities between the ESRD PPS wage index and the hospital wage index in rulemaking in the near future.

Response: We thank the commenters for their support, and we appreciate the suggestions for improving the ESRD PPS wage index. We did not propose changes to the ESRD PPS wage index methodology for CY 2022, and therefore we are not finalizing any changes to that methodology in this final rule. However, we will take these comments into consideration to potentially inform future rulemaking.

Comment: Three commenters, including a large dialysis organization, a non-profit health insurance organization in Puerto Rico, and a healthcare group in Puerto Rico, commented on the wage index for ESRD facilities located in Puerto Rico. These commenters recommended that CMS increase the wage index floor from 0.5000 to 0.5500; they noted that in the CY 2019 ESRD PPS proposed rule, CMS reported that its own analysis indicated that Puerto Rico's wage index likely lies between 0.5100 and 0.5500. They noted that CMS further stated that any wage index values less than 0.5936 are considered outlier values. They pointed out that CMS still finalized a floor at 0.50 and characterized it as a balance between providing additional payments to affected areas while minimizing the impact on the ESRD PPS base rate. The commenters also recommended that CMS align the ESRD PPS wage index with the hospital wage index by applying to the ESRD PPS wage index the policy finalized in the FY 2020 IPPS final rule (84 FR 42326 through 42328) that increases the wage index for hospitals with a wage index value below the 25th percentile wage index. Two of the commenters further suggested that CMS conduct a survey of registered nurse (RN) and health worker wages specifically in standalone ESRD facilities in Puerto Rico as a means for wage index reform, noting that there is specific professional scope of practice standards for technicians in Puerto Rico outpatient facilities. Commenters asserted that RNs must provide all ESRD care in Puerto Rico outpatient facilities per local scope of practice laws, and that CMS should evaluate inpatient and outpatient facility data separately in order to get a fully accurate projection of wage costs for ESRD providers in Puerto Rico. Another commenter recommended that CMS evaluate policy inequities between the ESRD PPS wage index for ESRD facilities located in Puerto Rico compared to other states and territories, taking into consideration the unique circumstances that affect Puerto Rico, including its shortage of healthcare specialists and labor work force, remote geography, transportation and freighting costs, drug pricing, and lack of transitional care services.

Response: We thank the commenters for sharing their concerns regarding the ESRD PPS wage index for ESRD facilities in Puerto Rico and their suggestions for wage index reform. As noted in the CY 2018 ESRD PPS final rule (82 FR 50747) and the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967), we have received conflicting information from commenters about the local scope of practice for RNs and other staff impact on facility costs in Puerto Rico. Since we did not propose any changes to the wage index floor or wage index methodology for CY 2022, we are not finalizing any changes to those policies in this final rule. However, we appreciate the concerns that commenters have raised and we will take these thoughtful suggestions into account when considering future rulemaking.

Final Rule Action: We are finalizing the CY 2022 ESRD PPS wage indices based on the latest hospital wage data as proposed. For CY 2022, the labor-related share to which a facility's wage index is applied is 52.3 percent. As we finalized in the CY 2021 ESRD PPS final rule (85 FR 71436), there will be no cap applied to the reduction in the ESRD PPS wage index for CY 2022. The final CY 2022 ESRD PPS wage index is set forth in Addendum A and is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.* Addendum A provides a crosswalk between the CY 2021 wage index and the CY 2022 wage index. Addendum B provides an ESRD facility level impact analysis. Addendum B is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-*

Renal-Disease-ESRD-Payment-Regulations-and-Notices.

c. CY 2022 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 secondary hyperparathyroidism. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237.

The policy provides that the following ESRD outlier items and services are included in the ESRD PPS bundle: (1) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B ; (3) renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (4) renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025; and (5) renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.

In the CY 2011 ESRD PPS final rule (75 FR 49142), CMS 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 specified in Transmittal 2134, dated January 14, 2011.[1] Furthermore, CMS uses administrative issuances to update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. For example, we use these updates to identify renal dialysis service drugs that were or would have been covered under Medicare Part D for outlier eligibility purposes and items and services that have been incorrectly identified as eligible outlier services.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its actual or imputed Medicare Allowable Payment (MAP) amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted and described in the following paragraphs) plus the fixed-dollar loss (FDL) amount. In accordance with § 413.237(c), 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 and codified in § 413.220(b)(4), using 2007 data, we established the outlier percentage, which is used to reduce the per treatment base rate to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments, 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 used to compute the payment adjustments.

For CY 2022, we proposed that the outlier services MAP amounts and FDL amounts would be derived from claims data from CY 2020. As we stated in the CY 2022 ESRD PPS proposed rule (86 FR 36329), we believe that any adjustments made to the MAP amounts under the ESRD PPS should be based upon the most recent data year available to best predict any future outlier payments; therefore, we proposed the outlier thresholds for CY 2022 would be based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2020.

We also stated that we recognize that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and FDL amounts every year under the ESRD PPS. As discussed in section II.B.1.c of this final rule, CY 2020 claims data show outlier payments represent approximately 0.6 percent of total payments.

(1) CY 2022 Update to the Outlier Services MAP Amounts and FDL Amounts

For this final rule, the outlier services MAP amounts and FDL amounts were updated using 2020 claims data, as we proposed to do for CY 2022. 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 2021 with the updated estimates for this final rule. The estimates for the CY 2022 outlier policy, which are included in Column II of Table 1, were inflation adjusted to reflect projected 2022 prices for outlier services.

[1] Transmittal 2033 issued August 20, 2010, was 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 included one technical correction. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2134CP.pdf.*

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

	Column I Final outlier policy for CY 2021 (based on 2019 data, price inflated to 2021)*		Column II Final outlier policy for CY 2022 (based on 2020 data, price inflated to 2022)	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	$30.33	$53.08	$25.91	$44.49
Adjustments				
Standardization for outlier services	1.0390	0.9789	1.0693	0.9805
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$30.88	$50.92	$27.15	$42.75
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$44.78	$122.49	$26.02	$75.39
Patient-month-facilities qualifying for outlier payment	8.80%	5.15%	12.89%	7.08%

*Note that Column I was obtained from Column II of Table 5 from the CY 2021 ESRD PPS final rule (85 FR 71437).

As demonstrated in Table 1, the estimated FDL amount per treatment that determines the CY 2022 outlier threshold amount for adults (Column II; $75.39) is lower than that used for the CY 2021 outlier policy (Column I; $122.49). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $50.92 to $42.75. For pediatric patients, there is a decrease in the FDL amount from $44.78 to $26.02. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from $30.08 to $27.15.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2022 will be 7.08 percent for adult patients and 12.89 percent for pediatric patients, based on the 2020 claims data. The 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).

(2) Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and 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 2020 claims, outlier payments represented approximately 0.6 percent of total payments, which is below the 1 percent target due to declines in the use of outlier services. As we stated in the CY 2022 ESRD PPS proposed rule (86 FR 36330), recalibration of the thresholds using 2020 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2022. We stated in the CY 2022 ESRD PPS proposed rule that we believe the update to the outlier MAP and FDL amounts for CY 2022 would increase payments for ESRD beneficiaries requiring higher resource utilization. This would move us closer to meeting our 1 percent outlier policy goal, because we are using more current data for computing the MAP and FDL, which is more in line with current outlier services utilization rates. We noted in the CY 2022 ESRD PPS proposed rule that recalibration of the FDL amounts 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.

The comments and our responses to the comments on our proposed updates to the outlier policy are set forth below.

Comment: Several commenters suggested alternatives to our proposed outlier MAP amounts, FDL amounts, and outlier percentage target for CY 2022. One large dialysis organization commented in support of using the most recent available CY 2020 claims data for determining the CY 2022 outlier services MAP amounts and FDL amounts, but suggested that CMS undertake further action to address the issue of outlier payments falling short of the 1 percent target. A professional organization of pediatric nephrologists expressed concern that the decreasing FDL and MAP amounts suggest that the cost of delivering pediatric ESRD care is not appropriately paid under Medicare by either the existing ESRD PPS bundled payment or through the outlier adjustment. Several commenters recommended that CMS set the CY 2022 outlier percentage less than 1 percent. For example, one commenter, a coalition of dialysis organizations, suggested that because the CY 2020 claims data showed that outlier payments represented approximately 0.6 percent of total ESRD PPS payments, CMS could set the CY 2022 outlier ''pool'' [percentage] at 0.6 percent. Similarly, a professional association suggested that because historical data shows that CMS regularly pays out between 0.5 and 0.6 percent of ESRD PPS payments as outlier payments, CMS should reduce the outlier percentage to better match the use of the outlier pool. Other commenters, including a large dialysis organization and a provider advocacy organization, urged CMS to reduce the CY 2022 outlier pool to no more than 0.5 percent of projected

aggregate ESRD PPS spending. Another large dialysis organization recommended CMS adopt the proposed FDL and MAP amounts for CY 2022, but urged CMS to set the outlier percentage to 0.6 percent.

Additionally, several of these commenters suggested that in any year when the outlier pool retains dollars that are not paid out, CMS should return those dollars to providers or reallocate those dollars to support reducing the barriers that create inequities in the care dialysis patients receive.

Response: We appreciate the support for the proposed use of CY 2020 data and the thoughtful suggestions provided by commenters. We acknowledge that, even with annually adjusting the MAP and FDL to reflect the most recent utilization and costs of ESRD PPS eligible outlier services, total outlier payments have not yet reached the 1 percent target. However, it is also true that use of eligible ESRD outlier services declined each year. That is, ESRD facilities incurred lower costs than anticipated, and those savings accrued to facilities more than offsetting the extent to which the consequent outlier payments fell short of the 1.0 percent target. We also note that declining FDL and MAP amounts do not in themselves suggest that the ESRD PPS fails to adequately pay for the delivery of either pediatric or adult ESRD care. Rather, the ESRD PPS outlier policy was established to account for unusual variations in the type or amount of medically necessary care. Declining FDL and MAP amounts suggest that there is less costly variation in such care that is not included in the ESRD PPS bundled payment.

We appreciate the comments suggesting solutions for refining the outlier policy methodology, for example, reducing the outlier percentage withhold to less than 1 percent or establishing a mechanism that pays back ESRD facilities those allocated outlier amounts that did not pay out in the year projected. We did not propose any modifications to the ESRD PPS outlier policy for CY 2022, so we are not finalizing any changes to the methodology in this final rule. However, as discussed in section VI.E of the CY 2022 ESRD PPS proposed rule (86 FR 36400), CMS is considering potential revisions to the calculation of the outlier percentage to address stakeholder concerns, including concerns about the 1 percent outlier percentage, and issued a request for information in the CY 2022 ESRD PPS proposed rule to seek feedback on the acceptability of possible payment adjustment methods and to solicit information that would better inform future modifications to the methodology through rulemaking.

Final Rule Action: After considering the public comments, we are finalizing the updated outlier thresholds for CY 2022 displayed in Column II of Table 1 of this final rule and based on CY 2020 data.

d. Final Impacts to the CY 2022 ESRD PPS Base Rate

(1) ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), CMS established the methodology for calculating the ESRD PPS per-treatment base rate, that is, ESRD PPS base rate, and calculating the per treatment payment amount, which are codified 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 our regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, training adjustment add-on, TDAPA, and TPNIES.

(2) Annual Payment Rate Update for CY 2022

We are finalizing an ESRD PPS base rate for CY 2022 of $257.90. This update reflects several factors, described in more detail as follows:

Wage Index Budget-Neutrality Adjustment Factor: We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2022, we did not propose any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the final CY 2022 wage index budget-neutrality adjustment factor using treatment counts from the 2020 claims and facility-specific CY 2021 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2021. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2022. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the ESRD PPS wage index for CY 2022. As discussed in section II.B.1.b of this final rule, the ESRD PPS wage index for CY 2022 includes an update to the most recent hospital wage data, use of the 2018 OMB delineations, and no cap on wage index decreases applied for CY 2022. The total of these payments becomes the new CY 2022 amount of wage-adjusted expenditures for all ESRD facilities. The wage index budget-neutrality factor is calculated as the target amount divided by the new CY 2022 amount. When we multiplied the wage index budget neutrality factor by the applicable CY 2022 estimated payments, aggregate payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget neutrality adjustment factor ensures that wage index adjustments do not increase or decrease aggregate Medicare payments with respect to changes in wage index updates. The CY 2022 wage index budget-neutrality adjustment factor is 0.99985. This application would yield a CY 2022 ESRD PPS base rate of $253.09 prior to the application of the market basket increase ($253.13 × 0.99985 = $253.09).

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 2022 projection of the ESRDB market basket percentage increase factor is 2.4 percent. In CY 2022, this amount must be 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. As discussed previously in section II.B.1.a of this final rule, the final productivity adjustment for CY 2021 is 0.5 percent, thus yielding an update to the base rate of 1.9 percent for CY 2022. Therefore, the final CY 2022 ESRD PPS proposed base rate is $257.90 ($253.02 × 1.019 = $257.90).

The comments and our responses to the comments on our updates to the CY 2022 ESRD PPS base rate are set forth below.

Comment: Several commenters raised concerns about the comorbidity case-mix adjustments under the ESRD PPS

and recommended eliminating them for CY 2022. Two commenters, including a large dialysis organization and a coalition of dialysis organizations encouraged CMS to eliminate the remaining comorbidity case-mix adjustments and thereby increase the ESRD PPS base rate for CY 2022. These commenters noted that the percent of claims with these conditions is relatively low and has been declining over time. These commenters argued that as the frequency of these conditions declines in the claims, maintaining these adjusters results in the loss of money from the system that could be redirected toward patient care. One of these commenters further argued that this means the dollars that Congress intended to go to providing items and services for individuals who receive dialysis are being inappropriately diverted away from that care. Both commenters further suggested that the years of discussion pertaining to patient-level adjustments, particularly the issues with the comorbid case-mix adjusters, and CMS's questions through the request for information (RFI) in the CY 2022 ESRD PPS proposed rule, should constitute enough notice to support their removal from the regression model for CY 2022, which includes the co-morbid case-mix adjusters in the calculation of the ESRD PPS payment.

Response: As the commenters noted, we included a detailed RFI regarding the ESRD PPS case mix adjustments in the CY 2022 ESRD PPS proposed rule (82 FR 36398 through 36409). A summary of the comments received in response to the RFI is provided in section VI.A of this final rule, and we will provide further information on the CMS ESRD PPS website in the future. CMS is considering alternative approaches to calculating the ESRD PPS case-mix adjustments that directly address stakeholder concerns, and appropriately reflect resource use and costs. The RFI in the CY 2022 ESRD PPS proposed rule both sought feedback on the variation of case-mix adjustments with duration of dialysis treatment, and solicited information on alternative proxies for resource utilization that can be reported at the patient/treatment level in order to better inform future modifications to this methodology through rulemaking.

With regard to the comment about removing the co-morbid adjustment from the case-mix for CY 2022, we note that due to the nature of regression analysis, which is how the current payment adjustors are set, making that type of adjustment would affect all the patient-level and facility-level adjustments. This can impact budget neutrality requirements and affect provider impacts differently than if adopted incrementally. Payment system changes can also require extensive efforts by CMS and providers to implement, and could not be implemented for CY 2022. While we discussed these case-mix adjustments in the RFI, we did not propose to make changes to the comorbidity case-mix adjustments for CY 2022; therefore, we are not finalizing any changes to that policy in this final rule.

Comment: Two commenters, a large dialysis organization and a non-profit health insurance organization in Puerto Rico, urged CMS to evaluate the accuracy of the ESRD PPS base rate as applied to payments for ESRD facilities located in Puerto Rico. These commenters encouraged CMS to consider the differences in patient characteristics between Puerto Rico and the mainland U.S., as well as differences in size, service capacity, and locality between the average ESRD facility in Puerto Rico versus other mainland providers.

Response: As mentioned previously in this section of the final rule, and as further discussed in section VI.D of the CY 2022 ESRD PPS proposed rule (86 FR 36399), CMS is considering alternative approaches to calculating the case-mix adjustment, including duration of dialysis treatment to allocate composite rate costs for patients with higher resource use due to patient characteristics as reflected in the case-mix adjustments. We are also considering all the commenters' suggestions in response to the RFI for alternative proxies for allocation of composite rate costs for those patients whose medical and physiologic characteristics require more resource use. We appreciate these comments and will take them into consideration to potentially inform future rulemaking.

Final Rule Action: We are finalizing a CY 2022 ESRD PPS base rate of $257.90. This amount reflects the CY 2022 wage index budget-neutrality adjustment factor of 0.99985, and the CY 2022 ESRD PPS productivity-adjusted market basket update of 1.9 percent.

e. Update to the Average per Treatment Offset Amount for Home Dialysis Machines

In the CY 2021 ESRD PPS final rule (85 FR 71427), we expanded eligibility for the TPNIES under § 413.236 to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. To establish the basis of payment for the TPNIES for these items, we finalized the additional steps that the Medicare Administrative Contractors (MACs) must follow to calculate a pre-adjusted per treatment amount, using the prices they establish under § 413.236(e) for a capital-related asset that is a home dialysis machine, as well as the methodology that CMS uses to calculate the average per treatment offset amount for home dialysis machines that is used in the MACs' calculation, to account for the cost of the home dialysis machine that is already in the ESRD PPS base rate. For purposes of this final rule, we will refer to this as the ''TPNIES offset amount.''

The methodology for calculating the TPNIES offset amount is set forth in § 413.236(f)(3). Section § 413.236(f)(3)(v) states that effective January 1, 2022, CMS annually updates the amount determined in § 413.236(f)(3)(iv) by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor. The TPNIES for capital-related assets that are home dialysis machines is based on 65 percent of the MAC-determined pre-adjusted per treatment amount, reduced by the TPNIES offset amount, and is paid for 2-calendar years.

As we discussed in the CY 2022 ESRD PPS proposed rule (86 FR 36331), the CY 2021 TPNIES offset amount for capital-related equipment that are home dialysis machines used in the home is $9.32. We stated that the proposed CY 2022 ESRD bundled market basket increase factor minus the productivity adjustment is 1.0 percent (1.6 percent minus 0.6 percent). Applying the proposed update factor of 1.010 to the proposed CY 2021 TPNIES offset amount resulted in a proposed CY 2022 TPNIES offset amount of $9.41 ($9.32 × 1.010). We proposed to update this calculation using the most recent data available in the CY 2022 ESRD PPS final rule.

The comments and our responses to the comments on the proposed update to the TPNIES offset amount are set forth below.

Comment: One large dialysis organization commented in support of the current TPNIES policy, but recommended that CMS recalculate the TPNIES offset amount using a 7-year depreciation schedule, which the commenter asserted would more accurately align with real-world home dialysis machine use. This commenter also recommended that CMS revise the TPNIES policy to allow for a modification to the ESRD PPS base rate to ensure ongoing access to innovative technologies.

Response: We appreciate the commenter's suggestion for improving

the TPNIES policy. As we discussed in the CY 2021 ESRD PPS final rule (85 FR 71421 through 71422), section 104.17 of the Provider Reimbursement Manual discusses that the useful life of a capital-related asset is its expected useful life to the provider, not necessarily the inherent useful or physical life. Further, the manual provides that under the Medicare program, only the American Hospital Association (AHA) guidelines may be used in selecting a proper useful life for computing depreciation. In keeping with the Medicare policy, we established reliance on the AHA guidelines to determine the useful life of a capital-related asset that is a home dialysis machine, which is 5-years and not the 7 years suggested by the commenter (see 42 CFR 413.236(f)(i)). We note that we considered alternatives, but concluded that this approach was simpler and appropriate for encouraging and supporting the uptake of new and innovative renal dialysis equipment and supplies (85 FR 71422).

We did not propose changes to the methodology for updating the TPNIES offset amount for CY 2022, and therefore we are not finalizing any changes to that methodology in this final rule. However, we will take these recommendations into consideration to potentially inform future rulemaking.

Final Rule Action: We are finalizing our proposal to calculate the CY 2022 TPNIES offset amount using the most recent data available. The CY 2021 TPNIES offset amount for capital-related equipment that are home dialysis machines used in the home is $9.32. As discussed previously in section II.B.1.a of this final rule, the CY 2022 ESRD bundled market basket increase factor minus the productivity adjustment is 1.9 percent (2.4 percent minus 0.5 percent). Applying the productivity adjustment factor of 1.019 to the CY 2021 TPNIES offset amount results in a CY 2022 TPNIES offset amount of $9.50 ($9.32 × 1.019).

f. TDAPA and TPNIES Public Comments and Responses

We also received several public comments on topics related to the TPNIES and the TDAPA policies under the ESRD PPS, including from individuals, such as ESRD beneficiaries, individual health care providers, manufacturers, healthcare groups, patient advocacy organizations, hospital associations, dialysis associations, as well as various dialysis, kidney, and professional organizations. While these comments related to issues that we either did not discuss in the CY 2022 ESRD PPS proposed rule or that we discussed for background or context, but for which we did not propose changes, a summary of the significant comments and our responses are set forth below.

Comment: Commenters overwhelmingly wrote in support of innovation in ESRD management generally and some specifically mentioned existing or upcoming technologies they thought would benefit ESRD patients. Other commenters expressed interest in seeing improvements in peritoneal dialysis, including on-line generation of dialysate and prevention of infections. Commenters also expressed support for home hemodialysis, citing its flexibility, convenience, and the comfort it provides patients. Commenters expressed interest in seeing improvements in home hemodialysis such as lower costs, more availability, better cannulation, reduced burden on patients and caregivers, and more convenient generation of dialysate. Commenters also stated they would like to see improvements in home dialysis that would increase retention, improve quality of delivered dialysate, or reduce complications.

Response: We appreciate the supportive comments regarding innovation in ESRD therapy. Like the commenters, CMS supports innovation in the ESRD space and we look forward to seeing new technologies that improve care for beneficiaries with ESRD.

Comments: Commenters provided input on the substantial clinical improvement criteria for the TPNIES under § 413.236(b)(5) and § 412.87(b)(1), offering specific recommendations on what CMS should consider in making a determination of substantial clinical improvement for the TPNIES. Commenters suggested that certain innovations could be considered evidence of substantial clinical improvement over existing technologies, such as: Technical specifications that make home dialysis easier for disadvantaged persons, real time dialysis fluid preparation, and real-time monitoring of patients' treatment sessions.

Many commenters encouraged CMS to utilize evidence outside of randomized controlled trials (RCTs) as a way of demonstrating significant clinical improvement due to the challenges of running clinical trials involving patients with ESRD, including difficulty in patient recruitment and financial barriers for innovators to conduct these types of large-scale, long-term trials. One commenter who agreed with this stated that CMS also should not only rely on short, small-scale studies conducted by device manufacturers as the standard for substantial clinical improvement. A home dialysis advocacy organization commented that evidence from a clinical trial, abstracts of data, and expert opinion, such as letters from medical professionals, are sufficient to support a showing of substantial clinical improvement, rather than RCTs. That same commenter added that given the challenges specific to conducting studies in the ESRD space, real-world evidence gathered from studies conducted outside the U.S. may be extrapolated to Medicare beneficiaries when appropriate. One commenter, a beneficiary, emphasized that patients may have a drastically different perspective of substantial clinical improvement compared to CMS. That commenter stated that greater flexibility is of the utmost importance to home dialysis patients and, therefore, therapies that allow patients with ESRD to resume their normal day-to-day activities should be considered to show substantial clinical improvement. Other commenters also encouraged the use of patient preferences, patient-reported outcomes, and other patient-centered data when evaluating substantial clinical improvement. A commenter encouraged CMS to weigh the reduction of patient and care partner burden, improved communication with the care team, and improved safety through the reduction of severe adverse events in the evaluation of evidence.

Other commenters offered suggestions for CMS's current process of evaluating evidence of substantial clinical improvement. Commenters asked that CMS provide guidance on evidence of substantial clinical improvement specific to the ESRD space, such as the development of a set of ESRD patient-reported outcomes for assessing substantial clinical improvement criteria. Other commenters also suggested using a panel of patients with ESRD to assist with tasks such as developing the set of patient-reported outcomes or providing insight for these outcomes during the evaluation process. Some commenters asked CMS to clarify how data and real-world evidence submitted as part of a TPNIES application is reviewed and weighed during the review process.

Response: We appreciate the comments regarding the CMS evaluation process for the substantial clinical improvement criterion for the TPNIES. In response to commenters' suggestions regarding the use of expert opinions, clinical trials, abstracts of data, unpublished sources, and letters from health care providers in our analysis, we note that under § 413.236(b)(5), CMS may consider all of these types of data,

among others, in making a determination of substantial clinical improvement. A list of information sources that we may consider in our determination is set forth in § 412.87(b)(1)(iii). Additionally, under § 412.87(b)(1)(iii)(N), CMS may consider other appropriate information sources not otherwise listed in our regulations on substantial clinical improvement. Further, we are taking the opportunity to clarify that RCTs, while potentially informative, are not required under existing regulations to demonstrate substantial clinical improvement for purpose of the TPNIES. While we did not propose changes to the substantial clinical improvement criteria for the TPNIES in the CY 2022 ESRD PPS proposed rule, we will consider these comments for future rulemaking. We encourage ESRD patients and patient advocacy organizations to submit comments on our annual ESRD PPS proposed rules to provide their perspectives on TPNIES applications.

Comment: Several commenters suggested changes to the TPNIES policy under the ESRD PPS. Commenters suggested using FDA determinations (for example, Breakthrough Device designations) in evaluating TPNIES applications. Commenters also asked for CMS to provide increased feedback to applicants throughout the TPNIES application process, including providing: Parallel feedback on data needed to support a TPNIES application as the manufacturers are working towards FDA marketing authorization, public review of the complete application prior to finalizing TPNIES application decisions, and an appeal process for manufacturers whose TPNIES applications were not approved. In addition, commenters recommended that CMS remove MACs' discretion in determining pricing of new and innovative renal dialysis equipment and supplies, as provided under § 413.236(e), and requested that CMS set more defined payment parameters and public transparency around pricing. Other commenters suggested expanding the TPNIES policy to allow TPNIES payments to ESRD facilities with home dialysis devices on operating leases and to expand the TPNIES eligibility to include all capital-related assets, not just home dialysis machines, as allowed under § 413.236(b)(6). We also received comments requesting various extensions to the TPNIES application deadlines and payment periods such as: Extending the duration of the TPNIES payment to 3 years, extending application timetables for device manufacturers applying for the TPNIES in the early years of the policy, and extending application timetables for manufacturers impacted by the COVID–19 PHE.

Response: We thank the public for their comments. Because we did not propose any changes to the TPNIES policy in the CY 2022 ESRD PPS proposed rule, we are not making any changes to that policy in this final rule; however, we will consider the commenters' recommendations for future rulemaking.

Comment: Several commenters also suggested changes to the TDAPA policy under § 413.234. For example, one commenter stated that CMS should consider implementing the substantial clinical improvement criteria used to evaluate the TPNIES applications for the TDAPA applications, and another commenter stated that CMS should not apply the TDAPA to biosimilar drugs.

Response: We thank the public for their comments. Because we did not propose any changes to the TDAPA policy in the CY 2022 ESRD PPS proposed rule, we are not making any changes to that policy in this final rule; however, we will consider the commenters' recommendations for future rulemaking.

C. Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for CY 2022 Payment

1. Background

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), CMS established the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS, under the authority of section 1881(b)(14)(D)(iv) of the Act, in order to support ESRD facility use and beneficiary access to these new technologies. We established this add-on payment adjustment to help address the unique circumstances experienced by ESRD facilities when incorporating new and innovative equipment and supplies into their businesses and to support ESRD facilities transitioning or testing these products during the period when they are new to market. We added § 413.236 to establish the eligibility criteria and payment policies for the TPNIES.

In the CY 2020 ESRD PPS final rule (84 FR 60650), we established in § 413.236(b) that for dates of service occurring on or after January 1, 2020, we will provide the TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) Has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning granted marketing authorization by the Food and Drug Administration (FDA) on or after January 1, 2020; (3) is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect; (4) has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year; (5) is innovative, meaning it meets the substantial clinical improvement criteria specified in the Inpatient Prospective Payment System (IPPS) regulations at § 412.87(b)(1) and related guidance, and (6) is not a capital related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

Regarding the innovation requirement in § 413.236(b)(5), in the CY 2020 ESRD PPS final rule (84 FR 60690), we stated that we will use the following criteria to evaluate substantial clinical improvement for purposes of the TPNIES under the ESRD PPS based on the IPPS substantial clinical improvement criteria in § 412.87(b)(1) and related guidance:

A new technology represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. First, CMS considers the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. Second, a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:

- The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or
- The new renal dialysis equipment or supply offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new renal

dialysis service to make a diagnosis affects the management of the patient; or

- The use of the new renal dialysis equipment or supply significantly improves clinical outcomes relative to renal dialysis services previously available as demonstrated by one or more of the following: A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance; or,
- The totality of the circumstances otherwise demonstrates that the new renal dialysis equipment or supply substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Third, evidence from the following published or unpublished information sources from within the U.S. or elsewhere may be sufficient to establish that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

Fourth, the medical condition diagnosed or treated by the new renal dialysis equipment or supply may have a low prevalence among Medicare beneficiaries. Fifth, the new renal dialysis equipment or supply may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new renal dialysis equipment or supply.

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we also established a process modeled after IPPS's process of determining if a new medical service or technology meets the substantial clinical improvement criteria specified in § 412.87(b)(1). Specifically, similar to the IPPS New Technology Add-On Payment, we wanted to align our goals with the agency's efforts to transform the healthcare delivery system for the ESRD beneficiary through competition and innovation to provide patients with better value and results. As we discussed in the CY 2020 ESRD PPS final rule (84 FR 60682), we believe it is appropriate to facilitate access to new and innovative equipment and supplies through add-on payments similar to the IPPS New Technology Add-On Payment and to provide stakeholders with standard criteria for both inpatient and outpatient settings. In § 413.236(c), we established a process for our announcement of TPNIES determinations and a deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. CMS will consider whether a new renal dialysis equipment or supply meets the eligibility criteria specified in § 413.236(b) and summarize the applications received in the annual ESRD PPS proposed rules. Then, after consideration of public comments, we will announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS in the ESRD PPS final rule. In the CY 2020 ESRD PPS final rule, we also specified certain deadlines for the application requirements. We noted that we would only consider a complete application received by February 1 prior to the particular calendar year. In addition, we required that FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular calendar year. We also stated in the CY 2020 ESRD PPS final rule (84 FR 60690 through 60691) that we would establish a workgroup of CMS medical and other staff to review the materials submitted as part of the TPNIES application, public comments, FDA marketing authorization, and HCPCS application information and assess the extent to which the product provides substantial clinical improvement over current technologies.

In the CY 2020 ESRD PPS final rule, we established § 413.236(d) to provide a payment adjustment for a new and innovative renal dialysis equipment or supply. We stated that the TPNIES is paid for 2-calendar years. Following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will become an eligible outlier service as provided in § 413.237.

Regarding the basis of payment for the TPNIES, in the CY 2020 ESRD PPS final rule, we finalized at § 413.236(e) that the TPNIES is based on 65 percent of the price established by the MACs, using the information from the invoice and other specified sources of information.

In the CY 2021 ESRD PPS final rule (85 FR 71410 through 71464), we made several changes to the TPNIES eligibility criteria at § 413.236. First, we revised the definition of new at § 413.236(b)(2) as within 3 years beginning on the date of the FDA marketing authorization. Second, we changed the deadline for TPNIES applicants' HCPCS Level II code application submission from September 1 of the particular calendar year to the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the calendar year. In addition, a copy of the applicable FDA marketing authorization must be submitted to CMS by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website in order for the equipment or supply to be eligible for the TPNIES the following year. Third, we revised § 413.236(b)(5) to remove a reference to related guidance on the substantial clinical improvement criterion, as the guidance had already been codified.

Finally, in the CY 2021 ESRD PPS final rule, we expanded the TPNIES policy to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. We explained that capital-related assets are defined in the Provider Reimbursement Manual (chapter 1, section 104.1) as assets that a provider has an economic interest in through ownership (regardless of the manner in which they were acquired). We noted that examples of capital-related assets for ESRD facilities are dialysis machines and water purification systems. We explained that, although we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38354) that we did not believe capital-related assets should be eligible for additional payment through the TPNIES because the cost of these items is captured in cost reports, they depreciate over time, and are generally used for multiple patients, there were a number of other factors we considered that led us to consider expanding eligibility for these technologies in the CY 2021 ESRD PPS

rulemaking. We explained that, following publication of the CY 2020 ESRD PPS final rule, we continued to study the issue of payment for capital-related assets under the ESRD PPS, taking into account information from a wide variety of stakeholders and recent developments and initiatives regarding kidney care. For example, we considered various HHS home dialysis initiatives, Executive Orders to transform kidney care, and how the risk of COVID–19 for particularly vulnerable ESRD beneficiaries could be mitigated by encouraging home dialysis.

After closely considering these issues, we proposed a revision to § 413.236(b)(6) in the CY 2021 ESRD PPS proposed rule to provide an exception to the general exclusion for capital-related assets from eligibility for the TPNIES for capital-related assets that are home dialysis machines when used in the home for a single patient and that meet the other eligibility criteria in § 413.235(b), and finalized the exception as proposed in the CY 2021 ESRD PPS final rule. We finalized the same determination process for TPNIES applications for capital-related assets that are home dialysis machines as for all other TPNIES applications; that we will consider whether the new home dialysis machine meets the eligibility criteria specified in § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. Per § 413.236(c), we will only consider, for additional payment using the TPNIES for a particular calendar year, an application for a capital-related asset that is a home dialysis machine received by February 1 prior to the particular calendar year. If the application is not received by February 1, the application will be denied and the applicant is able to reapply within 3 years beginning on the date of FDA marketing authorization in order to be considered for the TPNIES, in accordance with § 413.236(b)(2).

In the CY 2021 ESRD PPS final rule, at § 413.236(f), we finalized a pricing methodology for capital-related assets that are home dialysis machines when used in the home for a single patient, which requires the MACs to calculate the annual allowance and the preadjusted per treatment amount. The pre-adjusted per treatment amount is reduced by an estimated average per treatment offset amount to account for the costs already paid through the ESRD PPS base rate. The CY 2021 TPNIES offset amount was $9.32. We finalized that this amount will be updated on an annual basis so that it is consistent with how the ESRD PPS base rate is updated.

We revised § 413.236(d) to reflect that we would pay 65 percent of the pre-adjusted per treatment amount minus the offset for capital-related assets that are home dialysis machines when used in the home for a single patient.

We revised § 413.236(d)(2) to reflect that following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237, except a capital-related asset that is a home dialysis machine will not be an eligible outlier service as provided in § 413.237.

In summary, under the current eligibility requirements in § 413.236(b), CMS provides for a TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) Has been designated by CMS as a renal dialysis service under § 413.171; (2) Is new, meaning within 3 years beginning on the date of the FDA marketing authorization; (3) Is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect; (4) Has a complete HCPCS Level II code application submitted in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the calendar year; (5) Is innovative, meaning it meets the criteria specified in § § 412.87(b)(1); and (6) Is not a capital-related asset, except for capital-related assets that are home dialysis machines.

We received two applications for the TPNIES for CY 2022. One applicant, CloudCath (the applicant for the CloudCath Peritoneal Dialysis Drain Set Monitoring System), withdrew its application from consideration after the issuance of the CY 2022 ESRD PPS proposed rule because it did not receive FDA marketing authorization by July 6, 2021, which was the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services. Under § § 413.236(c), an applicant for the TPNIES must receive FDA marketing authorization for its new equipment or supply by the HCPCS Level II Code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year. Therefore, the CloudCath Peritoneal Dialysis Drain Set Monitoring System is not eligible for consideration for the TPNIES for CY 2022. We are not including in this final rule the description and discussion of this application, which was included in the CY 2022 ESRD PPS proposed rule. We note that we received public comments on the application that was withdrawn. However, because the application was withdrawn and thus the technology is ineligible for the TPNIES for CY 2022, we are not summarizing nor responding to public comments regarding the TPNIES criteria for this technology in this final rule. A discussion of the remaining application, which met this deadline, is presented in this final rule.

The application discussed in this final rule is for a technology commonly used for the treatment of ESRD: Hemodialysis (HD). A detailed definition for HD is included in Chapter 11, Section 10 of the Medicare Benefits Policy Manual (Pub. L. 100–02).[2] In brief, HD is a process that involves blood passing through an artificial kidney machine and the waste products diffusing across a manmade membrane into a bath solution known as dialysate after which the cleansed blood is returned to the patient's body. HD is accomplished usually in 3 to 5 hour sessions, 3 times a week.

a. Tablo® System

Outset Medical, Inc. submitted an application for the TPNIES for the Tablo® System for CY 2022. According to the applicant, the technology is an HD machine that has been designed for patient-driven self-care and to minimize system training time. The applicant stated that the system is intended to substantially improve the treatment of people with ESRD by removing barriers to home dialysis. The applicant explained that the Tablo® System is comprised of (1) the Tablo® Console with integrated water purification, on-demand dialysate production, and a touchscreen interface; (2) a proprietary, disposable, single-use pre-strung cartridge; and (3) the Tablo® Connectivity and Data Ecosystem. Per the applicant, the system is built to function in a connected setting with cloud-based system monitoring, patient analytics and clinical recordkeeping.

The applicant stated that the Tablo® System's features combine to provide a significantly differentiated HD solution with many benefits. First, the applicant stated that the Tablo® System's touchscreen interface made it easy to learn and use, guiding users through treatment using step-by-step

[2] Medicare Benefits Policy Manual (Pub. L. 100–102), available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf.*

instructions with simple words and animation. The applicant also stated that instructions include non-technical language and color-coded parts to enable easier training, faster set-up, and simpler management including clear alarm explanations and resolution instructions.

Second, the applicant stated that the Tablo® System can accommodate treatments at home, allowing for flexibility in treatment frequencies, durations, and flow rates. Per the applicant, the Tablo® System did not have a pre-configured dialyzer, which allows clinicians to use a broad range of dialyzer types and manufactures, allowing for greater customization of treatment for the patient. The applicant stated that this was an improvement over the incumbent home device, which requires a separate device component and complex process to switch to another dialyzer.

Third, the applicant stated that the Tablo® System is an all-in-one system with integrated water purification and on-demand dialysate production, eliminating the need for industrial water treatment rooms that are required to operate traditional HD machines. The applicant also stated that electronic data capture and automatic wireless transmission eliminate the need for manual record keeping by the patient, care partner, or nurse. Per the applicant, a single-use Tablo® Cartridge with pre-strung blood, saline, and infusion tubing and a series of sensor-receptors mounted to an organizer snaps into the system, minimizing difficult connections that require additional training. The applicant stated that automated features, including an integrated blood pressure monitor, air removal, priming, and blood return, minimize user errors, save time, and streamline the user experience.

Fourth, the applicant stated that the Tablo® System's two-way wireless connectivity and data analytics provide the ability to continuously activate new capabilities and enhancements through wireless software updates, while also enabling predictive preventative maintenance to maximize machine uptime.

The applicant stated that currently 88 percent of patients receive HD in a clinic 3 times per week, for 3.0 to 4.5 hours a day and fewer than 2 percent perform HD treatment at home.[3] The applicant stated that 25 to 36 percent of home HD patients return to in-center care within 1 year of initiating HD at home.[4] [5] Per the applicant, barriers to home dialysis adoption and retention have been well studied and include treatment burden for patients and care partner fatigue; technical challenges with operating a HD machine; space, home modifications, and supplies management; patients not wanting medical equipment in the home; and safety concerns.[6] [7]

The applicant stated that innovation in making home dialysis more accessible to patients has been lacking due to a lack of investment funding, limited incremental reimbursement for new technology, and a consolidated, price-sensitive dialysis provider market where the lack of market competition is costly and has been associated with increased hospitalizations in dialysis patients.[8] The applicant stated that the Tablo® System was designed to address many system-related barriers that result in patients deciding on in-center care and/or stopping home modalities due to the burden of self-managed therapy.

The applicant stated that while peritoneal dialysis (PD), like HD, removes excess fluid and waste from the body, it has a different mechanism of action and relies on the body's own membrane, the peritoneum, to act as the ''dialyzer''. Per the applicant, PD requires surgical placement of a catheter in the abdomen and utilizes a cleansing fluid, dialysate, that must be infused and dwell in the abdomen to remove waste products from the blood. The applicant stated that PD must be conducted daily to achieve adequate dialysis and can be conducted manually or via a cycler; while in contrast, HD directly cleanses the blood with the use of a HD machine, dialysate and a dialyzer, which acts as an artificial kidney in removing excess fluid and toxins. The applicant stated that HD also requires surgical placement of a dialysis access, which is usually in the form of a catheter or a more permanent arteriovenous fistula.[9]

The applicant asserted that PD is the dominant home therapy used around the world, but should not be solely relied upon to increase growth in home dialysis, as there are physiological contraindications.[10] The applicant also stated that there is recent evidence that post 90-day mortality is higher in PD patients than in HD patients. Per the applicant, multivariable risk–adjusted analyses demonstrated that the mortality hazard ratio of HD versus PD is 0.74 (95 percent confidence interval (CI), 0.68–0.80) in the 270 to 360-day period after starting dialysis.[11] The applicant stated that patients and clinicians should weigh the risks and benefits of both options and select the one that meets the individual patient's preferences, goals, values and physiology. Per the applicant, because PD relies on the patient's own membrane, physiologic changes can occur and result in patients who are unable to continue PD due to loss of the ability to achieve adequacy. The applicant stated that these home patients could consider home HD rather than a return to in-center and noted that the practice of transitioning from one home modality to another is acknowledged by experts to be underutilized and is particularly pronounced in the U.S., where the ratio of PD use to home HD is 6:1,[12] as compared to 4:1 in Canada.[13]

[3] United States Renal Data System. 2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States, End-Stage Renal Disease Chapter 2. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD 2020. Available at: *https://adr.usrds.org/2020/end-stage-renaldisease/introduction-to-volume-2*. Accessed on Jan. 21, 2021.

[4] Seshasai, R.K., et al. (2019). The home hemodialysis patient experience: A qualitative assessment of modality use and discontinuation. Hemodialysis International, 23: 139–150, 2019. doi:10.1111/hdi.12713.

[5] Weinhandl, Eric D., Collins Allan, Incidence of Therapy Cessation among Home Hemodialysis Patients in the United States, Abstract presented, American Society of Nephrology Kidney Week 2016.

[6] Seshasai, R.K., et al (2019). The home hemodialysis patient experience: A qualitative assessment of modality use and discontinuation. Hemodialysis International, 23: 139–150, 2019. doi:10.1111/hdi.12713.

[7] Chan, Christopher T. et al. (2018). Exploring Barriers and Potential Solutions in Home Dialysis: An NKF–KDOQI Conference Outcomes Report American Journal of Kidney Diseases, Volume 73, Issue 3, 363–371.

[8] Erickson, K.F., Zheng, Y., Ho, V., Winkelmayer, W.C., Bhattacharya, J., & Chertow, G.M. (2018). Market Competition and Health Outcomes in Hemodialysis. Health services research, 53(5), 3680–3703. *https://doi.org/10.1111/1475-6773.12835*.

[9] Blake, P.G., Quinn, R.R., & Oliver, M.J. (2013). Peritoneal dialysis and the process of modality selection. Peritoneal dialysis international: Journal of the International Society for Peritoneal Dialysis, 33(3), 233–241. *https://doi.org/10.3747/pdi.2012.00119*.

[10] Ibid.

[11] Mukhopadhyay, P., Woodside, K.J., Schaubel, D.E., Repeck, K., McCullough, K., Shahinian, V.B., . . . & Saran, R. (2020). Survival among incident peritoneal dialysis versus hemodialysis patients who initiate with an arteriovenous fistula. Kidney Medicine, 2(6), 732–741.

[12] United States Renal Data System. 2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States, End-Stage Renal Disease Chapter 2. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD 2020. Available at: *https://adr.usrds.org/2020/end-stage-renaldisease/introduction-to-volume-2*. Accessed on Jan 21, 2021.

[13] Canada Institute for Health Information (2020): Annual Statistics. Available at: *https://secure.cihi.ca/estore/productSeries.htm?locale=en&pc=PCC24&_ga=2.265337481.729263172.1612199530-510791291.1610562424*. Accessed on Jan. 31, 2021.

The applicant asserted that the Tablo® System presented a significant clinical improvement over NxStage® System One™ (NxStage®), the current standard of home HD care, with the goal of getting patients access to easier to use technology and increasing the number of patients who can do dialysis at home. Per the applicant, NxStage® is the only other mobile HD machine that is approved for home use.

(1) Renal Dialysis Service Criterion (§ 413.236(b)(1))

With respect to the first TPNIES eligibility criterion under § 413.236(b)(1), whether the item has been designated by CMS as a renal dialysis service under § 413.171, maintenance dialysis treatments and all associated services, including historically defined dialysis-related drugs, laboratory tests, equipment, supplies, and staff time, were included in the composite rate for renal dialysis services as of December 31, 2010 (75 FR 49036). An in-home HD machine would be considered equipment essential for the provision of maintenance dialysis. We received no public comments on whether the Tablo® System meets this criterion. Based on its status as an in-home HD machine, we consider the Tablo® System to be a renal dialysis service under § 413.171.

(2) Newness Criterion (§ 413.236(b)(2))

With respect to the second TPNIES eligibility criterion under § 413.236(b)(2), whether the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant indicated that the Tablo® System received FDA marketing authorization for home use on March 31, 2020.[14] We received no public comments on whether the Tablo® System meets the newness criterion. Based on the information provided by the applicant, we agree that the Tablo® System meets the newness criterion.

(3) Commercial Availability Criterion (§ 413.236(b)(3))

With respect to the third eligibility criterion under § 413.236(b)(3), whether the item is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, applicant indicated that the Tablo® System became available for home use on April 1, 2020. We received no public comments on whether the Tablo® System meets the commercial availability criterion. Based on the information provided by the applicant, we agree that the Tablo® System meets the commercial availability criterion.

(4) HCPCS Level II Application Criterion (§ 413.236(b)(4))

The fourth TPNIES eligibility criterion, under § 413.236(b)(4), is whether the applicant has submitted a complete HCPCS Level II code application in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year. The applicant indicated that it submitted a HCPCS Level II code application on July 6, 2021, which was same day as the deadline specified HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services specified in CMS guidance.[15] We received no public comments on whether the Tablo® System meets this criterion. Based on the information provided by the applicant, we agree the applicant has met the HCPCS Level II application criterion.

(5) Innovation Criterion (§§ 413.236(b)(5) and 412.87(b)(1))

With respect to the fifth TPNIES eligibility criterion under § 413.236(b)(5), that the item is innovative, meaning it meets the substantial clinical improvement criteria specified in § 412.87(b)(1), the applicant claimed that the Tablo® System significantly improves clinical outcomes relative to the current standard of care for home HD services, which it identified as the incumbent NxStage® home dialysis machine. The applicant presented the following substantial clinical improvement claims: (1) Decreased treatment frequency with adequate dialysis clearance; (2) increased adherence to dialysis treatment and retention to home therapy; and (3) improved patient quality of life. The applicant supported these claims with the Tablo® System Investigational Device Exemption (IDE) Study [16] and secondary support from four papers [17] [18] [19] [20] and two posters.[21] [22] The applicant also provided comparison data from three studies directly related to the incumbent [23] [24] [25] and an additional study that, based on the timeframe of the study, likely involved participants undergoing treatment with NxStage® although the article does not directly reference the incumbent.[26]

We provided an overview of these ten sources in the CY 2022 ESRD PPS proposed rule (86 FR 36333 through 36343), followed by the applicant's summary of how the data support each claim of substantial clinical improvement.[27] We also included in the CY 2022 ESRD PPS proposed rule a discussion of how we were applying the requirements of § 413.236(b)(5) to our review of the application and a summary of our preliminary concerns.

[14] As we stated in the CY 2022 ESRD PPS proposed rule (86 FR 36334), in reviewing the enclosure to which the March 31, 2020 FDA authorization letter refers, the applicant's Section 510(k) submission indicated that the Tablo® Cartridge was reviewed separately from the Tablo® System and has its own separate 510(k) clearance. We further stated that, in the CY 2021 ESRD PPS final rule, CMS determined that the cartridge did not meet the newness criterion for the TPNIES (85 FR 71464) and as such, the cartridge was not new.

[15] *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2020-HCPCS-Application-and-Instructions.pdf.*

[16] *Clinicaltrials.gov* website. *https://www.clinicaltrials.gov/ct2/show/NCT02460263.* Last Updated July 1, 2020. *https://www.clinicaltrials.gov/ProvidedDocs/63/NCT02460263/Prot_000.pdf.*

[17] Chertow, G.M., Alvarez, L., Plumb, T.J., Prichard, S.S., & Aragon, M. (2020). Patient-reported outcomes from the investigational device exemption study of the Tablo hemodialysis system. Hemodialysis International, 24(4), 480–486.

[18] Leypoldt, J.K., Prichard, S., Chertow, G.M., & Alvarez, L. (2019). Differential molecular modeling predictions of mid and conventional dialysate flows. Blood purification, 47(4), 369–376.

[19] Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019), Hemodialysis International.

[20] Plumb, Troy J., Luis Alvarez, Dennis L. Ross, Joseph J. Lee, Jeffrey G. Mulhern, Jeffrey L. Bell, Graham E. Abra, Sarah S. Prichard, Glenn M. Chertow, and Michael A. Aragon. ''Self-care training using the Tablo hemodialysis system.'' Hemodialysis International (2020).

[21] Alvarez, Luis et al. Urea Clearance Results in Patients Dialyzed Thrice-weekly Using a Dialysate Flow of 300 mL/min, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

[22] Chahal, Y., Plumb, T., Aragon M. (2020). Patient Device Preference for Home Hemodialysis: A Subset Analysis of the Tablo Home IDE Trial. Poster Presentation at National Kidney Foundation Spring Clinical Conference, March 2020.

[23] Kraus, M., et al, A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. Hemodialysis International, 11: 468–477, (2007).

[24] Finkelstein, F.O., et al. (2012). At-home short daily hemodialysis improves the long-term health-related quality of life. Kidney international, 82(5), 561–569.

[25] Weinhandl, E.D., Gilbertson, D.T., & Collins, A.J. (2016). Mortality, hospitalization, and technique failure in daily home hemodialysis and matched peritoneal dialysis patients: A matched cohort study. American Journal of Kidney Diseases, 67(1), 98–110.

[26] Suri, R.S., Li, L., & Nesrallah, G.E. (2015). The risk of hospitalization and modality failure with home dialysis. Kidney international, 88(2), 360–368.

[27] 86 FR 36335–36342.

We stated that we did not include detailed summaries of the remaining supplemental content included with the application. Specifically, the applicant submitted numerous supplemental background materials related to the dialysis industry, reimbursement patterns, modalities, treatment frequencies, patient adherence, hospitalization rates, and quality of life. The applicant also submitted several letters of support for the Tablo® System; three from dialysis patients, three from nephrologists, and one from a dialysis clinic nurse. These letters emphasized benefits of the Tablo® System, including reduced frequency of dialysis treatment, improved home dialysis retention, reduced patient and caregiver burden, reduced patient fatigue, and improved patient quality of life.

(a) Applicant Substantial Clinical Improvement Sources

As we discussed in the CY 2022 ESRD PPS proposed rule (86 FR 36335), the applicant's primary support for its three substantial clinical improvement claims came from a prospective, multicenter, open-label, non-randomized crossover study that compared in-center and in-home HD performance using the Tablo® System. Per the applicant, this study is referred to as the Tablo® System Investigational Device Exemption (IDE) Study and the original study protocol and amendments were approved by FDA and registered on *http://www.clinicaltrials.gov* as ID: NCT02460263. The applicant stated that of the 30 participants enrolled (17 White and 13 Black or African American), 28 (18 men and 10 women) completed the study. Thirteen of the participants had previous home HD experience with NxStage®, and the remainder had previously received conventional in-center HD care. The applicant also noted that the Tablo® System IDE study sample was comprised of a representative cohort of dialysis patients and reported that it was similar to the population studied for the IDE study for the incumbent NxStage®. As described in the study protocol, the primary and secondary efficacy endpoints were a standardized weekly Kt/V of greater than or equal to 2.1 and ultrafiltration (fluid removal) value as reported by the device within ten percent of the expected fluid removal based on the ultrafiltration prescription and the Tablo® System Console fluid removal algorithm, respectively.[28] We clarified in the CY 2022 ESRD PPS proposed rule that Kt/V is a value used to quantify dialysis treatment adequacy and ''K'' = dialyzer clearance, ''t'' = time, and ''V'' = Volume of distribution of urea. The applicant stated that each study participant served as his or her own control and remained in the trial for approximately 21 weeks, during which time they were prescribed HD with the Tablo® System on a 4 times per week schedule. The applicant explained that the trial consisted of 4 treatment periods: (1) A 1 week, in-center run-in period; (2) an in-center period of 32 treatments (approximately 8 weeks) during which ESRD facility staff managed the dialysis treatments; (3) a transition period of up to 4 weeks to train the patient and care partner in managing the dialysis; and (4) a final in-home period of 32 treatments (approximately 8 weeks).

With respect to the applicant's secondary sources of support, a poster presentation from Alvarez, et al., presented dialysis adequacy data collected from a retrospective review of 29 patients' (18 males, 11 females and 17 percent Black, 10 percent Hispanic) dialysis records. The study compared Kt/V results of patients aged 34–84 receiving dialysis using the Tablo® System to patients receiving dialysis from a conventional HD machine. The majority of patients used a fistula or graft (59 percent fistula, 28 percent graft, 10 percent catheter). One hundred ninety two dialysis treatments were conducted on a thrice-weekly schedule using the Tablo® System with a dialysate flow rate of 300 mL per minute. A single pool Kt/V of greater than 1.2 was achieved in 94 percent of treatments in patients less than 90 kg with an average duration of treatment at 224 +/−29 minutes and in 79 percent of treatments in patients greater than 90 kg with an average duration of treatment at 249 +/−27 minutes. The average achieved Kt/V was 1.4 +/−0.2 among treatments provided with the Tablo® System. Eighty-eight treatments were conducted using a conventional HD machine with a dialysate flow rate of 500 mL per minute. A single pool Kt/V of greater than 1.2 was achieved in 93 percent of treatments in patients less than 90 kg with an average duration of treatment at 227 +/−21 minutes and in 83 percent of treatments in patients greater than 90 kg with an average duration of treatment at 249 +/−14 minutes. The average achieved Kt/V was 1.6 +/−0.4 among the conventional HD treatments.[29]

Next, an article from Chertow, et al., described additional data from the Tablo® System IDE study (discussed previously), including health-related quality of life, to further assess the safety of home HD with the Tablo® System. Demographic information identified the mean age as 49.8 + 13 years, 62 percent male, 62 percent White, 38 percent Black or African American, 23 percent Hispanic or Latino, 68 percent Not Hispanic or Latino, and 8 percent not reported, among patients established on home HD. Among the patients new to home HD, the mean age was identified as 54.2 + 10.4 years, 65 percent male, 53 percent White, 47 percent Black or African American, 29 percent Hispanic or Latino, 71 percent Not Hispanic or Latino, and 0 percent not reported. Twenty-eight of 30 patients (93 percent) completed all trial periods. Adherence to the prescribed 4 treatments per week schedule was 96 percent in-center and 99 percent in-home. The median time to recovery was 1.5 hours during the in-center and 2 hours during the at-home phase of the trial. Median index values on the 5-level EuroQol-5 Dimension (EQ–5D–5L) (a self-assessed, health related, quality of life questionnaire) were similar during the in-center as compared to in-home dialysis at 0.832 and 0.826, respectively. Patients new to home HD had lower median values (0.751) for both in-center and in-home periods. Patients who had used home dialysis prior to the trial had higher median values during both in-center (0.903) and in-home (0.906) periods. Patients reported feeling alert or well-rested with little difficulty falling or staying asleep or feeling tired and worn out when using the Tablo® System in either environment. The authors concluded that when using the Tablo® System in-home, patients reported similar time to recovery, general health status, and sleep quality compared to using the Tablo® System in-center.[30]

Next, an article from Leypoldt, et al., described the use of uremic solute kinetic models to assess dialysis adequacy via theoretical single pool Kt/V levels when varying the dialysis blood flow rates and the patient urea volume of distribution. A comparison was made between dialysate flows of 300 and 500 mL/min at blood flows of both 300 and 400 mL/min. The patient urea volume of

[28] *Clinicaltrials.gov* website. *https://www.clinicaltrials.gov/ct2/show/NCT02460263*. Last Updated July 1, 2020. *https://www.clinicaltrials.gov/ProvidedDocs/63/NCT02460263/Prot_000.pdf.*

[29] Alvarez, Luis et al. Urea Clearance Results in Patients Dialyzed Thrice-weekly Using a Dialysate Flow of 300 mL/min, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

[30] Chertow, G.M., Alvarez, L., Plumb, T.J., Prichard, S.S., & Aragon, M. (2020). Patient-reported outcomes from the investigational device exemption study of the Tablo hemodialysis system. Hemodialysis International, 24(4), 480–486.

distribution range modeled by the authors ranged from 25 to 45 L. Under ideal conditions, the authors demonstrated that with a blood flow of 300 mL per minute, a single pool Kt/V of greater than 1.2 could be achieved in patients with a urea volume of distribution of 35 L and 240 minutes of dialysis. Patients with a urea volume of distribution of 40 L would require 255 minutes of dialysis. Patients with a urea volume of distribution of 45 L would require over 270 minutes of dialysis. With a blood flow of 400 mL per minute, patients with a urea volume of distribution of 40 L could achieve the target single pool Kt/V of greater than 1.2 with 240 minutes of dialysis. Patients with a volume of distribution of 45 L could achieve the target with 270 minutes of dialysis. The authors did not model urea kinetics for patients with volumes of distribution greater than 45 L.[31]

Next, an article by Plumb, et al., described the Tablo® System IDE study (discussed previously). Demographic information reflected the mean age as 52.3 + 11.6 years, 19 men and the following racial and ethnic representation: 17 White, 13 Black or African American, 8 Hispanic or Latino, and 21 Not Hispanic or Latino. Comparisons among the 28 patients in this study and subsequent secondary analyses were either made between the 8 weeks of using the Tablo® System for in-center HD and the 8 weeks of the Tablo® System for in-home HD or between using the Tablo® System in-home HD and the treatment provided prior to study enrollment. In both settings, patients dialyzed using the Tablo® System 4 times per week. The primary efficacy endpoint was achievement of a weekly standard Kt/V greater than or equal to 2.1 in both the 8-week in-center phase of the study and the 8-week in-home phase of the study. This endpoint was achieved in 199 of 200 weeks in the in-center dialysis period and in 168 of 171 weeks in the in-home dialysis period. The primary safety endpoint of adverse event rates were similar at 1.9 percent in the in-center dialysis period and 1.8 percent in the in-home dialysis period. The secondary efficacy endpoint was whether the ultrafiltration volume and rate achieved the prescribed levels. In both in-center and in-home dialysis, 94 percent of treatments achieved successful delivery of ultrafiltration, defined as a rate within ten percent of the prescribed value. Of 960 in-center dialysis services and 896 in-home dialysis services, 922 and 884 were completed respectively, yielding adherence rates of 96 percent and 99 percent.[32]

Next, a separate article by Plumb et al., reported additional data from the Tablo® System IDE study (previously discussed) regarding participants' assessment of the Tablo® System's ease-of-use, the degree of dependence on health care workers and caregivers after training with the system was complete, and the training time required for a participant to be competent in self-care. Demographic information reflected the mean age as 52.6 years, 18 men, 10 women, 16 White, 7 Hispanic or Latino, 9 Not Hispanic or Latino, and 12 Black or African American. Participants were stratified according to whether they were previously on self-care dialysis at home or conventional in-center HD. Thirteen participants had previous experience performing self-care HD. The remaining 15 participants had previous experience with in-center HD only. All participants rated the Tablo® System's setup, treatment, and takedown on a scale from 1 (very difficult) to 5 (very simple) and indicated whether they had required assistance with treatment over the prior 7 days. Set up times were similar regardless of whether the participants were previously on self-care HD or conventional in-center HD. For the participants previously on in-center HD, the average set up time for the concentrates was 0.93 minutes and for the cartridge, 9.35 minutes. For participants previously on self-care home HD, the average set up time for the concentrates was 1.22 minutes and for the cartridge, 10.28 minutes. The average rating of the Tablo® System's ease of use for setup was 4.5, treatment 4.6, and take down 4.6 among the participants previously on self-care home HD. In comparison, based on recollection (not based on rating during time of use) these participants' average rating of their previous device's ease of use for setup was 3.5, treatment 3.3, and take down 3.8. The average rating of the Tablo® System's ease of use for setup and treatment was 4.6 and 4.7 for take down among participants without prior self-care experience.

Among patients surveyed, caregiver assistance was required in 62 percent of patient-weeks during home self-care. Participants previously on self-care home HD required some caregiver assistance in 42 percent of the in-home dialysis treatment weeks. Participants previously on conventional in-center dialysis required some caregiver assistance in 35 percent of the in-home dialysis treatment weeks. The requirement for some form of assistance among participants with or without previous self-care experience was not meaningfully different. Finally, the authors noted that a protocol amendment allowed for the recording of the number of training sessions necessary to deem a patient competent to do self-care dialysis. This recording was limited to the last 15 participants enrolled into the study. Five of these participants had previous self-care dialysis at home experience. The average number of training sessions required to be deemed competent was 3.6 for participants with previous self-care dialysis at home experience and 3.9 sessions for participants with only conventional in-center HD experience.[33]

Next, a poster presentation from Chahal, et al., reported patient device preference of prior in-home HD patients based on data from the Tablo® System IDE study (previously discussed). The authors noted that 13 of the 30 participants in the Tablo® System IDE trial were performing in-home HD at the time of enrollment and that prior to the study, dialysis prescriptions averaged 4.5 treatments per week with an average time of 3.1 hours per session. Trial prescriptions were for 4 days per week and an average of 3.4 hours per session. Adherence to the study regimen was 97 percent and 92 percent of surveys were completed. The authors concluded that participants with prior home HD experience preferred the Tablo® System compared to their prior device and 85.6 percent found that the Tablo® System was easier to use.[34]

As stated previously in the CY 2022 ESRD PPS proposed rule (86 FR 36337), the applicant submitted several sources pertaining to the incumbent, NxStage®. First, an article from Kraus et al., described a feasibility study to demonstrate the safety of center-based versus home-based daily HD with the NxStage® portable HD device. This retrospective analysis examined the extent to which clinical effects

[31] Leypoldt, J.K., Prichard, S., Chertow, G.M., & Alvarez, L. (2019). Differential molecular modeling predictions of mid and conventional dialysate flows. Blood purification, 47(4), 369–376.

[32] Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019), Hemodialysis International.

[33] Plumb, Troy J., Luis Alvarez, Dennis L. Ross, Joseph J. Lee, Jeffrey G. Mulhern, Jeffrey L. Bell, Graham E. Abra, Sarah S. Prichard, Glenn M. Chertow, and Michael A. Aragon. ''Self-care training using the Tablo hemodialysis system.'' Hemodialysis International (2020).

[34] Chahal, Y., Plumb, T., Aragon M. (2020). Patient Device Preference for Home Hemodialysis: A Subset Analysis of the Tablo Home IDE Trial. Poster Presentation at National Kidney Foundation Spring Clinical Conference, March 2020.

previously associated with short-daily dialysis were also seen using the NxStage® device. The authors conducted a prospective, two-treatment, two-period, open-label, crossover study of in-center HD vs. home HD in 32 patients treated at six U.S. centers. Demographic information reflected the mean age as 51 years, 63 percent male, 38 percent female, 24 White, 6 Black or African American, 1 American Indian or Alaskan native, and 1 Asian. The 8-week In-Center Phase (6 days/week) was followed by a 2-week transition period and then followed by the 8-week Home Phase (6 days/week). Data was collected retrospectively on HD treatment parameters immediately preceding the study in a subset of patients. Twenty-six out of 32 patients (81 percent) successfully completed the study. Treatment compliance (defined as completing 43 to 48 treatments in a given phase) was comparable between the 2 treatment environments (88 percent In-Center vs. 89 percent Home). Successful delivery of at least 90 percent of prescribed fluid volume (primary endpoint) was achieved in 98.5 percent of treatments in-center and 97.3 percent at home. Total effluent volume as a percentage of prescribed volume was between 94 percent and 100 percent for all study weeks. The composite rate of intradialytic and interdialytic adverse events per 100 treatments was significantly higher for the In-Center Phase (5.30) compared with the Home Phase (2.10; p=0.007). Compared with the period immediately preceding the study, there were reductions in blood pressure, antihypertensive medications, and interdialytic weight gain. The study concluded that daily home HD with a small, easy-to-use HD device is a viable dialysis option for ESRD patients capable of self/partner administered dialysis.[35]

Second, an article from Finkelstein et al., reported on interim results of the Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements (FREEDOM) study, a multi-center, prospective, cohort study of at-home short daily HD with a planned 12-month follow-up (*ClinicalTrials.gov* identifier, NCT00288613). Eligible patients were adults with ESRD requiring dialysis who were being initiated on short daily HD (prescribed 6 times per week) at home using the NxStage® cycler and who had Medicare as their primary insurance payer. The authors examined the long-term effect of short daily HD on health-related quality of life, as measured by the Short Form–36 (SF–36) health survey. The survey was administered at baseline, 4 and 12 months after initiation of short daily HD to 291 (total cohort) participants. Demographic information reflected the mean age as 53 years, 66 percent male and 70 percent White. Of the 291 participants, 154 completed the 12-month follow-up (as-treated cohort).

In the total cohort analysis, both the physical- and mental-component summary scores improved over the 12-month period, as did all 8 individual domains of the SF–36. The as-treated cohort analysis showed similar improvements with the exception of the role-emotional domain. Significantly, in the as-treated cohort, the percentage of patients achieving a physical component summary score at least equivalent to the general population more than doubled. The authors concluded by noting that at-home short daily HD is associated with long-term improvements in various physical and mental health-related quality of life measures.[36]

Third, in Weinhandl, et al., authors described a cohort study in which 4,201 new home HD patients in 2007 were matched with 4,201 new PD patients in 2010 from the United States Renal Data System (USRDS) database to assess relative mortality, hospitalization, and technique failure. Demographic information reflected the mean age as 53.8 + 14.9 years, 67 percent male, 33 percent female, 24.4 percent Black, and 75.6 percent Nonblack. Daily home HD patients initiated use of NxStage® from 2007 through 2010. Authors reported home HD was associated with 20 percent lower risk for all-cause mortality, 8 percent lower risk for all-cause hospitalization, and 37 percent lower risk for technique failure, all relative to PD. Regarding hospitalization, risk comparisons favored home HD for cardiovascular disease and dialysis access infection and PD for bloodstream infection. Authors noted that matching was unlikely to reduce confounding attributable to unmeasured factors, including residual kidney function; lack of data regarding dialysis frequency, duration, and dose in daily home HD patients and frequency and solution in PD patients; and diagnosis codes used to classify admissions. The authors concluded that these data suggest that relative to PD, daily home HD is associated with decreased mortality, hospitalization, and technique failure but that risks for mortality and hospitalization were similar with these modalities in new dialysis patients.[37]

Fourth, in Suri et al., 1116, daily home HD patients were matched by propensity scores to 2,784, contemporaneous USRDS patients receiving home PD. The authors compared hospitalization rates from cardiovascular, infectious, access-related or bleeding causes, and modality failure risk. Similar analyses were performed for 1,187, daily home HD patients matched to 3,173, USRDS patients receiving in-center conventional HD. Demographic information identified the mean age as 50.5 years, 67.3 percent male, 70.9 percent White, 26.6 percent Black, and 2.5 percent Other, among the daily home HD patients. Among the home PD patients, the mean age was identified as 50.9 years, 66.9 percent male, 73.1 percent White, 25.1 percent Black and 1.2 percent Other. The composite hospitalization rate was significantly lower with daily home HD than with PD (0.93 vs. 1.35/patient-year). Daily home HD patients spent significantly fewer days in the hospital than PD patients (5.2 vs. 9.2 days/patient-year), and significantly more daily home HD patients remained admission-free (52 percent daily home dialysis vs. 32 percent PD). In contrast, there was no significant difference in hospitalizations between daily home HD and conventional HD (0.93 vs. 1.10/patient-year). Cardiovascular hospitalizations were lower with daily home HD than with conventional HD (0.68) while infectious and access hospitalizations were higher (1.15) and 1.25 respectively). Significantly more PD than daily home HD patients switched back to in-center HD (44 percent vs. 15 percent). In this prevalent cohort, daily home HD was associated with fewer admissions and hospital days than PD, and a substantially lower risk of modality failure.[38]

(b) Applicant Substantial Clinical Improvement Claims

Regarding the applicant's first claim that the Tablo® System decreases treatment frequency with adequate

[35] Kraus, M., et al., A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. Hemodialysis International, 11: 468–477, (2007).

[36] Finkelstein, F.O., et al. (2012). At-home short daily hemodialysis improves the long-term health-related quality of life. Kidney International, 82(5), 561–569.

[37] Weinhandl, E.D., Gilbertson, D.T., & Collins, A.J. (2016). Mortality, hospitalization, and technique failure in daily home hemodialysis and matched peritoneal dialysis patients: a matched cohort study. American Journal of Kidney Diseases, 67(1), 98–110.

[38] Suri, R.S., Li, L., & Nesrallah, G.E. (2015). The risk of hospitalization and modality failure with home dialysis. Kidney International, 88(2), 360–368.

dialysis clearance, the applicant stated that the Tablo® System is the only mobile HD device approved for use in the home that can achieve adequate dialysis in as little as 3 treatments per week, while also providing flexibility for more frequent dialysis and thus greater personalization of care. The applicant stated that adequate dialysis for a standard, thrice-weekly treatment schedule is a single treatment clearance of urea, expressed as a single-pool Kt/V (spKt/V) of greater than 1.2 where ''K'' = dialyzer clearance, ''t'' = time, and ''V'' = Volume of distribution of urea. The applicant also stated that dialyzer clearance, or ''K'', is dependent on the mass transfer coefficient (KoA) characteristics of the prescribed dialyzer and prescribed blood and dialysate flow rates. The applicant further noted that limitations in ''K'' or ''t'' affect the ability of a patient to achieve adequate clearance during a dialysis treatment. Per the applicant, across a broad range of weights, patients using the Tablo® System can achieve the target of dialysis adequacy, a single pool Kt/V of 1.2, with 3 treatments per week in less than 4 hours.[39] The applicant also stated that when used 4 times per week, patients using the Tablo® System had a higher mean weekly standard Kt/V with equivalent or better dialysis-related hospitalization rates,[40] as compared to NxStage® IDE patients prescribed therapy at 6 days per week.[41]

The applicant stated that the Tablo® System's on-demand dialysate production has no limitation to the volume of dialysate that can be produced and used during a single treatment. The applicant further stated that this facilitates the delivery of adequate dialysis clearance (Kt/V) in a standard duration and target frequency of 3 times per week, as well as alternate frequencies and durations as preferred by a patient or recommended by a health care provider.

The applicant asserted that NxStage,® when attached to its PureFlow™ device, requires users to batch a set amount of dialysate (maximum of 60 liters) in advance of a treatment or use sterile dialysate bags (maximum of 30 liters). The applicant also stated that at its maximum dialysate flow rate (Qd) of 300ml/min, NxStage® greatly limits time by restricting treatment to a maximum of 200 minutes before exhausting its dialysate capacity (200 min = 60L/300ml/min). The applicant stated that Dialysis Outcomes and Practice Patterns Study (DOPPS) data demonstrate that the current U.S. practice for thrice-weekly dialysis occurs at an average treatment time of greater than 220 minutes, and has increased in the last 25 years.[42] Per the applicant, with the limited ''t'', a single-pooled Kt/V of >1.2 cannot be expected to be achieved for the majority of U.S. patients with ESRD on a thrice-weekly schedule, requiring increased treatment frequency[43] at home for these patients to meet the desired clearance level.

In citing Leypoldt, et al., the applicant stated that data from the Hemodialysis (HEMO) trial combined with modeling results from Leypoldt, et al.,[44] allowed for an estimation of the patients with ESRD, based on weight, that cannot be expected to achieve target clearance with standard thrice-weekly dialysis at this treatment duration. The applicant explained that because urea is evenly distributed throughout a body's water, the volume of distribution of urea is equal to a patient's total volume of water. The applicant also stated that total body water and volume of distribution of urea can be expressed as a volume or as a percentage of total weight and can vary based on numerous factors including disease state. The applicant stated that it is possible to estimate the percent of water for the ESRD population from the HEMO trial as summarized in Leypoldt et al.[45] The applicant stated that in the trial, the mean patient weight was 69.8kg and the mean patient volume of body water (V) was 30.9L. The applicant further explained that from this, total body water (and volume of distribution of urea) were calculated as 44.3 percent of the mean weight of patients with ESRD ($44.3 = 30.9L/69.8kg \times 100$). Per the applicant, applying this 44.3 percent of total body weight to the volumes of distribution in Leypoldt et al.[46] allowed for the conversion of the kinetic model described into anticipated patient weights. The applicant further stated that in calculating with standard blood flow and a higher dialyzer mass transfer area coefficient for urea (KoA) dialyzer, a 200 minute treatment at a dialysate flow rate (Qd) of 300ml/min would not achieve what the applicant refers to as the CMS target spKt/V target 1.2 for patients with a volume of distribution of urea (V) of 35L or greater. The applicant stated that these assumptions were drawn from NxStage® technical specifications.[47] [48] The applicant stated that at 44.3 percent of total weight, this volume of distribution of urea correlated to patients with ESRD with a mean weight above 79 kg (79 = 35L/.443) or approximately 174 pounds. Per the applicant, patients at or above this weight cannot be expected to achieve a spKt/V urea of 1.2 on a thrice-weekly schedule using the NxStage® system at its maximal dialysate flow rate.

The applicant stated that for the majority of the U.S. prevalent ESRD population between the ages of 22–74, whose mean weight is between 84.3–89.1 kg by age group,[49] thrice-weekly therapy at home on NxStage® would not achieve the Medicare coverage standard. Specifically, per the applicant, Medicare's national coverage policy is to reimburse for dialysis care 3 times per week, regardless of the modality that is used, and health care providers are expected to ensure that patients receive adequate clearance with the 3 times per week cadence. The applicant also stated that MACs have discretion in reimbursing additional treatments with medical justification.[50] Per the applicant, an analysis of Medicare

[39] Alvarez, Luis et al. Urea Clearance Results in Patients Dialyzed Thrice-weekly Using a Dialysate Flow of 300 mL/min, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, TX.

[40] Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019). Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis. Hemodialysis International.

[41] NxStage Clearance Calculator. Available at: *https://dosingcalculator.nxstage.com/DosingCalculator/*. Accessed on Jan 21, 2021.

[42] Tentori F, Zhang J, Li Y, Karaboyas A, Kerr P, Saran R, Bommer J, Port F, Akiba T, Pisoni R, Robinson B. Longer dialysis session length is associated with better intermediate outcomes and survival among patients on in-center three times per week hemodialysis: Results from the Dialysis Outcomes and Practice Patterns Study (DOPPS). Nephrol Dial Transplant. 2012 Nov;27(11):4180–8. doi: 10.1093/ndt/gfs021. Epub 2012 Mar 19. PMID: 22431708; PMCID: PMC3529546.

[43] Health Management Associates (HMA) analysis of 2018 100% Medicare Outpatient file.

[44] Leypoldt, J.K., Prichard, S., Chertow, G.M., & Alvarez, L. (2019). Differential molecular modeling predictions of mid and conventional dialysate flows. Blood purification, 47(4), 369–376.

[45] Ibid.

[46] Ibid.

[47] Leypoldt, J.K., Prichard, S., Chertow, G.M., & Alvarez, L. (2019). Differential molecular modeling predictions of mid and conventional dialysate flows. Blood purification, 47(4), 369–376.

[48] Daugirdas JT, Greene T, Depner TA, Chumela C, Rocco, MJ, Chertow, GM for the Hemodialysis (HEMO) Study Group. Anthropometrically Estimated Total Body Water Volumes are Larger than Modeled Urea Volume in Chronic Hemodialysis Patients: Effects of Age, Race and Gender. 2003. Kidney Int. 64:1108–1119.

[49] United States Renal Data System. 2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States, End-Stage Renal Disease Chapter 2. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020. Available at: *https://adr.usrds.org/2020/end-stage-renaldisease/introduction-to-volume-2*. Accessed on Jan 21, 2021.

[50] Wilk, A.S., Hirth, R.A., Zhang, W., Wheeler, J.R., Turenne, M.N., Nahra, T. A., . . . & Messana, J.M. (2018). Persistent variation in Medicare payment authorization for home hemodialysis treatments. Health services research, 53(2), 649–670.

claims data from 2018 found that despite the limitations of the reimbursement policy, Medicare paid for 5 or more treatments per week in 50 percent of home HD patients nationwide, amounting to an estimated annual cost to Medicare of $122 to $126 million.[51] However, as we stated in the CY 2022 ESRD PPS proposed rule (86 FR 36339), based on CMS review of dialysis facility claims data, among all beneficiaries who had home dialysis treatments in 2018, 39.1 percent had 5 or more dialysis sessions at least once during any week. The overall percentage of beneficiary-weeks that had 5 or more home HD sessions in 2018 was 20.9 percent. Medicare payment for these additional sessions totaled $17 million. We noted that, as indicated in Local Coverage Determination ID L35014, ''Frequency of Dialysis'' (revised effective September 26, 2019),[52] CMS established payment for HD based on conventional treatment which is defined as 3 times per week. Sessions in excess of 3 times per week must be both reasonable and necessary in order to receive payment. Covered indications include metabolic conditions (acidosis, hyperkalemia, hyperphosphatemia), fluid positive status not controlled with routine dialysis, pregnancy, heart failure, pericarditis, and incomplete dialysis secondary to hypotension or access issues. The applicant asserted that the use of the Tablo® System would decrease the number of necessary dialysis treatments, without affecting patient outcomes such as clearance or hospitalizations.

The applicant stated that there was clinical evidence and expert consensus that as treatment frequency increases, native residual kidney function drops, patient and care partner burden increases, and vascular access complications increase.[53] [54] Per the applicant, home use of the Tablo® System could reduce the need for a fifth or sixth weekly treatment without increasing patients' symptom burden.[55] The applicant stated that by achieving adequacy targets with fewer treatments, Tablo® System patients could be expected to have fewer vascular access interventions and health care providers will have increased flexibility in personalizing the frequency and duration of patient treatments.[56] [57] The applicant stated that reducing treatment frequency while maintaining adequate patient clearance levels may also reduce complications that lead to hospitalizations. The applicant stated that during the Tablo® System IDE study, patients using the Tablo® System 4 times per week, for an average duration of less than 4 hours per treatment, had an all-cause hospital admission rate of 426 per 1,000 patient-years whereas in the general dialysis population, the all-cause admission rate was 1,688 per 1,000 patient-years, and for patients who utilized PD, the hospitalization rate was 1,460 per 1,000 patient years.[58]

The applicant stated that while NxStage® has not specifically reported the hospitalization rates per patient-year from its IDE study, published data from Weinhandl et al.,[59] and Suri et al.,[60] reported hospital admission rates amongst patients on daily home HD ranging from 930 to 1,663 per 1,000 patient-years, using a national sample of dialysis patients matched for comparison to similar peritoneal and in-center dialysis patients. We clarified in the CY 2022 ESRD PPS proposed rule (86 FR 36339–36340) that this would represent 930 to 1,663 cases observed among 1,000 persons during 1 year. The applicant also noted that all data on home patients in Weinhandl et al. came from a matched cohort of NxStage® patients. Per the applicant, in Suri et al., data were collected prior to 2015 and that during this timeframe, it could be reasonably assumed that home HD patients were using NxStage® for treatment. The applicant stated that the results from these studies suggested that patients receiving treatment at home with NxStage® 5 to 6 times per week do not have a lower all-cause hospitalization rate, relative to matched in-center HD patients. The applicant concluded by stating that because of the clinical and demographic diversity of the Tablo® System's patient population, the applicant's results showed incremental improvement over the hospitalization rate of the current home HD population.

Regarding the applicant's second claim that the Tablo® System increased adherence to dialysis treatment and retention to home therapy, the applicant stated that patients using the Tablo® System have improved adherence to prescribed treatments and a higher rate of retention to home therapy. The applicant further stated that this increased adherence and retention is likely to improve patient outcomes by reducing the rate of dialysis-related hospitalizations and other adverse events associated with missing treatment in this patient population.[61]

The applicant stated that adherence to prescribed dialysis treatments is crucial for dialysis patients because missed treatments increased the risk of dialysis dropout, hospitalization, and death.[62] Per the applicant, the Tablo® System IDE study demonstrated a 99 percent treatment adherence rate to all

[51] Health Management Associates (HMA) analysis of 2018 100 percent Medicare Outpatient file.

[52] Medicare Coverage Database. Retrieved May 24, 2021 from: *https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35014&ver=39&NCDId=79&ncdver=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7CCAL%7CNCD%7CMEDCAC%7CTA%7CMCD&ArticleType=Ed%7CKey%7CSAD%7CFAQ&PolicyType=Final&s=-%7C5%7C6%7C66%7C67%7C9%7C38%7C63%7C41%7C64%7C65%7C44&KeyWord=transplant&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAADgAAAAA&.*

[53] National Kidney Foundation. KDOQI clinical practice guideline for hemodialysis adequacy: 2015 update. Am J Kidney Dis. 2015; 66(5):884–930.

[54] Shafi T, Wilson RF, Greer R, Zhang A, Sozio S, Tan M, Bass EB. End-stage Renal Disease in the Medicare Population: Frequency and Duration of Hemodialysis and Quality of Life Assessment. Technology Assessment Program Project ID No. JHE51000. (Prepared by the Johns Hopkins University Evidence-based Practice Center under contract number HHSA 290–2015–00006I) Rockville, MD: Agency for Healthcare Research and Quality. July 2020. Available at: *http://www.ahrq.gov/research/findings/ta/index.html.*

[55] Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019), Hemodialysis International.

[56] FHN Trial Group. (2010). In-center hemodialysis six times per week versus three times per week. New England Journal of Medicine, 363(24), 2287–2300.

[57] Kuo, T.H., Tseng, C.T., Lin, W.H., Chao, J.Y., Wang, W.M., Li, C.Y., & Wang, M.C. (2015). Association Between Vascular Access Dysfunction and Subsequent Major Adverse Cardiovascular Events in Patients on Hemodialysis: A Population-Based Nested Case–Control Study. Medicine, 94(26).

[58] United States Renal Data System. 2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States, End-Stage Renal Disease Chapter 2. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020. Available at: *https://adr.usrds.org/2020/end-stage-renaldisease/introduction-to-volume-2.* Reference Table G2.

[59] Weinhandl, E.D., Gilbertson, D.T., & Collins, A.J. (2016). Mortality, hospitalization, and technique failure in daily home hemodialysis and matched peritoneal dialysis patients: a matched cohort study. American Journal of Kidney Diseases, 67(1), 98–110.

[60] Suri, R.S., Li, L., & Nesrallah, G.E. (2015). The risk of hospitalization and modality failure with home dialysis. Kidney international, 88(2), 360–368.

[61] Chan, K.E., Thadhani, R.I., & Maddux, F.W. (2014). Adherence barriers to chronic dialysis in the United States. Journal of the American Society of Nephrology, 25(11), 2642–2648. Supporting evidence of association between decreased dialysis adherence and poor patient health and utilization outcomes.

[62] Weinhandl, Eric D., Collins Allan, Incidence of Therapy Cessation among Home Hemodialysis Patients in the United States, Abstract presented, American Society of Nephrology Kidney Week 2016.

prescribed home treatments[63] among both prior in-center participants and prior self-care home HD participants who used NxStage®. The applicant also stated that the Tablo® System's adherence rates were similar among both the prior in-center and prior self-care participants. The applicant stated that these results represent a significant improvement over the treatment adherence rate reported in the NxStage® IDE, where the treatment compliance rate was defined less stringently as missing 5 or fewer treatments of the 48 possible treatments and was only 89 percent among patients at home and during the study period.[64] Per the applicant, using a comparable metric of missing 5 or fewer of all possible treatments at home, Tablo® System IDE patients at home had a 100 percent treatment compliance rate.

The applicant stated that technique failure in home HD, defined as reduced retention at home and a return to in-center care, has been high with NxStage®. Per the applicant, real world data show that technique failure occurs in 36 percent of home HD patients using NxStage® within 1 year of initiating treatment.[65] The applicant stated that this was challenging for the patient and taxing on the healthcare system that had invested in providing patients with home dialysis training and in paying for more frequent therapy.

The applicant stated that by directly comparing the Tablo® System's retention to that of NxStage®, the applicant assessed rates in the analogous IDE populations while excluding those who exited either study for reasons unrelated to the device such as receipt of a transplant or death. The applicant stated that the Tablo® System demonstrated a 97 percent (28 of 29) patient retention rate for the entire IDE study and a 100 percent retention rate in the in-home phase of the trial among both prior NxStage® users and prior in-center patients.[66] The applicant stated that in comparison, 81 percent of participants completed the NxStage® IDE study.[67]

The applicant stated that the Tablo® System's ease of use contributed to the improved adherence and retention rates and that the Tablo® System is designed to enable patients to become proficient and independent in using the Tablo® System after an average of 3.9 days.[68] Per the applicant, published NxStage® IDE data[69] reported an average of 14.5 days ''to complete device training on NxStage®.'' The applicant stated that, in comparison, device-related training time is reduced by at least 50 percent on the Tablo® System. Per the applicant, the reduced training time and ease of use would likely improve retention and potentially reduce the number of reimbursable training sessions. The applicant stated that because of the significant role that caregivers play in supporting home dialysis treatments,[70] care partner burnout and a patient's perception of being a burden is associated with discontinuation of home therapy.[71] [72]

Per the applicant, the 28 patients who entered the home phase of the Tablo® System IDE study were asked weekly if they needed help with their dialysis treatments during the prior 7 days. The applicant stated that a 96 percent response rate (216 of 224 possible) was achieved at the end of the study and that for both prior-in-center and NxStage® study participants, in 79 percent of the treatment weeks, patients reported needing no assistance from their care partner in performing dialysis set-up, treatment, or breakdown. The applicant explained that among the 13 prior in-home patients, all of whom were formerly NxStage® users, participants reported needing help from a trained individual with dialysis treatment in 69 percent of treatment weeks, with 46 percent of instances involving a need for device-related help. We clarified in the CY 2022 ESRD PPS proposed rule (86 FR 36340—36341) that per Plumb, et al.,[73] this was the baseline percentage and reflected 9 of the 13 patients with previous self-care experience. The applicant stated that patients reported needing help with treatment in only 42 percent of treatment weeks while using the Tablo® System, which was a 39 percent reduction from baseline NxStage® use; and only 18 percent of these instances related to use of the Tablo® System, which was a 61 percent reduction in rate from baseline NxStage® use.[74]

The applicant stated that it collected weekly data from patients by asking them to rate the extent to which they believed that they were a burden on a scale of 1 to 5, with 1 representing never and 5 representing always. The applicant stated that this measure was adapted from an instrument used in assessing terminally ill patients.[75] The applicant stated that the subpopulation of study participants who had previously used NxStage® reported an average score of 3.1 for self-perceived burden on their care partner when using their prior device, which subsequently reduced to 2.4 when using the Tablo® System (a 23 percent reduction in score from baseline NxStage® use).[76] Per the applicant, these data underscored that a significant increase in patients' confidence, ability to achieve treatment independence at home, and subsequent reduction in the sense of self burden can positively contributed to success in the home setting. The applicant further noted that the ease of use, reduced training time, and substantial reduction in care partner assistance required for

[63] Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019), Hemodialysis International.

[64] Kraus, M., et al. A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. Hemodialysis International, 11: 468–477, (2007). The authors performed a feasibility study to demonstrate the safety of center-based vs. home-based daily hemodialysis with the NxStage System One portable hemodialysis device.

[65] Weinhandl, Eric D., Collins Allan, Incidence of Therapy Cessation among Home Hemodialysis Patients in the United States, Abstract presented, American Society of Nephrology Kidney Week 2016.

[66] Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019), Hemodialysis International.

[67] Kraus M, Burkart J, Hegeman R, Solomon R, Coplon N, Moran J. A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. Hemodial Int. 2007 Oct; 11(4):468–77. doi: 10.1111/j.1542–4758.2007.00229.x. PMID: 17922746.

[68] Plumb, Troy J., Luis Alvarez, Dennis L. Ross, Joseph J. Lee, Jeffrey G. Mulhern, Jeffrey L. Bell, Graham E. Abra, Sarah S. Prichard, Glenn M. Chertow, and Michael A. Aragon. ''Self-care training using the Tablo hemodialysis system.'' Hemodialysis International (2020).

[69] Kraus, M., et al, A comparison of center-based vs. home-based daily hemodialysis for patients with end-stage renal disease. Hemodialysis International, 11: 468–477, (2007).

[70] Seshasai, R.K., et al. (2019) The home hemodialysis patient experience: A qualitative assessment of modality use and discontinuation. Hemodialysis International, 23: 139–150 (2019).

[71] Suri, R.S., Larive, B., Hall, Y., Kimmel, P.L., Kliger, A.S., Levin, N., . . . & Frequent Hemodialysis Network (FHN) Trial Group. (2014). Effects of frequent hemodialysis on perceived caregiver burden in the Frequent Hemodialysis Network trials. Clinical Journal of the American Society of Nephrology, 9(5), 936–942.

[72] Jacquet, S., & Trinh, E. (2019). The potential burden of home dialysis on patients and caregivers: a narrative review. Canadian journal of kidney health and disease, 6, 2054358119893335.

[73] Plumb, Troy J., Luis Alvarez, Dennis L. Ross, Joseph J. Lee, Jeffrey G. Mulhern, Jeffrey L. Bell, Graham E. Abra, Sarah S. Prichard, Glenn M. Chertow, and Michael A. Aragon. ''Self-care training using the Tablo hemodialysis system.'' Hemodialysis International (2020).

[74] Ibid.

[75] Chochinov, H.M., Kristjanson, L.J., Hack, T.F., Hassard, T., McClement, S., & Harlos, M. (2007). Burden to others and the terminally ill. Journal of pain and symptom management, 34(5), 463–471.

[76] Chertow, G.M., Alvarez, L., Plumb, T.J., Prichard, S.S., & Aragon, M. (2020). Patient-reported outcomes from the investigational device exemption study of the Tablo hemodialysis system. Hemodialysis International, 24(4), 480–486.

the Tablo® System correlated to the improved retention and adherence rates in the Tablo® System IDE study. The applicant stated that on a population level, this likely translated to reduced barriers to continuing home HD once initiated, and ultimately, a reduced risk of adverse outcomes due to missed treatments. The applicant also stated that the Tablo® System's electronic data capture and automatic wireless transmission eliminates the need for manual record keeping, which represented an improvement with respect to burden and monitoring as compared to NxStage®.

Regarding the applicant's third claim that the Tablo® System improved patient quality of life, the applicant stated that patients on the Tablo® System experienced reduced disease burden, dialysis related symptoms, and an improved quality of life at home as compared to in-center and existing home care options. Per the applicant, patients with ESRD experience significant dialysis-related symptoms including difficulty sleeping, dizziness, and pain associated with recovery time that affect mental and physical health and lead to decreased overall quality of life.[77] Per the applicant, the Tablo® System IDE study assessed several validated Patient-Reported Outcome Measures (PROMs) to better understand overall health-related quality of life (HR-QoL). The applicant explained that the overall measure was the EQ–5D–5L, a validated, preference-based PROM in which patients self-assess mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.[78] The applicant stated that from these domains, an index value is calculated to report a summary score that ranges from 0 (death) to 1 (full health).

Per the applicant, while the NxStage® IDE study did not report results for a quality-of-life instrument, HR-QoL was assessed in NxStage® patients in a prospective multicenter observational study referred to as the FREEDOM trial, which examined the effects of at-home dialysis 6 times per week with the NxStage® System on costs and HR-QoL using the SF–36 instrument. The applicant further stated that the reported results at 4-month follow-up among these patients[79] translates to a mean EQ–5D score of 0.70. The applicant included an appendix describing the Methodology to Derive EQ–5D Scores from the FREEDOM Study Results in its application and derived a predicted mean EQ–5D score of 0.695–0.70 at follow up for the FREEDOM study. The applicant further noted that because this estimate is based on the average aggregate change for an adjusted measure that was then translated to the EQ–5D scale, and the applicant did not have access to standard error estimates for the Mental Component Score (MCS) and Physical Component Score (PCS), its interpretation of this estimate and its variance is limited. Per the applicant, nonetheless, it provided a sense of the comparable HR-QoL of this sample of NxStage® patients at follow-up. The applicant further noted that mean EQ–5D index values for traditional HD and PD patients reported from a meta-analysis of existing studies in the literature are 0.56 (95 percent CI: 0.49–0.62) and 0.58 (95 percent CI: 0.5–0.67), respectively.[80]

Per the applicant, patients in the Tablo® System IDE study reported mean EQ–5D index values of 0.821 (SD: ±0.163)[81] in the home phase of the study with final measures taken at approximately 5 months from trial start. The applicant stated that this is a significant improvement when using traditional HD patients as a comparator, and higher overall HR-QoL as compared to NxStage® patients. The applicant emphasized that participants in the Tablo® System IDE trial underwent a reduced treatment frequency as compared to participants in the FREEDOM study who were prescribed 6 treatments per week on NxStage®. The applicant stated that among patients in the Tablo® System IDE study who had previously been using NxStage®, the mean EQ–5D score during the in-home phase of the study was 0.906 (SD: ±0.119) and asserted that this is significantly greater than index population values for HD and PD.

The applicant stated that sleep problems are present in 60 percent of patients with chronic kidney disease (CKD) and ESRD[82] and that patients ranked fatigue and lack of energy as the most important contributor to their decreased quality of life.[83] Per the applicant, the frequency of sleep-related symptoms among the Tablo® System's patients was assessed by a survey that was administered weekly during the Tablo® System IDE study. The applicant stated that, in the absence of a well-validated sleep survey specific to the ESRD population, study investigators selected survey questions from previously validated sleep questionnaires in the non-ESRD population, based on their relevance to the study population.[84] [85] The applicant explained that questions were designed to focus on quality of sleep and restfulness and noted that these measures are validated for use among chronically ill populations and measure the frequency of 4 key sleep-related symptoms. The applicant stated that, while at home, patients on the Tablo® System reported improved quality of sleep, with a measurable reduction in rate of patient-reported sleep symptoms ranging from a 10–60 percent reduction, depending on symptom.[86] The applicant stated that this reduction was observed among study participants who were previously receiving dialysis in-center (average magnitude of reduction in rate across symptoms: 42 percent) and among study participants who were previously receiving in-home dialysis on NxStage® (average magnitude of reduction in rate across symptoms: 27 percent). Per the applicant, on average, sleep-related difficulties reduced from being reported in 33 percent of treatment weeks while on NxStage® to 23 percent of treatment weeks while on the Tablo® System.

[77] Gabbay, E., Meyer, K.B., Griffith, J.L., Richardson, M.M., & Miskulin, D.C. (2010). Temporal trends in healthrelated quality of life among hemodialysis patients in the United States. Clinical journal of the American Society of Nephrology, 5(2), 261–267.

[78] Yang, F., Wong, C.K., Luo, N., Piercy, J., Moon, R., & Jackson, J. (2019). Mapping the kidney disease quality of life 36-item short form survey (KDQOL–36) to the EQ–5D–3L and the EQ–5D–5L in patients undergoing dialysis. The European Journal of Health Economics, 20(8), 1195–1206.

[79] Finkelstein, F.O., et al. (2012). At-home short daily hemodialysis improves the long-term health-related quality of life. Kidney international, 82(5), 561–569.

[80] Liem, Y.S., Bosch, J.L., & Hunink, M.M. (2008). Preference-based quality of life of patients on renal replacement therapy: a systematic review and meta-analysis. Value in Health, 11(4), 733–741.

[81] Chertow, G.M., Alvarez, L., Plumb, T.J., Prichard, S.S., & Aragon, M. (2020). Patient-reported outcomes from the investigational device exemption study of the Tablo hemodialysis system. Hemodialysis International, 24(4), 480–486.

[82] Davison SN, Levin A, Moss AH, Jha V, Brown EA, Brennan F, Murtagh FE, Naicker S, Germain MJ, O'Donoghue DJ, Morton RL, Obrador GT; Kidney Disease: Improving Global Outcomes. Executive summary of the KDIGO Controversies Conference on Supportive Care in Chronic Kidney Disease: developing a roadmap to improving quality care. Kidney Int. 2015 Sep;88(3):447–59.

[83] Urquhart-Secord, Rachel et al (2016). Patient and Caregiver Priorities for Outcomes in Hemodialysis: An International Nominal Group Technique Study American Journal of Kidney Diseases, Volume 68, Issue 3, 444–454.

[84] Morin, C.M., Belleville, G., Bélanger, L., & Ivers, H. (2011). The Insomnia Severity Index: psychometric indicators to detect insomnia cases and evaluate treatment response. Sleep, 34(5), 601–608.

[85] Natale, V., Fabbri, M., Tonetti, L., & Martoni, M. (2014). Psychometric goodness of the mini sleep questionnaire. Psychiatry and clinical neurosciences, 68(7), 568–573.

[86] Chertow, G.M., Alvarez, L., Plumb, T.J., Prichard, S.S., & Aragon, M. (2020). Patient-reported outcomes from the investigational device exemption study of the Tablo hemodialysis system. Hemodialysis International, 24(4), 480–486.

The applicant stated that hypotensive symptoms such as feelings of dizziness and lightheadedness are associated with the drops in blood pressure that can occur during dialysis and are also among the top ten symptoms dialysis patients report that impact their quality of life.[87] Per the applicant, participants in the Tablo® System IDE study were asked at the time of enrollment regarding symptoms previously experienced during dialysis. The applicant also stated that at the end of each study treatment, participants were surveyed regarding the presence of any symptoms during that treatment on the Tablo® System. Per the applicant, a total of 8 (26.7 percent) subjects reported hypotensive symptoms during the Tablo® System treatments during the in-home treatment period, compared to 27 (90 percent) subjects reporting hypotensive symptoms at baseline (prior to initiating care on the Tablo® System). The applicant reported a 70 percent reduction in the rate of patient-reported hypotensive symptoms while on the Tablo® System, though, as we stated in the CY 2022 ESRD PPS proposed rule (86 FR 36342), we were unable to validate the source of this statement.

The applicant stated that currently, ESRD patients on dialysis report meaningfully lower quality of life compared to those with other chronic illnesses.[88] The applicant further noted that decreased quality of life is associated with a meaningful decline in continuation of home therapy, dialysis frequency, and worse clinical and health care utilization outcomes.[89]

The applicant concluded by asserting that the totality of evidence submitted in support of the Tablo® System demonstrates substantial clinical improvement over the current standard of home dialysis care. The applicant also stated that patient preference for devices is currently used by FDA to guide marketing authorization decisions and provides important information on the benefit and risks that some patients are willing to trade when choosing a device.[90] Per the applicant, patients may be more likely to choose home dialysis to the extent that the device is both accessible and easy to use. The applicant also stated that 86 percent of prior NxStage® patients in the Tablo® System IDE study found the Tablo® System easier to use than their incumbent device and preferred to remain on the Tablo® System at the end of the study.[91]

In summary, the applicant claimed that the Tablo® System improves the treatment of Medicare beneficiaries relative to the incumbent by focusing on outcomes set forth in § 412.87(b)(1)(ii)(C), including a decreased number of treatments to achieve dialysis adequacy, which the applicant stated leads to greater adherence to prescribed therapy, and improved quality of life.

(c) CMS Assessment of Substantial Clinical Improvement Claims and Sources

As discussed in the CY 2022 ESRD PPS proposed rule (86 FR 36342), after a review of the information provided by the applicant, we had identified the following preliminary concerns regarding the substantial clinical improvement eligibility criterion for the TPNIES. We noted that, consistent with § 413.236(c), CMS would announce its final determination regarding whether the Tablo® System meets the substantial clinical improvement criterion and other eligibility criteria for the TPNIES in this CY 2022 ESRD PPS final rule.

With respect to the applicant's claim that patients can achieve dialysis adequacy in as little as 3 treatments per week, we noted that the Tablo® System IDE study did not test whether patients receive adequate dialysis on a thrice-weekly schedule. Instead, data published from the Tablo® System IDE study addressed a weekly measure of dialysis adequacy among patients treated on a 4 times per week schedule. The applicant relied on modeling and unpublished data on patients receiving thrice-weekly dialysis in making the conclusion that dialysis adequacy can be reached on a thrice-weekly schedule. Specifically, the applicant referred to a theoretical modeling study based on historical data from the USRDS, Medicare claims, and historical outcomes from NxStage® observational studies. The applicant also stated that findings from a retrospective review of 29 patients receiving treatment with the Tablo® System on a thrice-weekly schedule affirmed the results from the modeling study. We also noted that the authors in Alvarez et al.[92] stated that conclusions about fluid removal could not be made from their study.

We stated that we were interested in whether additional studies were available that address issues related to effective fluid removal using home self-care dialysis thrice-weekly with the Tablo® System. We invited comments on whether less frequent dialysis sessions would represent substantial clinical improvement over shorter, more frequent sessions that, according to the applicant, were common among users of the incumbent technology.

The applicant's second claim was that the Tablo® System increased adherence to dialysis treatment and retention to home therapy, which may reduce dialysis-related hospitalizations and other adverse events associated with missing treatment. This claim was supported by the Tablo® System IDE study (28 participants completed the study) and the use of historical comparisons to prior studies involving the NxStage® System. The applicant noted that hospitalization rates from the Tablo® System IDE trial were lower than rates in the general dialysis population and rates reported in two observational studies of patients using the NxStage® device. While the applicant cited an all-cause hospitalization rate of 426 per 1000 patient years in the Tablo® System IDE study, we pointed out in the CY 2022 ESRD PPS proposed rule that it did not appear that the sources[93] [94] published these hospitalization rates. We further noted that the applicant relied on historical comparisons in asserting that that patients treated with the Tablo® System experience reduced

[87] Urquhart-Secord, Rachel et al (2016). Patient and Caregiver Priorities for Outcomes in Hemodialysis: An International Nominal Group Technique Study American Journal of Kidney Diseases, Volume 68, Issue 3, 444–454.

[88] Liem, Y.S., Bosch, J.L., Arends, L.R., Heijenbrok-Kal, M.H., & Hunink, M.M. (2007). Quality of life assessed with the Medical Outcomes Study Short Form 36-Item Health Survey of patients on renal replacement therapy: a systematic review and meta-analysis. Value in Health, 10(5), 390–397.

[89] Lowrie, E.G., Curtin, R.B., LePain, N., & Schatell, D. (2003). Medical outcomes study short form-36: a consistent and powerful predictor of morbidity and mortality in dialysis patients. American Journal of Kidney Diseases, 41(6), 1286–1292.

[90] Food and Drug Administration Center for Devices and Radiological Health (2020). ''Patient Preference-Sensitive Areas: Using Patient Preference Information in Medical Device Evaluation'' Available at: *https://www.fda.gov/about-fda/cdrh-patient-engagement/patient-preference-sensitive-areas-using-patientpreference-information-medical-device-evaluation*. Accessed Jan 21, 2021.

[91] Chahal, Y., Plumb, T., Aragon M. (2020). Patient Device Preference for Home Hemodialysis: A Subset Analysis of the Tablo Home IDE Trial. Poster Presentation at National Kidney Foundation Spring Clinical Conference, March 2020.

[92] Alvarez, Luis et al. Urea Clearance Results in Patients Dialyzed Thrice-weekly Using a Dialysate Flow of 300 mL/min, clinical abstract, presented March 2019, Annual Dialysis Conference, Dallas, Texas.

[93] Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis Plumb, T.J., Alvarez, L., Ross, D.L., Lee, J.J., Mulhern, J.G., Bell, J.L., Abra, G., Prichard, S.S., Chertow, G.M. and Aragon, M.A. (2019), Hemodialysis International.

[94] Chertow, G.M., Alvarez, L., Plumb, T.J., Prichard, S.S., & Aragon, M. (2020). Patient-reported outcomes from the investigational device exemption study of the Tablo hemodialysis system. Hemodialysis International, 24(4), 480–486.

disease burden and improved quality of life.

We noted in the CY 2022 ESRD PPS proposed rule (86 FR 36343) that in the Tablo® System IDE study, the before-after comparisons in patients with NxStage® regarding improved sleep compared to prior to the Tablo® System may be prone to recall bias in that participants' experiences with NxStage® were not recorded at the time they were receiving NxStage® treatments, but rather, were based on recall at the time of the Tablo® System IDE study.

We stated that we understood that greater flexibility for patients in the way that they receive their dialysis treatments may represent a benefit to Medicare beneficiaries who are candidates to receive this treatment in the home setting. We invited comments on whether this potential benefit represents substantial clinical improvement, including whether the Tablo® System represented an advance that substantially improves, relative to renal dialysis services previously available, the treatment of Medicare beneficiaries.

We received multiple comments on the substantial clinical improvement claims made in the TPNIES application for the Tablo® System, ranging from commenters with concerns about the claims, including from a manufacturer of a competitor device, to comments in support of the application, including from the applicant. The comments on the three substantial clinical improvement claims made by the applicant, and our responses to the comments, are set forth below.

Comment: A commenter, a manufacturer of a competitor device, asserted that the Tablo® System does not meet the substantial clinical improvement criterion. The commenter asserted that the applicant's claims were not supported by robust clinical evidence. The commenter made several criticisms about the Tablo® System IDE trial and the other clinical evidence provided by the applicant, emphasizing the lack of a direct head-to-head comparison with the NxStage® device as well as relying on theoretical modeling. For example, the commenter stated that the applicant did not submit adequate evidence to demonstrate its first claim, that decreased home HD treatment frequency with the Tablo® System offered a substantial clinical benefit for home HD patients, because the applicant's study examined patients that dialyzed on the Tablo® System more than three times per week and did not compare the Tablo® System machine to the NxStage® machine, which the commenter claimed is also capable of thrice-weekly dialysis. Further, the commenter stated that current models of the NxStage® System One™ offer dialysate flow rates of 300ml/minute and NxStage® patients can currently dialyze with any amount of dialysate prescribed by their doctor. The commenter asserted that the NxStage® machine is more flexible than the Tablo® System and that other incumbent systems, such as the Fresenius 2008K@home™, are capable of even more urea clearance than the Tablo® System in the same amount of time. Even though the commenter stated that patients using other home HD machines are able to achieve dialysis adequacy on a thrice-weekly dialysis schedule, the commenter also stated that it was not aware of any additional data in support of adequate fluid removal using a thrice-weekly dialysis schedule with the Tablo® System.

The commenter also expressed concerns with the applicant's claim that less frequent dialysis sessions may represent substantial clinical improvement over shorter, more frequent sessions because certain clinical and quality of life advancements, like more energy and vitality, are closely linked to more frequent treatments, which more closely mirror the natural function of a patient's kidney. This same point was also raised by other commenters, including health care providers. These other commenters also expressed a preference for more frequent dialysis stating that it results in increased energy levels, improved sleep and mental health, and that patients undergoing more frequent dialysis need fewer dietary restrictions and antihypertensive and phosphate binder medications. Additionally, the commenter stated that evidence suggests there is no disadvantage in access complications for patients that undergo more frequent dialysis, while also noting that the applicant did not present studies that compared vascular access with the Tablo® System to NxStage®.

The commenter stated that the applicant did not provide sufficient clinical evidence for its claim that the Tablo® System results in an incremental improvement in hospitalization rates because the sources that the applicant provided were not yet published.

Similarly, the commenter asserted that the applicant did not demonstrate that the Tablo® System increases adherence to the dialysis treatment and retention to home therapy because the studies cited by the applicant did not compare adherence, retention, or ease of use for the Tablo® System with the NxStage® or the Fresenius 2008K@home™ systems. The commenter stated that the Tablo® System IDE study on which the applicant relied to demonstrate treatment adherence and retention had several weaknesses including a small patient population, narrow patient inclusion criteria, and short duration. While the commenter acknowledged that the applicant did compare adherence rates from the Tablo® System IDE Study to adherence in the NxStage® IDE study, the commenter explained that this methodology was not appropriate because the studies had different definitions of treatment compliance. The commenter noted that the applicant's comparison of patient retention rates from the Tablo® System and NxStage® IDE studies was similarly not appropriate because the equipment used during the time of the NxStage® IDE study was completely different from that which is widely used today (that is, NxStage® touchscreen VersiHD™, Express Warmer, PureFlow™ SL).

Also, regarding the applicant's adherence claim, the commenter identified several factors that it argued may reduce dialysis adherence using the Tablo® System and restrict its use to a small subset of dialysis patients. First, the commenter stated that patients without consistent access to clean tap water may be at risk for disruptions in dialysis treatment with the Tablo® System. The commenter identified potential tap water disruptions such as water main breaks or the loss tap water during power outages for patients who rely on well-based water. The commenter further stated that water source disruptions do not hinder NxStage® patients from continuing their treatment because they can treat with pre-mixed dialysate bags. The commenter concluded that the Tablo® System's on-demand dialysate production is not a substantial clinical improvement over the NxStage® System One™ with PureFlow™ SL's on-site dialysate production. Second, the commenter stated, as did several other commenters, that the Tablo® System increases electric and water utility expenses by requiring a large volume of water to complete the reverse osmosis process and because the system must heat the water prior to use for dialysate and for sterilization after treatment. Third, the commenter stated that the Tablo® System has not received FDA marketing authorization for solo home hemodialysis (hemodialysis without a care partner) during waking hours, as well as nocturnal home hemodialysis, whereas the NxStage® System One™ has received these FDA marketing authorizations.

The commenter stated that the applicant did not provide sufficient evidence to advance its claim that the Tablo® System improves patient quality of life. The commenter stated that no comparison of incremental benefit in quality of life of the Tablo® System over NxStage® was provided. The commenter further stated that studies involving hundreds of patients have been specifically designed to test quality of life outcomes, among NxStage® users and have been published in peer-reviewed journals demonstrating quality of life improvements among NxStage® users. The commenter stated that there is a high bar for relying on quality of life evidence to demonstrate innovation, recognizing the breadth of evidence that exists for current technologies. Regarding the applicant's evidence on its improved patient quality of life claim, the commenter stated that it was unable to confirm the applicant's claim of a 70 percent reduction in the rate of patient-reported hypotensive symptoms while on the Tablo® System and asserted that data also supports a reduction in intradialytic hypotensive episodes among NxStage® patients, referring to an article by Murashima et al.[95]

The commenter similarly questioned the applicant's claims regarding sleep quality and related symptoms stating that the Tablo® System IDE data did not compare the Tablo® System to NxStage, relied on a small sample size, was of short duration, and was not accurate because study results may have been affected by recall bias. Regarding the recall bias concern, additional commenters also wrote in with concurring comments. These commenters explained that participants' experiences with NxStage® were not recorded at the time they were receiving NxStage® treatments, but rather, were based on recall at the time of the Tablo® System IDE study.

Regarding the applicant's claim that the Tablo® System users spend less time in training compared to existing technologies, the commenter questioned the applicant's reference to 14.5 days to complete training on NxStage, stating that this timeframe includes training about aspects of home dialysis beyond the functionality of the machine. The commenter stated that only approximately 5 session-equivalents are machine-focused during training with NxStage®. The commenter also stated that because 13 patients in the Tablo® System IDE study had previous home HD experience, the study participants would have already been trained on the most difficult aspects of home therapy, such as self-cannulation. Therefore, the commenter suggested review of a larger number of patients who are truly new to home therapy.

The commenter rejected the applicant's assertions that the Tablo® System's features are unique and stated that the applicant did not submit data demonstrating that the Tablo® System is easier to use than other devices. The commenter stated its belief that many aspects of the Tablo® System are more difficult to use than NxStage® and highlighted key features that have become available since publication of the NxStage® IDE study. The commenter also challenged the applicant's description of the Tablo® System's cartridge as being ''pre-strung'' compared to existing cartridges and stated that NxStage® offers a cartridge that requires 4 fewer blood tubing connections. The commenter also stated that NxStage® systems are the only home HD systems approved for self-treatment without a care partner, addressing partner fatigue.

The commenter and several members of the public identified the ability to travel as a quality of life issue. They stated that because the Tablo® System weighs nearly 200 pounds, it is not portable, while the NxStage® device is lighter and portable. Due to its portability, the competitor commenter added that 70 percent of NxStage® users reported traveling while using the machine.

Finally, this commenter stated that while certain patients may prefer certain features of the Tablo® System, the presence of an additional option for home dialysis machine does not in itself represent a clinical improvement.

Response: We appreciate the input provided by the commenters. We have taken this information into consideration in our determination of whether the Tablo® System meets the eligibility criteria at § 413.236(b)(5) and § 412.87(b)(1), and have responded in further detail to comments discussing the significant clinical improvement claims for the Tablo® System at the end of this section of the final rule.

Comment: We received a comment from the applicant in support of the TPNIES approval for the Tablo® System.

With respect to the claim that patients can achieve dialysis adequacy in as little as three treatments per week and the concern we expressed in the CY 2022 ESRD PPS proposed rule that the Tablo® System IDE study did not test whether patients receive adequate dialysis on a thrice-weekly schedule, the applicant clarified that the intent was not to position three times per week home dialysis as substantial clinical improvement over short daily or more frequent dialysis. Instead, their claim is that more frequent dialysis, which they believe is a requirement for NxStage, is significantly more burdensome for patients with ESRD for whom thrice-weekly treatments may be appropriate.

The applicant stated that the Tablo® System's ability to achieve Kt/V targets of 1.2 on a thrice-weekly treatment schedule at home represents substantial clinical improvement because they believe it allows patients the benefits of home dialysis whether administered three or four times per week, which had not been an option previously because of the technical limitations of the NxStage® system. Specifically, per the applicant, on a standard treatment duration, three day per week schedule patients with weights above 79kg do not have sufficient dialysate with NxStage® (maximum of 60L) to achieve the CMS mandated target without increasing the amount of time per treatment that the patient has to dialyze. The applicant further stated that the Tablo® System can achieve levels of efficiency nearly on par with in-center hemodialysis on conventional hardware. The applicant also noted that patients treated with NxStage® would exhaust its dialysate at 3 hours 20 minutes at an equivalent dialysate flow rate of 300ml/min. In support of that claim, the applicant referred to kinetic modeling, the clearance kinetics of the NxStage® dialyzer, and the percentage of body water[96] [97] in patients weighing 174 pounds or greater. The applicant concluded that patients treated with NxStage® would require greater than thrice-weekly treatments to achieve hemodialysis adequacy with spKt/V of >1.2. The applicant stated that because the Tablo® System is able to generate dialysate on demand at 300ml/min for up to 12 hours without volume limitations, it allows patients the flexibility to adequately dialyze at the frequency that is best for them rather

[95] Murashima M, Kumar D, Doyle AM, Glickman JD. Comparison of intradialytic blood pressure variability between conventional thrice-weekly hemodialysis and short daily hemodialysis. Hemodial Int. 2010 Jul;14(3):270–7. doi: 10.1111/j.1542–4758.2010.00438.x. PMID: 20337744.

[96] Leypoldt, J. K., Prichard, S., Chertow, G. M., & Alvarez, L. (2019). Differential molecular modeling predictions of mid and conventional dialysate flows. Blood purification, 47(4), 369–376. Depner T, Beck G, Daugirdas J, Kusek J, Eknoyan G. Lessons from the Hemodialysis (HEMO) Study: an improved measure of the actual hemodialysis dose. Am J Kidney Dis. 1999 Jan;33(1):142–9.

[97] Depner T, Beck G, Daugirdas J, Kusek J, Eknoyan G. Lessons from the Hemodialysis (HEMO) Study: an improved measure of the actual hemodialysis dose. Am J Kidney Dis. 1999 Jan;33(1):142–9.

than requiring them to perform more frequent treatments.

The applicant stated that their evidence on achieving Kt/V of 1.2 on a conventional three times per week dialysis schedule came from an observational study conducted on an in-center patient population using the Tablo® System prior to its FDA marketing authorization for home HD. The applicant referred to abstracts presented at the 2019 Annual Dialysis Conference as summarized in the CY 2022 ESRD PPS proposed rule. The applicant emphasized that evidence from published and unpublished sources may be sufficient in establishing substantial clinical improvement.

In response to concerns regarding the sufficiency of the clinical evidence presented, the applicant commented that because the patient population in the Tablo® System IDE study, was more diverse and reflective of the general dialysis population with respect to diabetes and other comorbidities than the population in the NxStage® IDE study, study results regarding Tablo® System can be better applied to the Medicare population.

In their application, the applicant claimed that Tablo® System patients can be expected to have fewer vascular access interventions, and health care providers will have increased flexibility in personalizing the frequency and duration of patient treatments.[98] [99] The applicant emphasized in its comment that Tablo® System users may experience reduced vascular access infection related hospitalizations, relying on data from the Tablo® System IDE study. The applicant stated that patients prescribed 5–6 days weekly dialysis sessions with NxStage® who were converted to 4 weekly dialysis sessions with the Tablo® System, experienced no hospitalizations during the home arm of the trial. The applicant commented that these data were not included in the Tablo® System IDE publication because the sample size was modest and relatively few patients required hospitalization. The applicant also stated that 14 of the 35 patients enrolled in the NxStage® IDE dropped out before completing the trial, making it difficult to calculate an unbiased estimate of the hospitalization rate. The applicant compared the Tablo® System IDE hospitalization rate to two North American observational studies by Weinhandl et al.[100] and Suri et al.[101] of patients receiving home HD (likely NxStage® or K@Home). The applicant further stated that Suri et al. reported a hospitalization rate of 930 per 1000 patient-years and Weinhandl et al. noted a rate of 1663 per 1000 patient-years. The applicant stated that results from these studies suggest that patients receiving treatment at home with NxStage® 5–6 times per week had similar, not lower, rates of hospitalization relative to matched patients receiving in-center hemodialysis. The applicant further noted that the modest sample size of the Tablo® System IDE precludes valid inference testing, but that the hospitalization rate observed (426 per 1000 patient-years) was roughly one-quarter that seen among a national cohort of patients on home HD in the US, and less than one-half that seen among a Canadian cohort, despite the high proportion of non-white patients and patients with diabetes, characteristics typically associated with higher rates of hospitalization.

With respect to the claim that the Tablo® System increases adherence to dialysis treatment and retention to home therapy, the applicant provided additional support. Specifically, the applicant stated that in its real-world home population, to date, no patients have chosen to return to in-center HD once going home with the Tablo® System. The applicant submitted new data to further establish first-year attrition comparisons. The applicant stated that it contracted with a third-party research firm [102] to conduct an analysis of patients dialyzing at home using the Tablo® System, matched to patients in the USRDS who completed home HD training between the years 2016 through 2018. Per the applicant, home HD attrition was defined as either death or conversion to in-facility HD and kidney transplantation was excluded from attrition. The applicant further stated that the cohort included 39 patients that initiated home HD with the Tablo® System since the device's FDA marketing authorization for home use in March of 2020.

The applicant further clarified that this patient population is separate and distinct from the participants in the Tablo® System IDE study. The applicant stated that there were 4 attrition events among the 39 Tablo® System users and 3,602 attrition events among the 9,827 home HD starts in the broader population of patients receiving home HD. The applicant further noted that the cumulative incidence of attrition at 1 year was 26.8 percent among Tablo® System users and 42.5 percent among all home HD starts with the unadjusted Cox regression hazard ratio of home HD attrition among Tablo® System users versus home HD starts in years 2016 through 2018 at 0.38 (95% confidence interval, 0.14–1.02; $p = 0.06$), a more than 60 percent reduction in attrition with the Tablo® System. The applicant also acknowledged that the limited sample size reduces power in demonstrating a statistically significant result, but asserted that the preliminary data suggest that use of the Tablo® System should reduce home HD attrition.

In the CY 2022 ESRD PPS proposed rule, CMS acknowledged the applicant's claim regarding the benefit of greater flexibility for patients in the way that they receive their dialysis treatments. The applicant stated in their comment that the Tablo® System represents substantial clinical improvement over NxStage® in several ways: Allowing patients, in consultation with their clinicians, to develop a treatment schedule tailored to their individual needs, reducing the time spent on dialysis-related tasks including the elimination of a 6–8 hour pre-treatment dialysate production, and reducing supply storage requirements.

With respect to the claim that the Tablo® System improves patient quality of life, the applicant stated in their comment that Tablo® System IDE showed favorable effects on patient-reported outcomes, including the EQ–5D survey instrument that has been widely applied to many chronic disease populations, as well as a number of surveys related to the process of home dialysis.

The applicant's comment included the results from an online survey conducted by a third-party research firm [103] and a network of dialysis organizations and regional offices [104] between July 29 and August 9, 2021. Per

[98] FHN Trial Group. (2010). In-center hemodialysis six times per week versus three times per week. New England Journal of Medicine, 363(24), 2287–2300.

[99] Kuo, T.H., Tseng, C.T., Lin, W.H., Chao, J.Y., Wang, W.M., Li, C.Y., & Wang, M.C. (2015). Association Between Vascular Access Dysfunction and Subsequent Major Adverse Cardiovascular Events in Patients on Hemodialysis: A Population-Based Nested Case-Control Study. Medicine, 94(26).

[100] Weinhandl, E. D., Gilbertson, D. T., & Collins, A. J. (2016). Mortality, hospitalization, and technique failure in daily home hemodialysis and matched peritoneal dialysis patients: a matched cohort study. American Journal of Kidney Diseases, 67(1), 98–110.

[101] Suri, R. S., Li, L., & Nesrallah, G. E. (2015). The risk of hospitalization and modality failure with home dialysis. Kidney international, 88(2), 360–368.

[102] Analysis conducted by the Chronic Disease Research Group (CDRG), a division of the Hennepin Healthcare Research Institute.

[103] Health Advances, US Home Hemodialysis Nephrologist and Patient Perspectives Presentation, August 13, 2021.

[104] National Kidney Foundation.

the applicant, 184 nephrologists and 202 patients were surveyed regarding a list of potential benefits and system features of a blinded home HD system concept reflecting the features of the Tablo® System. The applicant stated that 77 percent of nephrologists rated the Tablo® System's features as a substantial clinical improvement in home HD care and 98 percent indicated that the Tablo® System's benefits would make them more likely to recommend home HD to their patients. The applicant further stated that 72 percent of patients receiving in-center HD or PD rated the Tablo® System's features as a significant improvement in home HD care and 77 percent of those patients stated they would be more likely to try home HD. The applicant stated that of the current home HD population dialyzing on the incumbent device, 84 percent rated the Tablo® System's features as a significant improvement in home HD care.

The applicant's comment acknowledged that NxStage® would be an available option to patients who prefer to travel with a home dialysis device but stated that the majority of patients ranked the effectiveness of treatment above the ability to travel with their device.

With respect to CMS's recall bias concern that participants' experiences with NxStage® were not recorded at the time they were receiving NxStage® treatments, but rather, were based on recall at the time of the Tablo® System IDE study, the applicant clarified that 13 of the 29 Tablo® System IDE study participants who completed the trial had been dialyzing at home with NxStage® in advance of the Tablo® System IDE study and that baseline surveys were taken while patients were actively treating with NxStage®. The applicant commented that survey questions were sourced from validated sleep questionnaires and did not ask patients for a comparison to a prior time point, but focused on a rating of sleep during the prior week.

The applicant commented that to further assess the prevalence of sleep related symptoms in home HD patients, a third-party research firm conducted a survey of current non-Tablo® System HD patients. The applicant stated that of home HD respondents, 64 percent reported very poor to poor sleep quality and all respondents stating that improved sleep would represent substantial clinical improvement.[105] The applicant stated that collectively, its results confirm that achieving satisfactory sleep remains a major challenge for patients on dialysis and that using the Tablo® System has the potential to improve sleep quality, which may also enhance physical, cognitive, and sexual function, and expand functional capacity.

The applicant's comment emphasized the safety features and ease-of-use of the Tablo® System. The applicant stated that the Tablo® System offers patients a differentiated level of safety in having met higher, more updated safety standards of performance, such as fluid removal, air detection, temperature, dialysate flow rate and other parameters than the previously approved NxStage® device. The applicant also stated that the remote monitoring and remote technical support features are only available with the Tablo® System and reduce patient apprehension to perform treatments at home. The applicant's comment again asserted that, overall, the totality of the evidence demonstrates that the Tablo® System offers substantial clinical improvement in home HD treatment.

Response: We thank the applicant for their comment and have taken the additional information provided into consideration in our determination of whether the Tablo® System meets the eligibility criteria at § 413.236(b)(5) and § 412.87(b)(1). We have responded in further detail to comments discussing the significant clinical improvement claims for the Tablo® System at the end of this section (II.C.5.c) of the final rule.

Comment: We received many comments from clinicians, patients, and caregivers supporting the Tablo® System's TPNIES application. For example, many commenters stated that using the Tablo® System is convenient and allows for the flexibility to personalize treatment for a diversity of patient needs. Commenters stated that patients are allowed to create their own schedules, which enables them to continue working and enjoying life's activities. Patient commenters stated that they have become more active and engaged participants in their own care. Commenters appreciated the convenience and comfort of being able to dialyze at home instead of in-center, stating that doing so alleviates stress, reduces exposure to COVID–19 and reduces the burden of arranging for and traveling to in-center treatments.

Patient and caregiver commenters expressed appreciation for the Tablo® System's on-demand dialysate for several reasons. First, commenters stated that patients have more dialysis-free time by not needing to prepare solution or handle heavy bags of dialysate. Second, commenters stated that there are fewer supplies to store for the Tablo® System as compared to the NxStage® System for which it was necessary to store up to 20 boxes of dialysate and supplies. Third, commenters stated that dialysate delivery may be challenged in regions with extreme climates and could compromise treatment. Commenters also stated that there is less wasted dialysate with use of the Tablo® System.

Patient commenters identified several clinical improvements that they attribute to treatment with the Tablo® System including reduced cramping and fatigue after dialysis treatment, reduced need for blood pressure medication, improved mood, and less frequent use and wear on the vascular access site with fewer weekly treatments. Commenters also stated that that features and conveniences of the Tablo® System result in less burn out[106] of patients and caregivers, better adherence, retention and overall quality of life.

Many commenters including patients, caregivers and clinicians commented on the Tablo® System's features and ease-of-use. Commenters stated that the complexity of a dialysis machine and lengthy training can be intimidating and act as a deterrent in the adoption of home dialysis. Commenters stated that some patients and caregivers cannot afford extended absences from work, childcare or other responsibilities to complete dialysis training and that training with the Tablo® System ranges from 10 days to 2 weeks compared to training with NxStage® which averages 4–6 weeks. Several commenters stated that patients with prior home dialysis experience can begin home treatments using the Tablo® System after just 3–4 training days. One commenter stated that a comparison of training for the Tablo® System versus other devices in the market does not exist.

Commenters stated that patients may also fear not being able to remember what to do in an urgent situation and highlighted the Tablo® System's safety features that prevent patient harm, including step-by-step instructions with less memorization, and fewer treatment steps, and 24/7 technical support.

[105] Health Advances, US Home Hemodialysis Nephrologist and Patient Perspectives Presentation, August 13, 2021.

[106] As discussed in the CY 2021 ESRD PPS final rule (85 FR 71462), a significant challenge to increasing the use of home dialysis includes burn out (or technique failure) and return to in-center HD. According to one recent observational study, approximately 25 percent of patients who initiate home HD return to in-center HD within the first year (Seshasai RK, Mitra N, Chaknos CM, Li J, Wirtalla C, Negoianu D, Glickman JD, Dember LM. Factors Associated With Discontinuation of Home Hemodialysis. Am J Kidney Dis. 2016 Apr;67(4):629–37.)

Commenters stated that remote treatment monitoring in real time, allows clinicians to intervene as needed with treatment modifications. Commenters stated that the Tablo® System's instructions can be set in other languages. Commenters also expressed appreciation for the Tablo® System's built-in warmer that helps to prevent hypothermia during treatment, built-in blood pressure monitoring, flush feature, closed loop cartridge to minimize risk of infection, automatic record keeping, and the quicker set up and take down times. Commenters stated that the Tablo® System looks less like an intrusive medical device and the built-in wheels make it easy to move it from room to room.

One commenter stated that patients previously not deemed suitable for home HD, due to large body size, work schedules, etc. may now become candidates with the use of the Tablo® System. Another commenter stated that patients lacking social support and financial resources may not be good candidates for home dialysis.

Response: We appreciate the input provided by these commenters. We have taken this information into consideration in our determination of whether the Tablo® System meets the eligibility criteria at § 413.236(b)(5) and § 412.87(b)(1). We have responded in further detail to comments discussing the significant clinical improvement claims for the Tablo® System at the end of this section (II.C.5.c) of the final rule.

Comment: We received several comments from health care providers and patients regarding the Tablo® System and less frequent dialysis treatments. A physician commenter stated that the question of whether less frequent dialysis is clinically preferable to shorter, more frequent [dialysis] sessions does not appear to be definitively decided in clinical research for all patients. The commenter stated that while patients derive significant benefit from more frequent dialysis, having the ability to achieve at least adequate dialysis at three days per week is a significant advancement compared with what has been offered. Commenters stated that the treating clinician remains in the best position to prescribe the appropriate frequency of dialysis for their patients but that it is possible for researchers to accurately assess improvements in clinical outcomes related to frequency of dialysis treatments. A commenter, who is a health care provider, shared their experience with the Tablo® System in a dialysis unit, stating that their unit tested the Tablo® System and found that on the whole, the patients could reach dialysis adequacy on a traditional thrice-weekly frequency. While this commenter referred to an abstract documenting these results, it was not provided.

Response: We appreciate the input provided by these commenters. We have taken this information into consideration in our determination of whether the Tablo® System meets the eligibility criteria at § 413.236(b)(5) and § 412.87(b)(1). We have responded in further detail to comments discussing the significant clinical improvement claims for the Tablo® System at the end of this section (II.C.5.c) of the final rule.

Comment: We received several comments from the public, including health care providers and patients, regarding how to demonstrate substantial clinical improvement in connection with a home hemodialysis machine such as the Tablo® System. One commenter stated that clinical trials, abstract data and expert opinion is sufficient to support substantial clinical improvement and that this type of evidence is often the basis of clinical guidelines from the National Kidney Foundation (NKF) Kidney Disease Outcome Quality Initiative. The commenter stated that new companies are not equipped to conduct in-depth studies until they have significant numbers of patients on their device or therapy which creates a barrier to recruiting study participants and thus, limiting investment in the new technology. Another commenter stated that the ESRD sector does not easily lend itself to robust clinical trials, and this fact should be considered when determining whether an applicant for TPNIES has demonstrated substantial clinical improvement. Commenters referred to the CMS TPNIES application template, which indicates that published, unpublished, and clinical expertise are all acceptable forms of supporting evidence and that placing a heavy emphasize on published long-term studies for purposes of evaluating substantial clinical improvement limits the ability of new companies to enter the market and deprives patients of potentially lifesaving technologies. A non-profit dialysis association stated that CMS should consider the extent to which the technology has demonstrated improved quality of life in determining whether the technology represents substantial clinical improvement.

Many commenters stated that patients should be given a choice in deciding which home hemodialysis machine is best for them, and that providing patients with an additional choice is evidence of substantial clinical improvement. A physician commenter indicated that it is not clear why patients prefer one machine over another or feel better with one prescription over another, but a choice based on patient preference can improve patient retention to a particular therapy, one of the ways to demonstrate substantial clinical improvement. This commenter stated that evidence that a home dialysis machine improves retention should be sufficient evidence to approve the TPNIES for that home dialysis machine.

Response: We appreciate the commenters' input regarding whether the Tablo® System meets the innovation criterion at § 413.236(b)(5) and substantial clinical improvement criteria at § 412.87(b)(1). After carefully reviewing the application, the information submitted by the applicant addressing our concerns raised in the CY 2022 ESRD PPS proposed rule, as well as the many comments submitted by the public, we agree with the applicant and several members of the dialysis community that the Tablo® System represents an advance that substantially improves, relative to renal dialysis services previously available, the treatment of Medicare beneficiaries. We find that the data submitted demonstrate greater medication adherence or compliance of home HD among users of the Tablo® System that is not as evident for users of existing home HD technologies, as specified under § 412.87(b)(1)(C)(7). We also believe that the Tablo® System may provide added flexibility around the frequency and duration of home HD that could benefit some patients, specifically, patients who may prefer fewer, slightly longer treatments but who would otherwise be limited to more frequent home HD treatments. We believe additional flexibilities around home HD treatments may represent an improvement in one or more activities of daily living and an improved quality of life for Medicare beneficiaries, as specified under § 412.87(b)(1)(C)(4) and § 412.87(b)(1)(C)(5), respectively. We also recognize that patient preference and choice is especially important for patients with ESRD, who undergo demanding, often grueling, dialysis therapy, and we believe that patients who prefer their method and frequency of dialysis are more likely to adhere to the therapy, and thus increase adherence rates overall.

We acknowledge the concerns raised by commenters regarding the substantial clinical improvement claims in the Tablo® System application. As we had previously noted in the CY 2022 ESRD PPS proposed rule, we had some of the same concerns as commenters regarding

the evidence submitted to support the claims of significant clinical improvement. However, at this time, we feel that our concerns have been sufficiently addressed. For example, with respect to the applicant's claim that the Tablo® System increases adherence to dialysis treatment and retention to home therapy, although the adherence and retention data provided in the initial application had limitations, additional information was submitted by the applicant to support this claim in its comment on the CY 2022 ESRD PPS proposed rule. This data showed lower attrition rates at 1 year between patients using the Tablo® System for home HD, separate from the group of patients in the Tablo® System IDE, matched with patients who had completed home HD patients, using data from the USRDS. With respect to the applicant's claim that the Tablo® System improves patient quality of life, we note that the applicant addressed our concerns about the potential for recall bias in their claim of improved sleep quality and related symptoms in their comment, explaining that baseline surveys were taken while patients were actively treating with NxStage®. Also, while some commenters opposed the applicant's use of unpublished data to support its claim of improved hospitalization, we note that under § 413.236(b)(5) and 412.87(b)(1)(iii), CMS may consider unpublished data in making a determination of substantial clinical improvement as we recognize in some situations, published data may not be available. Overall, we believe the applicant was able to address our concerns about its substantial clinical improvement claims from the discussion in the CY 2022 ESRD proposed rule.

We also note that, under our TPNIES policy and § 412.87(b)(1)(i), CMS is required to consider the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. We believe the circumstances we may consider in our review of the TPNIES applications, specifically within the context of the ESRD PPS, include the state of the ESRD landscape and the particular challenges and vulnerabilities of patients with ESRD. While we recognize that published studies and randomized controlled trials are often the gold standard in demonstrating superiority of one product over another, our review is not limited to evidence from large randomized controlled trials; we also consider a range of evidence from published or unpublished information sources, including other appropriate information sources not otherwise listed under § 412.87(b)(1)(iii). As codified under § 412.87(b)(1)(iii), evidence from published or unpublished information sources may be sufficient to establish that a new technology represents a substantial clinical improvement.

Additional information we considered in our review of the Tablo® System was the new data provided by the applicant surveying over 180 nephrologists and over 200 patients undergoing dialysis treatment HD, along with substantial supportive comments from patients, caregivers, and health care providers, about the benefits of the Tablo® System in providing an improved quality of life, an improvement in one or more activities of daily living, and a decreased rate of at least one subsequent therapeutic intervention, as specified under §§ 12.87(b)(1)(C)(6), 412.87(b)(1)(C)(5), 412.87(b)(1)(C)(2), respectively.

We also note that, at this time, patients with ESRD are facing new, additional risks when receiving dialysis treatment due to the COVID–19 pandemic. As some of the commenters noted, ESRD patients are among the most vulnerable in the Medicare population and are at an increased risk for COVID–19 associated morbidity and mortality.[107] [108] As we discussed in the CY 2021 ESRD PPS final rule, Medicare's ESRD population aligns with the profile of patients who are more susceptible to COVID–19. As we stated in that rule, we believe it is important to reduce the risk of infection among beneficiaries with ESRD, and this can be done through isolating patients from in-center exposure by encouraging home HD (85 FR 71416). We also believe that providing patients with an additional option for home HD is especially important given that the adoption of home HD has been limited, with approximately only 1% of ESRD patients utilizing this modality.[109] Therefore, we are interested in supporting the use of technologies that expand patient options for dialyzing safely at home at this time.

For all of these reasons, we conclude that the Tablo® System meets the TPNIES innovation criteria under § 413.236(b)(5) and § 412.87(b)(1).

(6) Capital Related Assets Criterion (§ 413.236(b)(6))

Regarding the final TPNIES eligibility criterion under § 413.236(b)(6), whether the item is a ''capital-related asset'' that is a ''home dialysis machine,'' these terms are defined in § 413.236(a)(2). The applicant identified the Tablo® System as an asset that an ESRD facility has an economic interest in through ownership, is subject to depreciation, and is an HD machine that received FDA marketing authorization for home use. We received no public comments on this criterion. We agree that the Tablo® System is a capital-related asset and home dialysis machine and therefore meets this criterion.

The remaining comments and our responses regarding the Tablo® System and its eligibility for the TPNIES are set forth below.

Comment: We received a comment that 70% of the patient population in the Tablo® System IDE study were non-white, suggesting Tablo® System's ability to create greater home adoption and retention in ways that are aligned with the proposed incentive for closing gaps in health equity access to home HD.

Response: We thank the commenter for their input. While health equity is not a specific TPNIES eligibility criteria under § 413.236(b), we strongly support health equity and believe that the approval of the Tablo® System under the criterion of § 413.236(b) will encourage uptake of home HD for vulnerable patients with ESRD.

Comment: We received several comments pertaining to the relationship between the cost of the Tablo® System and its connection to beneficiary access. Several commenters stated that the initial cost of the Tablo® System is 2 to 3 times that of older technologies, and that combined with potentially fewer treatments over which to amortize the cost, it would be difficult for ESRD facilities to incorporate the Tablo® System into their businesses without a payment adjustment under the ESRD PPS. These commenters expressed support for CMS approving the TPNIES for the Tablo® System.

The applicant stated that after the initial capital investment, the per treatment costs of using the Tablo® System are considerably less than that of the NxStage® System. Another commenter stated that the Tablo® System is more affordable than other home dialysis machines and is cost

[107] Ziemba R, Campbell KN, Tang T, et al. Excess Death Estimates in Patients with End-Stage Renal Disease—United States, February–August 2020. MMWR Morb Mortal Wkly Rep 2021;70:825–829. DOI *http://dx.doi.org/10.15585/mmwr.mm7022e2.*

[108] *https://www.cdc.gov/coronavirus/2019-ncov/hcp/dialysis/home-dialysis.html.*

[109] Mailloux LU, Blagg CR. Berns JS (ed.) Home Hemodialysis. Uptodate. Nov 18, 2016.

effective. Commenters stated that a TPNIES approval for the Tablo® System would help to offset the Tablo® System's acquisition costs, particularly for small and mid-size dialysis organizations and independent providers and facilitate economies of scale, allowing ESRD facilities to lower the cost of home HD care in the future.

Commenters also asserted that a TPNIES approval would increase home dialysis utilization and retention of patients on home dialysis, and improve clinical and patient-reported outcomes, overall. For example, several commenters stated that use of the Tablo® System may help to push the national home hemodialysis prevalence above its stagnant level of 2 percent and a TPNIES approval would further support the goals of the ETC Model.

Response: We appreciate the commenters' input. We note that cost is not a consideration for TPNIES eligibility under § 413.236(b), and therefore is not relevant to our review of the Tablo® System's application. However, we believe that approval of the Tablo® System supports the goals of the ETC model by expanding beneficiary access to and retention of home HD.

Comment: The Tablo® System applicant commented on the CMS spending estimate of Medicare payment for additional home HD sessions, noting differences between its analysis and that of CMS but agreeing with CMS' estimates on spending for the fifth treatment. Several commenters stated that while existing guidance [110] allows for treatments more than three times per week when they are reasonable and necessary, coverage decisions are unrelated to the TPNIES eligibility determination. A commenter stated that the applicant provided no evidence regarding dialysis frequency for the population of patients that meet Medicare's clinical coverage criteria for additional treatments.

Response: We thank the commenters for their input and note that our CMS spending estimate of Medicare payment for additional home HD sessions that was included in the CY 2022 ESRD PPS proposed rule (86 FR 36339) was not part of our analysis of the TPNIES eligibility criteria in § 413.236(b). In addition, while Medicare clinical coverage criteria are beyond the scope of this rulemaking, we are not suggesting that the way in which ESRD facilities reflect home HD treatments on their claims would change due to our decision on the Tablo® System application.

Comment: We received several comments from health care professionals with experience in using the Tablo® System in a clinical setting, rather than a home setting. One commenter stated that the Tablo® System is a benefit for ESRD facilities with staffing shortages because less time will need to be spent with each patient. Several commenters shared their favorable experiences in using the Tablo® System in the hospital inpatient and intensive care unit settings and in treating COVID–19 patients. One commenter stated that 15 AKI inpatients with a mean age of 65 years were provided multiple Tablo® System treatments 3–6 times per week. The commenter further explained that the best urea reduction ratio achieved in the first 1–4 treatments, if available, was 41%; most treatments were successful and were slowed for hypotension or tachycardia; and some were aborted because of water pressure alarms signaling the need for filter replacement or clotted lines related to hypercoagulability among COVID–19 patients. The commenter further stated that most treatments were limited to 3–4 hours but up to 8 hours. Some commenters stated that patients treated with the Tablo® System in the hospital or ESRD facility setting gain familiarity and comfort with the device making it an easier transition to using the system at home.

Response: We thank the commenters for their input. Currently, the only capital-related assets not excluded from eligibility for the TPNIES under § 413.236(b)(6) are home dialysis machines used in the home for a single patient, as defined in § 413.236(a)(2). While these commenters' experiences with the Tablo® System do not involve its use in the home setting, we appreciate the additional input regarding the benefits of the Tablo® System.

After a consideration of all the public comments received, we have determined that the evidence and public comments submitted are sufficient to demonstrate that the Tablo® System meets all of the eligibility criteria to qualify for the TPNIES for CY 2022. As a result, the Tablo® System will be paid for using a TPNIES per § 413.236(d).

III. Calendar Year (CY) 2022 Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and 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 subsection (r) to provide 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 adjusted (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 that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies 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, and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD PPS base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the CY 2022 Payment for Renal Dialysis Services Furnished to Individuals With AKI

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment

[110] Medicare Coverage Database. Retrieved May 24, 2021 from: *https://www.cms.gov/medicarecoverage-database/details/lcd-details.aspx?LCDId=35014&ver=39&NCDId=79&ncdver=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7CCAL%7CNCD%7CMEDCAC%7CTA%7CMCD&ArticleType=Ed%7CKey%7CSAD%7CFAQ&PolicyType=Final&s=-%7C5%7C6%7C66%7C67%7C9%7C38%7C63%7C41%7C64%7C65%7C44&KeyWord=transplant&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAADgAAAAA&.*

for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'' (86 FR 36322 through 36437), referred to as the ''CY 2022 ESRD PPS proposed rule,'' was published in the **Federal Register** on July 9, 2021, with a comment period that ended on August 31, 2021. In that proposed rule, we proposed to update the AKI dialysis payment rate for CY 2022. We received 6 public comments on our proposal from large dialysis organizations, a non-profit dialysis association, a professional association, a provider advocacy organization, and a healthcare group.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for CY 2022 payment for renal dialysis services furnished to individuals with AKI.

C. Annual Payment Rate Update for CY 2022

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, including the applicable annual productivity-adjusted market basket payment update, geographic wage adjustments, and any other discretionary adjustments, for such year. We note that ESRD facilities could 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.1.d of this final rule, the CY 2022 ESRD PPS base rate is $257.90, which reflects the application of the CY 2022 wage index budget-neutrality adjustment factor of 0.99985 and the CY 2022 ESRDB market basket increase of 2.4 percent reduced by the productivity adjustment of 0.5 percentage point, that is, 1.9 percent. Accordingly, we are finalizing a CY 2022 per treatment payment rate of $257.90 for renal dialysis services furnished by ESRD facilities to individuals with AKI. This payment rate is further adjusted by the wage index, as discussed in the next section of this final rule.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRD bundled market basket and reduced by the productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS and discussed in section II.B.1.b of this final rule. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that facility (81 FR 77868). 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 previously, we are finalizing a CY 2022 AKI dialysis payment rate of $257.90, adjusted by the ESRD facility's wage index.

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

Comment: Several commenters, including a large dialysis organization and a professional association, commented in support of the proposed update to the AKI dialysis payment rate for CY 2022. They also expressed support for using the same methodology as in previous years for the AKI update. A large dialysis organization expressed specific appreciation for the detailed explanation of the CMS process and methodology to develop the AKI payment amount that has been included in prior rules. This organization noted that CMS has recognized that treatment for AKI differs from treatment for ESRD. The organization stated that although the services provided to AKI patients may be the same, their frequency may exceed those typically required by patients with ESRD. The organization also noted that in the CY 2017 ESRD PPS final rule, CMS indicated that it planned to make available public use files on utilization of services by AKI patients once the agency had compiled one full year of claims. The organization stated that CMS subsequently reported that the agency would continue to monitor utilization trends of items and services furnished to individuals with AKI. Along with other commenters, the large dialysis organization supports the data collection effort and CMS's commitment to ensure a data-driven approach to developing methodological changes to the AKI's rate development. The commenters urged CMS to share its monitoring plans to allow the public to better understand the specific data elements that CMS is collecting and analyzing.

Response: We appreciate the comments in support of the AKI payment rate update. As the commenter stated, we have been monitoring the trends of AKI beneficiaries in ESRD facilities and acute inpatient hemodialysis. This has included quantification of drugs, laboratory tests and other services provided on acute inpatient dialysis claims. We also examine other diagnoses recorded before an acute inpatient dialysis claim.

During the TEP held in December 2020, we reviewed dialysis-related costs, resource utilization and characteristics of the AKI–D (outpatient dialysis for patients with AKI) population beginning January 1, 2017, when their outpatient dialysis treatment first became eligible under the ESRD PPS claims. That report can be found at the following link: *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.* As we continue to analyze costs, utilization and patient characteristics, we will also examine data as it relates to an additional site of service for AKI patients. We will also incorporate additional data monitoring for COVID–19 patients who have experienced AKI. The results of the data analysis will be shared in the future in public use files on the ESRD PPS website.

Final Rule Action: We are finalizing the AKI payment rate as proposed, that is, the AKI payment rate is based on the finalized ESRD PPS base rate. Specifically, the final CY 2022 ESRD PPS base rate is $257.90. Accordingly, we are finalizing a CY 2022 payment rate of $257.90 for renal dialysis services furnished by ESRD facilities to individuals with AKI.

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

A. Background

For a detailed discussion of the End-Stage Renal Disease Quality Incentive Program's (ESRD QIP's) background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the following final rules:

- CY 2011 ESRD PPS final rule (75 FR 49030),
- CY 2012 ESRD PPS final rule (76 FR 628),
- CY 2012 ESRD PPS final rule (76 FR 70228),
- CY 2013 ESRD PPS final rule (77 FR 67450),
- CY 2014 ESRD PPS final rule (78 FR 72156),
- CY 2015 ESRD PPS final rule (79 FR 66120),
- CY 2016 ESRD PPS final rule (80 FR 68968),

- CY 2017 ESRD PPS final rule (81 FR 77834),
- CY 2018 ESRD PPS final rule (82 FR 50738),
- CY 2019 ESRD PPS final rule (83 FR 56922),
- CY 2020 ESRD PPS final rule (84 FR 60648), and
- CY 2021 ESRD PPS final rule (85 FR 71398).

We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and 413.178.

B. Extraordinary Circumstances Exception (ECE) Previously Granted for the ESRD QIP Including Notification of ECE Due to ESRD Quality Reporting System Issues

1. Extraordinary Circumstance Exception (ECE) Previously Granted in Response to the COVID–19 PHE

On March 22, 2020, in response to the COVID–19 PHE, we announced relief for clinicians, providers, hospitals, and facilities participating in Medicare quality reporting and value-based purchasing programs.[111] On March 27, 2020, we published a supplemental guidance memorandum that described the scope and duration of the ECEs we were granting under each Medicare quality reporting and value-based purchasing (VBP) program.[112] Each of these ECEs relieved these providers and facilities of their obligation to report data for Q4 CY 2019, Q1 and Q2 CY 2020, but we stated that we would score such data if optionally reported.

The September 2020 IFC updated the ECE we granted in response to the COVID–19 PHE for the ESRD QIP and several other quality reporting programs (85 FR 54827 through 54838).

In the IFC, we updated the ECE policy for the ESRD QIP (85 FR 54828 through 54830). First, we updated our regulations at § 413.178(d)(7) to state that a facility has opted out of the ECE for COVID–19 with respect to the reporting of Q4 CY 2019 NHSN data if the facility actually reported the data by the March 31, 2020 deadline but did not notify CMS that it would do so. Additionally, we finalized that facilities would not have the option to opt-out of the ECE we granted with respect to Q1 and Q2 2020 ESRD QIP data. We stated that measures calculated using excepted data could affect the national comparability of these data due to the geographic differences of COVID–19 incidence rates and hospitalizations along with different impacts resulting from different State and local law and policy changes implemented in response to COVID–19, and therefore may not provide a nationally comparable assessment of performance in keeping with the program goal of national comparison.

In the September 2020 IFC, we welcomed public comments on our policy to update our regulations at § 413.178(d)(7) to consider a facility as having opted out of the ECE with respect to NHSN data reported for Q4 2019 if the facility actually reported the data by the submission deadline, without notifying CMS, and on the exception we finalized to the ECE opt out policy for the ESRD QIP to exclude any ESRD QIP data that facilities optionally reported during Q1 and Q2 2020 from our calculation of PY 2022 TPSs and from the baseline for PY 2023. The comments we received on these policies and our responses are set forth below.

Comment: Several commenters supported CMS' updated application of the ECE granted in response to the PHE due to COVID–19. A few commenters also agreed with CMS' concerns regarding the national comparability of data from Q1 and Q2 of CY 2020 and noted that the integrity and validity of any measurement calculations associated with these data could be compromised.

Response: We thank commenters for their support.

Comment: A few commenters expressed strong concern that the data collected under the ESRD QIP will not adequately reflect the quality of care provided due to the impact of COVID–19 and the shortened data collection period. A few commenters noted that the data collected under the ESRD QIP for 2020 will be limited due to the COVID–19 PHE and the nationwide ECE excluding Q1 and Q2 data from consideration, and will undermine the reliability of measure results for scoring purposes. A few commenters recommended that CMS suspend penalties and payment adjustments for the 2020 performance year, expressing concern that the data collected under the ESRD QIP will not adequately reflect the quality of care provided due to the impact of the COVID–19 PHE and the nationwide ECE.

Response: We share commenters' concerns regarding the potential impact on ESRD QIP measure calculations for PY 2022 due to the COVID–19 PHE and the shortened data collection period resulting from the nationwide ECE. In order to avoid unfairly penalizing facilities based on data that may not accurately reflect the quality of care provided due to circumstances beyond their control, in section IV.D of this final rule we are finalizing our proposal to adopt a special scoring and payment policy for PY 2022, under which we will not score or apply payment reductions to any ESRD facilities for PY 2022 under the ESRD QIP.

Comment: A few commenters expressed strong support for extending the ECE through the end of 2020, noting the continuing impact of COVID–19 on dialysis facilities. A few commenters also noted that COVID–19 case rates were higher in Q3 and Q4 of 2020 for patients attributed to dialysis facilities in certain geographic regions, and that these higher case rates may have affected performance scores under ESRD QIP.

Response: We agree that the impact of COVID–19 on dialysis facilities in 2020 has affected our ability to accurately measure their performance. We resumed data collection for the ESRD QIP on July 1, 2020 because we believe that collecting ESRD QIP measure data is important in order to better understand the impact of COVID–19 on the data as it relates to factors such as the changing geographic differences in COVID–19 incidence and the quality of ESRD care provided to Medicare beneficiaries. However, to avoid unfairly penalizing facilities based on data that may not accurately reflect their quality of care, we are finalizing a measure suppression policy for the duration of the COVID–19 PHE and a special scoring and payment policy for PY 2022 in sections IV.C. and IV.D. of this final rule.

Comment: One commenter expressed support for CMS' intention to provide subregulatory notice of decisions surrounding payment adjustments and penalties under the ESRD QIP.

Response: In the September 2020 IFC, we stated that in the interest of time and transparency, we may provide subregulatory advance notice of our intentions regarding payment adjustments and penalties (85 FR 54830). However, we would like to clarify that we would use rulemaking to propose any actual modifications to the ESRD QIP scoring and payment adjustment methodologies and that we

[111] CMS, Press Release, CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID–19 (Mar. 22, 2020), *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

[112] CMS, Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19 (Mar. 27, 2020), *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

are using this final rule to finalize our scoring and payment adjustment policy for PY 2022.

Comment: One commenter requested that CMS provide further guidance to facilities regarding the criteria for requesting an ECE during a pandemic.

Response: The criteria for requesting an ECE under the ESRD QIP during a pandemic are the same as the criteria for requesting an ECE under the ESRD QIP due to other extraordinary circumstances beyond a facility's control. These requirements can be found in our regulations at 42 CFR 413.178(d)(3) through (7). Under these requirements, a facility may request an ECE within 90 days of the extraordinary circumstance occurring and must submit an ECE request form to CMS with the following information:

(i) Facility CCN.

(ii) Facility name.

(iii) CEO name and contact information.

(iv) Additional contact name and contact information.

(v) Reason for requesting an exception.

(vi) Dates affected.

(vii) Date the facility will start submitting data again, with justification for this date.

(viii) Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper, and other media articles.

In certain circumstances, such as a determination that an extraordinary circumstance has occurred that affects an entire region or locale, CMS may grant exceptions to facilities without a request. We note that facilities may also reject an ECE granted by CMS under certain circumstances. Technical details can be viewed on the QualityNet website.[113]

As established in the September 2020 IFC, we have finalized our updated application of the ECE granted in response to the COVID–19 PHE.

2. ECE Due to ESRD Quality Reporting System (EQRS) Issues

On November 9, 2020,[114] we launched the ESRD Quality Reporting System (EQRS). The EQRS contains the functionalities of the following three legacy ESRD Systems in one global application: (1) A quality measure and VBP performance score review system (ESRD QIP System); (2) an ESRD patient registry and quality measure reporting system through the Consolidated Renal Operations in a Web-enabled Network (CROWNWeb); and (3) Medicare coverage determination support through the Renal Management Information System (REMIS). The transition to EQRS supports our efforts to consolidate the functionalities of the CROWNWeb, ESRD QIP System, and REMIS applications into a single system, and aims to provide ongoing support to the ESRD user community to foster accurate and timely monthly data submission. This migration eliminates the need for multiple user accounts, and will in the long-term also improve the overall user experience and reduce burden due to enhanced navigation features.

In order to access EQRS, all authorized users must create an account with the Health Care Quality Information Systems (HCQIS) Access Roles and Profile, known as HARP, which is a secure identity management portal provided by CMS. Previously, users created separate accounts for each ESRD application through CMS' Enterprise Identity Data Management (EIDM) system. Creating an account via HARP provides users with a user ID and password that can be used to access many CMS applications. It also provides a single location for users to modify their profile, change their password, update their challenge question, and add or remove two-factor authentication devices. Users can register for a HARP account by going to the QualityNet HARP Registration page, available at *https://harp.cms.gov/register/profile-info*.

We stated in the CY 2022 ESRD PPS proposed rule (86 FR 36348) that since the launch of EQRS, several critical data submission issues had been identified that impact the overall quality and accuracy of data available to support the implementation of the ESRD QIP, and we suspended all clinical data submissions into EQRS to allow time to resolve the issue.[115] Based on our assessment, the data submission issues only impacted ESRD QIP, Dialysis Star Ratings, Dialysis Facility Compare and data submitted for ESRD Network quality improvement activities. In the proposed rule, we noted that we had analyzed the data submission issues and stated our belief that the data systems issues would be resolved on or about July 12, 2021.[116]

We recognized that these operational systems issues would prevent facilities from submitting ESRD QIP clinical data until the data systems issues were resolved. Therefore, we announced a blanket extension of remaining CY 2020 clinical reporting deadlines (86 FR 36348 through 36349). Under this extension, facilities would have until September 1, 2021 to submit September through December 2020 ESRD QIP clinical data. In the proposed rule (86 FR 36348), we stated our belief that this reporting extension aligned with the time estimated for resolution of our operational systems issues and would give dialysis facilities nearly 7 weeks to submit their data to EQRS. We stated that we would provide further details to facilities when the EQRS issues were resolved, as well as when facilities could begin submitting their data for CY 2020 and CY 2021, through routine communication channels to facilities, vendors, Quality Improvement Organizations (QIOs) and ESRD Networks. We stated that the communications could include memos, emails, and notices on the public QualityNet website (*https://www.qualitynet.org/*). As this situation was ongoing at the time, we stated in the proposed rule that we would announce any relevant extension deadlines and data submission requirements for impacted CY 2021 data through the routine communication channels discussed above. On September 3, 2021, we announced that the September 1, 2021 data submission deadline for September-December 2020 clinical data had been extended to September 15, 2021 in order to give facilities additional time to submit their data.[117]

Because the current data submissions issue would not be resolved until or about July 12, 2021 and had impacted all facilities that participate in ESRD QIP, we stated our belief that granting a blanket ECE to all facilities without a request under 42 CFR 413.178(d)(6)(ii) was the appropriate remedy under these circumstances. We also stated our belief that requiring facilities to report the CY 2020 data impacted by this ECE by September 1, 2021 was reasonable. In our data suspension announcements, we noted that facilities were expected to continue to use EQRS to collect clinical data to complete tasks such as admit and discharge patients, complete CMS

[113] *https://qualitynet.cms.gov/esrd/esrdqip/participation#tab5.*

[114] *https://mycrownweb.org/2020/11/november-2020-newsletter/.*

[115] *https://mycrownweb.org/2021/02/eqrs-data-reporting-update-feb-2021/.*

[116] On July 9, 2021, we announced that the EQRS data suspension will be concluded as of July 12, 2021, and that EQRS testing had been performed to ensure that the system is working as expected. *https://mycrownweb.org/2021/07/eqrs-data-reporting-to-resume/.*

[117] *https://mycrownweb.org/2021/09/clarified-eqrs-2020-data-submission-deadline-extension-2021-clinical-data-submission-deadline/.* We also have provided additional information at: *https://mycrownweb.org/wp-content/uploads/2021/07/FAQ_Resuming-2020_2021Clinical-Data-Submission_Final_508.pdf.*

forms (such as the CMS–2728: End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration, CMS–2744: End Stage Renal Disease Annual Facility Survey Form, and CMS–2746: ESRD Death Notification), add or update treatment summaries, resolve notifications within a timely manner, and should also continue to keep facilities' information up-to-date.[118] In other words, although facilities were unable to submit clinical data through EQRS, facilities were advised that they must continue to collect the clinical data.

In the proposed rule (86 FR 36349), we stated that while we were working to resolve all known systems issues by July 12, 2021 and reopen submissions so that facilities may submit their September through December 2020 ESRD QIP data no later than September 1, 2021, we would only be able to ensure the validity of the impacted data after they are submitted. Given that the system issues experienced during the initial implementation of the EQRS, if not fully resolved, could potentially impact the accuracy and reliability of the data reported, we were concerned that facilities may be unfairly penalized because the current systems issues may impact the quality of the data. The EQRS system issues had resulted in multiple or incorrect dates of patient admissions and/or discharges, as well as showing duplicate patient records. Facilities had also expressed concerns about their experience with EQRS issues, noting that there was no way for a facility to verify accuracy or completeness. They had reported issues including missing record status in response files, which meant that facilities did not know if the records were accepted or received an error response, and issues with determining whether clinical data were accepted because the information did not show in the user interface or the reports that facilities were receiving from EQRS.

We stated in the proposed rule that we recognized stakeholders' concerns about the potential impact to the quality of data for CY 2020. We stated our belief that the observed system issues, and any unresolved issues that may be identified only after data submissions are resumed, could impact the quality and accuracy of the data needed to calculate accurate ESRD QIP scores used for PY 2022 ESRD QIP calculations because patient admittance dates, discharge dates, record status in response files, clinical data, and the number of active patient cases are data points that are included in measure calculations for all of the PY 2022 ESRD QIP measures. If these data points were incorrect, then this would impact our ability to accurately calculate measures and would distort a facility's measure performance.

Therefore, because of the EQRS system issues described above, and additionally, due to the impact of the COVID–19 PHE on some of the PY 2022 ESRD QIP measures, as described more fully in section IV.C. of this final rule, we proposed to not score or award a TPS to any facility, or reduce payment to any facility, in PY 2022. As discussed more fully in section IV.D below, we are finalizing that proposal in this final rule.

Although we considered if there may be any alternative data sources for the measures impacted by these EQRS system issues, we concluded that this was not feasible for several reasons. First, all 14 ESRD QIP measures for PY 2022 were impacted by these system issues. Although certain measures do not require that facilities submit clinical data into EQRS, we use EQRS data to determine whether a facility has treated a sufficient number of patients in order to meet the measure's minimum patient case threshold necessary to calculate the measure for ESRD QIP. For example, the National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) clinical measure requires that facilities report data to NHSN. However, the measure also has a requirement to exclude facilities that do not treat at least 11 eligible in-center hemodialysis patients during the 12 month performance period. In order to determine whether a facility has treated at least 11 eligible patients, we use EQRS admission data and Medicare claims data in order to determine whether the facility is eligible to receive a score on the measure.[119]

We ultimately decided to propose the special rule for PY 2022, as described further, because not only do these system issues impact all ESRD QIP measures, which could lead to distorted performance scores and unfair penalties, but we also wanted to provide facilities with the business certainty they need regarding their PY 2022 payments. In order to determine whether all data quality issues have been resolved when EQRS reopens for data submissions, we stated that we would need time to validate the impacted data after facilities are able to resume data submission. Due to the timing of this reporting extension, we stated our belief that there were no feasible alternative data sources for PY 2022. Therefore, we stated that the scoring and payment modifications we proposed for PY 2022 were appropriate in this situation.

Comment: Several commenters expressed appreciation and support for the reporting extension granted due to EQRS issues. A few commenters noted that facilities have experienced challenges with reporting data to EQRS and that the extension is helpful particularly as facilities continue to also address the impact of the COVID–19 PHE.

Response: We thank the commenters for their support.

Comment: A few commenters requested that CMS extend the reporting extension to the end of CY 2021, noting the ongoing COVID–19 PHE and continued challenges with data reporting. One commenter expressed the belief that extending the reporting deadline to the end of CY 2021 will help to ensure the accuracy and completeness of the data submitted. One commenter expressed concern that EQRS issues may not be fully resolved by the anticipated deadline, and requested that CMS issue further flexibilities if necessary.

Response: Although we initially extended the data submission deadline to September 1, 2021, we subsequently extended that deadline to September 15, 2021 in order to give facilities additional time to submit their data. We note that all outstanding EQRS issues have been resolved and we reopened access to EQRS on July 12, 2021. We believe that 2 months was sufficient time for facilities to report September through December 2020 ESRD QIP data.

Comment: A few commenters expressed support for the issuance of notifications through routine communication channels, in the event that an additional extension is granted due to unresolved EQRS issues.

Response: We thank the commenters for their support.

C. Flexibilities for the ESRD QIP in Response to the COVID–19 PHE

1. Adoption of a Measure Suppression Policy for the Duration of the COVID–19 PHE

In the CY 2022 ESRD PPS proposed rule, we stated that in previous rules, we have identified the need for flexibility in our quality measurement programs to account for changing conditions that are beyond participating facilities' or practitioners' control. We identified this need because we would like to ensure that participants in our

[118] *https://mycrownweb.org/2021/02/eqrs-data-reporting-update-feb-2021/.*

[119] *https://www.cms.gov/files/document/cy-2021-final-technical-specifications-20201130.pdf.*

programs are not affected negatively when their quality performance suffers for reasons not due to the care provided, but instead due to external factors.

A significant example of the type of external factor that may affect quality measurement is the COVID–19 PHE, which has had, and continues to have, significant and ongoing effects on the provision of medical care in the country and around the world. The COVID–19 pandemic and associated PHE have impeded effective quality measurement in many ways. Changes to clinical practices to accommodate safety protocols for medical personnel and patients, as well as unpredicted changes in the number of stays and facility-level case mixes, have affected the data used in quality measurement and the resulting quality scores. Measures used in the ESRD QIP need to be evaluated to determine whether their specifications need to be updated to account for new clinical guidelines, diagnosis or procedure codes, and medication changes that we have observed during the PHE. Additionally, because COVID–19 prevalence is not consistent across the country, dialysis facilities located in different areas have been affected differently at different times throughout the pandemic. Under those circumstances, we stated in the proposed rule that we remain significantly concerned that the ESRD QIP's quality measure scores that are calculated using data submitted during the PHE for COVID–19 will be distorted and will result in skewed payment incentives and inequitable payments, particularly for dialysis facilities that have treated more COVID–19 patients than others.

We further stated that it is not our intention to penalize dialysis facilities based on measure scores that we believe are distorted by the COVID–19 pandemic and, thus, not reflective of the quality of care that the measures in the ESRD QIP were designed to assess. As previously discussed, the COVID–19 pandemic has had, and continues to have, significant and enduring effects on health care systems around the world, and affects care decisions, including those made on clinical topics covered by the ESRD QIP's measures. As a result of the COVID–19 PHE, dialysis facilities could provide care to their patients that meets the underlying clinical standard but results in worse measured performance, and by extension, payment penalties in the ESRD QIP. We also stated that we are concerned that regional differences in COVID–19 prevalence during the performance period for PY 2022 have directly affected dialysis facilities' measure scores on the ESRD QIP for PY 2022. Although these regional differences in COVID–19 prevalence rates do not reflect differences in the quality of care furnished by dialysis facilities, they could directly affect the payment penalties that these facilities could receive and could result in an unfair and inequitable distribution of those penalties. These inequities could be especially pronounced for dialysis facilities that have treated a large number of COVID–19 patients.

We therefore proposed to adopt a policy for the duration of the COVID–19 PHE that would enable us to suppress the use of ESRD QIP measure data for all facilities if we determine that circumstances caused by the COVID–19 PHE have affected those measures and the resulting total performance scores (TPSs) significantly (86 FR 36350). We also proposed to suppress certain measures for the PY 2022 program year because we have determined that circumstances caused by the COVID–19 PHE have affected those measures significantly. In addition, due to both the impacts of the COVID–19 PHE on certain measures and the EQRS system issues described in section IV.B.2. we proposed to adopt a special scoring and payment rule for PY 2022, as described more fully in section IV.D.

In developing the proposed policy, we considered what circumstances caused by the COVID–19 PHE would affect a quality measure significantly enough to warrant its suppression in a value-based purchasing (VBP) program. We stated our belief that a significant deviation in measured performance that can be reasonably attributed to the COVID–19 PHE is a significant indicator of changes in clinical conditions that affect quality measurement. Similarly, we stated our belief that a measure may be focused on a clinical topic or subject that is proximal to the disease, pathogen, or other health impacts of the PHE. As has been the case during the COVID–19 pandemic, we stated our belief that rapid or unprecedented changes in clinical guidelines and care delivery, potentially including appropriate treatments, drugs, or other protocols may affect quality measurement significantly and should not be attributed to the participating facility positively or negatively. We also noted that scientific understanding of a particular disease or pathogen may evolve quickly during an emergency, especially in cases of new disease or conditions. Finally, we stated our belief that, as evidenced during the COVID–19 pandemic, national or regional shortages or changes in health care personnel, medical supplies, equipment, diagnostic tools, and patient case volumes or case mix may result in significant distortions to quality measurement.

Based on these considerations, we developed a number of Measure Suppression Factors that we believe should guide our determination of whether to propose to suppress ESRD QIP measures for one or more payment years that overlap with the COVID–19 PHE. We proposed to adopt these Measure Suppression Factors for use in the ESRD QIP and, for consistency, the following other VBP programs: Hospital VBP Program, Hospital Readmissions Reduction Program, Hospital-Acquired Condition (HAC) Reduction Program, and Skilled Nursing Facility VBP Program (see, for example, 86 FR 25460 through 25462, 25470 through 25472, and 25497 through 25499). We stated our belief that these Measure Suppression Factors will help us evaluate measures in the ESRD QIP and that their adoption in the other VBP programs noted previously will help ensure consistency in our measure evaluations across programs. The proposed Measure Suppression Factors are as follows:

- *Factor 1:* Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
- *Factor 2:* Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the COVID–19 PHE.
- *Factor 3:* Rapid or unprecedented changes in:
  - ++ Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or
  - ++ the generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.
- Factor 4: Significant national shortages or rapid or unprecedented changes in:
  - ++ Healthcare personnel;
  - ++ medical supplies, equipment, or diagnostic tools or materials; or
  - ++ patient case volumes or facility-level case mix.

In the CY 2022 ESRD PPS proposed rule, we also considered alternatives to this proposed policy that could fulfill our objective to not penalize dialysis facilities for measure results that are distorted due to the COVID–19 PHE. As previously noted, the country continues to grapple with the effects of the COVID–19 pandemic, and in March

2020, CMS issued a nationwide, blanket Extraordinary Circumstances Exception (ECE) for all hospitals and other facilities participating in our quality reporting and VBP programs in response to the COVID–19 PHE. This blanket ECE excepted all data reporting requirements for Q1 and Q2 2020 data, including claims data and data collected through the CDC's web-based surveillance system for this data period, and quality data collection resumed on July 1, 2020. For claims-based measures, we also stated that we would exclude all qualifying Q1 and Q2 2020 claims from our measure calculations. We considered extending this blanket ECE that we issued for Q1 and Q2 2020 to also include Q3 and Q4 2020. This alternative would have protected providers and suppliers from having their quality data used for quality scoring purposes if those data were likely to have been affected significantly by the COVID–19 PHE. However, this option would have made quality data collection and reporting to CMS no longer mandatory and would have left us with no comprehensive data available to provide confidential performance feedback to providers nor for monitoring and to inform decision-making for potential future programmatic changes, particularly as the PHE is extended.

As an alternative to the proposed quality measure suppression policy, we also considered not suppressing any measures under the ESRD QIP. However, this alternative would mean assessing dialysis facilities using quality measure data that has been significantly affected by the COVID–19 pandemic. Additionally, given the geographic disparities in the COVID–19 pandemic's effects, we stated in the proposed rule that implementation of the PY 2022 ESRD QIP as previously finalized would place dialysis facilities in regions that were more heavily impacted by the pandemic in Q3 and Q4 of 2020 at a disadvantage compared to facilities in regions that were more heavily impacted during the first two quarters for CY 2020 (86 FR 36350 through 36351).

We stated in the proposed rule that we viewed this measure suppression proposal as a necessity to ensure that the ESRD QIP does not penalize facilities based on external factors that were beyond the control of facilities. We intended for this proposed policy to provide short-term relief to dialysis facilities when we have determined that one or more of the Measure Suppression Factors warrants the suppression of an ESRD QIP measure.

We welcomed public comments on this proposal for the adoption of a measure suppression policy for the duration of the COVID–19 PHE, and also on the proposed Measure Suppression Factors that we developed for purposes of this proposed policy. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for the measure suppression policy for the duration of the COVID–19 PHE. Several commenters expressed appreciation that the proposed measure suppression policy would help to address the ongoing challenges of the COVID–19 PHE. Several commenters expressed support for the proposed measure suppression policy, noting that measure scores may be distorted due to the substantial impact of the COVID–19 PHE on facility performance and that such a policy would help to avoid penalizing facilities based on potentially distorted data due to the COVID–19 PHE.

Response: We thank commenters for their support.

Comment: One commenter acknowledged the benefit of the proposed measure suppression policy, but also expressed concern regarding the exclusion of data showing the high morbidity and mortality of ESRD patients with COVID–19.

Response: Although we will not score facilities using data submitted during the ECE, we do intend to make individual facility data that was reported available to that facility so that the facility has an opportunity assess the impact of COVID–19 on its ESRD patients. We will also publicly report the measure rates with appropriate caveats. We believe that providing as much information as possible to facilities in this way while also publicly reporting performance data to the public with appropriate caveats balances fairness in our value-based purchasing programs with the public's need for transparency.

Comment: Several commenters expressed support for the proposals to address the negative impact of the pandemic on the ESRD QIP and recommended that CMS consider similar considerations for CY 2021 measure data. A few commenters strongly recommended that CMS consider extending relief under the ESRD QIP to PY 2023, citing the rise of the Delta variant and continuing impact of COVID–19 on facilities as well as the healthcare system nationwide. These commenters noted the continuing impact of the PHE on ESRD QIP measures, due both to the impact of COVID–19 on ESRD patients which may result in new hospital admissions and impact facility performance on SHR and SRR measures, as well as the strain on the healthcare system due to the influx of COVID–19 patients which may impact the availability of vascular access procedures and transplant evaluations. A few commenters noted that geographic variations in the COVID–19 PHE during CY 2021 continue to exacerbate distortions in ESRD QIP measure performance.

Response: The measure suppression policy that we are finalizing in this final rule applies for the duration of the COVID–19 PHE. We will continue to monitor the impact of the COVID–19 PHE on dialysis facilities, and we would consider proposing in a future rulemaking to suppress one or more individual ESRD QIP measures for a future ESRD QIP payment year if we conclude that circumstances caused by the COVID–19 PHE have affected those measures and the resulting TPSs based on CY 2021 data.

Comment: Several commenters expressed support for the proposed Measure Suppression Factors. Several commenters noted that they will help to mitigate the negative impact of the challenges presented by the COVID–19 PHE such as significant deviation in national performance, the distorting impact on measures themselves, changing guidelines and protocols related to the PHE, and challenges due to shortages in both medical supplies, staffing, and patient volume and case-mix on quality measures. One commenter expressed support for the proposed Measure Suppression Factors, noting that they will help to ensure consistency in measure evaluation and suppression.

Response: We thank commenters for their support.

Comment: A few commenters expressed concern regarding the proposed Measure Suppression Factors. One commenter expressed concern that proposed Measure Suppression Factor 2 may overlook indirect or downstream clinical impacts that may not be considered ''proximate,'' noting for example the impact of the COVID–19 PHE shutdown on non-urgent scheduled vascular placement procedures leading to reduced catheter insertions and fistula rates as well as a delay in patient follow up regarding such procedures due to patient fears of COVID–19 exposure. One commenter expressed concern that proposed Measure Suppression Factor 4 does not sufficiently address regional or State-by-State impacts on personnel, patient volumes or case-mix, and medical

supplies or equipment, and recommended that CMS broaden application of its scope to include sub-national, regional, and State impacts. One commenter recommended that CMS consider under Measure Suppression Factor 4 the impact of healthcare personnel shortages on ESRD facilities as a result of the COVID–19 PHE. One commenter recommended that CMS consider including under Measure Suppression Factor 4 circumstances where there is a statistically meaningful lower denominator from prior years due to factors outside of a facility's control, such as changes in demographics.

Response: We developed the Measure Suppression Factors based on several considerations specifically related to the PHE for COVID–19, including national, regional, and State impacts. For example, we note that Measure Suppression Factor 4 addresses healthcare shortages in personnel as well as patient volumes and facility-level case mix. We believe the Measure Suppression Factors we are adopting for the COVID–19 PHE are sufficient to guide us in identifying whether circumstances caused by the COVID–19 PHE have affected ESRD QIP measures and the resulting TPSs.

Comment: One commenter recommended adding an additional measure suppression factor to suppress a measure in cases where the measure denominator is statistically meaningfully lower due to circumstances beyond the facility's control such as COVID–19 mortality, noting that this may significantly also impact measure performance.

Response: We believe that the commenter's suggestion would be captured by the proposed Measure Suppression Factor 4. As we discussed in the proposed rule (86 FR 36350), we developed these suppression factors to assess changing conditions due to the COVID–19 PHE and proposed them consistently in several of our value-based purchasing programs. As we stated above, we believe the Measure Suppression Factors we are adopting for the COVID–19 PHE are sufficient to guide us in identifying whether circumstances caused by the COVID–19 PHE have affected ESRD QIP measures and the resulting TPSs.

Comment: A few commenters expressed support for the proposal to provide confidential feedback reports to dialysis facilities under the proposed measure suppression policy, noting that it will allow facilities to focus on performance improvement and also allow CMS to track developments in the field.

Response: We thank the commenters for their support and note that we are finalizing this proposal in this final rule.

Comment: One commenter expressed support for the public reporting of performance scores from CY 2020 with appropriate caveats.

Response: We thank the commenter for its support.

Comment: A few commenters did not support the public reporting of suppressed measures, noting reliability concerns due to the impact of the COVID–19 PHE on measure data.

Response: We believe it is important to balance fairness with the public's need for transparency. Therefore, we intend to make the data publicly available. In order to address concerns about publicly reporting data that was collected by facilities during the COVID–19 PHE, we will appropriately caveat the publicly displayed data for suppressed measures to note that the measures have been suppressed for purposes of scoring and payment adjustments because of the effects of the COVID–19 PHE. We believe these caveats will mitigate any public confusion that could otherwise result from the display.

Final Rule Action: After considering public comments, we are finalizing our proposal to adopt a measure suppression policy for the duration of the COVID–19 PHE. We are also finalizing the proposed Measure Suppression Factors that we proposed for purposes of this measure suppression policy. We will also publicly report the data with appropriate caveats.

2. Suppression of Four ESRD QIP Measures for PY 2022

a. Background

In response to the PHE for COVID–19, we conducted analyses of the 14 current ESRD QIP measures to determine whether and how COVID–19 may have impacted the validity of these measures. For the reasons discussed in the CY 2022 ESRD PPS proposed rule, we concluded that COVID–19 has so severely impacted the validity of four measures that we believe we cannot fairly and equitably score these measures for the PY 2022 program year. Accordingly, we proposed to suppress these measures for the PY 2022 program year for all ESRD QIP participants (86 FR 36351). Specifically, the measures we proposed to suppress for the PY 2022 ESRD QIP are as follows:

- SHR clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years; and Measure Suppression Factor 4, Significant national shortages or rapid or unprecedented changes in:
  ++ healthcare personnel;
  ++ medical supplies, equipment, or diagnostic tools or materials; or
  ++ patient case volumes or facility-level case mix);
- Standardized Readmission Ratio (SRR) clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years; and Measure Suppression Factor 4, Significant national shortages or rapid or unprecedented changes in:
  ++ healthcare personnel;
  ++ medical supplies, equipment, or diagnostic tools or materials; or
  ++ patient case volumes or facility-level case mix);
- In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years); and
- Long-Term Catheter Rate clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years).

We received comments on additional measures that we should consider suppressing and address them below.

Comment: Several commenters recommended that we suppress the Standardized Fistula Rate measure. A few commenters noted that the Standardized Fistula Rate measure and the Long-Term Catheter Rate measure are both Hemodialysis Vascular Access measures, but only the Long-Term Catheter Rate measure is proposed for suppression. A few commenters noted that AV fistula placements may have been delayed because it was not clear whether such procedures were considered an ''elective surgery'' in the beginning of the PHE and also because

ESRD patients may have delayed or avoided medical treatments because of COVID–19 concerns. Several commenters recommended that CMS suppress the Percentage of Prevalent Patients Waitlisted (PPPW) measure, noting that the COVID–19 PHE had a significant negative impact on transplant surgeries, referrals and waitlists, as well as other related areas. A few commenters also noted that waitlist additions significantly decreased during the COVID–19 PHE.

A few commenters recommended that CMS consider suppressing the Kt/V Dialysis Adequacy measure, noting that the impact of the COVID–19 PHE on catheter rates has a corresponding impact on the Kt/V measure, as patients with catheters will have lower Kt/V rates. One commenter recommended suppressing the Kt/V Dialysis Adequacy measure under proposed Measure Suppression Factor 1, due to significant deviation in national measure performance. One commenter recommended that CMS suppress the NHSN BSI clinical measure under Measure Suppression Factor 3 and Factor 4, noting that challenges in care delivery and treatment related to catheter removal and AVF insertion resulted in an increased likelihood of patient infection, as well as an increase in patient volume and case-mix due to COVID–19 patients developing AKI and requiring catheterization.

Response: At the time of the proposed rule, there was not sufficient data to determine whether suppression was appropriate for the Standardized Fistula Rate measure, the PPPW measure, the Kt/V Dialysis Adequacy measure, or the NHSN BSI clinical measure. We note that the status of the data remains unchanged since the proposed rule was published. Although we agree with commenters that performance on the Standardized Fistula Rate measure is linked to measure performance on the Long-Term Catheter Rate measure, the data that was available at the time of the proposed rule indicated that the COVID–19 PHE had a comparatively lower impact on the Standardized Fistula Rate measure.

For the PPPW measure, our analysis of the relevant data available at the time of the proposed rule indicated temporal declines in waitlist removal among prevalent patients and similarly a decline in waitlisting and transplants in incident ESRD patients in March 2020 through May 2020 compared to prior years. However, we also observed that trends generally returned to normal starting in June and July 2020 and reflected data similar to prior years.

Although performance on the Kt/V Dialysis Adequacy measure deviated temporarily, our analysis indicated that Kt/V rates stabilized shortly thereafter and reflect measure performance similar to prior years. Based on our analysis, Kt/V rates in CY 2020 were similar to rates in CY 2019 until April, where they dropped by an average of 0.4 percent. However, beginning in June 2020, Kt/V rates were the same as or higher than national average rates in March 2020.

We were unable to assess the impact of the COVID–19 PHE on the NHSN BSI clinical measure, which requires a full 12 months of data in order to calculate measure performance. The CDC will not be able to calculate measure performance for the NHSN BSI clinical measure because the nationwide ECE granted in response to the COVID–19 PHE excepted data from Q1 and Q2 of CY 2020. As a result, facilities will not receive scores for the NHSN BSI clinical measure. We also note that suppressing the NHSN BSI clinical measure would be unlikely under Measure Suppression Factor 3 and Factor 4, as the links between those factors and the impacts on measure performance cited by the commenter are not sufficiently direct. Although challenges in care delivery and treatment related to catheter removal and AVF insertion resulted in an increased likelihood of patient infection, as well as an increase in patient volume and case-mix due to COVID–19 patients developing AKI and requiring catheterization, neither of those directly caused patients to develop more bloodstream infections as a result of the COVID–19 PHE.

However, we will continue to monitor and review the data and consider proposing in a future rulemaking to suppress one or more individual ESRD QIP measures for a future ESRD QIP payment year if we conclude that circumstances caused by the COVID–19 PHE have affected those measures and the resulting TPSs based on CY 2021 data.

b. Suppression of the SHR clinical measure for PY 2022

In the CY 2022 ESRD PPS proposed rule (86 FR 36351 through 36352), we proposed to suppress the SHR clinical measure for the PY 2022 program year under proposed Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse as compared to historical performance during the immediately preceding program years. The SHR clinical measure is an all-cause, risk-standardized rate of hospitalizations during a 1-year observation window. The standardized hospitalization ratio is defined as the ratio of the number of hospital admissions that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of hospitalizations that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. This measure is calculated as a ratio but can also be expressed as a rate. The intent of the SHR clinical measure is to improve health care delivery and care coordination to help reduce unplanned hospitalization among ESRD patients.

Based on our analysis of Medicare dialysis patient data from January 2020 through August 2020, we found that hospitalizations involving patients diagnosed with COVID–19 resulted in higher mortality rates, higher rates of discharge to hospice or skilled nursing facilities, and lower rates of discharge to home than hospitalizations involving patients who were not diagnosed with COVID–19. Specifically, the hospitalization rate for Medicare dialysis patients diagnosed with COVID–19 was more than 7 times greater than the hospitalization rate during the same period for Medicare dialysis patients who were not diagnosed with COVID–19, which is much greater than the relative risk of hospitalization for any other comorbidity. In the proposed rule (86 FR 36351), we stated that this indicates that COVID–19 has had a significant impact on the hospitalization rate for dialysis patients. Because COVID–19 Medicare dialysis patients are at significantly greater risk of hospitalization, and the SHR clinical measure was not developed to account for the impact of COVID–19 on this patient population, we expressed our concern about the effects of the observed COVID–19 hospitalizations on the SHR clinical measure. We also noted that COVID–19 affected different regions of the country at different rates depending on factors like time of year, geographic density, State and local policies, and health care system capacity. Because of the increased hospitalization risk associated with COVID–19 and the Medicare dialysis patient population, we expressed our concern that these regional differences in COVID–19 rates have led to distorted hospitalization rates such that we could not reliably measure national performance on the SHR clinical measure.

Our analysis of the available Medicare claims data indicated that the COVID–19 PHE has had significant effects on hospital admissions of dialysis patients,

and would result in significant deviation in national performance on the measure during the COVID–19 PHE which could be significantly worse as compared to historical performance during the immediately preceding program years. Not only are there effects on patients diagnosed with COVID–19, but the presence of the virus strongly affected hospital admission patterns of dialysis patients from March 2020 to June 2020, and we expressed our concern that similar effects would be seen in the balance of the calendar year (CY) as the PHE continued. Because the COVID–19 pandemic swept through geographic regions of the country unevenly, we expressed our concern that dialysis facilities in different regions of the country would have been affected differently throughout the 2020 year, thereby skewing measure performance and affecting national comparability due to significant and unprecedented changes in patient case volumes or facility-level case mix. Given the limitations of the data available to us for CY 2020, we stated our belief the resulting performance measurement on the SHR clinical measure would not be sufficiently reliable or valid for use in the ESRD QIP.

We proposed to suppress this measure for the PY 2022 program year, rather than remove it, because we believe that the SHR clinical measure is an important part of the ESRD QIP measure set. However, we were concerned that the COVID–19 PHE affected measure performance on the current SHR clinical measure such that we would not be able to score facilities fairly or equitably on it. Additionally, we stated that we would continue to collect the measure's claims data from participating facilities so that we could monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also stated our intent to publicly report PY 2022 data where feasible and appropriately caveated.

In the proposed rule, we stated that we were currently exploring ways to adjust effectively for the systematic effects of the COVID–19 PHE on hospital admissions for the SHR clinical measure. However, we are still working to improve these COVID–19 adjustments and verify the validity of a potential modified version of the SHR clinical measure as additional data become available. As an alternative, we considered whether we could exclude patients with a diagnosis of COVID–19 from the SHR clinical measure cohort, but we determined suppression will provide us with additional time and additional months of data potentially impacted by COVID–19 to more thoroughly evaluate a broader range of alternatives. We want to ensure that the measure reflects care provided to Medicare dialysis patients and we are concerned that excluding otherwise eligible patients may not accurately reflect the care provided, particularly given the unequal distribution of COVID–19 patients across facilities and hospitals over time. As an alternative approach, we stated that we also might consider updating the specifications for the SHR clinical measure to eliminate any exposure time and events after infection for patients who contract COVID–19, as COVID–19 symptoms may continue to affect patients after infection. We stated our belief that this approach might help distinguish between ESRD-related hospitalizations and COVID–19 related hospitalizations that might otherwise impact SHR clinical measure calculations.

We welcomed public comment on our proposal to suppress the SHR clinical measure for PY 2022. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for the proposal to suppress the SHR clinical measure for PY 2022, agreeing that the COVID–19 PHE has impacted the validity and reliability of performance scoring for PY 2022.

Response: We thank the commenters for their support.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the SHR clinical measure for PY 2022.

c. Suppression of the SRR Clinical Measure for PY 2022

In the CY 2022 ESRD PPS proposed rule (86 FR 36352 through 36353), we proposed to suppress the SRR clinical measure for the PY 2022 program year under proposed Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. The SRR assesses the number of readmission events for the patients at a facility, relative to the number of readmission events that would be expected based on overall national rates and the characteristics of the patients at that facility as well as the number of discharges. The intent of the SRR clinical measure is to improve care coordination between dialysis facilities and hospitals to improve communication prior to and post discharge.

Based on our analysis, we found that index discharge hospitalizations involving dialysis patients diagnosed with COVID–19 resulted in lower readmissions and higher mortality rates within the first 7 days. We used index hospitalizations occurring from January 1, 2020 through June 30, 2020 to identify eligible index hospitalizations and unplanned hospital readmissions. In an analysis of unadjusted readmission and death rates by COVID–19 hospitalization status and days since index discharge, during the first 4 to 7 days after discharge there was a readmission rate of 81.3 percent of dialysis patients hospitalized with COVID–19, as compared to 82.6 percent of dialysis patients hospitalized without COVID–19. During that same 4 to 7 day time period, the unadjusted mortality rate for dialysis patients hospitalized with COVID–19 was 16.9 percent, compared with 10.9 percent of patients hospitalized without COVID–19. Based on this discrepancy, we were concerned about the effects of these observations on the calculations for the SRR clinical measure. The denominator of SRR reflects the expected number of index discharges followed by an unplanned readmission within 4 to 30 days in each facility, which is derived from a model that accounts for patient characteristics, the dialysis facility to which the patient is discharged, and the discharging acute care or critical access hospitals involved. Our analysis indicated potential competing risks of higher mortality and lower readmissions due to patient death or discharge to hospice, both of which would remove them from the denominator for the SRR clinical measure. If readmissions rates are lower because patient mortality is higher due to the impact of COVID–19 on dialysis patients, then readmission rates would be distorted by appearing significantly better compared to historical performance during the immediately preceding program years. Based on the impact of COVID–19 on SRR results, including the deviance in measurement, we concluded that the SRR clinical measure met our criteria for Factor 1 where performance data would significantly deviate from historical data performance and would be considered unreliable. Therefore, we stated our belief that the resulting performance measurement on the SRR clinical

measure would not be sufficiently reliable or valid for use in the ESRD QIP.

We proposed to suppress this measure for the PY 2022 program year, rather than remove it, because we believe that the SRR clinical measure is an important part of the ESRD QIP Program measure set. However, we were concerned that the PHE for the COVID–19 pandemic affected measure performance on the current SRR clinical measure such that we would not be able to score facilities fairly or equitably on it. Additionally, we stated that we would continue to collect the measure's claims data from participating facilities so that we could monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also stated our intent to publicly report PY 2022 data where feasible and appropriately caveated.

In the proposed rule, we stated that we were currently exploring ways to adjust effectively for the systematic effects of the COVID–19 PHE on hospital admissions for the SRR clinical measure. However, we are still working to improve these COVID–19 adjustments and verify the validity of a potential modified version of the SRR clinical measure as additional data becomes available. As an alternative approach, we stated that we might also consider eliminating from the calculation of the SRR clinical measure any cases of patients who had a COVID–19 event prior to or at the time of index hospitalization. We stated our belief this approach might help distinguish between ESRD-related readmissions and COVID–19 related readmissions that might otherwise impact SRR clinical measure calculations.

We welcomed public comment on our proposal to suppress the SRR clinical measure for PY 2022. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for the proposal to suppress the SRR clinical measure for PY 2022, agreeing that the COVID–19 PHE has impacted the validity and reliability of performance scoring for PY 2022.

Response: We thank the commenters for their support.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the SRR clinical measure for PY 2022.

d. Suppression of the ICH CAHPS Clinical Measure for PY 2022

In the CY 2022 ESRD PPS proposed rule (86 FR 36353), we proposed to suppress the ICH CAHPS clinical measure for the PY 2022 program year under proposed Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. Based on our analysis of CY 2020 ICH CAHPS data, we found a significant decrease in response scores as compared to previous years.

The ICH CAHPS clinical measure is scored based on three composite measures and three global ratings.[120] Global ratings questions employ a scale of 0 to 10, worst to best; each of the questions within a composite measure use either ''Yes'' or ''No'' responses, or response categories ranging from ''Never'' to ''Always'' to assess the patient's experience of care at a facility. Facility performance on each composite measure is determined by the percent of patients who choose ''top-box'' responses (that is, most positive or ''Always'') to the ICH CAHPS survey questions in each domain. The ICH CAHPS survey is administered twice yearly, once in the spring and once in the fall.

Because of the ECE we granted in response to the COVID–19 PHE, facilities were not required to submit CY 2020 spring ICH CAHPS data for purposes of the ESRD QIP. On September 2, 2020, we published an interim final rule with comment (IFC) in the **Federal Register** titled, ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 54820) referred to herein as the ''September 2020 IFC''. In the September 2020 IFC, we noted that we would not use any first or second quarter CY 2020 data to calculate TPSs for the applicable performance period (85 FR 54829 through 54830). Because the PY 2022 performance period for the ICH CAHPS measure is January 1, 2020 through December 31, 2020, and the ICH CAHPS survey is administered twice a year (once in the spring and once in the fall), in the proposed rule we stated that we only have data available from the fall CY 2020 survey to calculate facility performance on this measure. Therefore, facilities would only be scored on data based on one ICH CAHPS survey administration for CY 2020, rather than two. Even if we were to score facilities based on the one ICH CAHPS survey administered in the fall, our preliminary data indicated that 95 percent of facilities would not be eligible for scoring on ICH CAHPS for CY 2020. By contrast, 58.9 percent of facilities were not eligible for ICH CAHPS during CY 2018. If we were to score the 5 percent of eligible facilities on ICH CAHPS, we stated our belief that there would be a significant deviation in national performance on this measure compared to the national performance based on 41.1 percent of facilities eligible for scoring on ICH CAHPS during 2018 (86 FR 36353). We also stated that this is a significant deviation in national performance on this measure compared to historical performance during the immediately preceding program years. Given this significant deviation in national performance during the PHE, we expressed our belief that the ICH CAHPS clinical measure meets the criteria for Measure Suppression Factor 1.

We also stated our belief that this significant change in performance may unfairly penalize facilities and that suppressing this measure for the PY 2022 program year would address concerns about the potential unintended consequences of penalizing facilities that treat COVID–19 diagnosed patients in the ESRD QIP. As alternative approaches, we considered changing the performance period or scoring facilities on one survey administration, but otherwise meeting the 30 completed surveys requirement. However, we found that neither of these approaches were feasible; extending the performance period would not accurately reflect ICH CAHPS performance during CY 2020, and as discussed above, an estimated 95 percent of facilities would not be eligible for ICH CAHPS scoring on one survey. Therefore, to avoid unfairly penalizing facilities due to their performance on the ICH CAHPS survey for the PY 2022 ESRD QIP, we stated our belief that it is appropriate to suppress the ICH CAHPS measure for CY 2020, which is the performance period for the PY 2022 ESRD QIP program year (83 FR 57010).

We proposed to suppress this measure for the PY 2022 program year, rather than remove it, because we believe that the ICH CAHPS measure is an important part of the ESRD QIP measure set.

[120] Groupings of questions and composite measures can be found at *https://ichcahps.org/Portals/0/SurveyMaterials/ICH_Composites_English.pdf.*

However, we were concerned that the COVID–19 PHE affected measure performance on the current ICH CAHPS measure such that we would not be able to score facilities fairly or equitably on it. Additionally, participating facilities would continue to report the measure's data to CMS so that we could monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. In the proposed rule, we stated that we would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe (86 FR 36353). We also stated our intent to publicly report PY 2022 data where feasible and appropriately caveated.

We welcomed public comment on our proposal to suppress the ICH CAHPS measure for the PY 2022 program year. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for the proposal to suppress the ICH CAHPS measure for PY 2022, agreeing that the COVID–19 PHE has impacted the validity and reliability of performance scoring for PY 2022.

Response: We thank the commenters for their support.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the ICH CAHPS measure for PY 2022.

e. Suppression of the Long-Term Catheter Rate Clinical Measure for PY 2022

In the CY 2022 ESRD PPS proposed rule (86 FR 36353 through 36354), we proposed to suppress the Long-Term Catheter Rate clinical measure for the PY 2022 program year under proposed Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. Based on our analysis of Long-Term Catheter Rate clinical measure data during CY 2020, we found a significant increase in long-term catheter use as compared to previous years, which may be the result of hesitancy to seek medical treatment among dialysis patients concerned about being exposed to COVID–19 during the PHE.

In the CY 2018 ESRD PPS final rule, we finalized the inclusion of the Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure in the ESRD QIP measure set beginning with the PY 2021 program (82 FR 50778). The Long-Term Catheter Rate clinical measure is defined as the percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access. The measure is based on vascular access data reported in CROWNWeb (now EQRS) and excludes patient-months where a patient has a catheter in place and has a limited life expectancy.

Our analysis based on the available data indicated that long-term catheter use rates increased significantly during the COVID–19 PHE. Average long-term catheter rates were averaging around 12 percent in CY 2017 and CY 2018. In CY 2019, rates increased to average around 12.25 percent. This increase continued into CY 2020, with rates reaching a peak of 14.7 percent in June 2020 and declining slightly to 14.3 percent in July and August 2020. After remaining around 12 percent for 3 consecutive years, in the proposed rule we stated that we view a sudden 2 percent increase in average long-term catheter rates as a significant deviation compared to historical performance during immediately preceding years (86 FR 36354). We were concerned that the COVID–PHE impacted the ability of ESRD patients to seek treatment from medical providers regarding their catheter use, either due to difficulty accessing treatment due to COVID–19 precautions at healthcare facilities, or due to increased patient reluctance to seek medical treatment because of risk of COVID–19 exposure and increased health risks resulting therefrom, and that these contributed to the significant increase in long-term catheter use rates.

We proposed to suppress this measure for the PY 2022 program year, rather than remove it, because we believe that the Long-Term Catheter Rate clinical measure is an important part of the ESRD QIP measure set. However, we were concerned that the PHE for COVID–19 affected measure performance on the current Long-Term Catheter Rate clinical measure such that we would not be able to score facilities fairly or equitably on it. Additionally, participating facilities would continue to report the measure's data to CMS so that we could monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. In the proposed rule (86 FR 36354), we stated that we would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also stated our intent to publicly report PY 2022 data where feasible and appropriately caveated.

We welcomed public comment on our proposal to suppress the Long-Term Catheter Rate clinical measure for the PY 2022 program year. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for the proposal to suppress the Long-Term Catheter Rate clinical measure for PY 2022, agreeing that the COVID–19 PHE has impacted the validity and reliability of performance scoring for PY 2022.

Response: We thank the commenters for their support.

Final Rule Action: After considering public comments, we are finalizing our proposal to suppress the Long-Term Catheter Rate clinical measure for PY 2022.

D. Special Scoring Methodology and Payment Policy for the PY 2022 ESRD QIP

As described in section IV.B.2. of the proposed rule, we have considered the impact of operational systems issues preventing facilities from submitting September through December 2020 patient and clinical data into the EQRS from November 1, 2020 through on or about July 12, 2021. Even when facilities are able to submit the September through December 2020 patient and clinical data by September 1, 2021, we will need time to validate the quality and reliability of the impacted data in order to determine whether all data quality issues have been resolved (86 FR 36354). In addition, as described in section IV.C. we stated our belief that four of the ESRD QIP measures have been impacted by the COVID–19 PHE that could result in distorted measure performance for PY 2022.

It is not our intention to penalize dialysis facilities based on the performance on data that are not reliable, thus, not reflective of the quality of care that the measures in the program are designed to assess. Therefore, we proposed a special rule for PY 2022 scoring for the ESRD QIP under which we would calculate measure rates for all measures, but would not calculate achievement and improvement points for any of them because they have all been impacted by the operational systems issues and, as we stated previously, we believe that four of them have additionally been significantly impacted by COVID–19. Because we would not calculate achievement and improvement scores for any measures, we also proposed under this special rule that we would

not score any of the measures in the four domains or calculate or award Total Performance Scores for any facility. We also proposed to not apply any payment reductions to ESRD facilities for PY 2022.

In order to ensure that a facility is aware of any changes to its measure rates that we have observed, we proposed to provide confidential feedback reports that contain the measure rates we calculated for PY 2022. Performance scores for facilities would be released on Dialysis Facility Compare and footnoted to indicate potential accuracy concerns with the scores. Performance score certificates would be generated with the TPS showing as ''Not Applicable.''

We proposed to codify these policies for PY 2022 at 42 CFR 413.177(a) and 413.178(h).

However, we stated that if the proposed measure suppression policies and proposed special scoring and payment policies in the proposed rule were not finalized, the PY 2022 ESRD QIP payment would be implemented in accordance with our current policy, as well as the payment reduction ranges finalized in the CY 2020 ESRD PPS final rule (84 FR 60725 through 60727).

We invited public comment on this proposed special scoring and payment policy for the PY 2022 ESRD QIP. The comments we received and our responses are set forth below.

Comment: Many commenters expressed support for the proposed special scoring methodology and payment policy for PY 2022. Several commenters agreed that quality measure data submitted during the COVID–19 PHE should not be used for performance scoring or payment in the ESRD QIP, and expressed their concerns regarding the impact of the COVID–19 PHE on quality measure data. Several commenters agreed that facilities should not be penalized due to the potential impact of EQRS issues on the reliability and accuracy of the data. One commenter expressed the belief that this proposal would allow staff members to remain focused on COVID–19 safety.

Response: We thank the commenters for their support.

Comment: A few commenters recommended that CMS apply this special scoring methodology and payment policy to PY 2023 and possibly future years, noting the continuing impact of the COVID–19 PHE on facilities and the ESRD patient population. A few commenters expressed the belief that it is appropriate to let the healthcare system stabilize from the effects of the PHE before imposing penalties.

Response: We thank the commenters for this feedback. We acknowledge the continuing impact of the COVID–19 PHE on facilities and the ESRD patient population. We will continue to monitor the impact of the COVID–19 PHE on the ESRD QIP in order to consider, based on the data, whether to propose changes to the scoring methodology for PY 2023.

Final Rule Action: After considering public comments, we are finalizing our special scoring and payment policy for the PY 2022 ESRD QIP as proposed. We are also finalizing our proposal to codify these policies for PY 2022 at 42 CFR 413.177(a) and 413.178(h).

E. Updates to Requirements Beginning With the PY 2024 ESRD QIP

1. PY 2024 ESRD QIP Measure Set

Under our current policy, we retain all ESRD QIP measures from year to year unless we propose through rulemaking to remove them or otherwise provide notification of immediate removal if a measure raises potential safety issues (77 FR 67475). Accordingly, the PY 2024 ESRD QIP measure set will include the same 14 measures as the PY 2023 ESRD QIP measure set (85 FR 71465 through 71466). These measures were described in Table 2 in the CY 2022 ESRD PPS proposed rule (86 FR 36355) and are described in Table 2 in this final rule. For the most recent information on each measure's technical specifications for PY 2024, we refer readers to the CMS ESRD Measures Manual for the 2021 Performance Period.[121]

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[121] *https://www.cms.gov/files/document/esrd-measures-manual-v61.pdf*. We note that information for the 2022 Performance Period is also now available at: *https://www.cms.gov/files/document/esrd-measures-manual-v70.pdf*.

TABLE 2: PY 2024 ESRD QIP Measure Set

National Quality Forum (NQF) #	Measure Title and Description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (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	Standardized Readmission Ratio (SRR), a clinical measure Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
Based on NQF #2979	Standardized Transfusion Ratio (STrR), a reporting measure Ratio of the 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 A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. 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.
2977	Hemodialysis Vascular Access: Standardized Fistula Rate clinical measure Measures the use of an arteriovenous (AV) fistula as the sole means of vascular access as of the last hemodialysis treatment session of the month.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
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	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on NQF #0418	Clinical Depression Screening and Follow-Up, a reporting measure Facility reports in End Stage Renal Disease Quality Reporting System (EQRS) one of six conditions for each qualifying patient treated during performance period.
N/A	Ultrafiltration Rate (UFR), a reporting measure Number of patient-months for which a facility reports elements required for ultrafiltration rates for each qualifying patient.
Based on NQF #1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (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 the Centers for Disease Control and Prevention (CDC).
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure Percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.

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We discuss our proposal to update the SHR clinical measure in the following section.

a. Update to the Standardized Hospitalization Ratio (SHR) Clinical Measure Beginning With the PY 2024 ESRD QIP

In the CY 2017 ESRD PPS final rule, we adopted the SHR clinical measure under the authority of section 1881(h)(2)(B)(ii) of the Act (81 FR 77906 through 77911). The SHR clinical measure is a National Quality Forum (NQF)-endorsed all-cause, risk-standardized rate of hospitalizations during a 1-year observation window. The standardized hospitalization ratio is defined as the ratio of the number of hospital admissions that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of hospitalizations that would be expected

given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. This measure is calculated as a ratio but can also be expressed as a rate.

In the CY 2022 ESRD PPS proposed rule (86 FR 36356), we stated that hospitalizations are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital nearly twice a year and spend an average of 11.2 days in the hospital per year.[122] Hospitalizations account for approximately 33 percent of total Medicare expenditures for ESRD patients.[123] Studies have shown that improved health care delivery and care coordination may help reduce unplanned acute care including hospitalization.[124] Hospitalization rates vary across dialysis facilities even after adjustment for patient characteristics, suggesting that hospitalizations might be influenced by dialysis facility practices. An adjusted facility-level standardized hospitalization ratio, accounting for differences in patients' characteristics, plays an important role in identifying potential problems, and helps facilities provide cost-effective quality health care to help limit escalating medical costs.

In the CY 2017 ESRD PPS final rule, we finalized our proposal to adopt the SHR clinical measure, which was a modified version of the NQF-endorsed SHR clinical measure (NQF #1463), as part of the ESRD QIP measure set (81 FR 77911). In that final rule, we stated that our modified SHR clinical measure would incorporate 210 prevalent comorbidities into our risk adjustment calculation, as our analyses suggested that incorporating prevalent comorbidities would result in a more robust and reliable measure of hospitalization (81 FR 77906 through 77907). In that final rule, we explained that data used to calculate the SHR clinical measure are derived from an extensive national ESRD patient database (81 FR 77908). We noted that the database is comprehensive for Medicare Parts A and B patients, and that non-Medicare patients are included in all sources except for the Medicare payment records. In that final rule, we also stated that the Standard Information Management System/CROWNWeb provides tracking by dialysis provider and treatment modality for non-Medicare patients, and information on hospitalizations and patient comorbidities are obtained from Medicare Inpatient Claims Standard Analysis Files. In the CY 2019 ESRD PPS final rule, we increased the weight of the SHR clinical measure from 8.25 percent to 14 percent of the TPS (83 FR 56992 through 56997).

On November 20, 2020, NQF completed its most recent review of the SHR clinical measure, a measure maintenance review, and renewed the measure's endorsement. As part of this review, the NQF endorsed updating the prevalent comorbidity adjustment, which would group 210 individual ICD–9–CM prevalent comorbidities into 90 condition groups, derived from the Agency for Healthcare Research and Quality (AHRQ) Clinical Classifications Software (CCS) groups. The updated prevalent comorbidity adjustment would also limit the source of prevalent comorbidities to inpatient claims. The switch to using only Medicare inpatient claims to identify prevalent comorbidities is due to the lack of Medicare outpatient claims data for the growing Medicare Advantage (MA) patient population. By using the original set of Medicare claims datasets (inpatient, outpatient, hospice, skilled nursing, and home health), the NQF stated its concern that MA patient prevalent comorbidities would be systematically biased. These MA patient prevalent comorbidities would only be populated by Medicare inpatient claims, as compared to non-MA patient prevalent comorbidities that would be populated by the aforementioned set of Medicare claim sources. The updated NQF-endorsed SHR clinical measure would also include all time at risk for MA patients, and added a MA indicator for adjustment in the model. The NQF-endorsed specifications also included updates to parameterization of existing adjustment factors and re-evaluation of interactions, and also created three distinct groups of patients to use in the SHR model based on time spent in a skilled nursing facility, noting that nursing home residence is a marker of higher morbidity.

The updated SHR clinical measure was included on the publicly available ''List of Measures under Consideration for December 21, 2020'' (MUC List), a list of measures under consideration for use in various Medicare programs.[125] When the Measure Applications Partnership Hospital Workgroup convened on January 11, 2021, it reviewed the MUC List, including the SHR clinical measure. The Measure Applications Partnership Hospital Workgroup recognized that hospitalization rates vary across dialysis facilities, even after adjusting for patient characteristics, which suggests that hospitalizations might be influenced by dialysis facility practices. The Measure Applications Partnership Hospital Workgroup also noted that the SHR clinical measure seeks to improve patient outcomes by measuring hospitalization ratios among dialysis facilities, and that the measure seeks to promote communication between the dialysis facilities and other care settings to improve care transitions.[126] In its final report, the Measure Applications Partnership supported this measure for rulemaking.[127]

In the CY 2022 ESRD PPS proposed rule (86 FR 36356), we proposed to update the SHR clinical measure specifications to align with the NQF-endorsed updates. These included updates to the risk adjustment method of the measure, which include a prevalent comorbidity adjustment, the addition of MA patients and a MA indicator in the model, updates to parameterization of existing adjustment factors and re-evaluation of interactions, and an indicator for a patient's time spent in a skilled nursing facility.

In the proposed rule, we expressed our belief that adopting these updates would be consistent with our stated goal of evaluating opportunities to more closely align ESRD QIP measures with NQF measure specifications (84 FR 60724). The SHR clinical measure seeks to improve patient outcomes by measuring hospitalization ratios among dialysis facilities, and we stated our belief that these updates would result in a more reliable and robust SHR clinical measure.

We sought comment on this proposal to update the SHR clinical measure

[122] United States Renal Data System. 2018 United States Renal Data System annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.

[123] Ibid.

[124] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Advancing American Kidney Health. 2019. Available at: *https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf.*

[125] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at: *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf* on January 29 2021.

[126] Measure Applications Partnership. Measure Applications Partnership Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[127] Measure Applications Partnership. Measure Applications Partnership 2020–2021: Considerations for Implementing Measures in Federal Programs: Clinician, Hospital & PAC/LTC. Accessed on April 28, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94893.*

specifications for use in the ESRD QIP beginning with PY 2024. The comments we received and our responses are set forth below.

Comment: A few commenters expressed support for the proposed updates to the SHR clinical measure specifications. One commenter noted that such updates are NQF-endorsed and supported by the MAP.

Response: We thank the commenters for their support.

Comment: A few commenters expressed concern regarding the proposed updates to the risk adjustment method of the SHR clinical measure and recommended that CMS perform a sensitivity analysis of the risk model fit, comparing the prior risk model's outcomes with the updated risk model's performance to assess the impact of the new approach.

Response: We are finalizing the proposed updates to the SHR clinical measure because they are endorsed by the NQF and would align the specifications of the SHR clinical measure with the NQF-endorsed specifications. Although we are not bound by the NQF's decisions regarding measure specifications, we believe that adopting these updates is consistent with our stated goal of evaluating opportunities to more closely align ESRD QIP measures with NQF measure specifications (84 FR 60724). The updates to the SHR clinical measure were reviewed and endorsed by NQF in 2020. As part of that NQF review, both the current and proposed SHR risk adjustment model results were presented in the Testing Forms and were available for discussion during the NQF review process. In addition, the NQF review included comparisons of both the prior and updated risk adjustment model performance for other aspects of the Scientific Acceptability criteria (reliability and validity). Both the NQF Methodology Panel and Admissions/Readmissions Standing Committee had the opportunity to review the models' performance (that is, the ''risk model fit'') on those and other endorsement criteria prior to NQF's decision to endorse the proposed model changes. Because the NQF review included an analysis of the risk model's performance, we believe that the NQF review effectively constituted a sensitivity review (that is, an analysis of the degree to which the elements of the risk model contribute to the risk of hospitalization) of the proposed specification changes, because it compared all important criteria used by NQF between the prior and proposed versions of SHR.

Comment: A few commenters expressed concern that the proposed update to the comorbidity adjustment may skew the model toward a sicker patient population, noting that the approach would result in inaccurately low hospitalization rates leading to erroneously high scores. One commenter expressed concern that this may be misleading to patients and might disincentivize improvements that might actually lower hospitalizations.

Response: We developed the proposed updated version of the SHR clinical measure to directly correct a progressive bias related to our prior definition of an ''active Medicare patient'' in the context of the rapid increase in Medicare chronic dialysis patients with Medicare Advantage coverage. In the prior version of the SHR clinical measure, ''active'' Medicare status was defined by ''use'' criteria. An individual patient met our use criteria if they either had $900 or more in paid Medicare outpatient dialysis claims or an acute inpatient hospitalization. Either claims-based criterion conveyed active Medicare status for purposes of the measure for the event month and two consecutive following months. Nearly all Medicare fee-for-service patients meet the use criterion of $900 paid claims for dialysis because this amount reflects between 2 to 3 outpatient dialysis treatments at current reimbursement rates. However, the only MA patients meeting these use criteria were those hospitalized in the year. As a result, the time at risk calculated in the old SHR clinical measure underestimated the time at risk for MA patients because not all are hospitalized in a year and virtually no MA patients meet the other use criterion, due to CMS' lack of access to outpatient claims for MA enrollees. The proposed updated version of the SHR clinical measure currently utilizes Medicare's Enrollment Database to identify Medicare Advantage patient status monthly. Combined with our patient-level treatment history file, we are able to calculate true MA patient time at risk at a given dialysis facility, without bias from the ''use'' test.

For the purposes of identifying co-morbidities from Medicare Claims for risk adjustment, we use all inpatient claims in the prior calendar year. We are able to obtain inpatient claims for both Medicare fee-for-service patients as well as MA patients, as hospitals and other inpatient providers furnish inpatient claims for MA patients to their Medicare Administrative Contractors (MACs) for informational purposes. For beneficiaries enrolled in Medicare Advantage, those inpatient claims are often referred to as ''shadow'' claims, as they are not used for direct billing. For Medicare Fee-for Service beneficiaries, we only use paid inpatient claims. Unlike for Medicare fee-for-service beneficiaries, CMS has virtually no access to outpatient claims for Medicare Advantage beneficiaries. We no longer use outpatient claims sources to identify co-morbidities, eliminating potential bias related to the lack of access to outpatient claims for MA patients. Identification of prevalent comorbidities based on only inpatient claims results in fewer comorbidities for each patient compared to use of the universe of Medicare claims. However, use of only inpatient claims results in similar numbers and types of comorbidities for MA patients and other Medicare patients. For instance, in an analysis of a set of comorbidity groups used in a recent SRR calculation, we found that inpatient claims identified 12 comorbid conditions for MA patients on average compared to 12.4 comorbid conditions for other (non-MA) Medicare patients.

In the revised SHR clinical measure, we use all available inpatient claims in the prior calendar year for both Fee-For-Service (FFS) and MA patients. While we agree that limiting co-morbidity ascertainment to inpatient claims results in a less comprehensive set of co-morbidities, our proposed updated risk-adjustment methodology protects against potential bias in determining comorbidity burden due to differences in our access to claims data for FFS and MA patients discussed above. As the SHR clinical measure relies on use of inpatient claims to identify co-morbidities in the prior calendar year, we expect that this lookback period reflects more current conditions that are more likely to be predictive of hospitalization risk. Therefore, we do not believe that outpatient claim derived co-morbidities are as clinically relevant to the risk-adjustment needed for the SHR clinical measure. Moreover, our approach does not require us to exclude MA patients from the measures. We do not want to eliminate a sizable percentage of the current observations from the SHR clinical measure, particularly given the anticipated growth of MA patients with diagnoses of ESRD that will result from changes to the MA program regulations related to the ability of prevalent ESRD patients to choose MA plans beginning in 2021, as finalized in the Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program final rule

(85 FR 33821 through 33824), which implemented provisions of the 21st Century Cures Act to remove the prohibition on ESRD beneficiaries enrolling in an MA plan.[128] Finally, to account for potential underlying co-morbidity differences between MA and FFS patients that cannot be observed due to potentially incomplete claims-based ascertainment of health status for MA patients, we included all time at risk for Medicare Advantage patients and added a Medicare Advantage indicator for adjustment in the model.

Regarding the possibility that the SHR risk model changes described above would increase model bias, we disagree and believe that the concern that the revised model would bias the SHR toward sicker patients is unfounded. First, we have discussed above the frequency of inpatient claims diagnoses for FFS and MA patients under the new approach. The average number of diagnoses reported from inpatient claims for FFS and MA patients are very similar, strongly suggesting that using only the inpatient claims source is an accurate reflection of the comorbidities for both patient populations. The proposed SHR risk model also includes a Medicare Advantage indicator variable in the model that would guard against bias by minimizing the potential impact of differences in unobserved comorbidities from outpatient claims sources. Considering that the proposed model eliminates a sizeable known bias related to the lack of data about outpatient claims for MA patients, we believe the proposed SHR risk model provides a more accurate representation of dialysis facility performance and, therefore, utility to the dialysis community.

Comment: A few commenters expressed concern regarding the parameterization modifications of existing adjustment factors included in the proposed updates to the SHR clinical measure. Although a few commenters agreed that the updated parameterization of existing adjustment factors and reevaluation of interactions is important, they expressed concern that the p-values, or calculated probability values, of SHR risk models indicate that the model would not be generalizable.

Response: We believe that the proposed risk adjustment model, which includes updates to the parameterization of existing adjustment factors (that is, modifying the functional forms of adjustment factors) and re-evaluation of interactions, is more appropriate because it captures all Medicare patients. Since we are only using the SHR risk models for purposes of the SHR clinical measure, we believe that generalizability is not an issue.

Comment: One commenter requested that CMS indicate how Medicare Advantage patients will be identified under the proposed SHR measure specifications.

Response: Medicare Advantage patient status will be obtained from the Medicare Enrollment Database (EDB). We will confirm the presence of usable ICD diagnosis codes from MA inpatient claims.

Comment: A few commenters recommended that the ESRD QIP should use true risk-standardized rate measures in order to more accurately reflect facility performance, as the ratio measures have relatively wide confidence intervals that can lead to facilities being misclassified and their actual performance not being reported. One commenter expressed the belief that a more direct, transparent, risk-adjusted rate measure would result in more significant improvement, noting that ESRD patient hospitalization rates have increased between 2016 and 2018 and questioned whether the SHR clinical measure has had a meaningful impact.

Response: We believe that the use of a ratio is appropriate for the SHR clinical measure. The ratio estimate that we proposed is the ratio of the facility adjusted rate to the standard rate. The ratio is also a scientifically valid approach, and ratio measures are well accepted in the published literature. Additionally, the risk-adjustment approach (which is based on application of a specific risk-adjustment model) currently used for the SHR, SRR, and SWR measures leads naturally to a standardized ratio, which compares the rate for this facility with the national rate, having adjusted for the patient mix and is relatively straightforward. We do not believe that rates are more direct and transparent than ratios, and we disagree with the commenter who stated that a risk-adjusted rate measure would lead to significant improvement in performance on the SHR clinical measure. Like ratios, risk-adjusted rates are not the same as actual rates and require a consideration of the patient mix adjustment for interpretation. Furthermore, because the indirect standardized rate is equal to the multiplication of the indirect standardized ratio and a national rate, where the national rate is a constant for all facilities, classifications of facilities based on indirect standardized ratios and rates are equivalent. Finally, we disagree that hospitalization rates have increased between 2016 and 2018. Hospitalization rates have decreased since 2015 as evidenced by the negative coefficients for calendar year from the SHR model. The hospitalization rate for 2016 decreased by 2.7 percent compared to 2015 (p-value <0.0001). Subsequent years had a larger decrease in the hospitalization rate compared to 2015 at 6.8 percent lower for 2017 and about 5.7 percent lower for 2018 (p-value<0.0001 for both) compared to 2015. Although 2018 had a slightly higher rate than 2017, there is an overall downward trend.

Final Rule Action: After considering public comments, we are finalizing our proposal to update the SHR clinical measure specifications for use in the ESRD QIP beginning with PY 2024.

2. Performance Standards for the PY 2024 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively.

a. Update to the Performance Standards Applicable to the PY 2024 Clinical Measures

Our current policy is to automatically adopt a performance and baseline period for each year that is 1 year advanced from those specified for the previous payment year (84 FR 60728). Under this policy, CY 2022 is currently the performance period and CY 2020 is the baseline period for the PY 2024 ESRD QIP. However, under the nationwide ECE that we granted in

[128] The 21st Century Cures Act (Pub. L. 114–255) amended sections 1851, 1852, and 1853 of the Act to expand enrollment options for individuals with ESRD and make associated payment and coverage changes to the MA and original Medicare programs. Specifically, since the beginning of the MA program, individuals with ESRD have not been able to enroll in MA plans subject to limited exceptions. Section 17006(a) of the Cures Act removed this prohibition effective for plan years beginning on or after January 1, 2021.

response to the COVID–19 PHE, first and second quarter data for CY 2020 are excluded from scoring for purposes of the ESRD QIP. In the CY 2022 ESRD PPS proposed rule (86 FR 36357), we stated that we were concerned that it would be difficult to assess levels of achievement and improvement if the performance standards were based on partial year data.[129] Our preliminary analysis indicated that the effect of the excluded data would create higher performance standards for certain measures and lower performance standards for other measures, which may skew achievement and improvement thresholds for facilities and therefore may result in performance standards that do not accurately reflect levels of achievement and improvement.

Our current policy substitutes the performance standard, achievement threshold, and/or benchmark for a measure for a performance year if final numerical values for the performance standard, achievement threshold, and/or benchmark are worse than the numerical values for that measure in the previous year of the ESRD QIP (82 FR 50764). We stated in the proposed rule that we adopted this policy because we believe that the ESRD QIP should not have lower performance standards than in previous years (86 FR 36357). However, our general policy provides flexibility to substitute the performance standard, achievement threshold, and benchmark in appropriate cases (82 FR 50764).

Although the lower performance standards would be substituted with those from the prior year, the higher performance standards would be used to set performance standards for certain measures, even though they would be based on partial year data. In the proposed rule (86 FR 36357), we stated that we were concerned that this may create performance standards for certain measures that would be difficult for facilities to attain with a full 12 months of data.

[129] We note that for most ESRD QIP measures, this partial year data would be measure data from July and August 2020.

Therefore, in the CY 2022 ESRD PPS proposed rule (86 FR 36357), we proposed to calculate the performance standards for PY 2024 using CY 2019 data, which are the most recently available full calendar year of data we can use to calculate those standards. Due to the impact of CY 2020 data that are excluded from the ESRD QIP for scoring purposes, we stated our belief that using CY 2019 data for performance standard setting purposes is appropriate. Consistent with our established policy, we would continue to use the prior year's numerical values for performance standard, achievement threshold, and benchmark if the most recent full CY's final numerical values are worse.

We welcomed public comments on this proposal. The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for the proposed use of CY 2019 data for calculating performance standards, achievement thresholds, and benchmarks for PY 2024. A few commenters noted that the significant impact of the COVID–19 PHE would make CY 2020 measure data inappropriate for setting PY 2024 performance standards. A few commenters supported the proposal because CY 2019 is the most recently available full calendar year of data.

Response: We thank the commenters for their support.

Comment: One commenter expressed concern with the proposed use of CY 2019 data for calculating performance standards, achievement thresholds, and benchmarks for PY 2024, noting that the ongoing COVID–19 PHE continues to impact measure performance and that using CY 2019 as a pre-pandemic baseline for setting performance standards may unfairly penalize facilities.

Response: We acknowledge the commenter's concern regarding the ongoing impact of the COVID–19 PHE, but disagree that using CY 2019 data for calculating performance standards will unfairly penalize facilities. We note that, due to the nationwide ECE granted in response to the COVID–19 PHE that excluded first and second quarter data from CY 2020, only 6 months of CY 2020 data would be used to calculate performance standards, achievement thresholds, and benchmarks for PY 2024. We believe that there is a greater risk of unfairly penalizing facilities based on performance standards calculated using only 6 months of CY 2020 data, as our preliminary analysis indicated that the effect of the excluded data would create higher performance standards for certain measures and lower performance standards for other measures which may not accurately reflect levels of achievement and improvement.

Comment: One commenter expressed concern that the proposed update only addresses achievement scores, and requested that CMS clarify what year improvement scores will be based on.

Response: We proposed to use CY 2019 data to calculate all performance standards for PY 2024, including achievement and improvement thresholds. This is consistent with the definition of ''performance standards'' codified at 42 CFR 413.178(a)(12), which includes all of the performance levels used to award points to a facility. Therefore, the improvement scores will be calculated using CY 2019 as the baseline year.

Final Rule Action: After considering public comments, we are finalizing our proposal to calculate the performance standards for PY 2024 using CY 2019 data.

b. Finalized Performance Standards for the PY 2024 ESRD QIP

Table 3 displays the achievement thresholds, 50th percentiles of the national performance, and benchmarks for the PY 2024 clinical measures, and in the proposed rule we stated that we would use these standards if our proposal to use CY 2019 as the baseline period is finalized (86 FR 36357). As discussed in IV.E.2.a. of this final rule, we are finalizing our proposal to calculate the performance standards for the PY 2024 ESRD QIP using CY 2019 data.

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TABLE 3: Performance Standards for the PY 2024 ESRD QIP Clinical Measures

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Vascular Access Type (VAT)			
Standardized Fistula Rate	53.29%	64.36%	76.77%
Catheter Rate	18.35%	11.04%	4.69%
Kt/V Comprehensive	94.33%	97.61%	99.42%
Hypercalcemia	1.54%	0.49%	0.00%*
Standardized Readmission Ratio	1.268*	0.998*	0.629*
NHSN BSI	1.193	0.516	0*
Standardized Hospitalization Ratio	1.230	0.971	0.691
PPPW	8.12%*	16.73%*	33.90%*
ICH CAHPS: Nephrologists' Communication and Caring	58.20%	67.90%	79.15%
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.64%	63.08%	72.66%
ICH CAHPS: Providing Information to Patients	74.49%	81.09%	87.80%
ICH CAHPS: Overall Rating of Nephrologists	49.33%*	62.22%*	76.57%*
ICH CAHPS: Overall Rating of Dialysis Center Staff	50.02%	63.37%	78.30%
ICH CAHPS: Overall Rating of the Dialysis Facility	54.51%	69.04%	83.72%
Note: Values marked with an asterisk (*) are also the final performance standards for those measures for PY 2023. In accordance with our longstanding policy, we are using those numerical values for those measures for PY 2024 because they are higher standards than the PY 2024 numerical values for those measures.			

Data sources: VAT measures: 2019 CROWNWeb; SRR, SHR: 2019 Medicare claims; Kt/V: 2019 CROWNWeb; Hypercalcemia: 2019 CROWNWeb; NHSN: 2019 CDC; ICH CAHPS: CMS 2019; PPPW: 2019 CROWNWeb and 2019 OPTN.

In addition, we summarize in Table 4 existing requirements for successful reporting on reporting measures in the PY 2024 ESRD QIP. We did not make any proposals to change these standards as a result of the COVID–19 PHE.

TABLE 4: Requirements for Successful Reporting on the PY 2024 ESRD QIP Reporting Measures

Measure	Reporting Frequency	Data Elements
Ultrafiltration	4 data elements are reported for every HD Kt/V session during the week of the monthly Kt/V draw, and the number of sessions of dialysis is reported monthly	• In-Center Hemodialysis (ICHD) Kt/V Date • Post-Dialysis Weight • Pre-Dialysis Weight • Delivered Minutes of BUN Hemodialysis • Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting Month
MedRec	Monthly	• Date of the medication reconciliation. • Type of eligible professional who completed the medication reconciliation: o physician, o nurse, o ARNP, o PA, o pharmacist, or o pharmacy technician personnel • Name of eligible professional
Clinical Depression Screening and Follow-Up	1 of 6 conditions reported annually	• Screening for clinical depression is documented as being positive and a follow-up plan is documented. • Screening for clinical depression documented as positive, a follow-up plan is not documented, and the facility possesses documentation that the patient is not eligible. • Screening for clinical depression documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given. • Screening for clinical depression documented as negative and no follow-up plan required. • Screening for clinical depression not documented, but the facility possesses documentation stating the patient is not eligible. • Clinical depression screening not documented, and no reason is given.
NHSN Dialysis Event	Monthly	Three types of dialysis events reported: • IV antimicrobial start; • positive blood culture; and • pus, redness, or increased swelling at the vascular access site.
STrR		At least 10 patient-years at risk during the performance period.

3. Eligibility Requirements for the PY 2024 ESRD QIP

Our current minimum eligibility requirements for scoring the ESRD QIP measures are described in Table 5.

TABLE 5: Eligibility Requirements for Scoring on ESRD QIP Measures

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Standardized Fistula 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 October 1 prior to the performance period that applies to the program year.	11-25 qualifying patients
NHSN Dialysis Event (Reporting)	11 qualifying patients	N/A	N/A
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Reporting)	10 patient-years at risk	N/A	N/A
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 October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A
Ultrafiltration (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	N/A
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients

4. Payment Reduction Scale for the PY 2024 ESRD QIP

Under our current policy, a facility will not receive a payment reduction for a payment year in connection with its performance for the ESRD QIP if it achieves a TPS that is at or above the minimum TPS (mTPS) that we establish for the payment year. We have defined the mTPS in our regulations at § 413.178(a)(8) as, with respect to a payment year, the TPS that an ESRD facility would receive if, during the baseline period it performed at the 50th percentile of national performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.

Our current policy, which is codified at § 413.177 of our regulations, also implements the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the mTPS (76 FR 634 through 635).

For PY 2024, based on available data, a facility must meet or exceed a mTPS of 57 in order to avoid a payment reduction. We note that the mTPS in this final rule is based on data from CY 2019 because we are finalizing our proposal to calculate the performance standards using CY 2019 data.

We refer readers to Table 3 of this final rule for the finalized values of the 50th percentile of national performance for each clinical measure. We stated in the CY 2022 ESRD PPS proposed rule that under our current policy, a facility that achieves a TPS of 56 or below would receive a payment reduction based on the TPS ranges indicated in Table 6 (86 FR 36360 through 36361). Table 6 of this final rule is a reproduction of Table 6 from the CY 2022 ESRD PPS proposed rule without any changes.

TABLE 6: Estimated Payment Reduction Scale for PY 2024 Based on CY 2019 Data

Total performance score	Reduction (%)
100-57	0%
56-47	0.5%
46-37	1.0%
36-27	1.5%
26-0	2.0%

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In the CY 2022 ESRD PPS proposed rule (86 FR 36361), we stated that if we did not finalize the proposed update to our performance standards policy as described in the proposed rule (86 FR 36357), then we would update the mTPS for PY 2024, as well as the payment reduction ranges for that payment year, in the CY 2022 ESRD PPS final rule using data from CY 2020. However, as discussed in section IV.E.2.a. of this final rule, we are finalizing as proposed the update to our performance standards for PY 2024, and therefore we will use the mTPS and payment reduction ranges for PY 2024 that are described in Table 6.

F. Updates for the PY 2025 ESRD QIP

1. Continuing Measures for the PY 2025 ESRD QIP

Under our previously adopted policy, the PY 2024 ESRD QIP measure set will also be used for PY 2025. We did not propose to adopt any new measures beginning with the PY 2025 ESRD QIP.

2. Performance Period for the PY 2025 ESRD QIP

We continue to believe that 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP. Under this policy, we would adopt CY 2023 as the performance period and CY 2021 as the baseline period for the PY 2025 ESRD QIP.

We did not propose any changes to this policy.

3. Performance Standards for the PY 2025 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2012 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at § 413.178(a)(1), (3), (7), and (12), respectively. In section IV.E.2.a. of this final rule, we note that we are finalizing our proposal to use CY 2019 data for purposes of calculating the performance standards for PY 2024 because, due to the anticipated impact of CY 2020 data that is excluded from the ESRD QIP for scoring purposes during CY 2020, we believe that using CY 2019 data for performance standard setting purposes would be appropriate.

a. Performance Standards for Clinical Measures in the PY 2025 ESRD QIP

At this time, we do not have the necessary data to assign numerical values to the achievement thresholds, benchmarks, and 50th percentiles of national performance for the clinical measures for the PY 2025 ESRD QIP because we do not have CY 2021 data. We intend to publish these numerical values, using CY 2021 data, in the CY 2023 ESRD PPS final rule.

b. Performance Standards for the Reporting Measures in the PY 2025 ESRD QIP

In the CY 2019 ESRD PPS final rule, we finalized the continued use of existing performance standards for the Screening for Clinical Depression and Follow-Up reporting measure, the Ultrafiltration Rate reporting measure, the NHSN Dialysis Event reporting measure, and the MedRec reporting measure (83 FR 57010 through 57011). In the CY 2022 ESRD PPS proposed rule (86 FR 36361), we stated that we will continue use of these performance standards in PY 2025.

4. Scoring the PY 2025 ESRD QIP

a. Scoring Facility Performance on Clinical Measures

In the CY 2014 ESRD PPS final rule, we finalized policies for scoring performance on clinical measures based on achievement and improvement (78 FR 72215 through 72216). In the CY 2019 ESRD PPS final rule, we finalized a policy to continue use of this methodology for future payment years (83 FR 57011) and we codified these scoring policies at § 413.178(e).

We did not propose any changes to this policy for PY 2025.

b. Scoring Facility Performance on Reporting Measures

Our policy for scoring performance on reporting measures is codified at § 413.178(e), and more information on our scoring policy for reporting measures can be found in the CY 2020 ESRD PPS final rule (84 FR 60728). We previously finalized policies for scoring performance on the NHSN Dialysis Event reporting measure in the CY 2018 ESRD PPS final rule (82 FR 50780 through 50781), as well as policies for scoring the MedRec reporting measure and Clinical Depression Screening and Follow-up reporting measure in the CY 2019 ESRD PPS final rule (83 FR 57011). We also previously finalized the scoring policy for the STrR reporting measure in the CY 2020 ESRD PPS final rule (84 FR 60721 through 60723). In the CY 2021 ESRD PPS final rule, we finalized our updated scoring methodology for the Ultrafiltration Rate reporting measure (85 FR 71468 through 71470).

We did not propose any changes to these policies for PY 2025.

5. Weighting the Measure Domains and the TPS for PY 2025

Under our current policy, we assign the Patient & Family Engagement Measure Domain a weight of 15 percent of the TPS, the Care Coordination Measure Domain a weight of 30 percent of the TPS, the Clinical Care Measure Domain a weight of 40 percent of the TPS, and the Safety Measure domain a weight of 15 percent of the TPS.

In the CY 2019 ESRD PPS final rule, we finalized a policy to assign weights to individual measures and a policy to redistribute the weight of unscored measures (83 FR 57011 through 57012). In the CY 2020 ESRD PPS final rule, we finalized a policy to use the measure weights we finalized for PY 2022 for the PY 2023 ESRD QIP and subsequent payment years, and also to use the PY 2022 measure weight redistribution policy for the PY 2023 ESRD QIP and subsequent payment years (84 FR 60728 through 60729). We did not propose any updates to these policies for PY 2025.

G. Requests for Information (RFIs) on Topics Relevant to ESRD QIP

1. Closing the Health Equity Gap in CMS Quality Programs Request for Information

Persistent inequities in health care outcomes exist in the United States (U.S.), including among Medicare patients. In recognition of persistent health disparities and the importance of closing the health equity gap, in the CY 2022 ESRD PPS proposed rule we requested information on expanding several related CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity, and disability more comprehensive and actionable for dialysis facilities, providers, and patients (86 FR 36362 through 36369). The RFI that was included in the proposed rule is part of an ongoing effort across CMS to evaluate appropriate initiatives to reduce health disparities. Feedback will be used to inform the creation of a future, comprehensive, RFI focused on closing the health equity gap in CMS programs and policies. This RFI contained four parts:

- *Background.* This section provided information on existing statements describing our commitment to health equity, and existing initiatives with an emphasis on reducing disparity.
- *Current CMS Disparity Methods.* This section described the methods, measures, and indicators of social risk currently used with the CMS Disparity Methods.
- *Future potential stratification of quality measure results.* This section described four potential future expansions of the CMS Disparity Methods, including (a) Future potential stratification of quality measure results by dual eligibility; (b) Future potential stratification of quality measure results by race and ethnicity; (c) Improving Demographic Data Collection; and (d) Potential Creation of an *ESRD Facility Equity Score* to Synthesize Results Across Multiple Social Risk Factors.
- *Solicitation of public comment.* This section specified 11 requests for feedback on these topics. We reviewed feedback on these topics and note our intention for an additional RFI or rulemaking on this topic in the future.

a. Background

Significant and persistent inequities in health care outcomes exist in the U.S.[130] Belonging to a racial or ethnic minority group, living with a disability, being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, living in a rural area, or being near or below the poverty level, is often associated with worse health outcomes.[131 132 133 134 135 136 137 138] Such disparities in health outcomes are the result of number of factors, but importantly for CMS programs, although not the sole determinant, poor access and provision of lower quality health care contribute to health disparities. For instance, numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of care, report lower experiences of care, and experience more frequent hospital readmissions and operative complications.[139 140 141 142 143 144] Readmission rates for common conditions in the Hospital Readmissions Reduction Program are higher for Black Medicare beneficiaries and higher for Hispanic Medicare beneficiaries with Congestive Heart Failure and Acute Myocardial Infarction.[145 146 147 148 149] Although Black Americans represent 7.5 percent of all older adult Medicare beneficiaries, they represent 28 percent of those with ESRD.[150] Among individuals with ESRD the odds of 30-day hospital readmission are 19 percent higher for Black beneficiaries as compared with white beneficiaries.[151] Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and

[130] United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities.*

[131] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[132] Lindenauer PK, Lagu T, Rothberg MB, et al. Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013;346.

[133] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014;371(24):2298–2308.

[134] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[135] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

[136] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[137] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[138] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7386532/.*

[139] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[140] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[141] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. Racial disparities in knee and hip total joint arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec;73(12):2107–15.

[142] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[143] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[144] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[145] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. Readmission rates for Hispanic Medicare beneficiaries with heart failure and acute myocardial infarction. Am Heart J. Aug 2011;162(2):254–261 e253.

[146] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014.

[147] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[148] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. Chronic obstructive pulmonary disease readmissions at minority-serving institutions. Ann Am Thorac Soc. Dec 2013;10(6):680–684.

[149] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[150] *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/ESRD-Infographic.pdf.*

[151] Ibid.

stroke.[152] The COVID–19 pandemic has further illustrated many of these longstanding health inequities with higher rates of infection, hospitalization, and mortality among Black, Latino, and Indigenous and Native American persons relative to white persons.[153] [154] In the ESRD patient population, one study found that the rate of COVID–19 hospitalizations among dialysis patients peaked at 40 times higher than the rate in the general population during the pandemic, with Black, Latino, and Asian persons hospitalized at a higher rate than white persons.[155] As noted by the Centers for Disease Control and Prevention, ''long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying from COVID–19.''[156] One important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across our programs and policies.

We are committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities.[157] For the purposes of this rule, we are using a definition of equity established in Executive Order 13985, as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [158] We note that this definition was recently established by the Biden administration, and provides a useful, common definition for equity across different areas of government, although numerous other definitions of equity exist.

Our ongoing commitment to closing the equity gap in CMS quality programs is demonstrated by a portfolio of programs aimed at making information on the quality of health care providers and services, including disparities, more transparent to consumers and providers. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Improvement Networks and Quality Improvement Organizations (QIN–QIOs); Federal, State, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity.[159] The CMS Equity Plan for Improving Quality in Medicare focuses on three core priority areas which inform our policies and programs: (1) Increasing understanding and awareness of disparities; (2) developing and disseminating solutions to achieve health equity; and (3) implementing sustainable actions to achieve health equity.[160] The CMS Quality Strategy [161] and Meaningful Measures Framework [162] include elimination of racial and ethnic disparities as a central principle. Our efforts aimed at closing the health equity gap to date have included both providing transparency of health disparities, supporting providers with evidence-informed solutions to achieve health equity, and reporting to providers on gaps in quality in the following:

- The *CMS Mapping Medicare Disparities Tool* which is an interactive map that identifies areas of disparities and is a starting point to understand and investigate geographic, racial and ethnic differences in health outcomes for Medicare patients.[163]
- The *Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage Stratified Report,* which highlights racial and ethnic differences in health care experiences and clinical care, compares quality of care for women and men, and looks at racial and ethnic differences in quality of care among women and men separately for Medicare Advantage plans.[164]
- The *Rural-Urban Disparities in Health Care in Medicare Report* which details rural-urban differences in health care experiences and clinical care.[165]
- The *Standardized Patient Assessment Data Elements* for certain post-acute care Quality Reporting Programs, which now includes data reporting for race and ethnicity and preferred language, in addition to screening questions for social needs (84 FR 42536 through 42588).
- The *CMS Innovation Center's Accountable Health Communities Model* which includes standardized collection of health-related social needs data.
- The *Guide to Reducing Disparities* which provides an overview of key issues related to disparities in readmissions and reviews set of activities that can help hospital leaders reduce readmissions in diverse populations.[166]
- The *Chronic Kidney Disease Disparities: Educational Guide for Primary Care,* which is intended to foster the development of primary care practice teams in order to enhance care for vulnerable patients with chronic kidney disease (CKD) and are at risk of progression of disease or complications. The guide provides information about disparities in the care of patients with CKD, presents potential actions that

[152] HHS. Heart disease and African Americans. (March 29, 2021). *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.*

[153] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

[154] Ochieng N, Cubanski J, Neuman T, Artiga S, and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

[155] Weinhandl ED, Wetmore, JB, Peng Y, et al. Initial effects of COVID–19 on patients with ESKD. J Am Soc Nephrol. Published online April 8, 2021.doi:10.1681/ASN.2021010009.

[156] *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[157] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[158] *https://www.federalregister.gov/documents/2021/01/25/2021–01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[159] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. 2015. *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[160] Centers for Medicare & Medicaid Services Office of Minority Health. Paving The Way To Equity: A Progress Report. 2015–2021. *https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf.*

[161] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[162] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[163] *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities.*

[164] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[165] Centers for Medicare & Medicaid Services. Rural-Urban Disparities in Health Care in Medicare. 2019. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Urban-Disparities-in-Health-Care-in-Medicare-Report.pdf.*

[166] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

may improve care, and suggests other available resources that may be used by primary care practice teams in caring for vulnerable patients.[167]

• *The CMS Disparity Methods* which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures currently included in the Hospital Readmissions Reduction Program (see 84 FR 42496 through 42500 for a discussion of using stratified data in additional measures).

These programs are informed by reports by the National Academies of Science, Engineering and Medicine (NASEM)[168] and the Office of the Assistant Secretary for Planning and Evaluation (ASPE)[169] which have examined the influence of social risk factors on several of our quality programs. In this request for public comment, we addressed only the eighth initiative listed above, the CMS Disparity Methods, which we have implemented for measures in the Hospital Readmissions Reduction Program and are considering in other programs, including the ESRD QIP. We discussed the implementation of these methods to date and presented considerations for continuing to improve and expand these methods to provide providers and ultimately consumers with actionable information on disparities in health care quality to support efforts at closing the equity gap.

b. Current CMS Disparity Methods

We first sought public comment on potential confidential and public reporting of ESRD QIP measure data stratified by social risk factors in the CY 2018 ESRD PPS proposed rule (82 FR 31202). We initially focused on stratification by dual eligibility, which is consistent with recommendations from ASPE's First Report to Congress which was required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (Pub. L. 113–185).[170] This report found that in the context of value-based purchasing (VBP) programs, dual eligibility was among the most powerful predictors of poor health outcomes among those social risk factors that ASPE examined and tested.

In the FY 2018 IPPS/LTCH PPS final rule, we also solicited feedback on two potential methods for illuminating differences in outcomes rates among patient groups within a provider's patient population that would also allow for a comparison of those differences, or disparities, across providers for the Hospital IQR Program (82 FR 38403 through 38409). The first method (the Within-Hospital disparity method) promotes quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors. This method also allows for a comparison of the magnitude of disparity across hospitals, so hospitals could assess how well they are closing disparity gaps compared to other hospitals. The second methodological approach (the Across-Hospital method) is complementary and assesses hospitals' outcome rates for dual-eligible patients only, across hospitals, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors. In the CY 2018 ESRD PPS proposed rule (82 FR 31202 through 31203), we also specifically solicited feedback on which social risk factors provide the most valuable information to stakeholders. In addition, feedback was solicited on the methodology for illuminating differences in outcomes rates among patient groups within a provider's patient population that would also allow for a comparison of those differences, or disparities, across providers. Overall, comments supported the use of dual eligibility as a proxy for social risk, although commenters also suggested investigation of additional social risk factors, and we continue to consider commenter suggestions for which risk factors provide the most valuable information to stakeholders.

c. Future Potential Expansion of the CMS Disparity Methods to the ESRD QIP

We are committed to advancing health equity by improving data collection to better measure and analyze disparities across programs and policies.[171] As we previously noted, we have been considering, among other things, expanding our efforts to provide stratified data for additional social risk factors and measures, optimizing the ease-of-use of the results, enhancing public transparency of equity results, and building towards provider accountability for health equity. We sought public comment on the potential stratification of quality measures in the ESRD QIP across two social risk factors: dual eligibility and race/ethnicity.

(1) Stratification of Quality Measure Results—Dual Eligibility

As described in the previous section, landmark reports by NASEM[172] and ASPE,[173] which have examined the influence of social risk factors on several of our quality programs, have shown that in the context of VBP programs, dual eligibility, as an indicator of social risk, is a powerful predictor of poor health outcomes. We are considering stratification of quality measure results in the ESRD QIP and are considering which measures would be most appropriate for stratification and if dual eligibility would be a meaningful social risk factor for stratification.

For the ESRD QIP, we would consider disparity reporting using two disparity methods derived from the Within-Facility and Across-Facility methods. The first method (based on the Within-Hospital disparity method, described previously) would aim to promote quality improvement by calculating differences in outcome rates between dual and non-dual eligible patient groups within a facility while accounting for their clinical risk factors. This method would allow for a comparison of those differences, or disparities, across facilities, so facilities could assess how well they are closing disparity gaps compared to other facilities. The second approach (based on the Across-Hospital method) would be complementary and assesses facilities' outcome rates for subgroups of patients, such as dual eligible patients, across facilities, allowing for a comparison among facilities on their performance caring for their patients with social risk factors.

(2) Stratification of Quality Measure Results—Race and Ethnicity

The Administration's Executive Order on Advancing Racial Equity and Support for Underserved Communities

[167] CMS. Chronic Kidney Disease Disparities: Educational Guide for Primary Care. February 2020. Available at: *https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf.*

[168] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21858.*

[169] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[170] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[171] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[172] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21858.*

[173] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

Through the Federal Government directs agencies to assess potential barriers that underserved communities and individuals may face to enrollment in and access to benefits and services in Federal programs. As summarized earlier in the preamble, studies have shown that among Medicare beneficiaries, racial and ethnic minority persons often experience worse health outcomes, including more frequent hospital readmissions and procedural complications.[174] We also note that the prevalence of ESRD is higher among racial minorities.[175] For example, in 2016 ESRD prevalence was approximately 9.5 times greater in Native Hawaiians and Pacific Islanders, 3.7 times greater in African Americans, 1.5 times greater in American Indians and Alaska Natives, and 1.3 times greater in Asians.[176] An important part of identifying and addressing inequities in health care is improving data collection to allow us to better measure and report on equity across our programs and policies. We are considering stratification of quality measure results in the ESRD QIP by race and ethnicity, and are identifying which measures would be most appropriate for stratification.

As outlined in the 1997 Office of Management and Budget (OMB) Revisions to the Standards for the Collection of Federal Data on Race and Ethnicity, the racial and ethnic categories which may be used for reporting the disparity methods are considered to be social and cultural, not biological or genetic.[177] The 1997 OMB Standard lists five minimum categories of race: (1) American Indian or Alaska Native; (2) Asian; (3) Black or African American; (4) Native Hawaiian or Other Pacific Islander; (5) and White. In the OMB standards, Hispanic or Latino is the only ethnicity category included, and since race and ethnicity are two separate and distinct concepts, persons who report themselves as Hispanic or Latino can be of any race.[178] Another example, the ''Race & Ethnicity—CDC'' code system in Public Health Information Network (PHIN) Vocabulary Access and Distribution Systems (VADS)[179] permits a much more granular structured recording of a patient's race and ethnicity with its inclusion of over 900 concepts for race and ethnicity. The recording and exchange of patient race and ethnicity at such a granular level can facilitate the accurate identification and analysis of health disparities based on race and ethnicity. Further, the ''Race & Ethnicity—CDC'' code system has a hierarchy that rolls up to the OMB minimum categories for race and ethnicity and, thus, supports aggregation and reporting using the OMB standard. The Office of the National Coordinator for Health Information Technology (ONC) includes both the CDC and OMB standards in its criterion for certified health IT products.[180] For race and ethnicity, a certified health IT product must be able to express both detailed races and ethnicities using *any* of the 900 plus concepts in the ''Race & Ethnicity—CDC'' code system in PHIN VADS, as well as aggregate each one of a patient's races and ethnicities to the categories in the OMB standard for race and ethnicity. This approach can reduce burden on providers recording demographics using certified products.

Self-reported race and ethnicity data remain the gold standard for classifying an individual according to race or ethnicity. However, historical inaccuracies in Federal data systems and limited collection classifications have contributed to the limited quality of race and ethnicity information in our administrative data systems.[181] In recent decades, to address these data quality issues, we have undertaken numerous initiatives, including updating data taxonomies and conducting direct mailings to some beneficiaries to enable more comprehensive race and ethnic identification.[182] [183] Despite those efforts, studies reveal varying data accuracy in identification of racial and ethnic groups in Medicare administrative data, with higher sensitivity for correctly identifying white and Black individuals, and lower sensitivity for correctly identifying individuals of Hispanic ethnicity or of Asian/Pacific Islander and American Indian/Alaskan Native race.[184] Incorrectly classified race or ethnicity may result in overestimation or underestimation in the quality of care received by certain groups of beneficiaries.

We continue to work with public and private partners to better collect and leverage data on social risk to improve our understanding of how these factors can be better measured in order to close the health equity gap. Among other things, we have developed an Inventory of Resources for Standardized Demographic and Language Data Collection[185] and supported collection of specialized International Classification of Disease, 10th Edition, Clinical Modification (ICD–10–CM) codes for describing the socioeconomic, cultural, and environmental determinants of health, and sponsored several initiatives to statistically estimate race and ethnicity information when it is absent.[186]

ONC included social, psychological, and behavioral standards in the 2015 Edition health information technology certification criteria (2015 Edition), providing interoperability standards LOINC (Logical Observation Identifiers Names and Codes) and SNOMED CT (Systematized Nomenclature of Medicine—Clinical Terms) for financial strain, education, social connection and isolation, and others. Additional stakeholder efforts underway to expand capabilities to capture additional social determinants of health data elements include the Gravity Project to identify and harmonize social risk factor data for interoperable electronic health

[174] *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

[175] United States Renal Data System. 2018 Annual Data Report: ESRD Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. Available online at *https://www.usrds.org/2018/view/Default.aspx.*

[176] United States Renal Data System. 2018 Annual Data Report, Vol 2, Figure 1.12. Available online at *https://www.usrds.org/2018/view/Default.aspx.*

[177] Executive Office of the President Office of Management and Budget, Office of Information and Regulatory Affairs. Revisions to the standards for the classification of federal data on race and ethnicity. Vol 62. **Federal Register**. 1997:58782–58790.

[178] *https://www.census.gov/topics/population/hispanic-origin/about.html.*

[179] *https://phinvads.cdc.gov/vads/ViewValueSet.action?id=67D34BBC-617F-DD11-B38D-00188B398520.*

[180] ONC criteria for certified health IT products: *https://www.healthit.gov/isa/representing-patient-race-and-ethnicity.*

[181] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. Health Care Financing Review, 29(3), 27–42.

[182] Filice CE, Joynt KE. Examining Race and Ethnicity Information in Medicare Administrative Data. Med Care. 2017;55(12):e170–e176. doi:10.1097/MLR.0000000000000608.

[183] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. Health Care Financing Review, 29(3), 27–42.

[184] Centers for Medicare & Medicaid Services. Building an Organizational Response to Health Disparities Inventory of Resources for Standardized Demographic and Language Data Collection. 2020. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Collection-Resources.pdf.*

[185] Centers for Medicare & Medicaid Services. Building an Organizational Response to Health Disparities Inventory of Resources for Standardized Demographic and Language Data Collection. 2020. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Collection-Resources.pdf.*

[186] *https://pubmed.ncbi.nlm.nih.gov/18567241/*, *https://pubmed.ncbi.nlm.nih.gov/30506674/*, Eicheldinger C, Bonito A. More accurate racial and ethnic codes for Medicare administrative data. *Health Care Finance Rev.* 2008;29(3):27–42. Haas A, Elliott MN, Dembosky JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Serv Res.* 2019;54(1):13–23. doi:10.1111/1475–6773.13099.

information exchange for EHR fields, as well as proposals to expand the ICD–10 (International Classification of Diseases, Tenth Revision) Z-codes, the alphanumeric codes used worldwide to represent diagnoses.[187]

While development of sustainable and consistent programs to collect data on social determinants of health can be considerable undertakings, we recognize that another method to identify better race and ethnicity data is needed in the short term to address the need for reporting on health equity. In working with our contractors, two algorithms have been developed to *indirectly estimate* the race and ethnicity of Medicare beneficiaries (as described further in the next section). We believe that using indirect estimation can help to overcome the current limitations of demographic information and enable timelier reporting of equity results until longer term collaborations to improve demographic data quality across the health care sector materialize. The use of indirectly estimated race and ethnicity for conducting stratified reporting does not place any additional collection or reporting burdens on facilities as these data are derived using existing administrative and Census-linked data.

Indirect estimation relies on a statistical imputation method for inferring a missing variable or improving an imperfect administrative variable using a related set of information that is more readily available.[188] Indirectly estimated data are most commonly used at the population level (such as the facility or health plan-level), where aggregated results form a more accurate description of the population than existing, imperfect data sets. These methods often estimate race and ethnicity using a combination of other data sources which are predictive of self-identified race and ethnicity, such as language preference, information about race and ethnicity in our administrative records, first and last names matched to validated lists of names correlated to specific national origin groups, and the racial and ethnic composition of the surrounding neighborhood. Indirect estimation has been used in other settings to support population-based equity measurement when self-identified data are not available.[189]

As discussed earlier in the preamble, we have previously supported the development of two such methods of indirect estimation of race and ethnicity of Medicare beneficiaries. One indirect estimation approach, developed by our contractor, uses Medicare administrative data, first name and surname matching, derived from the U.S. Census and other sources, with beneficiary language preference, State of residence, and the source of the race and ethnicity code in Medicare administrative data to reclassify some beneficiaries as Hispanic or Asian Pacific Islander (API).[190] In recent years, we have also worked with another contractor to develop a new approach, the Medicare Bayesian Improved Surname Geocoding (MBISG), which combines Medicare administrative data, first and surname matching, geocoded residential address linked to the 2010 U.S. Census, and uses both Bayesian updating and multinomial logistic regression to estimate the probability of belonging to each of six racial/ethnic groups.[191]

The MBISG model is currently used to conduct the national, contract-level, stratified reporting of Medicare Part C & D performance data for Medicare Advantage Plans by race and ethnicity.[192] Validation testing reveals concordances with self-reported race and ethnicity of 0.96–0.99 for API, Black, Hispanic, and White beneficiaries for MBISG version 2.1.[193] [194] The algorithms under consideration are considerably less accurate for individuals who self-identify as American Indian or Alaskan Native as well as for those who self-identify as multiracial.[195] Indirect estimation can be a statistically reliable approach for calculating population-level equity results for groups of individuals (such as the facility-level) and is not intended, nor being considered, as an approach for inferring the race and ethnicity of an individual.

However, despite the high degree of statistical accuracy of the indirect estimation algorithms under consideration there remains the small risk of unintentionally introducing bias. For example, if the indirect estimation is not as accurate in correctly estimating race and ethnicity in certain geographies or populations it could lead to some bias in the method results. Such bias might result in slight overestimation or underestimation of the quality of care received by a given group. We believe this amount of bias is considerably less than would be expected if stratified reporting was conducted using the race and ethnicity currently contained in our administrative data. Indirect estimation of race and ethnicity is envisioned as an intermediate step, filling the pressing need for more accurate demographic information for the purposes of exploring inequities in service delivery, while allowing newer approaches, as described in the next section, for enhancing demographic data collection. We expressed interest in learning more about, and solicited comments about, the potential benefits and challenges associated with measuring facility equity using an imputation algorithm to enhance existing administrative data quality for race and ethnicity until self-reported information is sufficiently available.

(3) Improving Demographic Data Collection

Stratified facility-level reporting using indirectly estimated race and ethnicity and dual eligibility would represent an important advance in our ability to provide equity reports to facilities. However, self-reported disability status, race, ethnicity, sexual orientation and gender identity data remain the gold standard for classifying an individual according to disability status, race, or ethnicity. The CMS Quality Strategy outlines our commitment to strengthening infrastructure and data systems by ensuring that standardized demographic information is collected to identify disparities in health care delivery outcomes.[196] Collection and

[187] *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[188] IOM. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[189] IOM. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[190] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. Health Care Financing Review, 29(3), 27–42.

[191] Haas, A., Elliott, M. et al (2018). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Services Research,* 54:13–23.

[192] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[193] Haas, A., Elliott, M. et al (2018). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Services Research, 54:13–23.

[194] *https://www.cms.gov/files/document/racial-ethnic-gender-disparities-health-care-medicare-advantage.pdf.*

[195] Haas, A., Elliott, M. et al. (2018). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Services Research,* 54:13–23 and Bonito AJ, Bann C, Eicheldinger C, Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008.

[196] The Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. *https://www.cms.gov/*

sharing of a standardized set of social, psychological, and behavioral data by facilities, including disability status and race and ethnicity, using electronic data definitions which permit nationwide, interoperable health information exchange, can significantly enhance the accuracy and robustness of our equity reporting.[197] This could potentially include expansion to additional social risk factors, such as language preference and disability status, where accuracy of administrative data is currently limited. We are mindful that additional resources, including data collection and staff training may be necessary to ensure that conditions are created whereby all patients are comfortable answering all demographic questions, and that individual preferences for non-response are maintained.

We are also interested in learning about and solicited comments on current data collection practices by facilities to capture demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), language preference, and disability status). Further, we are interested in potential challenges facing facility collection of a minimum set of demographic data elements in alignment with national data collection standards (such as the standards finalized by the Affordable Care Act [198]) and standards for interoperable exchange (such as the U.S. Core Data for Interoperability put forth by ONC for incorporation in certified health IT products as part of the 2015 Edition of health IT certification criteria [199]). Advancing data interoperability through collection of a minimum set of demographic data collection has the potential for improving the robustness of the disparity methods results, potentially permitting reporting using more accurate, self-reported, information, such as race and ethnicity, and expanding reporting to additional dimensions of equity, including stratified reporting by disability status.

(4) Potential Creation of an ESRD Facility Equity Score To Synthesize Results Across Multiple Social Risk Factors

As we describe previously, we are considering expanding the disparity methods to include two social risk factors (dual eligibility and race/ethnicity). This approach would improve the comprehensiveness of health equity information provided to facilities. Aggregated results from multiple measures and multiple social risk factors, from the CMS Disparity Methods, in the format of a summary score, can improve the usefulness of the equity results. In working with our contractors, we recently developed an equity summary score for Medicare Advantage contract/plans, the Health Equity Summary Score (HESS), with application to stratified reporting using two social risk factors: Dual eligibility and race and as described in Incentivizing Excellent Care to At-Risk Groups with a Health Equity Summary Score.[200]

The HESS calculates standardized and combined performance scores blended across the two social risk factors. The HESS also combines results of the within-plan (similar to the Within-Facility method) and across-plan method (similar to the Across-Facility method) across multiple performance measures.

We are considering building an *ESRD Facility Equity Score,* not yet developed, which would be modeled off the HESS but adapted to the context of risk-adjusted facility outcome measures and potentially other ESRD QIP quality measures. We envision that the *ESRD Facility Equity Score* would synthesize results for a range of measures and using multiple social risk factors, using measures and social risk factors which would be reported to facilities as part of the CMS Disparity Methods. We believe that creation of the *ESRD Facility Equity Score* has the potential to supplement the overall measure data already reporting on the *Care Compare* or successor website, by providing easy to interpret information regarding disparities measured within individual facilities and across facilities nationally. A summary score would decrease burden by minimizing the number of measure results provided and providing an overall indicator of equity.

The *ESRD Facility Equity Score* under consideration would potentially:

- Summarize facility performance across multiple social risk factors (initially dual eligibility and indirectly estimated race and ethnicity, as described above).
- Summarize facility performance across the two disparity methods (that is, the Within-Facility Disparity Method and the Across-Facility Disparity Method) and potentially multiple measures.

Prior to any future public reporting of stratified measure data using indirectly estimated race and ethnicity information, if we determine that an *ESRD Facility Equity Score* can be feasibly and accurately calculated, we would provide results of the *ESRD Facility Equity Score,* in confidential facility specific reports which facilities and their ESRD Networks would be able to download. Any potential future proposal to display the *ESRD Facility Equity Score* on the *Care Compare* or successor website would be made through future RFI or rulemaking.

d. Solicitation of Public Comment

We sought comment on the possibility of stratifying ESRD QIP measures by dual eligibility and race and ethnicity. We solicited public comments on the application of the within-facility or across-facility disparities methods if we were to stratify ESRD QIP measures. We also sought comment on the possibility of facility collection of standardized demographic information for the purposes of potential future quality reporting and measure stratification. In addition, we sought comment on the potential design of a facility equity score for calculating results across multiple social risk factors and measures, including race and disability. Any data pertaining to these areas that are recommended for collection for measure reporting for a CMS program and any potential public disclosure on *Care Compare* or successor website would be addressed through a separate and future notice-and-comment rulemaking. We plan to continue working with ASPE, facilities, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all patients and minimizing unintended consequences. We noted for readers that responses to the RFI will not directly impact payment decisions. We also noted our intention for additional RFI or rulemaking on this topic in the future.

Specifically, we invited public comment on the following:

Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.

[197] The Office of the National Coordinator for Health Information Technology. United State Core Data for Interoperability Draft Version 2. 2021. *https://www.healthit.gov/isa/sites/isa/files/2021-01/Draft-USCDI-Version-2-January-2021-Final.pdf.*

[198] *https://minorityhealth.hhs.gov/assets/pdf/checked/1/Fact_Sheet_Section_4302.pdf.*

[199] *https://www.healthit.gov/sites/default/files/2020–08/2015EdCures_Update_CCG_USCDI.pdf.*

[200] Agniel D, Martino SC, Burkhart Q, et al. Incentivizing Excellent Care to At-Risk Groups with a Health Equity Summary Score. J Gen Intern Med. Published online November 11, 2019 Nov 11. doi: 10.1007/s11606–019–05473–x.

Future Potential Stratification of Quality Measure Results

- The possible stratification of facility-specific reports for ESRD QIP measure data by dual-eligibility status, including which measures would be most appropriate for stratification;
- The potential future application of indirect estimation of race and ethnicity information to permit stratification of measure data for reporting ESRD facility-level disparity results;
- Appropriate privacy safeguards with respect to data produced from the indirect estimation of race and ethnicity to ensure that such data is properly identified if/when it is shared with facilities.
- Ways to address the challenges of defining and collecting, accurate and standardized self-identified demographic information, including information on race and ethnicity, disability, and language preference for the purposes of reporting, measure stratification and other data collection efforts relating to quality.
- Recommendations for other types of readily available data elements for measuring disadvantage and discrimination for the purposes of reporting, measure stratification and other data collection efforts relating to quality, in addition, or in combination with race and ethnicity
- Recommendations for types of quality measures or measurement domains to prioritize for stratified reporting by dual eligibility, race and ethnicity, and disability.
- Examples of approaches, methods, research, and/or considerations for use of data-driven technologies that do not facilitate exacerbation of health inequities, recognizing that biases may occur in methodology or be encoded in datasets.

We received comments on these topics.

Comments: Many commenters expressed support for stratification by dual eligibility, race, and ethnicity. A few commenters expressed the belief that stratification of quality measures by social risk factors, such as dual eligibility and race and ethnicity, is essential to advancing health equity as such factors have been shown to have a likely impact on health outcomes. A few commenters expressed the belief that stratification will improve transparency, help identify existing disparities and inform efforts to reduce those disparities. A few commenters recommended that CMS take a stepwise approach to stratification. A few commenters stated that stratifying data is important to help identify health equity gaps, but recommended that CMS take action on its findings in order to address the health equity gap and reduce disparities in care. A few commenters recommended that CMS make stratified data publicly available to inform both CMS and stakeholders of the diverse needs of different patient populations, and identify needed policy changes to improve patient access to treatment. A few commenters expressed support for stratification but suggested setting a threshold at the 10th decile of low-income patient distribution to include facilities that serve a disproportionately high percentage of low-income patients. One commenter recommended that adjusting measures for social risk factors, including dual-eligibility or income, may reduce the likelihood of program penalties increasing existing disparities. One commenter supported the proposed stratification of facility-specific reports for ESRD QIP measure data by dual-eligibility status and race and ethnicity; however, this commenter also recommended CMS monitor for unintended consequences believing that stratification risks disparities in patient treatment.

Many commenters expressed support for stratification by dual eligibility. A few commenters supported stratification by dual eligible status, noting that it can be used as a proxy for socio-economic status and is an objective classification that may have less biased data. A few commenters expressed the belief that stratification could help facilities identify and reduce disparities, but noted that differences in Medicaid eligibility between states may impact comparability when stratifying measures by dual eligibility. One commenter expressed concern that dual eligibility may be too blunt a data point to identify the underlying cause of disparity, noting that disparities experienced by ESRD patients stem from a wide range of social risk factors. One commenter noted that understanding differences between dual-eligible and non-dual-eligible patients in baseline chronic kidney disease care could inform ways to allocate resources aimed at slowing the progression of CKD. One commenter noted the correlation between a facility's dual-eligible patient population and a facility's payment reduction based on its ESRD QIP scores, citing studies indicating that facilities serving a higher proportion of dual eligible/low-income patients are more likely to have higher ESRD QIP payment reductions.

Several commenters noted that, although stratification may help identify and address health equity gaps, many disparities begin decades prior to starting dialysis, and encouraged CMS to explore ways to address health disparities earlier in the progression of kidney disease. One commenter expressed concern that stratification may create unintended consequences such as disparities in patient treatment based on social determinants of health. One commenter recommended CMS consider options beyond stratification of ESRD QIP measures by dual eligible status or race and ethnicity to address health equity gaps. One commenter expressed its belief that the segmentation of populations using dual eligibility or race and ethnicity as the proxy for ''social risk,'' for example, is problematic and that the primary goal across all CMS programs should be to prioritize self-reported race, ethnicity, and other social determinants of health data as the sole source of stratifying populations to understand disparities.

Many commenters expressed support for stratification of measures by race and ethnicity, noting that such factors have been identified as likely having an impact on health outcomes. A few commenters expressed support for the use of indirect estimation of race and ethnicity for purposes of calculating facility level performance measures as a preliminary step while more precise methods are developed. One commenter expressed support for the expansion of CMS Disparity Methods to the ESRD QIP and stratifying by race and ethnicity, both within and across facilities. One commenter recommended that disparities methods should be implemented in a way that is minimally burdensome and confidentially reported.

A few commenters requested clarification regarding the application of disparity methods to the ESRD QIP, noting that disparity methods are currently applied to hospital readmissions measures which may be linked to factors outside the facility's ability to influence. A few commenters expressed concern regarding the indirect estimation of race and ethnicity, believing that it was not worth the increased and unknown risk of bias that it could unintentionally create and recommended that indirect data be evaluated to ensure CMS is not introducing bias into the system or underestimating or overestimating the quality of care for a certain population. A few commenters expressed concern that the imputation method is imprecise, particularly for indigenous and multi-racial patients and recommended that self-reported data was more accurate. One commenter

questioned whether either of the two disparities methods would help close the health equity gap, and suggested that CMS consider whether an indirect estimation approach might divert resources away from developing better methods. One commenter recommended a step-wise approach to use the ''Within Facility Disparity Method'' before expanding to apply an ''Across-Facility Disparity Method'' to assess how a facility is addressing equity, as well as to better establish what resources may be required to effectively address equity.

Several commenters expressed support for the stratification of the SRR, STrR, and SHR measures by dual-eligibility status and race/ethnicity, noting that evidence has indicated disparities may factor into measure performance in other healthcare settings, and that such stratification may inform clinical practices and care. Several commenters suggested that the vascular access measures are appropriate for stratification by dual eligibility and race/ethnicity. A few commenters also recommended that these measures be stratified by insurance status at the time of dialysis initiation in order to provide insight into patients' abilities to access pre-dialysis care and vascular access placement. A few commenters stated that the PPPW measure is appropriate for potential stratification by dual eligibility status, race/ethnicity, as well as geographic area. A few commenters recommended that stratification is adopted for measures where it has been shown, or is clearly suspected based on research from other care settings, that disparities are driving differences in the outcomes being reported. A few commenters expressed the belief that most ESRD QIP measures would benefit from stratification. One commenter recommended that CMS encourage all health care providers and organizations to collect and stratify both patient and caregiver data for all measures.

A few commenters recommended that CMS develop best practices to ensure the security of data and its utilization, noting the sensitive nature of the data and the importance of gaining beneficiaries' trust. A few commenters agreed that data elements should be subject to existing privacy and security requirements, and recommended that CMS establish an open and transparent process to work with NQF and other stakeholders to develop data options. One commenter expressed its belief in the unassailable importance of privacy safeguards for all uses of sensitive personal information such as race, ethnicity, and other social risk factors and recommended CMS consider using only self-reported data to alleviate risk of misidentification and to promote robust collection of patient-reported information.

A few commenters expressed the belief that patient self-reporting is the most appropriate way to collect social determinants of health data such as race and ethnicity, agreeing with CMS' assessment that self-reported patient data is the gold standard. A few commenters noted that one challenge may be that the concept of race is subjective and may be imprecise due to differences in cultural understanding. A few commenters recommended that CMS encourage facilities to collect self-reported race and ethnicity data, as well as establish a timeframe for meeting specific data collection goals including data completeness and accuracy requirements. One commenter noted that many health care organizations are already collecting self-reported demographic information and have been for years. One commenter expressed its belief that the primary goal across all CMS programs should be to prioritize self-reported race, ethnicity, and other social determinants of health data as the sole source of stratifying populations to understand disparities. One commenter recommended that, given the importance of self-reported data, CMS work on developing data collection language that is more person-centric in order to encourage trust among those patients whose data are being collected.

Several commenters expressed support for collecting additional information that will likely impact patient outcomes, such as insurance status at dialysis initiation and geographic area of residence. Several commenters recommended the use of Z-codes or other data sources to collect data to report on factors such as housing insecurity, financial insecurity, caregiver support, mental illness, physical illness, age, education level, transportation insecurity, food insecurity, marital status, violence, safety concerns, and child care. One commenter recommended that CMS adopt a definition of health equity that takes into account the needs of various patient populations and structural issues associated with equity, such as race, ethnicity, sex, SOGI, language preference, tribal membership, and disability status.

A few commenters recommended that CMS work with the kidney care community to develop risk adjusters for measures. A few commenters requested that methodologies use data elements that are available to providers and that calculations can be replicated to promote transparency. A few commenters recommended that CMS also consider eliminating bias in kidney function testing, noting for example that the eGFR test is biased based on racial assumptions and can impact transplant eligibility among Black patients. One commenter expressed concern that many approaches based on data-driven technologies are less accessible to vulnerable patient populations and would potentially exacerbate existing inequities. This commenter also noted that smartphone technologies may be more promising as an example of a data-driven technology that does not facilitate exacerbation of health inequities.

Response: We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity quality measurement efforts.

Improving Demographic Data Collection

- Experiences of users of certified health IT regarding local adoption of practices for collection of social, psychological, and behavioral data elements, the perceived value of using these data for improving decision-making and care delivery, and the potential challenges and benefits of collecting more granular, structured demographic information, such as the ''Race & Ethnicity—CDC'' code system.
- The possible collection of a minimum set of social, psychological, and behavioral data elements by ESRD facilities at the time of admission using structured, interoperable electronic data standards, for the purposes of reporting, measure stratification and other data collection efforts relating to quality.

We received comments on these topics.

Comments: Many commenters expressed support for CMS' efforts to address inequities in health outcomes through improving data collection and patient outcome measurement. Several commenters supported the use of minimally burdensome data collection efforts. A few commenters noted that much of the information that CMS would like to collect is reported on Form 2728—ESRD Medical Evidence Report Medicare Entitlement And/Or Patient Registration (OMB control number 0938–0046), and encouraged that CMS to be economical in its expansion of data collection on the Form 2728 so as to not create additional patient concerns. One commenter recommended that a system of data

collection and reporting should not add to the confusion about what the terms race and ethnicity mean, and what labels appropriately fit either of these broad concepts. One commenter recommended that CMS collect data on demographic characteristics in a way that aligns with adoption of FHIR standards, noting that FHIR may be used to appropriately group demographic characteristics in a standardized way. One commenter noted the potential challenge of uploading data from facility EMR systems to CMS for measure calculation purposes. A few commenters expressed concerns with adjusting for social factors when there is a ''small numbers'' problem in ESRD QIP that can impact the accuracy of performance measurement and that will be aggravated with dividing categories into smaller subsets. One commenter expressed its belief that modifications to current data collection related to social, psychological, and behavioral data could be useful to CMS to address equity and quality of care. However, the commenter did not recommend the application of CDC's 900-variable system of identifying race and ethnicity, as provided in the CDC's Race and Ethnicity Code Set Version 1.0, in a highly granular way believing the volume of data that would need to be collected would make the process labor intensive for clinical staff. One commenter recommended that CMS work to improve and standardize the underlying data collection and metrics; this commenter recommended a joint development process that includes the Center for Medicare & Medicaid Innovation (CMMI) and the Office of the National Coordinator for Health Information Technology (ONC) in collaboration with health systems, practices, and patient/community representation.

Other commenters noted the importance of closing the health equity gap through measurement of demographic characteristics. One commenter suggested that agencies leverage the role of social workers in identifying sociodemographic factors and barriers to health equity. Another commenter supported this method, noting that although this may add another step to data collection processes, it would be valuable in addressing health equity gaps. To reduce possible workload burden on organizations that are new to this process, a commenter recommended a gradual approach to data collection. In addition, commenters suggested reducing burden by adopting standardized screening tools to collect this information, such as ICD–10–CM Z-codes, which in practice would allow patients to be referred to resources and initiatives when appropriate. Several commenters encouraged collection of comprehensive social determinants of health and demographic information in addition to race and ethnicity, such as disability, sexual orientation, and primary language. Several commenters provided feedback on the potential use of an indirect estimation algorithm when race and ethnicity are missing or incorrect, and emphasized the sensitivity of demographic information and recommended that CMS use caution when using estimates from the algorithm, including assessing for potential bias, reporting the results of indirect estimation alongside direct self-report at the organizational level for comparison, and establishing a timeline to transition to entirely directly collected data. Commenters also advised that CMS be transparent with beneficiaries and explain why data are being collected and the plans to use these data. A commenter noted that information technology infrastructure should be established in advance to ensure that this information is being used and exchanged appropriately.

Response: We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity quality measurement efforts.

Potential Creation of an ESRD Facility Equity Score To Synthesize Results Across Multiple Social Risk Factors

- The possible creation and confidential reporting of an ESRD Facility Equity Score to synthesize results across multiple social risk factors and disparity measures.
- Interventions ESRD facilities could institute to improve a low facility equity score and how improved demographic data could assist with these efforts.

We received comments on these topics.

Comments: Several commenters expressed support for the concept of an ESRD Facility Equity Score, but requested that CMS provide further details. Several commenters recommended that CMS work with stakeholders in the kidney care community to develop an equity score in order to ensure transparency and to make sure providers are able to address identified inequities. One commenter recommended that CMS include education, training, and resources for implementation of an equity score.

A few commenters noted the challenge of developing a scoring methodology that could address risk across different factors. A few commenters questioned whether the score would be meaningful for patients. A few commenters expressed concern for public reporting of a Facility Equity Score, noting that it might be misleading to patients and may not reflect quality of care because facilities are limited in their ability to influence disparities that impact health outcomes. One commenter expressed the belief that a Facility Equity Score is premature, and that CMS should focus on establishing the right set of patient characteristics and contrasting them with meaningful clinical and consumer measures in order to develop a meaningful scoring methodology to propose in future notice and comment rulemaking. One commenter expressed caution that the component measures should reflect actual differences in care provided by ESRD facilities and not factors outside of those facilities' control, believing the inclusion of measures not much under the control of ESRD facilities will penalize those facilities serving a large number of ''vulnerable'' patients and not really speak to issues of equity in the care provided. This commenter recommended that measures are selected carefully to reflect activities and factors that are under facilities' control and then apply all of the standard tools of quality improvement. One commenter expressed its belief that the use of an imputed race/ethnicity methodology risks misattributing people to the wrong categories, and carrying that over into a facility equity score could lead to incorrect or misguided responses. This commenter recommended a careful, inclusive development process to avoid establishing processes and metrics that exacerbate harms and recommended a CMMI initiative to test and shape reporting.

A few commenters expressed support for the production of reports to help facilities, patients and payers understand the disparities in their patient populations. A few commenters noted that many barriers such as anti-kickback rules and other regulations prevent facilities from providing additional services and supports that would help to address health disparities, and recommended that CMS work to find ways to remove these barriers. A few commenters recommended that CMS provide support to facilities in order to help them close gaps in health equity. One

commenter recommended that additional resources be allocated to help assist and support facilities in their health equity goals, such as taking money from ESRD QIP penalties to reward facilities that attain the benchmarks and also allocate funds to help low performing facilities improve. One commenter noted that anything that requires additional staff time and effort without either additional payment or some tangible savings elsewhere, will not be sustainable. This commenter gave examples of care coordination, more time in patient education, more frequent patient home visits, and additional electronic home monitoring, as potential paths to equity improvement that require additional funding.

We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity quality measurement efforts.

We also received comments on the general topic of health equity in the ESRD QIP.

Comments: Many commenters expressed overall support of CMS' goals to advance health equity. There were a few comments regarding the need to further extend and specify the definition of equity provided in the proposed rule. Commenters also noted that equity initiatives should be based on existing disparities and population health goals, be mindful of the needs of the communities served, and work to bridge dialysis facilities with community-based providers. Several commenters recommended that CMS further investigate ways to provide outreach and education aimed at slowing down the progress of chronic kidney disease and address health disparities before dialysis is necessary. Several commenters encouraged CMS to be mindful about whether collection of additional quality measures and standardized patient assessment elements might increase provider burden.

We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into account for future development.

2. COVID–19 Vaccination Measures Request for Information

a. Background

On January 31, 2020, the Secretary declared a PHE for the U.S. in response to the global outbreak of SARS–CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[201] COVID–19 is a contagious respiratory infection[202] that can cause serious illness and death. Older individuals and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[203]

As of April 2, 2021, the U.S. reported over 30 million cases of COVID–19 and over 550,000 COVID–19 deaths.[204] Hospitals and health systems saw significant surges of COVID–19 patients as community infection levels increased.[205] From December 2, 2020 through January 30, 2021, more than 100,000 Americans were in the hospital with COVID–19 at the same time.[206] As of September 16, 2021, the U.S. has reported over 41.5 million cases of COVID–19 and over 666,000 COVID–19 deaths.[207]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[208] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[209] Thus, the CDC advises that infections mainly occur through exposure to respiratory droplets when a person is in close contact with someone who has COVID–19.[210] Although less common, COVID–19 can also spread when individuals are not in close contact if small droplets or particles containing the virus linger in the air after the person who is infected has left the space.[211] Another means of less common transmission is contact with a contaminated surface.[212]

Subsequent to the publication of the proposed rule, the CDC confirmed that the three main ways that COVID–19 is spread are: (1) Breathing in air when close to an infected person who is exhaling small droplets and particles that contain the virus; (2) Having these small droplets and particles that contain virus land on the eyes, nose, or mouth, especially through splashes and sprays like a cough or sneeze; and (3) Touching eyes, nose, or mouth with hands that have the virus on them.[213] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed SARS–CoV–2 infection, regardless of whether the individual has symptoms.[214] Although personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, COVID–19 can spread between healthcare personnel (HCP) and patients, or from patient to patient given the close contact that may occur during the provision of care.[215] The CDC has emphasized that health care settings can be high-risk places for COVID–19 exposure and transmission.[216]

[201] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[202] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[203] Ibid.

[204] Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.*

[205] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895.* Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at: *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html.*

[206] US Currently Hospitalized | The COVID Tracking Project. Accessed January 31, 2021 at: *https://covidtracking.com/data/charts/us-currently-hospitalized.*

[207] Centers for Disease Control and Prevention. (2021). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.*

[208] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[209] Ibid.

[210] Ibid.

[211] Ibid.

[212] Ibid.

[213] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on July 15, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[214] Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html.*

[215] Centers for Disease Control and Prevention. (2021). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on April 2 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission.*

[216] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[217] On December 11, 2020, FDA issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[218] Subsequently, FDA issued EUAs for additional COVID–19 vaccines and approved a vaccine.[219]

As part of its national strategy to address COVID–19, the Biden Administration stated that it would work with states and the private sector to execute an aggressive vaccination strategy and outlined a goal of administering 200 million shots in 100 days.[220] After achieving this goal,[221] the Biden Administration announced a new goal to administer at least one COVID–19 vaccine shot to 70 percent of the U.S. adult population by July 4, 2021.[222] Although the goal of the U.S. government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, Federal agencies recommended that early vaccination efforts focus on those critical to the PHE response, including HCP providing direct care to patients with COVID–19, and individuals at highest risk for developing severe illness from COVID–19.[223] For example, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccination, given the potential for transmission in health care settings and the need to preserve health care system capacity.[224] Research suggests most states followed this recommendation,[225] and HCP began receiving the vaccine in mid-December of 2020.[226] Although the vaccination strategy for individuals at highest risk for developing severe illness from COVID–19, including ESRD patients, has varied from State to State,[227] ACIP recommendations indicated that ESRD patients would be offered the COVID–19 vaccine based on their high-risk status as part of phase 1c.[228]

As of July 30, 2021 the CDC reported that over 344 million doses of COVID–19 vaccine had been administered, and approximately 164.2 million people had received a complete vaccination course.[229] President Biden indicated on April 6, 2021 that the U.S. has sufficient vaccine supply to make every adult eligible to receive a vaccine beginning April 19, 2021.[230] Furthermore, on March 25, 2021, the Biden Administration announced a new partnership with dialysis facilities to provide COVID–19 vaccinations directly to people receiving dialysis and HCP in dialysis facilities.[231] Finally, as part of the Biden Administration's efforts to vaccinate those who are still unvaccinated through increasing the number of Americans covered by vaccination requirements,[232] on September 9, 2021, the Biden Administration announced that COVID–19 vaccination will be required of all staff within Medicare and Medicaid-certified facilities to protect both patients and HCP against COVID–19.[233]

b. COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure

In the CY 2022 ESRD PPS proposed rule (86 FR 36369), we stated our belief that it is important to incentivize and track HCP vaccination in dialysis facilities through quality measurement in order to protect health care workers, patients, and caregivers, and to help sustain the ability of these facilities to

[217] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on April 3, 2021 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[218] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/150386/download.* (as reissued on September 22, 2021)

[219] U.S. Food and Drug Administration. (2020). Moderna COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download* (as reissued on August 12, 2021); U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download* (as reissued on June 10, 2021). FDA Approves First COVID–19 Vaccine, Available at *https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.*

[220] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on April 3, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/.*

[221] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on June 2, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/21/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations-2/.*

[222] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on June 4, 2021, at: *https://www.whitehouse.gov/briefing-room/statements-releases/2021/05/04/fact-sheet-president-biden-to-announce-goal-to-administer-at-least-one-vaccine-shot-to-70-of-the-u-s-adult-population-by-july-4th/.*

[223] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at: *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf;* Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[224] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[225] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First? '' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/.*

[226] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f.*

[227] Kates, J, Michaud, J, Tolbert, J. ''The COVID–19 Vaccine Priority Line Continues to Change as States Make Further Updates.'' Kaiser Family Foundation. January 21, 2021. Accessed on January 29 at *https://www.kff.org/policy-watch/the-covid-19-vaccine-priority-line-continues-to-change-as-states-make-further-updates/.*

[228] Dooling K, Marin M, Wallace M, et al. ''The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID–19 Vaccine—United States, December 2020.'' MMWR Morb Mortal Wkly Rep 2021; 69:1657–1660. ACIP recommended that the COVID–19 vaccine should be offered to persons aged ≥75 years and non-health care frontline essential workers in Phase 1b, and to persons aged 16–64 years with high-risk medical conditions in Phase 1c.

[229] Centers for Disease Control and Prevention. COVID Data Tracker. COVID–19 Vaccinations in the United States. Accessed June 23, 2021 at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations.*

[230] The White House. Remarks by President Biden Marking the 150 Millionth COVID–19 Vaccine Shot. Accessed April 8, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/06/remarks-by-president-biden-marking-the-150-millionth-covid-19-vaccine-shot/.*

[231] The White House. FACT SHEET: Biden Administration Announces Historic $10 Billion Investment to Expand Access to COVID–19 Vaccines and Build Vaccine Confidence in Hardest-Hit and Highest-Risk Communities. March 25, 2021. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/25/fact-sheet-biden-administration-announces-historic-10-billion-investment-to-expand-access-to-covid-19-vaccines-and-build-vaccine-confidence-in-hardest-hit-and-highest-risk-communities/.*

[232] The White House. Path Out of the Pandemic: President Biden's COVID–19 Action Plan. Accessed on October 14, 2021. Available at: *https://www.whitehouse.gov/covidplan/#vaccinate.*

[233] CMS. Press Release: Biden-Harris Administration to Expand Vaccination Requirements for Health Care Settings. September 9, 2021. Available at: *https://www.cms.gov/newsroom/press-releases/biden-harris-administration-expand-vaccination-requirements-health-care-settings.* In order to implement this plan, CMS is working with the CDC to develop an Interim Final Rule with Comment Period that will extend emergency regulations to require vaccination among staff in a wide range of healthcare settings including dialysis facilities. This action will create a consistent standard across the country, while giving patients assurance of the vaccination status of those delivering care.

continue serving their communities throughout the PHE and beyond. We recognize the importance of COVID–19 vaccination, and have finalized proposals to include a COVID–19 HCP vaccination measure in various pay for reporting programs, such as the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the Hospital Inpatient Quality Reporting Program (86 FR 45374 through 45382), the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (86 FR 45428 through 45434), the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) (86 FR 45438 through 45446), the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) (86 FR 42385 through 42396), and the Skilled Nursing Facility Quality Reporting Program (86 FR 42480 through 42489). In the proposed rule, we noted that there is not a pay for reporting program under the ESRD PPS, however, we stated our belief that the public reporting of vaccination data on Dialysis Facility Compare is important and would help to inform patients of a facility's COVID–19 vaccination rates of HCP. Currently, there is a measure for HCP [234] and another for patient COVID–19 vaccination [235] rates and such measures are currently reported to CDC's National Healthcare Safety Network via ESRD Networks. The two measures track the proportions of a facility's HCP and patient population, respectively, that have been fully vaccinated against COVID–19. Facilities were able to begin weekly COVID–19 vaccination reporting for HCP in December 2020,[236] and were able to begin weekly COVID–19 vaccination reporting for patients in March 2021.[237] When the proposed rule was published, we noted that 89 percent of ESRD facilities were reporting HCP vaccination rates and almost 95 percent of ESRD facilities were reporting patient vaccination rates on these measures. In the proposed rule (86 FR 36369), we stated that we were evaluating options for publicly reporting the data on official CMS datasets that compare the quality of care provided in Medicare-certified dialysis facilities nationwide. We further stated that we were also exploring the potential future inclusion of a COVID–19 vaccination measure to the ESRD QIP. Therefore, we sought public comment on adding a new measure, COVID–19 Vaccination Coverage Among HCP, to the ESRD QIP measure set in the next rulemaking cycle. The measure would assess the proportion of a facility's health care workforce that has been vaccinated against COVID–19.

HCP are at risk of carrying COVID–19 infection to patients, experiencing illness or death as a result of COVID–19 themselves, and transmitting it to their families, friends, and the general public. In the proposed rule (86 FR 36369), we stated our belief that facilities should track the level of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19 within their facilities. HCP vaccination can potentially reduce illness that leads to work absence and limit disruptions to care.[238] Data from influenza vaccination demonstrates that provider uptake of the vaccine is associated with that provider recommending vaccination to patients,[239] and we stated our belief that HCP COVID–19 vaccination in dialysis facilities could similarly increase uptake among that patient population. We also stated our belief that publishing the HCP vaccination rates would be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19, as they choose facilities from which to seek treatment. Under CMS' Meaningful Measures Framework, the COVID–19 measure would address the quality priority of ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

c. COVID–19 Vaccination Coverage for Patients in End-Stage Renal Disease (ESRD) Facilities Measure

In the CY 2022 ESRD PPS proposed rule (86 FR 36370), we stated our belief that it is important to encourage patient vaccination in dialysis facilities in order to protect health care workers, patients, and caregivers, and to help sustain the ability of these facilities to continue serving their communities throughout the PHE and beyond. COVID–19 can cause outbreaks in ESRD facilities, and may disproportionately affect ESRD patients due to the nature of the treatment and sharing of common spaces.[240] Many patients treated in ESRD facilities have other underlying chronic conditions, and therefore are highly susceptible to illness and disease.[241] Sufficient vaccination coverage among patients in ESRD facilities may reduce transmission of SARS–CoV–2, thereby protecting them from COVID–19 mortality. Therefore, we sought public comment on adding new measure, COVID–19 Vaccination Coverage Among Patients, to the ESRD QIP measure set in future rulemaking. The measure would assess the proportion of a facility's patient population that has been vaccinated against COVID–19.

In the proposed rule, we stated our belief that facilities should track the level of vaccination among their patients as part of their efforts to assess and reduce the risk of transmission of COVID–19 within their facilities. We also expressed our belief that publishing the vaccination rates would be helpful to many ESRD patients, including those who are at high-risk for developing serious complications from COVID–19, as they choose facilities from which to seek treatment. Under CMS' Meaningful Measures Framework, the COVID–19 measure addresses the quality priority of ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

d. Review by the Measures Application Partnership and NQF

The COVID–19 HCP vaccination measure and the COVID–19 patient vaccination measure were included on the publicly available ''List of Measures under Consideration for December 21, 2020'' (MUC List), a list of measures under consideration for use in various Medicare programs.[242] When the Measure Applications Partnership Hospital Workgroup convened on January 11, 2021, it reviewed measures on the MUC List including the two COVID–19 vaccination measures. The Measure Applications Partnership Hospital Workgroup recognized that the proposed measures represent a promising effort to advance measurement for an evolving national pandemic and that it would bring value to the ESRD QIP measure set by

[234] *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html.*

[235] *https://www.cdc.gov/nhsn/dialysis/pt-covid-vac/index.html.*

[236] *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/weekly-covid-guidance-508.pdf.*

[237] *https://www.cdc.gov/nhsn/pdfs/dialysis/covidvax/getting-started-508.pdf.*

[238] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm.*

[239] Measure Application Committee Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[240] Verma, A., Patel, A., Tio, M., Waikar, S., ''Caring for Dialysis Patients in a Time of COVID–19''. Kidney Medicine, Volume 2, Issue 6, 2020, Pages 787–792, ISSN 2590–0595. Available at *https://doi.org/10.1016/j.xkme.2020.07.006.*

[241] Ibid.

[242] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at: *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf* on January 29 2021.

providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[243] The Measure Applications Partnership Hospital Workgroup also stated that collecting information on COVID–19 vaccination coverage among HCP and ESRD patients, and providing feedback to facilities, will allow facilities to benchmark coverage rates and improve coverage in their facility. The Measure Applications Partnership Hospital Workgroup further noted that reducing rates of COVID–19 in HCP and ESRD patients may reduce transmission among a patient population that is highly susceptible to illness and disease, and also reduce instances of staff shortages due to illness.[244]

In its preliminary recommendations, the Measure Applications Partnership Hospital Workgroup did not support these two measures for rulemaking, subject to potential for mitigation.[245] To mitigate its concerns, the Measure Applications Partnership Hospital Workgroup believed that both measures needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.[246] Subsequently, the Measure Applications Partnership Coordinating Committee met on January 25, 2021, and reviewed the COVID–19 Vaccination Coverage Among HCP measure and the COVID–19 Vaccination Coverage for Patients in ESRD Facilities Measure. In the 2020–2021 Measure Applications Partnership Final Recommendations, Measure Applications Partnership offered conditional support for rulemaking contingent on CMS bringing the measures back to Measure Applications Partnership once the specifications are further refined.[247] The Measure Applications Partnership specifically stated, ''the incomplete specifications require immediate mitigation and further development should continue.'' [248] The Measure Applications Partnership further noted that the measures would add value to the ESRD QIP measure set by providing visibility into an important intervention to limit COVID–19 infections in HCP and the ESRD patients for whom they provide care.[249] CMS brought both measures back to the Measure Applications Partnership on March 15, 2021 to provide additional information and continue discussing mitigation.

e. Request for Public Comment

In the proposed rule, we sought public comment on potentially adding the two new COVID–19 vaccination measures discussed above, the COVID–19 vaccination measure for HCP and the COVID–19 vaccination measure for patients, to the ESRD QIP measure set.[250]

We were also interested in public comment on data collection, submission, and reporting for the COVID–19 vaccination measure for HCP and the COVID–19 vaccination measure for patients. For example, we stated that we were considering requiring reporting for these measures on an annual basis for the performance period for each calendar year corresponding to the associated payment year, and the reporting period would be January 1 through December 31 annually. Based on the measures currently being developed by the CDC that were submitted to the Measure Applications Partnership, facilities would report the measures through the National Healthcare Safety Network (NHSN) web-based surveillance system. We also sought public comment from stakeholders on other ways to collect data on COVID–19 vaccination rates at dialysis facilities for ESRD QIP purposes and their associated costs and burdens. Given the immediacy of the PHE for COVID–19, as well as the importance of continuing to monitor and make publicly available COVID–19 vaccination rates as the PHE ends, we stated that we anticipate rulemaking on this requirement in the CY 2023 rulemaking cycle.

The comments we received and our responses are set forth below.

Comment: Several commenters expressed support for future adoption of both COVID–19 vaccination measures. Several commenters expressed the belief that COVID–19 vaccination measures are important because they would help to prevent the spread of COVID–19 in a facility and would also help to prevent mortality due to the impact of COVID–19 on an immunocompromised patient population. A few commenters stated that such measures would help encourage COVID–19 vaccination for both staff and patients at ESRD facilities. One commenter noted that the nature of treatment sessions in the dialysis care setting may make other COVID–19 mitigation strategies less effective.

A few commenters expressed support for the possible adoption of both COVID–19 vaccination measures, noting that making such data publicly available would help patients make informed choices. A few commenters expressed support for reporting possible COVID–19 vaccination measures through NHSN as it already does so and therefore would be less burdensome.

Several commenters expressed support for tracking and reporting COVID–19 vaccination rates among HCPs and ESRD patients on Care Compare or Dialysis Facility Compare in order to help patients make informed decisions when choosing a dialysis facility. One commenter expressed support the application of a uniform reporting metric for COVID–19 vaccination among HCPs and patients across all Medicare-covered health settings.

A few commenters expressed support for all efforts to increase vaccination coverage among HCPs for their own safety and for patient safety as well. One commenter expressed its belief that all medically-eligible HCPs should be vaccinated against COVID–19.

A few commenters expressed support for the COVID–19 Vaccination among ESRD patients measure. One commenter expressed the belief that it may be useful for the public to know the percent of patients vaccinated at a facility.

Response: We thank the commenters for their support, and will take commenters' feedback into consideration for future rulemaking.

Comment: Although several commenters expressed support for vaccination efforts and the belief that patients and HCPs should follow CDC vaccination guidelines, these commenters did not support the inclusion of COVID–19 vaccination measures in the ESRD QIP. A few commenters recommended that COVID–19 vaccination measures should not be added to the ESRD QIP, noting the MAP's initial hesitancy to recommend the measures. A few commenters expressed the belief that such measures would not help to address vaccine hesitancy among patients and HCPs, and suggested that Federal agencies

[243] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[244] Ibid.

[245] Ibid.

[246] Ibid.

[247] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 3, 2021 at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx.*

[248] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[249] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[250] Specifications for both measures available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650.*

coordinate vaccination education and outreach efforts instead. A few commenters expressed concern that including COVID–19 vaccination measures in the ESRD QIP would hold facilities accountable for vaccination rates of patients and HCPs, noting that the individual decision to get vaccinated is beyond the facility's control.

One commenter recommended that such measures incorporate factors that take into account facility vaccination efforts, rather than a numeric threshold. One commenter expressed support for including the COVID–19 vaccination measures as performance measures in the ESRD QIP. One commenter recommended that such measures be included in the ESRD QIP as reporting measures.

Response: We thank the commenters for their feedback, and will take this input into consideration for future rulemaking. We note that the MAP now recommends both COVID–19 vaccination measures for inclusion in the ESRD QIP.[251] We also note that the COVID–19 vaccination measures that we describe in this final rule and are considering for adoption in future rulemaking would be reporting measures. Under these measures, facilities would only be required to report vaccination rates and would not be penalized based on the vaccination rates themselves.

Comment: Several commenters expressed concern that establishing the specifications for such measures would be challenging due to changing COVID–19 vaccination guidelines and differences in regional policies, which may undermine the validity or reliability of a COVID–19 vaccination measure. A few commenters requested that CMS provide more specific details regarding proposed vaccination measure specifications, including defined numerators and denominators, as well as inclusion and exclusion criteria.

A few commenters expressed concern that defining the denominator for the COVID–19 HCP Vaccination measure will be challenging because many ESRD facilities are parts of larger organizations and may share staff who spend some time working in the ESRD unit or facility and time working elsewhere. One commenter requested that the possible COVID–19 Vaccination among HCP measure limit data collection to HCPs employed by the dialysis organizations and only require the reporting of information within the facilities' purview, noting that the CDC is able to obtain non-clinic staff information directly from providers.

Response: We thank the commenters for their feedback, and will take this input into consideration for future rulemaking. We acknowledge that measure specifications may evolve based on changes to COVID–19 vaccination guidelines, and would provide more specific details regarding measure specifications in future rulemaking as part of our proposals to adopt the COVID–19 vaccination measures.

Comment: A few commenters expressed concern that implementing such measures would result in staff quitting in order to avoid vaccination, which would in turn negatively impact patient care.

Response: We acknowledge that staffing shortages are a national issue, especially for the healthcare system. However, we disagree that staffing shortages would impact patient safety more than unvaccinated HCPs. We believe that vaccination is one of the most effective tools right now for protecting an immunocompromised patient population that has particularly high mortality rates due to COVID–19 infection. We also note that the COVID–19 Vaccination among HCP measure that we are considering for future adoption would not require vaccination, but would rather require facilities to report vaccination rates.

Comment: One commenter recommended that patients (such as children 11 and under) who are not yet eligible for vaccination under an EUA or approval should be excluded from any vaccination measure.

Response: The current COVID–19 Vaccination among Patients measure being considered for possible adoption in future rulemaking excludes patients who are ineligible for vaccination.

Comment: A few commenters did not support the future inclusion of a COVID–19 Vaccination among Patients measure. One commenter acknowledged that a COVID–19 patient vaccination measure likely would marginally increase and sustain vaccination rates, but expressed concern that tying a COVID–19 patient vaccination measure to payment may have unintended consequences such as undermining patient autonomy and creating barriers to facility access for unvaccinated patients. One commenter did not support the COVID–19 vaccination measure for patients believing there is no point to collecting data that mostly reflects patient demographics based on vaccination status, not clinical quality. This commenter stated its belief that providers are already motivated to ensure their patients are vaccinated given the high COVID–19 mortality rate among ESRD patients.

Response: The COVID–19 patient vaccination measure that we are considering for adoption in future rulemaking is a reporting measure; facilities would only be required to report vaccination rates and would not be penalized based on actual vaccination rates. We agree that the COVID–19 vaccination measure for patients would collect data that indicates patient vaccination rates at an individual facility. However, we also believe that this measure would motivate providers to ensure their patients are vaccinated against COVID–19 and that this information is also relevant to patient safety since a facility's vaccination rates would be important for patients to know when choosing an individual facility for treatment.

3. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR)

We aim to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. As part of this modernization of our quality measurement enterprise, we issued a request for information (RFI). The purpose of this RFI was to gather broad public input solely for planning purposes for our transition to digital quality measurement. Any updates to specific program requirements related to providing data for quality measurement and reporting provisions would be addressed through future rulemaking, as necessary. This RFI contained four parts:

- *Background.* This part provided information on our quality measurement programs and our goal to move fully to digital quality measurement by 2025. This part also provided a summary of other recent HHS policy developments that are advancing interoperability and could support our move towards full digital quality measurement.
- *Definition of Digital Quality Measures (dQMs).* This part provided a potential definition for dQMs. Specific requests for input are included in the section.
- *Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025.* This part introduced four possible steps that would enable transformation of CMS' quality measurement enterprise to be

[251] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on September 29, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

fully digital by 2025. Specific requests for input are included in the section.

• *Solicitation of Comments.* This part listed all requests for input included in the above sections of this RFI.

a. Background

As required by law, we implemented quality measurement programs and value-based purchasing programs across a broad range of inpatient, outpatient, and post-acute care (PAC) settings, consistent with our mission to improve the quality of health care for Americans through measurement, transparency, and increasingly, value-based purchasing. These quality programs are foundational for incentivizing value-based care, contributing to improvements in health care, enhancing patient outcomes, and informing consumer choice. We aim to move fully to digital quality measurement by 2025. We acknowledge providers within the various care and practice settings covered by our quality programs may be at different stages of readiness, and therefore, the timeline for achieving full digital quality measurement across our quality reporting programs may vary.

We also continue to evolve the Medicare Promoting Interoperability Program that advances the use of certified electronic health record (EHR) technology, from an initial focus on electronic data capture to enhancing information exchange and expanding quality measurement (83 FR 41634). However, reporting quality data via EHRs remains burdensome, and our current approach to quality measurement does not readily incorporate emerging data sources such as patient-reported outcomes (PRO) and patient-generated health data (PGHD).[252] There is a need to streamline our approach to data collection, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, improvement, and learning.

Additionally, advancements in technical standards and regulatory initiatives to improve interoperability of healthcare data are creating an opportunity to significantly improve our quality measurement systems. In May 2020, we finalized interoperability requirements in the CMS Interoperability and Patient Access final rule (85 FR 25510) to support beneficiary access to data held by certain payers. At the same time, the Office of the National Coordinator for Health Information Technology (ONC) finalized policies in the ONC 21st Century Cures Act final rule (85 FR 25642) to advance the interoperability of health IT as defined in section 4003 of the Cures Act, including the ''complete access, exchange, and use of all electronically accessible health information.'' Closely working with ONC, we collaboratively identified HL7 Fast Healthcare Interoperability Resources (FHIR®) Release 4.0.1 as the standard to support Application Programming Interface (API) policies in both rules. ONC, on behalf of HHS, adopted the HL7 FHIR Release 4.0.1 for APIs and related implementation specifications at 45 CFR 170.215. We believe the FHIR standard has the potential to be a more efficient and modular standard to enable APIs. We also believe this standard enables collaboration and information sharing, which is essential for delivering high-quality care and better outcomes at a lower cost. By aligning technology requirements for payers, health care providers, and health IT developers, HHS can advance-an interoperable health IT infrastructure that ensures providers and patients have access to health data when and where it is needed.

In the ONC 21st Century Cures Act final rule ONC adopted a ''Standardized API for Patient and Population Services'' certification criterion for health IT that requires the use of the FHIR Release 4 and several implementation specifications. Health IT certified to this criterion will offer single patient and multiple patient services that can be accessed by third party applications (85 FR 25742).[253] The ONC 21st Century Cures Act final rule also requires health IT developers update their certified health IT to support the U.S. Core Data for Interoperability (USCDI) standard.[254] The scope of patient data identified in the USCDI and the data standards that support this data set are expected to evolve over time, starting with data specified in Version 1 of the USCDI. In November 2020, ONC issued an interim final rule with comment period extending the date when health IT developers must make technology meeting updated certification criteria available under the ONC Health IT Certification Program until December 31, 2022 (85 FR 70064).[255]

The CMS Interoperability and Patient Access final rule (85 FR 25510) and program policies build on the ONC 21st Century Cures Act final rule (85 FR 25642). The CMS Interoperability and Patient Access final rule and policies require certain payers (for example, Medicare Advantage organizations, Medicaid, and CHIP fee for service programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan [QHP] issuers on the Federally-facilitated Exchanges [FFEs]) to implement and maintain a standards-based Patient Access API using HL7 FHIR Release 4.0.1 to make available certain data to their enrollees and beneficiaries (called ''patients'' in the CMS interoperability rule). These certain data include data concerning claims and encounters, with the intent to ensure access to their own health care information through third-party software applications. The rule also established new Conditions of Participation for Medicare and Medicaid participating hospitals, psychiatric hospitals, and critical access hospitals (CAHs), requiring them to send electronic notifications to another healthcare facility or community provider or practitioner when a patient is admitted, discharged, or transferred (85 FR 25603). In the CY 2021 Physician Fee Schedule (PFS) final rule (85 FR 84472), we finalized a policy to align the certified EHR technology required for use in the Promoting Interoperability programs and the MIPS Promoting Interoperability performance category with the updates to health IT certification criteria finalized in the ONC 21st Century Cures Act. Under this policy, eligible clinicians, MIPS eligible clinicians, and eligible hospitals and CAHs participating in the Promoting Interoperability Programs, must use technology meeting the updated certification criteria for performance and reporting periods beginning in 2023 (85 FR 84825).

The use of APIs can also reduce long-standing barriers to quality measurement. Currently, health IT developers are required to implement individual measure specifications within their health IT product. The health IT developer must also accommodate how that product connects with the unique variety of systems within a specific care setting.[256]

[252] What are patient generated health data: *https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data.*

[253] Application Programming Interfaces (API) Resource Guide, Version 1.0. Available at: *https://www.healthit.gov/sites/default/files/page/2020-11/API-Resource-Guide_v1_0.pdf.*

[254] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[255] Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the Covid-19 Public Health Emergency. *https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-24376.pdf.*

[256] The Office of the National Coordinator for Health Information Technology, Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, Final Report (Feb. 2020). Available at: *https://*

This may be further complicated by systems which integrate a wide range of data schemas. This process is burdensome and costly, and it is difficult to reliably obtain high quality data across systems. As health IT developers map their health IT data to the FHIR standard and related implementation specifications, APIs can enable these data to be easily accessible for measurement or other use cases, such as care coordination, clinical decision support, and supporting patient access.

We believe the emerging data standardization and interoperability enabled by APIs will support the transition to full digital quality measurement by 2025, and are committed to exploring and seeking input on potential solutions for the transition to digital quality measurement as described in this RFI.

b. Definition of Digital Quality Measures

In the proposed rule, we sought to refine the definition of digital quality measures (dQMs) to further operationalize our objective of fully transitioning to dQMs by 2025. We previously noted dQMs use ''sources of health information that are captured and can be transmitted electronically and via interoperable systems'' (85 FR 84845). In this RFI, we sought input on future elaboration that would define a dQM as a software that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources. We also noted that dQMs are intended to improve the patient experience including quality of care, improve the health of populations, and/or reduce costs.

We discuss one potential approach to developing dQM software in section IV.G.3.c. of this final rule. In this section, we sought comment on the potential definition of dQMs in this RFI.

We also sought feedback on how leveraging advances in technology (for example, FHIR APIs) to access and electronically transmit interoperable data for dQMs could reinforce other activities to support quality measurement and improvement (for example, the aggregation of data across multiple data sources, rapid-cycle feedback, and alignment of programmatic requirements).

The transition to dQMs relies on advances in data standardization and interoperability. As providers and payers work to implement the required advances in interoperability over the next several years, we will continue to support reporting of eCQMs through CMS quality reporting programs and through the Promoting Interoperability programs.[257] These fully digital measures continue to be important drivers of interoperability advancement and learning. We are currently re-specifying and testing these measures to use FHIR rather than the currently adopted Quality Data Model (QDM) in anticipation of the wider use of FHIR standards. We intend to apply significant components of the output of this work, such as the re-specified measure logic and the learning done through measure testing with FHIR APIs, to define and build future dQMs that take advantage of the expansion of standardized, interoperable data.

c. Changes Under Consideration To Advance Digital Quality Measurement: Potential Actions in Four Areas To Transition to Digital Quality Measures by 2025

Building on the advances in interoperability and learning from testing of FHIR-converted eCQMs, we aim to move fully to dQMs, originating from sources of health information that are captured and can be transmitted electronically via interoperable systems, by 2025.

To enable this transformation, we are considering further modernizing the quality measurement enterprise in four major ways: (1) Leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based APIs; (2) redesign our quality measures to be self-contained tools; (3) better support data aggregation; and (4) work to align measure requirements across our reporting programs, other Federal programs and agencies, and the private sector where appropriate.

These changes would enable us to collect and utilize more timely, actionable, and standardized data from diverse sources and care settings to improve the scope and quality of data used in quality reporting and payment programs, reduce quality reporting burden, and make results available to stakeholders in a rapid-cycle fashion. Data collection and reporting efforts would become more efficient, supported by advances in interoperability and data standardization. Aggregation of data from multiple sources would allow assessments of costs and outcomes to be measured across multiple care settings for an individual patient or clinical conditions. We believe that aggregating data for measurement can incorporate a more holistic assessment of an individual's health and healthcare and produce the rich set of data needed to enable patients and caregivers to make informed decisions by combining data from multiple sources (for example, patient reported data, EHR data, and claims data) for measurement.

Perhaps most importantly, these steps would help us deliver on the full promise of quality measurement and drive us toward a learning health system that transforms healthcare quality, safety, and coordination and effectively measures and achieves value-based care. The shift from a static to a learning health system hinges on the interoperability of healthcare data, and the use of standardized data. dQMs would leverage this interoperability to deliver on the promise of a learning health system wherein standards-based data sharing and analysis, rapid-cycle feedback, and quality measurement and incentives are aligned for continuous improvement in patient-centered care. Similarly, standardized, interoperable data used for measurement can also be used for other use cases, such as clinical decision support and care coordination and care decision support, which impacts health care and care quality.

We requested comments on four potential future actions that would enable transformation to a fully digital quality measurement enterprise by 2025.

(1) Leveraging and Advancing Standards for Digital Data and Obtaining All EHR Data Required for Quality Measures via Provider FHIR-Based APIs

We are considering targeting the data required for our quality measures that utilize EHR data to be data retrieved via FHIR-based APIs based on standardized, interoperable data. Utilizing standardized data for EHR-based measurement (based on FHIR and associated implementation guides) and aligning where possible with interoperability requirements can eliminate the data collection burden providers currently experience with required chart-abstracted quality measures and reduce the burden of reporting digital quality measure results. We can fully leverage this advance to adapt eCQMs and expand to other

www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf.

[257] eCQI Resource Center, *https://ecqi.healthit.gov/.*

dQMs through the adoption of interoperable standards across other digital data sources. We are considering methods and approaches to leverage the interoperability data requirements for APIs set by the ONC 21st Century Cures Act final rule for certified health technology to support modernization of CMS quality measure reporting. As discussed previously, these requirements will be included in certified technology in future years (85 FR 84825), including availability of data included in the USCDI via standards-based APIs, and CMS will require clinicians and hospitals participating in MIPS and the Promoting Interoperability Programs, respectively, to transition to use of certified technology updated consistent with the 2015 Cures Edition Update (85 FR 84825).

Digital data used for measurement could expand beyond data captured in traditional clinical settings, administrative claims data, and EHRs. Many important data sources are not currently captured digitally, such as survey and PGHD. We intend to work to innovate and broaden the digital data used across the quality measurement enterprise beyond the clinical EHR and administrative claims. Agreed upon standards for these data, and associated implementation guides will be important for interoperability and quality measurement. We will consider developing clear guidelines and requirements for these digital data that align with interoperability requirements, for example, expressing in standards, exposing via APIs, and incentivizing technologies that innovate data capture and interoperability.

High quality data are also essential for reliable and valid measurement. Hence, in implementing the shift to capture all clinical EHR data via FHIR-based APIs, we would support efforts to strengthen and test the quality of the data obtained through FHIR-based APIs for quality measurement. We currently conduct audits of electronic data with functions including checks for data completeness and data accuracy, confirmation of proper data formatting, alignment with standards, and appropriate data cleaning. These functions would continue and be applied to dQMs and further expanded to automate the manual validation of the data compared to the original data source (for example, the medical record) where possible. Analytic advancements such as natural language processing, big data analytics, and artificial intelligence, can support this evolution. These techniques can be applied to validating observed patterns in data and inferences or conclusions drawn from associations, as data are received, to ensure high quality data are used for measurement.

We sought feedback on the goal of aligning data needed for quality measurement with interoperability requirements and the strengths and limitations of this approach. We also sought feedback on the importance of and approaches to supporting inclusion of PGHD and other currently non-standardized data. We also welcomed comment on approaches for testing data quality and validity.

(2) Redesigning Quality Measures To Be Self-Contained Tools

We are considering approaches for deploying quality measures to take advantage of standardized data and interoperability requirements that have expanded flexibility and functionality compared to CMS' current eCQMs. We are considering defining and developing dQM software as end-to-end measure calculation solutions that retrieve data from primarily FHIR resources maintained by providers, payers, CMS, and others; calculate measure score(s); and produce reports. In general, we believe to optimize the use of standardized and interoperable data, the software solution for dQMs should do the following:

- Have the flexibility to support calculation of single or multiple quality measure(s).
- Perform three functions: (i) Obtain data via automated queries from a broad set of digital data sources (initially from EHRs, and in the future from claims, PRO, and PGHD); (ii) calculate the measure score according to measure logic; and (iii) generate measure score report(s).
- Be compatible with any data source systems that implement standard interoperability requirements.
- Exist separately from digital data source(s) and respect the limitations of the functionality of those data sources.
- Be tested and updated independently of the data source systems.
- Operate in accordance with health information protection requirements under applicable laws and comply with governance functions for health information exchange.
- Have the flexibility to be deployed by individual health systems, health IT vendors, data aggregators, and health plans; and/or run by CMS depending on the program and measure needs and specifications.
- Be designed to enable easy installation for supplemental uses by medical professionals and other non-technical end-users, such as local calculation of quality measure scores or quality improvement.
- Have the flexibility to employ current and evolving advanced analytic approaches such as natural language processing.
- Be designed to support pro-competitive practices for development, maintenance, and implementation and diffusion of quality measurement and related quality improvement and clinical tools through for example the use of open-source core architecture.

We sought comment on these suggested functionalities and other additional functionalities that quality measure tools should ideally have particularly in the context of the pending availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs).

We were also interested whether and how this more open, agile strategy may facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research.

(3) Building a Pathway to Data Aggregation in Support of Quality Measurement

Using multiple sources of collected data to inform measurement would reduce data fragmentation (or, different pieces of data regarding a single patient stored in many different places). Additionally, we are also considering expanding and establishing policies and processes for data aggregation and measure calculation by third-party aggregators that include, but are not limited to, HIEs and clinical registries. Qualified Clinical Data Registries and Qualified Registries that report quality measures for eligible clinicians in the Merit-based Incentive Payment System (MIPS) program are potential examples [258] at 42 CFR 414.1440(b)(2)(iv) and (v) and § 414.1440(c)(2)(iii) and (iv) and can also support measure reporting. We are considering establishing similar policies for third-party aggregators to maintain the integrity of our measure reporting process and to encourage market innovation.

We sought feedback on aggregation of data from multiple sources being used

[258] Calendar Year (CY) 2021 Physician Fee Schedule Final Rule: Finalized (New and Updated) Qualified Clinical Data Registry (QCDR) and Qualified Registry Policies, *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1362/QCDR%20and%20QR%20Updates%202021%20Final%20Rule%20Fact%20Sheet.pdf.*

to inform measurement. We also sought feedback on the role data aggregators can and should play in CMS quality measure reporting in collaboration with providers, and how we can best facilitate and enable aggregation.

(4) Potential Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

We are committed to using policy levers and working with stakeholders to solve the issue of interoperable data exchange and to transition to full digital quality measurement. We are considering the future potential development and multi-staged implementation of a common portfolio of dQMs across our regulated programs, agencies, and private payers. This common portfolio would require alignment of: (1) Measure concepts and specifications including narrative statements, measure logic, and value sets, and (2) the individual data elements used to build these measure specifications and calculate the measure logic. Further, the required data elements would be limited to standardized, interoperable data elements to the fullest extent possible; hence, part of the alignment strategy will be the consideration and advancement of data standards and implementation guides for key data elements. We would coordinate closely with quality measure developers, Federal and State agencies, and private payers to develop and to maintain a cohesive dQM portfolio that meets our programmatic requirements and that fully aligns across Federal and State agencies and payers to the extent possible.

We intend for this coordination to be ongoing and allow for continuous refinement to ensure quality measures remain aligned with evolving healthcare practices and priorities (for example, PROs, disparities, care coordination), and track with the transformation of data collection, alignment with health IT module updates including capabilities and standards adopted by ONC (for example, standards to enable APIs). This coordination would build on the principles outlined in HHS' National Health Quality Roadmap.[259] It would focus on the quality domains of safety, timeliness, efficiency, effectiveness, equitability, and patient-centeredness. It would leverage several existing Federal and public-private efforts including our Meaningful Measures 2.0 Framework; the Federal Electronic Health Record Modernization (DoD/VA); the Agency for Healthcare Research and Quality's Clinical Decision Support Initiative; the Centers for Disease Control and Prevention's Adapting Clinical Guidelines for the Digital Age initiative; the Core Quality Measure Collaborative, which convenes stakeholders from America's Health Insurance Plans (AHIP), CMS, NQF, provider organizations, private payers, and consumers and develops consensus on quality measures for provider specialties; and the NQF-convened Measure Applications Partnership, which recommends measures for use in public payment and reporting programs. We would coordinate with HL7's ongoing work to advance FHIR resources in critical areas to support patient care and measurement such as social determinants of health. Through this coordination, we would identify which existing measures could be used or evolved to be used as dQMs, in recognition of current healthcare practice and priorities.

This multi-stakeholder, joint Federal and industry, made possible and enabled by the pending advances towards true interoperability, would yield a significantly improved quality measurement enterprise. The success of the dQM portfolio would be enhanced by the degree to which the measures achieve our programmatic requirements for measures as well as the requirements of other agencies and payers.

We sought feedback on initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools, and data standards). We also sought to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities across sectors.

d. Solicitation of Comments

We plan to continue working with other agencies and stakeholders to coordinate and to inform any potential transition to dQMs by 2025. We have summarized the comments to this RFI below but note that we will not be responding to them in this final rule. We will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

As noted previously, we sought input on the future development of the following:

• *Definition of Digital Quality Measures:* We sought feedback on the following as described in section IV.G.3.c.(2).:

++ Do you have feedback on the dQM definition?

++ Does this approach to defining and deploying dQMs to interface with FHIR-based APIs seem promising? We also welcomed more specific comments on the attributes or functions to support such an approach of deploying dQMs.

We received comments on these topics.

Comment: Several commenters expressed support for the proposed definition of dQM. Several commenters recommended additional clarity on the proposed definition of dQM, including more detail on what the measures would be, how they differ from current ESRD QIP measures, and the sources of data for those measures. One commenter recommended that CMS refine its definition of dQMs, focus on currently available valid and reliable digital data sources, and set clear and specific parameters for what they expect of dialysis providers during this transition.

Several commenters expressed support for transitioning toward interoperability through dQMS to interface with FHIR-based resources. One commenter noted that FHIR cannot solve or improve data quality alone without extensive development of FHIR extensions and profiles noting that many ESRD-specific data elements are not part of hospital EHR systems because they are not part of meaningful use requirements; this commenter made recommendations for data elements to be included in future versions of United States Core Data for Interoperability (USCDI). One commenter recommended that CMS evaluate the progress of developers and providers in adopting FHIR standards to ensure that the adoption of FHIR standards is not cost-prohibitive or overly burdensome and that CMS establish a clear timeframe for adoption of FHIR standards, including a trial or voluntary participation period prior to formal adoption. One commenter recommended that CMS ensure that dQMs can be linked with patient-level data such as patient experience of care and patient-reported outcomes. One commenter expressed support for CMS' approach to defining and deploying dQMs on FHIR believing it has the potential to further enhance value-based care that puts patient interests as the focal point. This

[259] Department of Health and Human Services, National Health Quality Roadmap (May 2020). Available at: *https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf.*

commenter recommended that implementation of dQMs be gradual, transparent, and based on robust technology. The commenter also noted its belief that the market of software developers would very quickly be able to respond to the CMS request for dQMs. One commenter expressed agreement that data sources should include administrative systems, electronically submitted clinical assessment data, case management systems, electronic health records, instruments such as medical devices or wearable devices, patient portals or applications, health information exchanges or registries, and other sources. One commenter recommended that dQMs be developed using standardized data collection measures that enable end users to interact with quality measures in an interoperable and consistent format and to ensure consistency in the collection and data analysis. This commenter also recommended the use of Smart on FHIR apps using a FHIR Questionnaire to enable powerful data capture, reduce burden, and that would allow for the continuous data driven development of quality measures over time, with the software/hardware layers providing greater stability. One commenter recommended that CMS add a digital measure confirming the presence and accessibility of advance directive information.

Several commenters expressed concerns about shifting to a FHIR-based application programming interface including that the utility of an ESRD-specific FHIR standard outside of quality reporting to CMS is limited, it introduces complicating factors, the burden may outweigh the benefit with CMS' current focus on CROWNWeb and EQRS, it may not achieve the data flow intended by CMS for the dialysis industry, and that shifting to a new system does not make sense at this time. One commenter expressed caution about the adoption of FHIR noting that the current ESRD quality data submission process captures 90 percent of data electronically and recommended piloting the FHIR approach to ensure that FHIR improves quality reporting over and above EQRS. One commenter recommended that CMS consider the burden on facilities related to compliance, noted implementation uncertainties, and recommended CMS allocate resources to help with the transition to new data systems and processes. One commenter expressed concerns with transitioning the ESRD programs to another platform and recommended that interoperability standards should be incorporated into the EQRS. One commenter recommended that CMS not reinvent the wheel but rather continue to work with the kidney care community to address the next generation of quality and data policies.

Response: We appreciate all of the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. We will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

• Changes Under Consideration To Advance Digital Quality Measurement: Actions in Four Areas To Transition to Digital Quality Measures by 2025

++ We sought feedback on the following as described in section IV.G.3.c.(1). of this final rule:

—Do you agree with the goal of aligning data needed for quality measurement with that required for interoperability? What are the strengths and limitations of this approach?

—How important is a data standardization approach that also supports inclusion of PGHD and other currently non-standardized data?

—What are possible approaches for testing data quality and validity?

We received comments on these topics.

Comments: Several commenters expressed support for the goal of aligning data needed with interoperability. One commenter expressed its belief that quality measurement data must be aligned with and based on tools and methods of interoperability within healthcare believing this is core to the achievement of value-based healthcare. This commenter also noted its belief that aligning the incentives for all major stakeholders in healthcare (patients, providers, payers, regulators) is key to enabling a robust healthcare system and that when quality is measured according to the patient through the proxy measures of outcomes and cost of care, having data that are interoperable among these stakeholders is crucial. One commenter expressed support conceptually for the goal of aligning data, but needed more clarity on the specific quality measures CMS is considering for these purposes.

One commenter recommended approaches for standardization including that CMS develop: (1) Standard sets of outcomes measures only utilize validated PROMs as defined by ISOQOL validation guidelines; (2) strictly defined standard sets (standardized outcome definition including allowed response options, validated PROMs and defined data collection time points) ensures consistency in data collection and allow for consistent data quality checks; and (3) variables used in standard sets mapped to SNOMED/LOINC concepts allow for in-depth data validity audits. One commenter recommended that CMS establish guidance to ensure data security and to define roles and responsibilities regarding data validation and data cleaning. This commenter also noted that data validation and cleaning is currently managed by third party intermediaries and is necessary to maintain measure integrity and for reducing provider burden.

One commenter expressed its concerns with standardization including burden on providers and questioned the value of moving from a standardized data format that already serves 90 percent of the dialysis community to an interoperability format that is standardized for data movement between providers beyond the dialysis industry.

A few commenters expressed concerns with the inclusion of patient generated health data and other currently non-standardized data into a data standardized approach. One commenter noted that CMS' definition of patient gathered health data is overly broad. One commenter expressed its belief that such data elements will vary by therapeutic area and be difficult to standardize. One commenter expressed its belief that additional research is needed prior to integration of patient-generated health data into quality measurement believing that while the data can augment the overall picture of health, it can be full of bias, noise, and variability.

Response: We appreciate all of the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. We will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

++ We sought feedback on the following as described in section IV.G.3.c.(2). of this final rule:

—What functionalities, described in section IV.G.3.c.(2). of this final rule

or others, should quality measure tools ideally have in the context of the pending availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs)?

—How would this more open, agile strategy for end-to-end measure calculation facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research?

We received comments on these topics.

Comments: One commenter recommended common measure sets that gather data based on standard ontologies (for example, ICD–10, SNOMED–CT) believing that the use of resources that enable the use of shareable, digital data need be part of quality measure tools. The commenter also noted that the use of such measure sets, such as ICHOM Standard Sets, are also essential when on FHIR in a fully interoperable context.

One commenter expressed its belief that broader engagement would lead to incremental gains on quality measure development noting that CMS already provides its contracted measure developers with access to the CROWNWeb and EQRS data for measure development and to the community via USRDS, an NIH sponsored registry, and noted that FHIR API may provide these data in a timelier fashion than providing data files.

One commenter noted that international experience has shown that open cycle work groups, developed under an agile method, leads to the establishment of value based healthcare in a manner that works best for patient outcomes, and in a manner that develops the standards in a way that is independent to the payment rate-setting development process, which can lead to better outcomes for patients and better methods for data collection for providers. This commenter also expressed its belief that making measure collection seamless through the use of standard ontologies and FHIR-based API apps will allow both large scale data collection for use in value-based healthcare initiatives and the local usage of data for improvement of care as well as reducing reporting burden.

One commenter expressed concern that the investments and progress the ESRD community has made to develop the current digital quality framework would be reversed with the adoption of a third new digital quality measurement approach.

Response: We appreciate all of the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. We will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

++ We sought feedback on the following as described in section IV.G.3.c.(3). of this final rule:

—Do you have feedback on policy considerations for aggregation of data from multiple sources being used to inform measurement?

—Do you have feedback on the role data aggregators can and should play in CMS quality measure reporting in collaboration with providers? How can CMS best facilitate and enable aggregation?

We received comments on these topics.

Comments: One commenter expressed support for CMS gathering data from multiple sources to inform quality measurement; however, this commenter also expressed caution about the use of FHIR API as the most appropriate digital data collection method. One commenter expressed its belief that CMS is best served to very early define the format in which they need to have the measures reported and that an open publication of the requested data formats and annotation, for example, a common data model, is the key to initiate a health market adjustment. This commenter recommended that CMS set forth policy that requires the collection of data using standardized measure sets, based on easily collectable data (using standard ontologies and PGHD tools), and transported using the FHIR interoperable transport API.

A few commenters expressed their belief that aggregation of data from multiple sources is not an issue for the renal community noting the use of CROWNWeb, EQRS, and HIE.

A few commenters expressed their concerns with the use of data aggregators. One commenter expressed its concerns that moving to an undefined new standard under FHIR will require significant additional investments from industry when such investments already have been made to create the highly efficient HIE and other means of electronic data submission. One commenter expressed its belief that there is no need for data aggregators for the ESRD quality program because of existing data standardization and availability of required data in provider EMRs or CMS claims data noting the successful ability of 90 percent of the industry to submit data electronically in a standard format via batch, and the remaining 10 percent to do the same via manual interface; however, this commenter also noted that if CMS requires data elements that are not able to be collected by dialysis providers then data aggregators may be helpful.

Response: We appreciate all of the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. We will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

++ We sought feedback on the following as described in section IV.G.3.c.(4). of this final rule:

—What are initial priority areas for the dQM portfolio (for example, measurement areas, measure requirements, tools)?

—We also sought to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities and across sectors.

We received comments on these topics.

Comments: One commenter recommended that the priority areas for the dQM portfolio be around health equity and quality measures for which data supports that additional access to care can improve quality outcomes.

A few commenters had recommendations for CMS collaboration related to adopting standards and technology-driven solutions. One commenter recommended opportunities to collaborate with the Social Security Administration, Centers for Disease Control and Prevention, and the United Network for Organ Sharing. One commenter recommended collaboration with an objective, independent and patient centered non-profit organization that collaborates with patients and healthcare professionals. One commenter recommended that CMS work with states and other Federal agencies who might require these same data elements as an API from EQRS then that could create benefit and reduce administrative burden.

Response: We appreciate all of the comments on and interest in this topic.

We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. We will continue to take all comments into account as we develop future regulatory proposals or other guidance for our digital quality measurement efforts.

V. End-Stage Renal Disease Treatment Choices (ETC) Model

A. Background

1. Overview of the ETC Model

As described in the Specialty Care Models final rule (85 FR 61114), beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. ESRD Beneficiaries require dialysis or kidney transplantation to survive, and the majority of ESRD Beneficiaries receiving dialysis receive hemodialysis in an ESRD facility. However, as described in the Specialty Care Models final rule, alternative renal replacement modalities to in-center hemodialysis, including home dialysis and kidney transplantation, are associated with improved clinical outcomes, better quality of life, and lower costs than in-center hemodialysis (85 FR 61264).

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care furnished to such programs' beneficiaries. The purpose of the ETC Model is to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians to encourage greater utilization of home dialysis and kidney transplantation, support beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care.

The ETC Model is a mandatory payment model, as we seek to test the effect of payment incentives on availability and choice of treatment modality among a diverse group of providers and suppliers. ESRD facilities and Managing Clinicians are selected as ETC Participants based on their location in Selected Geographic Areas—a set of 30 percent of Hospital Referral Regions (HRRs) that have been randomly selected to be included in the ETC Model, as well as HRRs with at least 20 percent of component ZIP codes [260] located in Maryland. CMS excludes all U.S. Territories from the Selected Geographic Areas.

Under the ETC Model, ETC Participants are subject to two payment adjustments. The first is the Home Dialysis Payment Adjustment (HDPA), which is an upward adjustment on certain payments made to participating ESRD facilities under the ESRD PPS on home dialysis claims, and an upward adjustment to the MCP paid to participating Managing Clinicians on home dialysis-related claims. The HDPA applies to claims with claim service dates beginning in January 1, 2021, and ending on December 31, 2023.

The second payment adjustment under the ETC Model is the Performance Payment Adjustment (PPA). For the PPA, we assess ETC Participants' home dialysis rate and transplant rate during a Measurement Year (MY), which includes 12 months of performance data. Each MY overlaps with the previous MY, if any, and the subsequent MY, if any, for a period of 6 months. Each MY has a corresponding PPA Period—a 6-month period which begins 6 months after the conclusion of the MY. We adjust certain payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate, calculated as the sum of the transplant waitlist rate and the living donor transplant rate, during the corresponding MY. Based on an ETC Participant's achievement in relation to benchmarks based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year, and the ETC Participant's improvement in relation to its own home dialysis rate and transplant rate during the Benchmark Year, we make an upward or downward adjustment to certain payments to the ETC Participant. The magnitude of the positive and negative PPAs for ETC Participants increases over the course of the ETC Model. These PPAs apply to claims with claim service dates beginning July 1, 2022, and ending June 30, 2027.

2. Summary of Proposed Changes to the ETC Model

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury; End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'' (85 FR 36322 through 36437), referred to herein as the ''CY 2022 ESRD PPS proposed rule,'' was published in the **Federal Register** on July 9, 2021. In the CY 2022 ESRD PPS proposed rule, we proposed a number of policy changes to the ETC Model beginning for the third Measurement Year (MY3) of the Model, which begins January 1, 2022. We proposed changes to the methodology for attributing Pre-emptive LDT Beneficiaries to Managing Clinicians to better reflect the care relationship between beneficiaries who receive pre-emptive LDT transplants and the Managing Clinicians who provide their care. We proposed to include nocturnal in-center dialysis in the numerator of the home dialysis rate calculation for ESRD facilities not owned in whole or in part by a large dialysis organization (LDO) as well as Managing Clinicians, to incentivize additional alternative renal replacement modalities. In addition, we proposed to exclude beneficiaries who are diagnosed with and receiving treatment with chemotherapy or radiation for vital solid organ cancers from the transplant rate to align with common transplant center requirements.

We proposed to modify the PPA achievement benchmarking methodology to increase achievement benchmarks by 10 percent above rates observed in Comparison Geographic Areas every two MYs, beginning for MY3 (2022). We proposed to stratify PPA achievement benchmarks based on the proportion of attributed beneficiaries who are dually-eligible for Medicare and Medicaid or receive the LIS during the MY, and to introduce the Health Equity Incentive to the PPA improvement scoring methodology, both in an effort to encourage ETC Participants to address disparities in renal replacement modality choice among beneficiaries with lower socioeconomic status. We proposed to modify the PPA improvement benchmarking and scoring methodology to ensure an ETC Participant can receive an improvement score even if its home dialysis rate or transplant rate was zero during the relevant Benchmark Year.

We proposed to add processes and requirements for CMS to share certain model data with ETC Participants. We also proposed an additional programmatic waiver as necessary solely for purposes of allowing Managing Clinicians who are ETC participants to furnish kidney disease patient education services via telehealth under the ETC Model. In addition, we proposed to permit Managing Clinicians who are ETC Participants to reduce or waive beneficiary coinsurance for kidney disease patient education services, subject to certain requirements. In the CY 2022 ESRD PPS proposed rule, we stated our expectation that the proposed changes would continue to

[260] ZIP code™ is a trademark of the United States Postal Service.

promote the larger goals of increased renal replacement modality choice and are based on many of the issues we laid out in the Specialty Care Models final rule as issues for which CMS was considering further rulemaking, including updating benchmarks for ETC Participants and adjusting model parameters based on our implementation experience (86 FR 36376).

3. Impact of the Changes on the ETC Model Evaluation

As we described in the Specialty Care Models final rule, an evaluation of the ETC Model will be conducted in accordance with section 1115A(b)(4) of the Act, which requires the Secretary to evaluate each model tested by the Innovation Center. We noted that we believe an independent evaluation of the Model is necessary to understand the impacts of the Model on quality of care and Medicare program expenditures (85 FR 61345).

In the CY 2022 ESRD PPS proposed rule (86 FR 36376), we proposed to update the evaluation plan presented in the Specialty Care Models final rule to account for all the policies in that proposed rule, if finalized. However, we noted that changes in the construction of the PPA would have no impact on the evaluation approach to analyzing the final PPA values. This is because the evaluation plan already includes a consideration of the final PPA values, rather than an evaluation of each step in the PPA calculation. However, we stated our expectation that we would conduct subgroup analyses in the evaluation to determine the effect of the proposed Health Equity Incentive, if finalized, in reducing health disparities among beneficiaries with lower socioeconomic status.

As part of the detailed economic analysis included in the CY 2022 ESRD PPS proposed rule and in section VIII.D.4 of this final rule, the transplant waitlist benchmarks were annually inflated by approximately 3-percentage points growth. This was a change from the Specialty Care Models final rule (85 FR 61352), in which the waitlist benchmarks were annually inflated by approximately 2-percentage points growth observed during years 2017 through 2019 to project rates of growth. By increasing the expected effect to a 3-percentage point change, we improve our ability to detect such an effect at the ETC Model's current size. In the Specialty Care Models final rule, we stated that to detect a 2-percentage point increase in the transplant waitlist rate, we would need 30 percent of the 306 HRRs in order to detect an effect of this size with 80 percent power and an alpha of 0.05. Further, we stated that a model of this size would be large enough to detect a one and one-half percentage point change in the home dialysis rate (85 FR 61280). In the CY 2022 ESRD PPS proposed rule (86 FR 36376), we clarified that our unadjusted power calculations show that the model requires 30 percent of the 306 HRRs to detect the one and one-half percentage point change in the home dialysis rate with 80 percent power and an alpha of 0.05. Given the updated expectation that the transplant waitlist rate is likely to increase by 3-percentage points as a result of the ETC Model, the power analysis shows the evaluation would also have sufficient sample size to detect, as statistically significant, a 3-percentage point change in the transplant waitlist rate with 80 percent power and an alpha of 0.05.

We did not receive any comments regarding our proposal to update the evaluation plan presented in the Specialty Care Models final rule to account for all the policies in the CY 2022 ESRD PPS proposed rule, if finalized. We are therefore finalizing our proposal and will modify the model evaluation to analyze the impact of the policies finalized in this final rule.

B. Summary of the Proposed Provisions, Public Comments, Responses to Comments, and Finalized Policies for the ETC Model

The CY 2022 ESRD PPS proposed rule was published in the **Federal Register** on July 9, 2021, with a comment period that ended on August 31, 2021. In that proposed rule, we proposed to make a number of changes to the ETC Model, to begin January 1, 2022, as described previously in section I.B.4 of this rule. We received 64 timely public comments on our proposals, including comments from: ESRD facilities; national renal, nephrologist, and patient organizations; patients; manufacturers; health care systems; and individual clinicians, including nephrologists, nurses, and social workers.

We also received comments related to issues that we did not discuss in the CY 2022 ESRD PPS proposed rule. These include, for example, comments recommending that CMS incorporate staff-assisted home dialysis into the ETC Model, support the training and education of home dialysis nurses, and including transplant providers as ETC Participants. These comments expressed concern over implementing home dialysis programs or the negative payment adjustments included in the Model. While we are generally not addressing those comments in this final rule, we thank the commenters for their input and may consider their recommendations in future rulemaking.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the ETC Model. These policies take effect January 1, 2022, unless otherwise specified.

Comment: Many commenters supported the goals of the ETC Model. Some of these commenters stated that they appreciate the effort to advance home dialysis during the COVID–19 pandemic since dialyzing at home allows patients to socially distance and avoid going into hospitals or medical centers.

Response: We thank the commenters for the support of the Model's goals.

Comment: One commenter suggested that CMS implement the ETC Model nationwide in order to improve quality of care for all ESRD beneficiaries.

Response: Section 1115A of the Act authorizes the Secretary to test payment and service delivery models intended to reduce Medicare costs while preserving or improving care quality that, if effective, are considered for expansion to the Medicare program. As noted in the Specialty Care Models final rule (85 FR 61280), the randomized selection of 30 percent of HRRs allows CMS sufficient statistical power to assess the effect of the ETC Model. If the test of the ETC Model satisfies the criteria for expansion in section 1115A(c) of the Act, CMS may consider expanding the duration and scope of the ETC Model, including on a nationwide basis.

Comment: One commenter suggested that the ETC Model be an Advanced Alternative Payment Model (APM) allowing ETC Participants to be eligible as qualifying APM participants (QP), similar to what is proposed for the Radiation Oncology (RO) Model.

Regarding the commenter's reference to the RO Model, we finalized our proposal that the RO Model be designed to qualify as an Advanced APM and MIPS APM in the Specialty Care Models final rule (85 FR 61231 through 61238).

Response: As noted in the Specialty Care Models final rule (85 FR 61326), modifying the ETC Model to be an Advanced APM would subject ETC Participants to significant downside risk from the outset, which we believe would put many ETC Participants in a difficult financial position. As further noted in the Specialty Care Models final rule (85 FR 61274), Managing Clinicians may simultaneously participate in the ETC Model and the complementary Kidney Care Choices Model, a voluntary

model we anticipate will meet the criteria to be an Advanced APM beginning in 2022.

Comment: Several commenters urged that patients should have the choice of modality that works best for them, and the ETC Model should support patient choices.

Response: We appreciate the commenters' feedback to support beneficiary choice of treatment modality. The ETC Model, as described in the Specialty Care Models final rule, aims to support beneficiaries choosing alternatives to in-center dialysis. Additionally, ETC Participants are subject to provisions protecting beneficiary freedom of choice set forth at § 512.120 of our regulations, as discussed in the Specialty Care Models final rule (85 FR 61339).

1. Technical Clarifications

For ESRD facilities that are ETC Participants, the ETC Model makes certain upward and downward adjustments to the Adjusted ESRD PPS per Treatment Base Rate for certain dialysis claims via the Home Dialysis Payment Adjustment (HDPA) and the Performance Payment Adjustment (PPA). The term ''Adjusted ESRD PPS per Treatment Base Rate'' is defined at 42 CFR 512.310 as the per-treatment payment amount as defined in § 413.230 of this chapter, including patient-level adjustments and facility-level adjustments, and excluding any applicable training adjustment, add-on payment amount, outlier payment amount, TDAPA amount, and TPNIES amount. In the CY 2022 ESRD PPS proposed rule (86 FR 36376), we clarified the claims that are subject to adjustment under the ETC Model. Specifically, as § 413.230 is specific to the calculation of payment amounts under the ESRD PPS, we clarify that the HDPA and PPA do not apply to claims from ESRD facilities that are not paid under ESRD PPS and are instead paid through other Medicare payment systems.

We are also updating the name of one of the sources of data used throughout the ETC Model. In the Specialty Care Models final rule, we specified that one source of data for the ETC Model is CROWNWeb, a data management system that CMS uses to collect data from ESRD facilities (85 FR 61317). As we explained in the CY 2022 ESRD PPS proposed rule (86 FR 36376), since publication of the Specialty Care Models final rule, CMS has replaced CROWNWeb with the End Stage Renal Disease Quality Reporting System (EQRS). As such, we will refer to CROWNWeb for data that was generated before the change to EQRS, which CMS began using in 2020, and EQRS for data that was generated after the change to EQRS.

The following is a summary of the comments received on our technical clarifications related to claims subject to adjustment under the ETC Model and the replacement of CROWNWeb data with EQRS data and our responses.

Comment: A few commenters stated that they support the technical clarification that the HDPA and PPA do not apply to claims from ESRD facilities that are not paid under ESRD PPS and are instead paid through other Medicare payment systems.

Response: We appreciate commenters' support for this technical clarification.

Comment: A few commenters stated that they support the technical clarification that the ETC Model will refer to EQRS data in place of CROWNWeb data.

Response: We appreciate commenters' support for this technical clarification.

Comment: A few commenters expressed concerns related to the challenges faced during the transition from CROWNWeb to EQRS, and resulting concerns over data quality.

Response: As discussed elsewhere in this final rule, we are aware of concerns related to the transition from CROWNWeb to EQRS. For the purposes of the ETC Model, we will continue to use the best data available and will work with ETC Participants to address any data issues that arise.

2. Performance Payment Adjustment (PPA) Beneficiary Attribution for Living Kidney Donor Transplants

In the Specialty Care Models final rule (85 FR 61297), we established that beneficiaries are attributed to Managing Clinicians for the purposes of calculating the home dialysis rate and transplant rate. For the home dialysis rate and the transplant waitlist and living donor kidney transplant portions of the transplant rate, as described in 42 CFR 512.360(c)(2)(i), an ESRD Beneficiary is generally attributed to the Managing Clinician with the earliest monthly capitation payment (MCP) claim billed during the month. If more than one Managing Clinician submits a claim for the MCP furnished to a single ESRD Beneficiary with the same earliest claim service date at the claim line through date for the month, the ESRD Beneficiary is randomly attributed to one of these Managing Clinicians.

However, a beneficiary who receives a pre-emptive living donor transplant (Pre-emptive LDT Beneficiary) is not on dialysis and therefore cannot be attributed to a Managing Clinician using an MCP claim. As a result, under § 512.360(c)(2)(ii), a Pre-emptive LDT Beneficiary is generally attributed to the Managing Clinician with whom the Pre-emptive LDT Beneficiary had the most claims between the start of the MY and the month of the transplant. If no Managing Clinician has had the plurality of claims for a given Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of claims for that beneficiary during the MY, the Pre-emptive LDT Beneficiary is attributed to the Managing Clinician associated with the latest claim service date during the MY up to and including the month of the transplant, as described in § 512.360(c)(2)(ii)(A). If no Managing Clinician had the plurality of claims for a given Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of services for that beneficiary during the MY, and more than one of those Managing Clinicians had the latest claim service date during the MY up to and including the month of the transplant, the Pre-emptive LDT Beneficiary is randomly attributed to one of these Managing Clinicians, as described in § 512.360(c)(2)(ii)(B).

As stated in the CY 2022 ESRD PPS proposed rule (86 FR 36377), upon further review of the beneficiary attribution methodology for living donor kidney transplants, we realized that an unintended consequence of the current attribution methodology is that Pre-emptive LDT Beneficiaries may be attributed to the nephrologist who manages their transplant, not the Managing Clinician who has seen them through the living donor transplant process. As stated in the CY 2022 ESRD PPS proposed rule, to avoid this effect, CMS believes it is necessary to update the attribution methodology for Pre-emptive LDT Beneficiaries. Living donor transplants are relatively rare events that require nephrologist support over time in order to inform beneficiaries of their transplant options and to assist them in finding a living donor. However, the current Pre-emptive LDT Beneficiary attribution methodology is based on visits from the beginning of a MY. As a result, if a Pre-emptive LDT Beneficiary has a transplant early in a MY, the beneficiary may be attributed to a transplant nephrologist who may have had only a single visit with the beneficiary, rather than the Managing Clinician who oversaw the largest share of the care that led to the beneficiary receiving the living donor transplant.

As a result, we proposed to update the attribution methodology for Pre-emptive

LDT Beneficiaries to Managing Clinicians, beginning for MY3, in new provisions at § 512.360(c)(2)(iii). Rather than attributing a Pre-emptive LDT Beneficiary to the Managing Clinician with the plurality of claims from the start of the MY and the month of the transplant, beginning for MY3, we proposed to attribute Pre-emptive LDT Beneficiaries to the Managing Clinician with whom the beneficiary has had the most claims during the 365 days prior to the transplant date. Further, we proposed that if no Managing Clinician has had the most claims for the Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of claims for that beneficiary in the 365 days preceding the date of the transplant, the Pre-emptive LDT Beneficiary would be attributed to the Managing Clinician associated with the latest claim service date at the claim line through date during the 365 days preceding the date of the transplant. We proposed that if more than one of those Managing Clinicians had the latest claim service date at the claim line through date during the 365 days preceding the date of the transplant, the Pre-emptive LDT Beneficiary would be randomly attributed to one of these Managing Clinicians. We proposed that the Pre-emptive LDT Beneficiary would be considered eligible for attribution to a Managing Clinician under this proposed new § 512.360(c)(2)(iii) if the Pre-emptive LDT Beneficiary has at least 1 eligible–month during the 12-month period that includes the month of the transplant and the 11 months prior to the transplant month. We proposed that an eligible month would refer to a month during which the Pre-emptive LDT Beneficiary not does not meet exclusion criteria in § 512.360(b). We proposed changes for Pre-emptive LDT Beneficiary attribution to Managing Clinicians in order to identify and attribute Pre-emptive LDT Beneficiaries to the Managing Clinician who assisted the Beneficiary through the living donor transplant process. We sought comment on these proposed changes for Pre-emptive LDT Beneficiary attribution to Managing Clinicians beginning for MY3 in proposed new § 512.360(c)(2)(iii).

The following is a summary of the comments received on the proposed changes for Pre-emptive LDT Beneficiary attribution to Managing Clinicians beginning for MY3 and our responses.

Comment: Several commenters supported our proposal to update the attribution methodology for Pre-emptive LDT Beneficiaries to Managing Clinicians to identify and attribute Pre-emptive LDT Beneficiaries to the Managing Clinician that assisted the Beneficiary through the living donor transplant process.

Response: We appreciate the support and feedback.

Comment: A few commenters expressed that the proposed changes to the attribution methodology for Pre-emptive LDT Beneficiaries would have a limited impact, due to the small number of Pre-emptive LDT Beneficiaries.

Response: We appreciate the feedback from commenters and recognize the small number of Pre-emptive LDT Beneficiaries. We nonetheless believe it is necessary to update this methodology to ensure that those Pre-emptive LDT Beneficiaries are attributed to the Managing Clinician who oversaw the largest share of the care that led to the beneficiary receiving the living donor transplant to more accurately measure Managing Clinician performance.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.360(c)(2)(iii) to change Pre-emptive LDT Beneficiary attribution to Managing Clinicians beginning for MY3, without modification.

3. PPA Home Dialysis Rate

a. Background on Home Dialysis Rate Calculation

A primary goal of the ETC Model is to support beneficiary modality choice by encouraging ETC Participants to support beneficiaries in selecting alternatives to in-center dialysis. Under 42 CFR 512.365(b), CMS includes in-center self-dialysis treatment beneficiary years in the numerator of the home dialysis rate. Specifically, the home dialysis rate for both Managing Clinicians and ESRD facilities is calculated as the number of dialysis treatment beneficiary years during the MY in which attributed beneficiaries received dialysis at home, plus one half of the total number of dialysis treatment beneficiary years during the MY in which the attributed beneficiaries received self-dialysis in center. As described in the Specialty Care Models final rule, we included self-dialysis in the home dialysis rate calculation because we believe in-center self-dialysis may provide a gradual transition from in-center to home dialysis, and provide beneficiaries with the time needed to get comfortable conducting dialysis by themselves, under medical supervision (85 FR 61306).

The denominator for the home dialysis rate is the total dialysis treatment beneficiary years for attributed ESRD beneficiaries during the MY, as described in §§ 512.365(b)(1)(i) and 512.365(b)(2)(i). This includes the months during which attributed beneficiaries received maintenance dialysis at home or in an ESRD facility.

b. Nocturnal Dialysis

Nocturnal in-center dialysis is a form of in-center dialysis conducted overnight for extended hours while the beneficiary is asleep. This dialysis is longer and slower than traditional in-center dialysis, can take more than 5 hours per treatment, and can be performed 3 to 7 days a week. As this type of in-center dialysis is conducted overnight, it allows the beneficiary more time and flexibility to have a continuous job, as well as a social and family life.[261]

Dialysis conducted at a slower rate over a longer period of time is also associated with positive health impacts in comparison to traditional dialysis, including improved blood pressure control, better phosphate control, better management of anemia and bone and mineral metabolism, improved cardiovascular disease, increases in urea reduction ratio, and better beneficiary quality of life measures.[262] [263] [264] [265] [266]

In addition to the clinical benefits, nocturnal in-center dialysis also provides an alternative to traditional in-center dialysis for those beneficiaries for whom home dialysis is not an option

[261] Wilk, Adam S., Lea, Janice P. (2019). How Extended Hemodialysis Treatment Time Can Affect Patient Quality of Life. Clinical Journal of the American Society of Nephrology, 23, 479–485. doi:10.1111/hdi.12782.

[262] Burton, J. and Graham-Brown, M., 2018. Nocturnal hemodialysis. Current Opinion in Nephrology and Hypertension, 27(6), pp.472–477.

[263] Kalim, S., Wald, R., Yan, A.T., Goldstein, M.B., Kiaii, M., Xu, D., . . . Perl, J. (2018). Extended duration nocturnal hemodialysis and changes in plasma metabolite profiles. Clinical Journal of the American Society of Nephrology, 13(3), 436–444. doi:10.2215/cjn.08790817.

[264] Nesrallah, G.E., Lindsay, R.M., Cuerden, M.S., Garg, A.X., Port, F., Austin, P.C., . . . Suri, R.S. (2012). Intensive hemodialysis associates with improved survival compared with CONVENTIONAL HEMODIALYSIS. Journal of the American Society of Nephrology, 23(4), 696–705. doi:10.1681/asn.2011070676.

[265] Wong, B., Collister, D., Muneer, M., Storie, D., Courtney, M., Lloyd, A., . . . Pauly, R.P. (2017). In-center nocturnal hemodialysis versus conventional hemodialysis: A systematic review of the evidence. American Journal of Kidney Diseases, 70(2), 218–234. doi: 10.1053/j.ajkd.2017.01.047.

[276] Wilk, Adam S., Lea, Janice P. (2019). How Extended Hemodialysis Treatment Time Can Affect Patient Quality of Life. Clinical Journal of the American Society of Nephrology, 23, 479–485. doi:10.1111/hdi.12782.

[266] Lacson E, Diaz-Buxo J. In-center nocturnal hemodialysis performed thrice-weekly—a provider's perspective. Semin Dial. 2011 Nov–Dec;24(6):668–73. doi: 10.1111/j.1525–139X.2011.00998.x. Epub 2011 Nov 22. PMID: 22106828.

due to limited financial resources, housing insecurity, lack of social support, or personal preference. For example, a beneficiary experiencing housing insecurity may be unable to dialyze at home due to inability to receive and store home dialysis materials. However, that beneficiary could receive nocturnal in-center dialysis, thereby receiving the clinical benefits of a longer, slower dialysis process and the flexibility associated with not having to receive traditional in-center dialysis during the day.[267] [268]

While nocturnal in-center dialysis offers some of the same clinical and quality of life benefits as home dialysis in comparison to traditional in-center dialysis, use of nocturnal in-center dialysis is rare. Based on analyses described in the CY 2022 ESRD PPS proposed rule and in section VIII.D.4.e of this final rule, less than 1 percent of beneficiaries eligible for attribution to ETC Participants were receiving self-dialysis or nocturnal in-center dialysis in 2019. Potential limitations to nocturnal in-center dialysis utilization include supply factors. At present, few ESRD facilities offer nocturnal dialysis; in 2019, approximately 1 percent of ESRD facilities furnished nocturnal in-center dialysis based on our analysis of claims data. ESRD facilities may face staffing challenges to initiating a nocturnal dialysis program. Potential limitations to nocturnal in-center dialysis also include demand factors: Beneficiaries may be unaware of nocturnal in-center dialysis, or may be averse to sleeping at an ESRD facility or experience difficulty sleeping while receiving dialysis.[269]

c. Inclusion of Nocturnal In-Center Dialysis in Home Dialysis Rate

We proposed to modify the home dialysis rate calculation, for ETC Participants that are either ESRD facilities not owned in whole or in part by an LDO or Managing Clinicians, to include nocturnal in-center dialysis in the numerator beginning for MY3. As described in the CY 2022 ESRD PPS proposed rule and previously in this section of the final rule, we believe this modality allows beneficiaries to continue to receive maintenance dialysis in an ESRD facility under medical supervision, but at a time of day that is more convenient for them, and in a manner that is associated with improved health outcomes. In particular, in the CY 2022 ESRD PPS proposed rule (86 FR 36378), we stated our belief that including nocturnal in-center dialysis in the home dialysis rate may improve access to alternative renal replacement modalities for beneficiaries who are unable to dialyze at home.

In addition to promoting access to the benefits of additional alternative renal replacement modalities for ESRD Beneficiaries who may not be able to dialyze at home, in the CY 2022 ESRD PPS proposed rule we stated our belief that including nocturnal in-center dialysis in the calculation of the home dialysis rate offers an additional pathway to success for ETC Participants with more limited resources. As described in the Specialty Care Models final rule, we received comments that some ESRD facilities, particularly independent ESRD facilities or ESRD facilities owned by small dialysis organizations, may be unable to develop and maintain a home dialysis program (85 FR 61322 through 61324). Operating a home dialysis program requires specialized staff, as well as upfront investment in additional equipment and certification. Establishing a nocturnal in-center dialysis program does not require additional equipment or certification, and may be more feasible for independent ESRD facilities or ESRD facilities owned by small dialysis organizations, and by extension, the Managing Clinicians who serve their patients.

In the CY 2022 ESRD PPS proposed rule (86 FR 36378), we considered including nocturnal in-center dialysis in the numerator of the home dialysis rate for ESRD facilities owned in whole or in part by LDOs as well. However, we noted in the CY 2022 ESRD PPS proposed rule that we do not believe that ESRD facilities owned in whole or in part by LDOs face the same resource constraints in establishing a home dialysis program as independent ESRD facilities or ESRD facilities owned by small dialysis organizations. ESRD facilities owned in whole or in part by LDOs may be more likely to have access to a home dialysis program, either in the ESRD facility itself or within the network of facilities owned by the same parent company in that facility's aggregation group. ESRD facilities owned in whole or in part by LDOs may also have greater access to the upfront capital necessary to establish a home dialysis program if they do not already have, or have access to, a home dialysis program.

At present, there is not a single definition of what qualifies a legal entity that owns ESRD facilities as an LDO. In general, definitions of LDO focus on the number of ESRD facilities owned by the legal entity. Other Innovation Center models have used such definitions: The Comprehensive ESRD Care (CEC) Model defined an LDO as a legal entity owning 200 or more ESRD facilities; the Kidney Care Choices (KCC) Model defines an LDO as a legal entity owning 35 or more ESRD facilities. Outside of Innovation Center models, definitions used by academic researchers vary significantly. For example, in 2015, the United States Renal Data System (USRDS), a national data registry funded by the National Institutes of Health (NIH), defined an LDO as a dialysis organization one that owns and operates 200 or more ESRD facilities.[270] Other academic research has employed thresholds as low as owning 20 or more ESRD facilities and as high as owning 1,000 or more ESRD facilities to consider a legal entity an LDO.[271] [272] Other definitions do not focus on the number of ESRD facilities owned, but on the relative size of dialysis organizations in the market, or rather, the individual dialysis organizations themselves. For example, in its March 2021 report to Congress, the Medicare Payment Advisory Commission (MedPAC) refers to the two largest dialysis organizations in the country as LDOs based on their relative share of ESRD facilities and Medicare treatments.[273]

Based on our review of definitions commonly used, for the purposes of the ETC Model we proposed to define the term ''ETC Large Dialysis Organization,'' abbreviated ''ETC LDO,'' as a legal entity that owns, in whole or in part, 500 or more ESRD facilities (86 FR 36379). Based on the current

[267] Bugeja A, Dacouris N, Thomas A, Marticorena R, McFarlane P, Donnelly S, Goldstein M. In-center nocturnal hemodialysis: Another option in the management of chronic kidney disease. Clin J Am Soc Nephrol. 2009 Apr;4(4):778–83. doi: 10.2215/CJN.05221008. Epub 2009 Apr 1. PMID: 19339410; PMCID: PMC2666425.

[268] Lacson E, Diaz-Buxo J. In-center nocturnal hemodialysis performed thrice-weekly—a provider's perspective. Semin Dial. 2011 Nov–Dec;24(6):668–73. doi: 10.1111/j.1525–139X.2011.00998.x. Epub 2011 Nov 22. PMID: 22106828.

[269] Ibid.

[270] United States Renal Data System. 2015. ''2015 Researcher's Guide to the USRDS Database.'' *https://usrds.org/media/2219/2015_usrds_researchers_guide_15.pdf.*

[271] Mehrotra R, Khawar O, Duong U, Fried L, Norris K, Nissenson A, Kalantar-Zadeh K. Ownership patterns of dialysis units and peritoneal dialysis in the United States: Utilization and outcomes. Am J Kidney Dis. 2009 Aug;54(2):289–98. doi: 10.1053/j.ajkd.2009.01.262. Epub 2009 Apr 8. PMID: 19359081.

[272] Gander JC, Zhang X, Ross K, et al. Association Between Dialysis Facility Ownership and Access to Kidney Transplantation. *JAMA*. 2019;322(10):957–973. doi:10.1001/jama.2019.12803.

[273] Medicare Payment Advisory Commission. 2021. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC. *http://www.medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf.*

distribution of numbers of ESRD facilities owned by dialysis organizations operating in the market, we stated our belief that this threshold is appropriate, as it differentiates the largest dialysis organizations, which at present own over 2,500 ESRD facilities, from smaller dialysis organizations, the next largest of which owns approximately 350 ESRD facilities. We further stated our belief that the difference in size represents a meaningful difference in access to resources necessary to establish a home dialysis program, as well as the likelihood that an ESRD facility's aggregation group would have at least one ESRD facility with a home dialysis program in the aggregation group. We solicited comment on our proposal to include nocturnal in-center dialysis beneficiary years in the numerator of the home dialysis rate calculation only for ESRD facilities not owned in whole or in part by an ETC LDO, as well as our proposal to define an ETC LDO as a legal entity owning 500 or more ESRD facilities.

While nocturnal in-center dialysis can potentially result in better patient health outcomes and savings to Medicare compared to traditional in-center dialysis, we acknowledged in the CY 2022 ESRD PPS proposed rule that its inclusion in the home dialysis rate may reduce the incentive for ESRD facilities not owned in whole or in part by an LDO to invest in a home dialysis infrastructure. We therefore proposed to include nocturnal in-center dialysis as one half of the total number of dialysis treatment beneficiary years during the MY in which the attributed beneficiaries received nocturnal in-center dialysis in the numerator of the home dialysis rate calculation for ESRD facilities not owned in whole or in part by an ETC LDO as well as Managing Clinicians. We further stated our belief that this policy would effectively balance the benefits of nocturnal in-center dialysis and its ability to help beneficiaries transition to home dialysis with the recognition that in-center nocturnal dialysis is not home dialysis and does not have all of the same benefits. As described in the Specialty Care Models final rule, we included one half of the total number of dialysis treatment beneficiary years during the MY in which the attributed beneficiaries received self-dialysis in center in the home dialysis rate calculation for a similar reason (85 FR 61306).

As such, we proposed to amend § 512.365(b) such that, beginning for MY3, the numerator for the home dialysis rate for ESRD facilities not owned in whole or in part by an ETC LDO and Managing Clinicians would be the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis at home, plus one half of the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis via self-dialysis, plus one half of the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis via in-center nocturnal dialysis. We further proposed to add paragraph (C) to both §§ 512.365(b)(1)(ii) and 512.365(b)(2)(ii) to specify that nocturnal in-center dialysis beneficiary years included in the numerator of the home dialysis rate calculation would be composed of those months during which attributed ESRD Beneficiaries received nocturnal in-center dialysis, such that 1-beneficiary year is comprised of 12-beneficiary months. The months in which an attributed ESRD Beneficiary received nocturnal in-center dialysis would be identified by claims with Type of Bill 072X, where the type of facility code is 7 and the type of care code is 2, and with the modifier UJ, which specifies that a claim with Type of Bill 072X is for nocturnal in-center dialysis. We sought comment on these proposed changes to § 512.365(b).

The following is a summary of the comments received on our proposal to include nocturnal in-center dialysis in the home dialysis rate beginning for MY3 and our responses, and on the home dialysis rate in general.

Comment: Several commenters expressed support for the ETC Model for creating incentives to increase patient choice in the modality of their dialysis care. A few commenters also expressed support for the Model's potential to close gaps in health equity by making home dialysis more available to previously underserved populations.

Response: We appreciate the feedback and support from commenters.

Comment: A commenter expressed concern that the PPA may not account for barriers to home dialysis such as patient socioeconomic status, energy and infrastructure needs, and caregiver status, and may inadvertently penalize the Managing Clinician if home dialysis is not a suitable option for the beneficiary.

Response: As we noted in the Specialty Care Models final rule (85 FR 61267), we recognize that there are a variety of barriers that prevent ESRD Beneficiaries from choosing home dialysis at present. ESRD facilities and Managing Clinicians are the clinical experts in dialysis provision in general, and in the clinical and non-clinical needs of individual ESRD Beneficiaries specifically. We therefore continue to believe that ESRD facilities and Managing Clinicians are uniquely positioned to assist ESRD Beneficiaries in overcoming these barriers, given their close care relationship to and frequent interaction with ESRD Beneficiaries. Therefore, we have designed the ETC Model to test whether outcomes-based payment adjustments for ESRD facilities and Managing Clinicians can maintain or improve quality and reduce costs by increasing rates of home dialysis, transplant waitlisting, and living donor transplants. The payment adjustments in the ETC Model test one approach to addressing existing disincentives to home dialysis and transplant in the current Medicare FFS payment system.

There are several features of how we assess a Managing Clinician's performance on the home dialysis rate to calculate the Managing Clinician's PPA that address the concern about barriers that prevent individual ESRD Beneficiaries from choosing home dialysis. First, we exclude certain ESRD Beneficiaries from attribution who may not be suitable candidates for home dialysis or transplantation, detailed in § 512.360(b). Second, in this final rule, we are finalizing our proposals to modify the Model's benchmark methodology to recognize the additional resources required to increase the home dialysis rate and transplant rate among beneficiaries who are dual-eligible or LIS recipients. Specifically, as described in section V.B.5.c.(2) of this final rule, we are finalizing our proposal to stratify achievement benchmarks based on dual eligible and LIS recipient status in recognition that socioeconomic factors impact a beneficiary's likelihood of dialyzing at home. Additionally, as described in section V.B.6.c.(2) of this final rule, we are finalizing our proposal to add a Health Equity Incentive to the improvement scoring methodology for ETC Participants who demonstrate sufficiently significant improvement on the home dialysis rate or transplant rate among their attributed beneficiaries who are dual eligible or receive the LIS between the Benchmark Year and the MY. Lastly, as described in section V.B.3.c of this final rule, we are finalizing our proposal to include partial credit for nocturnal in-center dialysis in the home dialysis rate, which may be a more accessible alternative to traditional in-center dialysis for ESRD Beneficiaries facing the barriers identified by the commenter.

Comment: Several commenters expressed their support for nocturnal dialysis as an alternative to traditional in-center dialysis. A few commenters noted that nocturnal in-center dialysis is a valuable treatment option for beneficiaries for whom limited financial resources, housing insecurity, or lack of social support make electing home dialysis difficult, and would thereby promote health equity. A commenter stated that evidence exists to support nocturnal dialysis as an alternative to traditional in-center dialysis because it is associated with improved clinical markers, better sleep and fewer apnea events, and improved nutritional status, and because nocturnal dialysis creates greater opportunity for beneficiaries to hold gainful employment compared to traditional in-center dialysis.

Response: We appreciate the feedback and support from the commenters.

Comment: Multiple commenters expressed agreement with barriers to the provision of nocturnal dialysis identified in the CY 2022 ESRD PPS proposed rule, including supply factors and lack of patient awareness. Commenters also identified system-level factors that may impact an ESRD facility's ability to offer nocturnal dialysis, including labor and operational costs associated with keeping a facility open overnight and the need for additional equipment such as additional water systems to support nocturnal dialysis machines and beds or recliners to facilitate beneficiary sleep. One commenter also noted that beneficiaries would still be required to come into the ESRD facility during traditional hours to receive additional related services, such as nutrition counseling, which cannot be done while the beneficiary is asleep.

Response: We recognize that there are a variety of barriers that prevent ESRD Beneficiaries from choosing nocturnal in-center dialysis at present. As noted previously in this section of this final rule, nocturnal in-center dialysis also provides an alternative to traditional in-center dialysis for those beneficiaries for whom home dialysis is not an option due to limited financial resources, housing insecurity, lack of social support, or personal preference. We believe encouraging the provision of nocturnal in-center dialysis helps to promote beneficiary choice of treatment modalities while mitigating some of the barriers beneficiaries face when considering home dialysis.

Comment: Several commenters expressed their support for including nocturnal in-center dialysis beneficiary years in the numerator of the home dialysis rate calculation. These commenters agreed with CMS's position that incentivizing nocturnal in-center dialysis will create more patient choice and improve health outcomes, and may address certain socioeconomic factors that inhibit beneficiaries from selecting home dialysis.

Response: We agree with commenters that including nocturnal in-center dialysis in the home dialysis rate may improve access for beneficiaries who, due to their home condition, cannot dialyze at home. We believe that supporting patient choice in modality selection is vital, and we believe the ETC Model will support providers and suppliers in their ability to assist beneficiaries choosing renal replacement modalities other than traditional in-center dialysis.

Comment: A few commenters noted that including nocturnal in-center dialysis in the numerator of the home dialysis rate calculation may not provide sufficient incentive for an ESRD facility to launch or expand a nocturnal in-center dialysis program due to increased labor and operational costs. A commenter recommended that to address these challenges, CMS should consider including beneficiaries that are referred to a nocturnal in-center dialysis program in the home dialysis rate numerator.

Response: We recognize that there are a variety of barriers that prevent ESRD facilities from offering nocturnal in-center dialysis. However, we believe including nocturnal in-center dialysis in the home dialysis rate calculation will help promote beneficiary choice of treatment modalities while mitigating some of the barriers beneficiaries face when considering home dialysis. We are not considering including referrals to nocturnal in-center dialysis in the home dialysis rate calculation at this time. We believe the administrative burden associated with tracking referrals may be too great to implement this policy in the ETC Model; however, we may take this recommendation into consideration in the future.

Comment: A few commenters expressed concern that including nocturnal in-center dialysis in the PPA rate may slow adoption of home dialysis, as nocturnal in-center dialysis allows ESRD facilities to use existing the existing in-center dialysis infrastructure rather than modifying or creating new infrastructure and processes to implement a home dialysis program.

Response: A focus of the ETC Model remains promoting beneficiary choice of alternative treatment modalities to traditional in-center dialysis and improving beneficiary adoption of home dialysis. We believe including nocturnal in-center dialysis in the numerator of the home dialysis rate will effectively balance the benefits of nocturnal in-center dialysis and its ability to transition ESRD Beneficiaries to home dialysis, with the recognition that nocturnal in-center dialysis is not home dialysis and does not have all of the same benefits. Specifically, each beneficiary month for which an attributed beneficiary receives nocturnal in-center dialysis will contribute only one-half month to the numerator.

Comment: A commenter urged CMS to further define nocturnal in-center dialysis. The commenter stated that a Medicare manual indicates that nocturnal in-center dialysis should be for periods greater than five hours and performed while the patient is sleeping. The commenter further noted that this definition may allow for in-center dialysis conducted outside of traditional business hours to be considered nocturnal dialysis. The commenter recommended that CMS define nocturnal in-center dialysis as ''in-center hemodialysis treatments dialyzing for at least five hours with a treatment time beginning on one day and terminating after 1 a.m. on the following day'' to avoid confusion and consistency in billing.

Response: As the commenter points out, nocturnal in-center dialysis is already defined by Medicare. Specifically, effective January 1, 2017, nocturnal hemodialysis is identified under the ESRD PPS by the modifier UJ, which identifies services provided at night. The UJ modifier is for ESRD facilities to indicate that the treatment furnished is for nocturnal hemodialysis. That is, longer and slower hemodialysis that can be performed at home or in-facility for greater than 5 hours per treatment, 3 to 7 days a week. Consistent with this definition, as described elsewhere in this final rule, we are finalizing our proposal to identify months in which an attributed ESRD Beneficiary received nocturnal in-center dialysis by claims with Type of Bill 072X, where the type of facility code is 7 and the type of care code is 2, and with the modifier UJ, which specifies that a claim with Type of Bill 072X is for nocturnal in-center dialysis. As such, we do not believe it is necessary to further define nocturnal in-center dialysis in this final rule.

Comment: A few commenters agreed with the proposal to include nocturnal in-center dialysis in the home dialysis rate calculation for Managing Clinicians and for ESRD facilities not owned in whole or in part by an ETC LDO.

Response: We appreciate the commenters' support and feedback.

Comment: Multiple commenters expressed opposition to the proposal to not include nocturnal in-center dialysis in the home dialysis rate for ESRD facilities owned in whole or in part by an ETC LDO. Commenters stated that this policy undermines the incentive to increase access to nocturnal in-center dialysis, as ESRD facilities owned in whole or in part by an ETC LDO provide approximately 75 percent of dialysis care nationally. A few commenters stated that excluding ESRD facilities owned in whole or in part by an ETC LDO from the proposal to include nocturnal in-center dialysis beneficiary years in the numerator of the home dialysis rate calculation may severely limit beneficiary access to the modality, especially beneficiaries in rural and high-poverty areas, which are majority serviced by ESRD facilities owned in whole or in part by an ETC LDO, as these LDOs may not expand their nocturnal in-center dialysis capabilities without the proper incentive. Commenters noted that Managing Clinicians often partner with LDOs and should not be incentivized to refer patients to ESRD facilities not owned in whole or in part by an ETC LDO. Several commenters expressed concern that the proposed policy would arbitrarily apply different standards to ESRD facilities in the Model based on ownership and would set a precedent for future Medicare programs, and may exceed the scope of the Innovation Center's authority.

Response: We agree with commenters that excluding ESRD facilities owned in whole or in part by an ETC LDO from the proposal to include nocturnal in-center dialysis in the home dialysis rate calculation would exclude the majority of beneficiaries from the potential benefits of the policy, as ESRD facilities owned in whole or in part by an ETC LDO provide the majority of dialysis care. We continue to recognize the differences in resource availability to invest in home dialysis programs between ESRD facilities owned in whole or in part by LDOs, and those ESRD facilities that are either independent or owned by small dialysis organizations. However, after considering the comments received, we now believe that it is more important to incentivize access to nocturnal in-center dialysis for all ESRD Beneficiaries, regardless of the ownership of the ESRD facility at which they dialyze. As such, we will not be finalizing the proposal to exclude ESRD facilities owned in whole or in part by an ETC LDO from the modification to include nocturnal in-center dialysis in the home dialysis rate.

Comment: We received multiple comments from multiple smaller dialysis organizations, commonly referred to as non-large dialysis organizations (non-LDO), agreeing with the definition of an ETC LDO as a legal entity that owns, in whole or in part, 500 or more ESRD facilities. These commenters pointed out the resource differential faced by smaller companies from larger companies. Another commenter urged more changes to the ETC Model to relieve potential financial burden for non-LDOs such as including referrals made to nocturnal in-center dialysis programs in the numerator of the home dialysis rate.

Response: As described previously in this section of the final rule, we are not finalizing our proposal include nocturnal in-center dialysis in the numerator only for those ESRD facilities not owned in whole or in part by an ETC LDO. Therefore, we will not be finalizing a definition of an ETC LDO in this final rule. However, we also will not be updating model parameters to include referrals made to nocturnal in-center dialysis programs in the numerator of the home dialysis rate, as suggested by the commenter. As stated previously in this final rule, we believe the administrative burden associated with tracking such referrals may be too great to implement in the ETC Model; however, we may take this recommendation into consideration in the future.

Comment: We received comments from an LDO pointing out that the proposed definition of ETC LDO as a legal entity owning 500 or more ESRD facilities could be viewed as arbitrary, pointing out different definitions used across CMS and in other areas, which range from 20 facilities to 1,000 facilities.

Response: As we noted in the CY 2022 ESRD PPS proposed rule (85 FR 36378), at present there is not a single definition of what qualifies as a legal entity that owns ESRD facilities as an LDO. CMS chose the proposed definition after reviewing definitions commonly used to align with the current distribution of numbers of ESRD facilities owned by dialysis organizations operating in the market. Specifically, our proposed definition differentiated the largest dialysis organizations, which at present each own over 2,500 ESRD facilities, from smaller dialysis organizations, the next largest of which owns under 400 ESRD facilities. This definition is also currently used by the Kidney Care Choices Model, which changed its definition of an LDO after the publication of the CY 2022 ESRD PPS proposed rule, such that the Kidney Care Choices Model now defines an LDO as a legal entity that owns, in whole or in part, 500 or more ESRD facilities. However, as noted above, we will not be finalizing a definition of an ETC LDO in this final rule.

Comment: A few commenters suggested giving ETC Participants who refer patients to home dialysis programs credit in the home dialysis rate, regardless if the home dialysis program is located in the same HRR.

Response: We are not considering this change at this time. As noted previously in this final rule, we believe the administrative burden associated with tracking such referrals may be too great to implement in the ETC Model; however, we may take this recommendation into consideration in the future.

Final Rule Action: After considering public comments, we are finalizing our proposal to amend § 512.365(b) with modification. We are modifying our proposal such that the numerator of the home dialysis rate calculation for all ESRD facilities and for Managing Clinicians includes one half of the total number of nocturnal in-center dialysis beneficiary years for attributed ESRD Beneficiaries. Therefore, we are modifying § 512.365(b)(1)(ii) to remove references to a separate home dialysis rate calculation for ESRD facilities owned in whole or in part by an ETC LDO. Similarly, we are not finalizing the proposed ETC LDO definition at this time.

4. PPA Transplant Rate

a. Status of Organ Availability

The ETC Model is designed to encourage greater rates of transplantation. In the proposed rule published on July 18, 2019 in the **Federal Register** titled, ''Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' (84 FR 34478), referred to herein as the ''Specialty Care Models proposed rule,'' CMS proposed to include the rate of transplants, both living and deceased donor transplants, in the numerator for the ETC Model's transplant rate. However, in the Specialty Care Models final rule, we recognized the limitations of supply of deceased donor organs and updated the transplant rate to be calculated as the sum of the transplant waitlist rate and the living donor transplant rate (85 FR 61310). We stated that though a transplant is often the best treatment for a beneficiary with ESRD, in light of the current shortage of deceased donor organs for transplant, the transplant

waitlist rate and living donor transplant rate are currently more within the control of an ETC Participant (85 FR 61309).

However, in the Specialty Care Models final rule, we indicated our intent to observe the supply of deceased donor organs available for transplantation, with the goal of potentially modifying the transplant rate calculation for the future (85 FR 61309). Since the Specialty Care Models final rule was published on September 29, 2020, there have been several initiatives pursued by the Federal Government that could potentially have the effect of increasing the supply of both living donor organs and deceased donor organs.

On September 22, 2020, the Health Resources and Services Administration (HRSA) published a final rule in the **Federal Register** titled ''Removing Financial Disincentives to Living Organ Donation'' (85 FR 59438). This rule removes financial barriers to organ donation by expanding the scope of reimbursable expenses incurred by living organ donors to include lost wages, and child-care and elder-care expenses incurred by a caregiver. The rule went into effect on October 22, 2020.

Additionally, on December 2, 2020, CMS published in the **Federal Register** a final rule titled, ''Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations'' (85 FR 77898), revising Conditions for Coverage (CfCs) for Organ Procurement Organizations (OPOs). The final rule revised the CfCs for OPOs in order to increase donation rates and organ transplantation rates and replaced the old outcome measures with new transparent, reliable, and objective measures. The final rule went into effect on March 30, 2021. The new outcome measures will be implemented for the recertification cycle beginning in 2022 and ending in 2026. The goals of this rule are complementary to the goals of the ETC Model, as the revised CfCs are intended to increase the supply of organs, and the ETC Model is designed to incentivize higher rates of transplantation.

Finally, as described in the Specialty Care Models final rule, CMS is in the process of implementing the ETC Learning Collaborative (85 FR 61346). The ETC Learning Collaborative is a voluntary learning system focused on increasing the availability of deceased donor kidneys for transplantation. The ETC Learning Collaborative works with and supports ETC Participants and other stakeholders required for successful kidney transplantation, such as transplant centers, OPOs, and large donor hospitals. CMS is currently in the process of jointly implementing the ETC Learning Collaborative with HRSA.

We are pleased that these efforts have progressed since the publication of the Specialty Care Models final rule. However, given that these efforts are still in the implementation process, we stated in the CY 2022 ESRD PPS proposed rule that we do not believe it would be appropriate to update the transplant rate to include accountability for deceased donor transplants, rather than transplant waitlisting, at this time (86 FR 36380). We further stated that we still intend to update the transplant rate through future rulemaking to include accountability for deceased donor transplants, but we are not proposing to do so at this time.

The following is a summary of the comments received on the status of organ availability and related topics and our responses.

Comment: Multiple commenters expressed support for continuing to monitor the transplant rate for ETC Participants based on transplant waitlisting, rather than updating the transplant rate to include accountability for deceased donor transplants.

Response: We appreciate the support and will continue to monitor organ supply, with the goal of eventually including accountability for deceased donor transplants through future rulemaking.

Comment: One commenter stated that an artificial kidney would have the best outcomes for transplant recipients and supports continued research towards the development of an artificial kidney.

Response: We agree that the creation of an artificial kidney could have clinical benefits for beneficiaries. To assist in the development of new technologies such as an artificial kidney, HHS is part of the KidneyX public-private partnership to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases. More information on the KidneyX initiative is available at *kidneyx.org*.

Comment: One commenter stated that we should create a larger model that includes other key actors in the transplant process, including organ procurement organizations and transplant centers.

Response: We appreciate the feedback and will keep it in mind as we think about designing future models for testing. We view the ETC Model, including its ETC Learning Collaborative, as complementary to other efforts around the Department related to increasing the number of transplants, including the Kidney Care Choices Model, the OPO Conditions for Coverage updates (85 FR 77898), and the HRSA rule on Removing Financial Disincentives to Living Organ Donation (85 FR 59438). We will evaluate the ETC Model's interventions in the context of the effects of existing regulatory initiatives, but we may also consider a larger transplant model in the future.

Comment: One commenter suggested that we measure the number of beneficiaries referred for transplant rather than the length of time a beneficiary is on the transplant waitlist.

Response: In the Specialty Care Models final rule (85 FR 61310), we recognized the limitations of supply of deceased donor organs and updated the transplant rate to be calculated as the sum of the transplant waitlist rate and the living donor transplant rate. We selected the transplant waitlist rate specifically because inclusion on the waitlist was more within the control of the ETC Participant. While we did not discuss the possibility of referrals for transplant in the Specialty Care Models final rule, we believe that referrals for transplant is one step further removed from the actual receipt of a transplant relative to the beneficiary's inclusion on the transplant waitlist. A measure based on referrals would be operationally burdensome for CMS to collect and for ETC Participants to report. Additionally, such a measure would seem to have the potential for gaming, as ETC Participants could be incentivized to submit numerous referrals for individuals who would not qualify for inclusion on the transplant waitlist, or even for individuals previously denied inclusion. Accordingly, we are not adopting the commenter's suggestion at this time.

Comment: One commenter suggested that CMS establish new metrics for transplant providers, under the ETC Model, similar to the CMS quality measures published for ESRD facilities, as transplant providers play a large role in transplantation. One other commenter suggested that CMS establish a payment adjustment for transplant personnel to conduct transplant-related education activities in order to provide more accurate details about transplant to beneficiaries.

Response: At this time, we are not contemplating incorporating additional participant types, such as transplant providers, into the ETC Model. Accordingly, we are not adding quality measures or payment adjustments for transplant personnel, into the Model in this final rule. However, we appreciate

the feedback and suggestions, which we may use to inform future model design.

b. Beneficiary Exclusions From the Transplant Rate

As we discussed in the Specialty Care Models final rule (85 FR 61300), CMS received comments about excluding ESRD Beneficiaries with cancer from attribution to ETC Participants, as there was concern about treatment appropriateness. However, at that time, CMS did not have any evidence to suggest that this is a concern. Accordingly, we did not exclude beneficiaries with cancer from attribution to ETC Participants for purposes of calculating the home dialysis rate or the transplant rate in the Specialty Care Models final rule.

Nevertheless, as described in the CY 2022 ESRD PPS proposed rule (86 FR 36380), after we published the Specialty Care Models final rule, we conducted further analysis, to determine if a difference existed in either the home dialysis rate or transplant rate in beneficiaries with cancer and beneficiaries without cancer. Using the Medicare claims data and input from clinical specialists in the field of nephrology, we found that the majority of ESRD Beneficiaries with cancer, specifically ESRD Beneficiaries with cancer in vital solid organs (heart, lung, liver, and kidney), are not considered to be eligible candidates for transplant. Many transplant centers do not consider these beneficiaries for transplant and require them to be cancer-free for a specific period of time prior to assessing their eligibility for transplant. This is true for getting on a transplant waitlist and for receiving living donor transplants, as a beneficiary either needs to be cancer-free or be in an initial stage of cancer diagnosis to be considered for transplant.

In addition, we found that ESRD Beneficiaries who have a diagnosis of solid organ cancer for which they were receiving treatment, specifically radiation or chemotherapy, are less likely to be in the numerator of the transplant rate—so, being placed on the transplant waitlist or receive a living donor transplant—than ESRD Beneficiaries without a diagnosis of vital solid organ cancer. By contrast, we did not find any evidence to suggest that ESRD Beneficiaries with cancer had a significant difference in the home dialysis rate compared to the ESRD Beneficiaries without cancer.

As noted previously, under §§ 512.310 and 512.365(c), the transplant rate has two components: The transplant waitlist rate and the living donor transplant rate. Upon further review and analysis, beginning for MY3, we proposed to exclude ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries who have been diagnosed with vital solid organ cancers (heart, lung, liver, and kidney) and who are receiving treatment, in the form of radiation or chemotherapy, for such cancers from both components of the denominator of the transplant rate for both ESRD facilities and Managing Clinicians for the duration of the MY.

Furthermore, we proposed to include a lookback period, a period of time prior to the MY, to appropriately identify the ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries with a diagnosis of vital solid organ cancer for which they are receiving chemotherapy or radiation therapy. Both a diagnosis code and a treatment code are necessary to appropriately identify an ESRD Beneficiary or Pre-emptive LDT Beneficiary with a vital solid organ cancer who is receiving treatment with either radiation or chemotherapy. However, through our analysis we have identified beneficiaries who have only a treatment code available during the MY and do not have a diagnosis code during that period. Hence, we proposed to include a lookback period of 6-months prior to the MY, so that the appropriate diagnosis code can be identified for ESRD Beneficiaries and Pre-emptive LDT Beneficiaries who have only treatment codes available in the current MY. In the alternative, we considered a 12-month lookback period, but did not find any significant difference in the number of ESRD Beneficiaries and Pre-emptive LDT Beneficiaries that had a diagnosis code for a vital organ solid cancer during a 12-month lookback period as compared to a 6-month lookback period.

We proposed to identify ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries with a diagnosis of vital solid organ cancer and receiving treatment with radiation or chemotherapy by using Medicare claims. For purposes of the transplant rate calculations, we proposed that an ESRD Beneficiary or Pre-emptive LDT Beneficiary would be considered to have a diagnosis of vital solid cancer during the MY, if the ESRD Beneficiary has a claim with one of the following ICD–10 diagnosis codes:

- C22.0–C22.9 (malignant neoplasm of liver and intrahepatic bile ducts),
- C34.10–C34.12 (malignant neoplasm of upper lobe, bronchus or lung),
- C34.2 (malignant neoplasm of middle lobe, bronchus or lung),
- C34.30–C34.32 (malignant neoplasm of lower lobe, bronchus or lung),
- C34.80–C34.82 (malignant neoplasm of overlapping sites of bronchus and lung),
- C34.90–C34.92 (malignant neoplasm of unspecified part of bronchus or lung),
- C38.0 (malignant neoplasm of heart),
- C38.8 (malignant neoplasm of overlapping sites of heart, mediastinum and pleura),
- C46.50–C46.52 (Kaposi's sarcoma of lung),
- C64.1, C64.2, C64.9 (malignant neoplasm of kidney, except renal pelvis),
- C78.00–C78.02 (secondary malignant neoplasm of lung),
- C78.7 (secondary malignant neoplasm of liver and intrahepatic bile duct),
- C79.00–C79.02 (secondary malignant neoplasm of kidney and renal pelvis),
- C7A.090 (malignant carcinoid tumor of the bronchus and lung),
- C7A.093 (malignant carcinoid tumor of the kidney), or
- C7B.02 (secondary carcinoid tumors of liver).

We proposed that for the purposes of the transplant rate calculations, an ESRD Beneficiary or Pre-emptive LDT Beneficiary would be considered to be receiving treatment for vital solid organ cancer with either chemotherapy or radiation in the MY if the ESRD Beneficiary or Pre-emptive LDT Beneficiary has a claim with one of the following codes:

- CPT® 96401–96402, 96405–96406, 96409, 96411, 96413, 96415–96417, 96420, 96422–26423, 96425, 96440, 96446 (chemotherapy administration);
- CPT® 96549 (unlisted chemotherapy procedure);
- CPT® 77373 (stereotactic body radiation therapy);
- CPT® 77401–77402, 77407, 77412 (radiation treatment delivery);
- CPT® 77423 (high energy neutron radiation treatment delivery);
- CPT® 77424–77425 (Intraoperative radiation treatment delivery);
- CPT® 77520, 77522–77523, 77525 (proton treatment delivery);
- CPT® 77761–77763 (intracavitary radiation source application);
- CPT® 77770–77772, 77778, 77789, 77799 (clinical brachytherapy radiation treatment);
- CPT® 79005, 79101, 79200, 79300, 79403, 79440, 79445, 79999 (radiopharmaceutical therapy);
- ICD–10–PCS DB020ZZ, DB021ZZ, DB022ZZ, DB023Z0, DB023ZZ,

DB024ZZ, DB025ZZ, DB026ZZ, DB1297Z, DB1298Z, DB1299Z, DB129BZ, DB129CZ, DB129YZ, DB12B6Z, DB12B7Z, DB12B8Z, DB12B9Z, DB12BB1, DB12BBZ, DB12BCZ, DB12BYZ, DB22DZZ, DB22HZZ, DB22JZZ, DBY27ZZ, DBY28ZZ, DBY2FZZ, DBY2KZZ (radiation of lung);

- ICD–10–PCS DB070ZZ, DB071ZZ, DB072ZZ, DB073Z0, DB073ZZ, DB074ZZ, DB075ZZ, DB076ZZ, DB1797Z, DB1798Z, DB1799Z, DB179BZ, DB179CZ, DB179YZ, DB17B6Z, DB17B7Z, DB17B8Z, DB17B9Z, DB17BB1, DB17BBZ, DB17BCZ, DB17BYZ, DB27DZZ, DB27HZZ, DB27JZZ, DBY77ZZ, DBY78ZZ, DBY7FZZ, DBY7KZZ (radiation of chest wall);
- ICD–10–PCS DF000ZZ, DF001ZZ, DF002ZZ, DF003Z0, DF003ZZ, DF004ZZ, DF005ZZ, DF006ZZ, DF1097Z, DF1098Z, DF1099Z, DF109BZ, DF109CZ, DF109YZ, DF10B6Z, DF10B7Z, DF10B8Z, DF10B9Z, DF10BB1, DF10BBZ, DF10BCZ, DF10BYZ, DF0DZZ, DF20HZZ, DF20JZZ, DFY07ZZ, DFY08ZZ, DFY0CZZ, DFY0FZZ, DFY0KZZ (radiation of liver);
- ICD–10–PCS DT000ZZ, DT001ZZ, DT002ZZ, DT003Z0, DT003ZZ, DT004ZZ, DT005ZZ, DT006ZZ, DT1097Z, DT1098Z, DT1099Z, DT109BZ, DT109CZ, DT109YZ, DT10B6Z, DT10B7Z, DT10B8Z, DT10B9Z, DT10BB1, DT10BBZ, DT10BCZ, DT10BYZ, DT20DZZ, DT20HZZ, DT20JZZ, DTY07ZZ, DTY08ZZ, DTY0CZZ, DTY0FZZ (radiation of kidney);
- ICD–10–PCS DW020ZZ, DW021ZZ, DW022ZZ, DW023Z0, DW023ZZ, DW024ZZ, DW025ZZ, DW026ZZ, DW1297Z, DW1298Z, DW1299Z, DW129BZ, DW129CZ, DW129YZ, DW12B6Z, DW12B7Z, DW12B8Z, DW12B9Z, DW12BB1, DW12BBZ, DW12BCZ, DW12BYZ, DW22DZZ, DW22HZZ, DW22JZZ, DWY27ZZ, DWY28ZZ, DWY2FZZ (radiation of chest); or
- ICD–10–PCS DW030ZZ, DW031ZZ, DW032ZZ, DW033Z0, DW033ZZ, DW034ZZ, DW035ZZ, DW036ZZ, DW1397Z, DW1398Z, DW1399Z, DW139BZ, DW139CZ, DW139YZ, DW13B6Z, DW13B7Z, DW13B8Z, DW13B9Z, DW13BB1, DW13BBZ, DW13BCZ, DB13BYZ, DW23DZZ, DW23HZZ, DW23JZZ, DWY37ZZ, DWY38ZZ, DWY3FZZ (radiation of abdomen).

We sought comment on the proposal to amend § 512.365(c) to exclude ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries with a diagnosis of vital solid organ cancer and receiving treatment with chemotherapy or radiation from the denominator of the transplant rate as a whole, including both the transplant waitlist rate component and the living donor transplant rate component, for the duration of the MY for both ESRD facilities and Managing Clinicians.

The following is a summary of the comments received on the proposal to exclude ESRD beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, with a diagnosis of vital solid organ cancer and receiving treatment with chemotherapy or radiation from the denominator of the transplant rate for the duration of the MY, beginning for MY3, and our responses.

Comment: Several commenters stated they agree with the proposal to exclude beneficiaries, including Pre-emptive LDT Beneficiaries, with vital solid organ (heart, liver, lung, and kidney) cancers from the denominator of the transplant rate. The majority of these commenters also agreed with our proposal to use a six-month lookback period to identify these beneficiaries.

Response: We appreciate the commenters' support.

Comment: Several commenters suggested that CMS exclude additional beneficiaries from the transplant rate based on one or more criteria. A few of these commenters suggested that CMS exclude beneficiaries with all cancers, while one of the commenters suggested specific additional cancers. Another commenter suggested that CMS add breast cancer to the list of cancer exclusions, if CMS does not exclude beneficiaries with all cancers. Another commenter, suggested that CMS exclude beneficiaries with all active malignancies.

Response: In response to the commenters' suggestions to exclude beneficiaries with additional cancers, all active malignancies, or all cancers from the transplant rate, we recognize that transplant centers may vary in the cancers used to determine eligibility for transplant. However, having cancer may not automatically eliminate a beneficiary from being eligible for transplant. As noted in the proposed rule (86 FR 36380), our internal analysis identified that ESRD Beneficiaries with cancer in vital solid organs (heart, kidney, liver, lung) for which they are receiving treatment with radiation or chemotherapy, are less likely to be in the numerator of the transplant rate—so being placed on the transplant waitlist or receiving a living donor transplant—than ESRD Beneficiaries without a diagnosis of vital solid organ cancer. As noted in the Specialty Care Models final rule (85 FR 61301), CMS would like to encourage ETC Participants to provide home dialysis and transplantation for as many beneficiaries that would benefit from these care modalities. Accordingly, we are excluding from the transplant rate calculation only those beneficiaries who are particularly unlikely to be eligible for transplants; specifically, those beneficiaries with vital solid organ cancers who are receiving treatment through radiation or chemotherapy.

Comment: One commenter suggested that CMS exclude all beneficiaries who have untreatable cardiopulmonary, cardiovascular, peripheral vascular disease, significant physical disability (Karnofsky Score <40 percent), severe pulmonary issues, severe morbid obesity (BMI >50), or recurrent chronic infections. In addition, other commenters suggested that we exclude beneficiaries with end-stage Chronic Obstructive Pulmonary Disease (COPD) and diagnoses involving heart failure.

Response: As noted above, transplant centers have varying criteria when considering a beneficiary as eligible for transplant. For instance, many transplant centers do not reject a beneficiary for transplant solely on the basis of the non-cancer conditions suggested by commenters. Thus, the general categorization of these conditions for exclusion is not appropriate. Moreover, as noted previously, CMS would like to encourage ETC Participants to provide home dialysis and transplantation for as many beneficiaries that would benefit from these care modalities; our ability to achieve this aim would be compromised were CMS to exclude too many categories of beneficiaries from the Model's financial calculations. Accordingly, we are not adding these conditions for beneficiary exclusion from the transplant rate at this time. Nonetheless, we will continue to consider whether any additional conditions should be added to the exclusion criteria for transplant rate through future rulemaking.

Comment: One commenter suggested that CMS operationalize the exclusion of beneficiaries with cancer in vital solid organs from the transplant rate by using only diagnosis codes, rather than a combination of diagnosis codes and treatment codes, to identify such beneficiaries, as treatment might not have started or might not be appropriate.

Response: As we noted in the CY 2022 ESRD PPS proposed rule (86 FR 36380), we proposed to include a lookback period, a period of time prior to the MY, to appropriately identify beneficiaries with a diagnosis of a vital

solid organ cancer for which they are receiving treatment in light of internal analysis that identified beneficiaries who have a treatment code, but not a diagnosis code, during the MY. In order to capture the ESRD beneficiaries with the vital solid organ cancer diagnosis appropriately, we proposed to include a lookback period of 6 months. While we considered a 12-month lookback period, as noted in the CY 2022 ESRD PPS proposed rule (86 FR 36380), our internal analysis did not identify any significant difference in the number of beneficiaries that had a diagnosis for a vital solid organ cancer during a 12-month lookback period as compared to a 6-month lookback period. In addition, a longer lookback period was not considered to identify diagnosis code(s) as the exclusion is to identify beneficiaries with active cancer because our internal analysis did not identify any significant difference in the number of beneficiaries that had a diagnosis for a vital solid organ cancer during a lookback period longer than 12 months as compared to a 6-month lookback period. We therefore decline to adopt the commenter's suggestion of using a 2-year lookback period to identify cancer diagnosis.

In the CY 2022 ESRD PPS proposed rule (86 FR 36280), we did not propose a lookback period for treatment codes. However, CMS did previously identify beneficiaries with a diagnosis code and no treatment code during the MY. Given that several commenters suggested that CMS include a lookback period for treatment, and considering that a beneficiary could have ended their most recent course of treatment immediately prior to the start of a given MY, we are modifying our proposal to include a lookback period of 6-months to identify radiation or chemotherapy treatment codes for beneficiaries with diagnosis code of vital solid organ cancer during the MY, similar to the proposed lookback period for diagnosis codes that we are finalizing in this rule. We are limiting the lookback period to identify radiation or chemotherapy treatment code(s) to 6 months because the purpose of this particular exclusion is to exclude from the transplant rate beneficiaries who have an active cancer and are receiving treatment, as these beneficiaries are less likely to be placed on the transplant waitlist. Beneficiaries who received radiation or chemotherapy treatment greater than 6 months before the start of the MY are unlikely to be actively receiving treatment and thus do not need to be excluded from the transplant rate for that reason.

After considering the comments received, we are finalizing a 6-month lookback period, as proposed, for identifying a vital solid organ cancer diagnosis code for beneficiaries who have only a treatment code during the MY. In addition, we are adding in a 6-month lookback period for identifying radiation and chemotherapy treatment codes for beneficiaries who have only a diagnosis code during the MY.

Final Rule Action: After considering public comments, we are finalizing our proposal with modification. First, we are amending our regulation at § 512.365(c) to exclude ESRD beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, who had a diagnosis of vital solid organ cancer and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY from the denominator of the transplant rate calculation, beginning for MY3. Second, we are making two modifications to correct the information included in the proposed rule (86 FR 36380–36381). Specifically, we are clarifying the list of ICD–10 diagnosis codes included in § 512.365(c)(1)(i)(A)(*1*) to replace ''C22.1–C22.9,'' with ''C22.0, C22.1, C22.2, C22.3, C22.4, C22.7, C22.8 and C22.9.'' The codes C22.1–C22.9 are not sequential—that is, there is no C22.5 or C22.6—and therefore should not have been grouped. In addition, while we referenced C22.0 in the preamble of the CY 2022 ESRD PPS proposed rule, this code was left out of the proposed regulation text in error. C22.2 was also left out of the proposed regulation text in error. In addition, we are also modifying the list of treatment codes at § 512.365(c)(1)(i)(A)(*2*)(*ii*) to correct a typo of the ICD–10–PCS codes from ''DF0DZZ,'' to ''DF20DZZ,'' which refers to radiation of the liver. Third, we are adding a 6-month lookback period to identify radiation and chemotherapy treatment codes for beneficiaries who only have a vital solid organ cancer diagnosis code during the MY.

5. PPA Achievement Benchmarking

a. Background on Achievement Benchmarking

Under the ETC Model, the PPA is a positive or negative adjustment on dialysis and dialysis-related Medicare payments, for both home dialysis and in-center dialysis. To calculate an ETC Participant's PPA, we assess ETC Participant achievement on the home dialysis rate and transplant rate in relation to achievement and improvement benchmarks, as described in 42 CFR 512.370(b) and § 512.370(c), respectively. The Model more heavily weights achievement of results, allowing participating Managing Clinicians or ESRD facilities to earn up to 2 points in the scoring methodology, as opposed to only 1.5 points for maximum level of improvement, as described in §§ 512.370(b) and 512.370(c).

The achievement benchmarks are constructed based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during corresponding Benchmark Years. Achievement benchmarks are percentile based, and an ETC Participant receives the achievement points that correspond with its performance, at the aggregation group level, on the home dialysis rate and transplant rate in relation to the achievement benchmarks, as described in § 512.370(b). Table 7 details the achievement score scale described in § 512.370(b).

TABLE 7: Current Scoring Methodology for Achievement Scores

Achievement Score Scale for MY1 and MY2	Points
90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	2
75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	1.5
50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	1
30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	0.5
<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year	0

In the Specialty Care Models proposed rule, we proposed to apply this achievement benchmark policy only for MY1 and MY2, and stated our intent to increase achievement benchmarks for ETC Participants above the rates observed in Comparison Geographic Areas. We stated our belief that increasing the achievement benchmarks for future MYs, which we would do through subsequent rulemaking, was necessary in order to provide sufficient incentive for ETC Participants to increase rates of home dialysis and transplantation at a rate faster than would occur absent the ETC Model (84 FR 34556 through 34557). In the Specialty Care Models final rule, in response to comments, we finalized the applicability of the achievement benchmarks for MY1 through MY2 and for subsequent MYs (85 FR 61323), but reiterated our intent to establish a different method for establishing achievement benchmarks for future years of the Model through subsequent rulemaking (85 FR 61320). We stated our belief that future modifications to the achievement benchmark methodology finalized in the Specialty Care Models final rule would be necessary to provide sufficient incentive for ETC Participants to raise home dialysis and transplant rates at a rate faster than would occur absent the ETC Model (85 FR 61321). However, we clarified that while we had stated a goal of 80 percent of an ETC Participant's receiving home dialysis or a transplant in order to receive the maximum upward payment adjustment by the final MYs, we were not finalizing that goal in the Specialty Care Models final rule (85 FR 61321).

b. Addressing Socioeconomic Factors That Impact ETC Participant Achievement

In the Specialty Care Models final rule, we acknowledged commenters' concerns that non-clinical factors, such as socioeconomic status, may impact a beneficiary's likelihood to receive home dialysis or transplant. We discussed commenters' suggestions to incorporate consideration of socioeconomic status in two elements of the ETC Model: (1) Beneficiary attribution; and (2) risk adjustment. However, we declined to exclude beneficiaries from attribution based on socioeconomic status. Noting the importance of not excluding these beneficiaries, CMS stated its intent to assess the use of various codes for purposes of adding any additional beneficiary exclusions from attribution to ETC Participants based on socioeconomic status, homelessness, or other social determinants of health through future rulemaking (85 FR 61299). We also noted that commenters' suggestions for ways to risk adjust the home dialysis rate based on socioeconomic status were a significant departure from the policy originally proposed (85 FR 61315).

In the CY 2022 ESRD PPS proposed rule (86 FR 36382), we continued to acknowledge the impact that non-clinical factors, such as socioeconomic status, have on a beneficiary's likelihood to receive home dialysis or a transplant. Our additional analysis of Medicare claims data shows that beneficiaries who are dual-eligible for Medicare and Medicaid or receive the Medicare Low-Income Subsidy (LIS) are less likely than beneficiaries who are not dual-eligible and are not LIS recipients to dialyze at home or to receive a kidney transplant. As such, ETC Participants who have a higher proportion of attributed beneficiaries who are dual-eligible or LIS recipients may be less likely to achieve high home dialysis and transplant rates than ETC Participants who have a lower proportion of attributed beneficiaries who are dual-eligible or LIS recipients.

c. Achievement Benchmarking and Scoring

(1) Achievement Benchmarking and Scoring for MY3 Through MY10

We proposed to modify the percentile-based achievement benchmarking methodology based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year as the basis for achievement benchmarks in MY3 through MY10 (86 FR 36382). Rather than using rates observed in Comparison Geographic Areas, we proposed to modify § 512.370(b)(1) to use rates observed in Comparison Geographic Areas as the base for the achievement benchmarks, and to increase the achievement benchmarks above the Comparison Geographic Area rates during the Benchmark Year by 10 percent every two MYs, beginning for MY3. As such, we proposed that achievement benchmarks would be calculated by multiplying the percentile rate observed in Comparison Geographic Areas during the Benchmark Year by 1.1 for MY3 and MY4, by 1.2 for MY5 and MY6, by 1.3 for MY7 and MY8, and by 1.4 for MY9 and MY10.

Based on our analyses detailed in the CY 2022 ESRD PPS proposed rule and in section VIII.C.4 of this final rule, this proposed methodology for increasing benchmarks by 10 percent every two MYs would produce results in keeping with the initial impact estimates for the ETC Model, as described in the Specialty Care Models final rule (85 FR 61353 through 61354). In the Specialty Care Models final rule, we estimated impacts based on projected growth rates for the home dialysis and transplant rates based on historical observation, projected a 1.5 percentage point growth rate (86 FR 36383). In the CY 2022 ESRD PPS proposed rule and in section VIII.C.4 of this final rule, updated projections assume the same projected growth rate, but note that observed rates of increase have accelerated in more recent data. As such, in the CY 2022

ESRD PPS proposed rule we stated our belief that this rate of increase would be attainable for ETC Participants, as initial impact estimates were based on rates of increase observed on the home dialysis rate and transplant rate before the ETC Model began (85 FR 61353). We also noted that, unlike in the Specialty Care Models proposed rule (84 FR 34556), we were not proposing to increase achievement benchmarks such that of 80 percent of an ETC Participant's attributed beneficiaries would need to be receiving home dialysis or a transplant in order for the ETC Participant to receive the maximum upward payment adjustment by the final MYs. Table 8 details the proposed scoring methodology for assessment of MY3 through MY10 achievement scores.

TABLE 8: Proposed Scoring Methodology for Assessment of Measurement Years 3 through 10 Achievement Scores on the Home Dialysis Rate and Transplant Rate

Achievement Score Scale				Points
MY3 and MY4	MY5 and MY6	MY7 and MY8	MY9 and MY10	
1.1 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.2 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.3 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.4 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	2
1.1 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.2 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.3 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.4 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.5
1.1 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.2 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.3 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.4 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1
1.1 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.2 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.3 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.4 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	0.5
1.1 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.2 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.3 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	1.4 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year)	0

In the CY 2022 ESRD PPS proposed rule, we considered increasing achievement benchmarks by a percentage point amount, rather than by a percent amount, every two MYs (for example, increasing achievement benchmarks by 10-percentage points for MY3 and MY4, by 20-percentage points for MY5 and MY6, etc.). However, we stated our belief that this percentage point-based approach would be less flexible to and accommodating of variation in the underlying distributions of home dialysis and transplant rates than the percent-based approach we are proposing. We also stated our belief that this percentage point-based approach would add additional complexity, as we would likely need to develop separate percentage point amounts by which to increase benchmarks as the home dialysis rate and transplant rate observed in Comparison Geographic Areas are not sufficiently similar to expect the same percentage point growth rate for the two rates.

In the CY 2022 ESRD PPS proposed rule, we also considered proposing to modify the Benchmark Year, such that the Benchmark Year would be a fixed duration (for example, July 1, 2018 through June 30, 2019), rather than a period of time defined in relation to the relevant MY. However, we determined that this approach would not account for aggregate changes in the home dialysis rate and transplant rate over time.

In the CY 2022 ESRD PPS proposed rule we stated our belief that the proposed approach for increasing achievement benchmarks over the course of the ETC Model would balance the intent of the model design to increase rates of home dialysis and transplantation above what would have occurred in the absence of the Model with what is achievable for ETC Participants, based on rates of home dialysis and transplantation observed at the high ends of the distributions (for additional discussion, see 86 FR 36427). We also stated our belief that the proposed approach would provide

clarity to ETC Participants about the benchmarking methodology for the duration of the ETC Model while maintaining flexibility in that methodology to address long term trends in the home dialysis rate and transplant rate.

We sought public comment on our proposal to modify the achievement benchmarking methodology under § 512.370(b) beginning for MY3 to increase achievement benchmarks, and the proposal to increase achievement benchmarks by 10 percent every two MYs above percentile-based rates of observed in Comparison Geographic Areas.

The following is a summary of the comments received on our proposal to modify the achievement benchmarking methodology beginning for MY3 to increase achievement benchmarks by 10 percent every two MYs above rates observed in Comparison Geographic Areas, and our responses.

Comment: Many commenters stated that they support increasing achievement benchmarks over the duration of the ETC Model.

Response: We appreciate the support for increasing the PPA achievement benchmarks throughout the duration of the ETC Model.

Comment: Two commenters opposed increasing achievement benchmarks over time. One such commenter stated that the increasing magnitude of the PPA, and the use of improvement scoring, collectively create a sufficient incentive for ETC Participants to continue to increase rates of home dialysis and transplant. The other such commenter stated that they opposed increasing achievement benchmarks over time, as doing so will ensure that ETC Participants cannot be successful in the ETC Model, resulting in payment cuts.

Response: In response to the comment that the increasing magnitude of the PPA and use of improvement scoring create a sufficient incentive to promote continued increases in rates of home dialysis and transplant, we disagree that these two factors alone are sufficient. As such, we believe it is necessary to increase achievement benchmarks over the course of the ETC Model. Similarly, we disagree with the commenter that increasing achievement benchmarks will result in payment cuts for all ETC Participants. While we project that the ETC Model will reduce Medicare expenditures, ETC Participants can still earn positive payment adjustments through their performance in the Model.

Comment: Several commenters stated that they appreciate and support that CMS is establishing the achievement benchmarking methodology for the remaining years of the Model through this rulemaking.

Response: As stated in the Specialty Care Models final rule (85 FR 61321), we believe that establishing changes to the achievement benchmarking methodologies for subsequent MYs through notice-and-comment rulemaking is transparent and will provide sufficient notice to ETC Participants to plan for the updated achievement benchmarking methodology.

Comment: Several commenters stated that CMS should ensure that achievement benchmarks are achievable for ETC Participants.

Response: We agree that the achievement benchmarks should be achievable, while ensuring that there is sufficient incentive for ETC Participants to continue to increase rates of home dialysis and transplantation through the duration of the Model. As discussed in the CY 2022 ESRD PPS proposed rule and section V.B.5.c.(1) of this final rule, we believe that the achievement benchmarking methodology we are finalizing is achievable.

Comment: Several commenters stated that they agree with the proposal to increase achievement benchmarks by 10 percent every two MYs. One of these commenters stated that this increase is necessary to sustain continued growth in the home dialysis rate and transplant rate.

Response: We appreciate the commenters' support for increasing benchmarks by 10 percent every two MYs. We agree that this increase is necessary to sustain continued growth in rates of home dialysis and transplantation in the ETC Model.

Comment: A few commenters stated that increasing the home dialysis rate by 10 percent is, or may be, achievable based on growth in home dialysis rates observed in 2019, 2020, and 2021.

Response: We appreciate commenters' statements that a 10 percent increase in the home dialysis rate is or may be achievable for ETC Participants. We agree that a 10 percent increase is achievable for ETC Participants based on recent historical growth rates. Specifically, in the Specialty Care Models final rule (85 FR 61354), we projected a 1.5 percentage point growth rate in the home dialysis and transplant rates. While the updated projections in the CY 2022 ESRD PPS proposed rule and in section VIII.C.4 of this final rule assume the same projected growth rate, initial impact estimates were based on rates of increase observed on the home dialysis rate and transplant rate before the ETC Model began and observed rates of increase have accelerated in more recent data.

Comment: Several commenters stated that CMS should not increase achievement benchmarks by 10 percent every two MYs. Some such commenters stated that 10 percent is an arbitrary amount, that 10 percent is too large, and that 10 percent is not achievable. As evidence that a 10 percent increase in achievement benchmarks every two MYs is not achievable, one such commenter pointed to the lack of growth in home dialysis observed as a result of the shift to the ESRD PPS bundled payment system in 2011, and between 2018 and 2021, and that transplant waitlist rates were relatively stable between 2014 and 2019. Another commenter, who is a dialysis provider, stated that 10 percent home dialysis growth is not consistent with their own growth rate over the past year.

Response: We disagree with commenters that a 10 percent increase in the achievement benchmarks every two MYs is not attainable, as we believe that 10 percent is neither too large nor not achievable. We also disagree that a 10 percent increase is arbitrary. As stated in the CY 2022 ESRD PPS proposed rule and in sections V.B.5.c.(1) and VIII.C.5.d.(10) of this final rule, we selected 10 percent based on analysis of historical observations, attainability, transparency for ETC Participants, and the need to preserve the expectation for model net savings. We have also noted, as did a few commenters, that in the recent years these observed rates of increase in the home dialysis rate and transplant rate have accelerated and as such we continue to believe the proposed rate of increase would be attainable for ETC Participants.

In regards to the home dialysis rate specifically, CMS acknowledges the lack of growth in home dialysis observed following the shift to the ESRD PPS bundled payment system in 2011. Indeed, as described in the Specialty Care Models final rule (85 FR 61273), while CMS has undertaken previous efforts expected to increase rates of home dialysis, low rates of home dialysis have persisted. Therefore, the ETC Model was designed to test the effectiveness of more significant incentives to increase rates of home dialysis by tying payment incentives directly to increasing rates of home dialysis. However, we disagree with the commenter that stated that home dialysis rates have not grown in recent years. Prior to the announcement of the ETC Model in 2019, the home dialysis rate increased by 7.9 percent among prevalent patients with ESRD from 2017

to 2018.[274] More recently, as described in section VIII.C.5.d.(3) of this final rule, the aggregate home dialysis rate grew by approximately 4 percent in CY 2020. Regarding the commenter who stated that 10 percent was not consistent with their own historical growth rate for home dialysis, we have not asserted that any individual dialysis provider has experienced this growth rate, nor do we expect any individual dialysis provider's experience prior to the ETC Model to be representative of future potential growth in home dialysis rates for all ETC Participants. Instead, we have set the 10 percent increase in the achievement benchmark based on projected growth rates in home dialysis and transplant, based on historical observations, and we believe that a 10-percent increase will be attainable for ETC Participants.

Regarding the transplant rate specifically, we acknowledge that the transplant waitlist rates were stable between 2014 and 2019, as noted by the commenter. However, CMS and HHS are undertaking a number of efforts regarding transplantation, as we described in the CY 2022 ESRD PPS proposed rule and in section V.B.4.a of this final rule. This coordinated effort around transplant availability did not exist prior to 2019, and we believe that this effort will facilitate increasing rates of transplantation during the remaining MYs of the ETC Model.

Comment: One commenter stated that if CMS increases achievement benchmarks as proposed, it should do so only for ESRD facilities owned by LDOs, as the commenter is concerned about the ability of ESRD facilities not owned by LDOs to increase their home dialysis and transplant rates.

Response: We disagree with the commenter that CMS should increase achievement benchmarks only for ESRD facilities owned by LDOs. As discussed in the Specialty Care Models final rule (85 FR 61284), the ETC Model is designed to test the effectiveness of using payment adjustments to maintain or improve quality while decreasing costs by increasing rates of home dialysis and transplants for all types of ESRD facilities nationally, including those owned by both large and small dialysis organizations. To determine if payment adjustments can achieve the Model's goals of increasing rates of home dialysis utilization and kidney transplant and, as a result, improving or maintaining the quality of care while reducing Medicare expenditures among all types of ESRD facilities, we need to test the model with ESRD facilities owned by all types of dialysis organizations. By extension, we believe that it is necessary to increase the achievement benchmarks in a consistent manner for all ESRD facilities participating in the ETC Model, regardless of type of ownership, to create the same incentives for all ESRD facilities to increase rates of home dialysis and transplants. Using the same achievement benchmarks also increases the generalizability of the ETC Model results.

Comment: A few commenters stated that they agreed with the proposal to set achievement benchmarks in relation to rates observed in Comparison Geographic Areas.

Response: We appreciate commenters' support for setting achievement benchmarks in relation to rates observed in Comparison Geographic Areas.

Comment: Several commenters opposed setting achievement benchmarks in relation to rates observed in Comparison Geographic Areas. These commenters stated that basing benchmarks on BY rates in Comparison Geographic Areas may cause dialysis organizations with ESRD facilities to focus their resources on increasing rates in Selected Geographic Areas to the detriment of those in Comparison Geographic Areas. Similarly, these commenters, including LDOs, stated that this approach could create an opportunity for dialysis organizations with ESRD facilities in both Selected Geographic Areas and Comparison Geographic Areas to manipulate achievement benchmarks by keeping home dialysis and transplant rates artificially low in Comparison Geographic Areas. These commenters stated that any such gaming by dialysis organizations would be harmful to beneficiaries and would run counter to the intent of the ETC Model. Another commenter stated that this dynamic could disadvantage ESRD facilities not owned by LDOs, and further market consolidation. Several commenters stated that CMS should use ''absolute'' or ''fixed'' benchmarks, to avoid gaming opportunities by dialysis organizations with ESRD facilities in both Selected Geographic Areas and Comparison Geographic Areas. These commenters suggested setting fixed benchmarks based on rates observed in Comparison Geographic Areas during a fixed period of time, such as Benchmark Year 1, or based on historical rates observed in Selected Geographic Areas instead of Comparison Geographic Areas.

Response: We understand commenters' concerns that entities that own ESRD facilities in both Selected Geographic Areas and Comparison Geographic Areas may choose to engage in practices that limit the growth of home dialysis and transplantation in Comparison Geographic Areas, either because they are incentivized under the Model to focus on Selected Geographic Areas or because they seek to manipulate or ''game'' achievement benchmarks based on rates observed in Comparison Geographic Areas for financial gain.

The purpose of the ETC Model is to test whether the Model's payment adjustments will change the behavior of ETC Participants to increase rates of home dialysis and transplantation such that quality is maintained or improved while costs are reduced. If the Model test achieves these aims, we expect ETC Participants to behave differently than ESRD facilities and Managing Clinicians who are not ETC Participants. That is, we expect ETC Participants to respond to the Model's incentives to increase rates of home dialysis and transplantation over the course of the Model.

However, we do not expect or intend that testing the ETC Model will harm or disadvantage beneficiaries whose ESRD facilities and Managing Clinicians are not ETC Participants. First, there are a number of factors that mitigate the risk that ESRD facilities owned by entities operating in both Selected Geographic Areas and Comparison Geographic Areas can manipulate achievement benchmarks based on rates observed in Comparison Geographic Areas. For instance, organizations that own ESRD facilities in both Selected Geographic Areas and Comparison Geographic Areas do not have sole control over the rates of home dialysis, transplant waitlisting, or living donation in Comparison Geographic Areas. Each ESRD Beneficiary has a Managing Clinician who is responsible for managing their dialysis care, as well as other healthcare providers. Managing Clinicians, in particular, provide education about renal replacement options to ESRD Beneficiaries and Preemptive LDT Beneficiaries, and prescribe dialysis for ESRD Beneficiaries. Unlike ESRD facilities owned by organizations with ESRD facilities in both Selected Geographic Areas and Comparison Geographic Areas, few Managing Clinicians are in practices that operate in both Selected Geographic Areas and Comparison Geographic Areas, and as such are unlikely to even be able to provide differential care in different areas.

[274] United States Renal Data System. 2020. *2020 Annual Data Report.* ''Figure 1.13 Number of prevalent ESRD patneits performing home dialysis, 2000–2018.'' *https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities.*

Regarding the transplant rate in particular, we recognize that ESRD facilities play an important role in transplant waitlisting and living donor transplants. As ESRD Beneficiaries interact with their ESRD facility multiple times a week, ESRD facilities are well positioned to support beneficiaries through the transplant process. Additionally, ESRD facilities are required to conduct certain transplant-related activities for their patients, as described in 42 CFR 494.70, 494.80, and 494.90. However, an ESRD Beneficiary's Managing Clinician and other healthcare providers are equally important for supporting a beneficiary through the transplant process.

Regarding the home dialysis rate in particular, while we recognize that certain ESRD facilities located in both Selected Geographic Areas and Comparison Geographic Areas—namely those owned in whole or in part by LDOs—provide the majority of dialysis, they are not the sole providers of dialysis. Smaller chains and independent ESRD facilities, many of which do not operate in both Selected Geographic Areas and Comparison Geographic Areas, provide a significant volume of dialysis services and are less likely to face the incentive described by commenters to provide differential care in different areas, for either resource or gaming reasons. Additionally, if the demand for home dialysis increases but ESRD facilities owned by organizations that operate in both Selected Geographic Areas and Comparison Geographic Areas are unable or unwilling to increase the availability of home dialysis in Comparison Geographic Areas, ESRD facilities owned by smaller chains or independent ESRD facilities may be able to increase supply to meet the unmet demand in those areas.

Second, as described in the Specialty Care Models final rule (85 FR 61320), CMS will engage in active monitoring for adverse outcomes, including behavior described by commenters, and we intend to make adjustments to the Model through subsequent rulemaking should such unintended consequences arise. We also note that CMS may take remedial action under § 512.160 of our regulations if an ETC Participant fails to comply with any terms of the Model, including the provisions protecting beneficiary freedom of choice and availability of services under § 512.120 of our regulations, or if an ETC Participant has taken any action that threatens the health or safety of a beneficiary or other patient.

Taken together we believe that these factors, coupled with CMS's monitoring efforts and ability to take remedial action, mitigate the risk that entities that own ESRD facilities in both Selected Geographic Areas and Comparison Geographic areas will alter achievement benchmarks by manipulating rates in Comparison Geographic Areas.

Comment: A few commenters stated that CMS should use the methodology used to set the performance standards under the ESRD QIP for setting achievement benchmarks under the ETC Model. One such commenter stated that the ESRD QIP performance standard setting methodology is preferable to the achievement benchmarking approaches described in the CY 2022 ESRD PPS proposed rule because it would continue to incentivize improved performance while not relying on rates observed in Comparison Geographic Areas, and is simple and familiar to ESRD facilities. This commenter also stated that the ESRD QIP methodology was preferable because it does not allow performance standards to decrease over time.

Response: As stated in the Specialty Care Models final rule, we do not believe the ESRD QIP methodology is well suited for the ETC Model (85 FR 61322 through 61323). In particular, we continue to believe that the ESRD QIP performance standard setting methodology does not ensure escalating performance standards over time, which is an important design feature for the ETC Model. Similarly, we continue to recognize that, while ESRD facilities are familiar with the ESRD QIP performance standard setting methodology because they are already subject to it, Managing Clinicians are not.

Comment: A few commenters stated that CMS should use population-weighted achievement benchmarks, to account for variation in size among aggregation groups. One such commenter stated that population-weighted benchmarks are more appropriate because of the difference in absolute change necessary for larger and smaller aggregation groups to achieve the same relative performance. That is, relative to smaller aggregation groups, larger aggregation groups need to have a larger number of individual beneficiaries change from in-center dialysis to home dialysis, self-dialysis, or nocturnal in-center dialysis to increase their home dialysis rate; or to have a larger number of individual beneficiaries be waitlisted for transplant or receive a living donor transplant to increase their transplant rate to achieve the same level of performance. The commenter also stated that larger aggregation groups have a larger absolute impact on the number of beneficiaries who dialyze at home or are placed on the transplant waitlist, and therefore should not be compared to smaller aggregation groups who may have the same relative level of performance but a smaller absolute impact.

Response: We appreciate commenters' suggestion that we use population-weighted benchmarks. However, we did not propose this approach, and we are not contemplating this change at this time.

Additionally, we disagree with the commenter who stated that population-weighted benchmarks are more appropriate because larger aggregation groups need to increase rates of home dialysis, transplant waitlisting, and living donor transplants among a larger number of beneficiaries relative to smaller aggregation groups to achieve the same level of performance. We believe that that this approach would unfairly disadvantage smaller aggregation groups, holding them to a higher relative standard solely because they have fewer attributed beneficiary months. We also disagree that larger aggregation groups should be held to a lower relative standard than smaller aggregation groups because they have a larger absolute impact.

Comment: One commenter opposed the negative payment adjustments included in the ETC Model and suggested that the Model instead have only positive payment adjustments.

Response: As noted in the Specialty Care Models final rule (85 FR 61264), the purpose of the ETC Model is to test whether the payment adjustments included in the Model will reduce Medicare expenditures while improving or maintaining quality of care. As further stated in the Specialty Care Models final rule (85 FR 61323), we believe that downside risk is a critical component of this Model in order to create strong incentives for behavioral change among ETC Participants, that is by encouraging participating Managing Clinicians and ESRD facilities to support beneficiaries choosing home dialysis and transplantation. We therefore disagree that eliminating the negative adjustments would provide sufficient incentive to encourage behavior change leading to the achievement of the goals of the Model.

Comment: One commenter stated that, instead of increasing achievement benchmarks to increase rates of home dialysis and transplantation, CMS should instead focus on increasing participation in the ETC Model in more areas of the country, if the ETC Model is successful at increasing rates of home dialysis and transplantation.

Response: As described previously in section V.A.3 of this final rule, the purpose of the ETC Model is to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians to encourage greater utilization of home dialysis and kidney transplantation, support beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. If the Model meets the criteria set forth in section 1115A(c) of the Act, we may consider expanding the duration and scope of the ETC Model. However, the Model calculates benchmarks and assesses ETC Participant performance against rates of home dialysis, transplant waitlisting, and living donor transplantation among similar Managing Clinicians or ESRD facilities located in Comparison Geographic Areas. A limitation on Model participation is therefore currently necessary to ensure there are sufficient comparators for these purposes.

Comment: One commenter stated that we should update the PPA methodology by increasing the weight of the transplant rate to be equal to the home dialysis rate, or by separating out the transplant rate completely so that one is not dependent on the other.

Response: As discussed in the Specialty Care Models final rule (85 FR 61319), CMS had considered making the home dialysis rate score and the transplant rate score equal components of the Modality Performance Score (MPS) used in calculating the PPA. However, we recognized that transplant rates may be more difficult for ETC Participants to improve than home dialysis rates, due to the limited supply of organs and the number of other providers or suppliers that are part of the transplant process. For this reason, under the PPA methodology, home dialysis rates take a greater weight than transplant rates.

Comment: One commenter suggested that CMS modify the Model such that the MPS applies only to Managing Clinicians as, by the time a beneficiary begins dialysis with an ESRD facility, it is too late for the ESRD facility to encourage pre-emptive transplant and pre-emptive transplant recipients will see an ESRD facility only after a transplant rejection.

Response: We would like to clarify for the commenter that the MPS is calculated for all ETC Participants based on their home dialysis rate and transplant rate, in order to determine the ETC Participant's PPA. However, the pre-emptive transplant rate is part of the transplant rate calculation only for Managing Clinicians.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.370(b) to increase achievement benchmarks by 10 percent every two MYs above rates observed in Comparison Geographic Areas, as proposed.

(2) Achievement Benchmark Stratification by Dual-Eligible and Low Income Subsidy (LIS) Status

We also proposed to modify § 512.370(b) to stratify achievement benchmarks based on the proportion of beneficiary years attributed to the ETC Participant's aggregation group for which attributed beneficiaries were dually-eligible for Medicare and Medicaid or received the LIS, based on rates in Comparison Geographic Areas (86 FR 36384). Under our proposal, we would create two strata with the cutpoint set at 50 percent of attributed beneficiary years being for attributed beneficiaries who were dual-eligible or received the LIS. As such, there would be one stratum for ETC Participants whose aggregation groups had 50 percent or more of their attributed beneficiary years during the MY for beneficiaries who were dual-eligible or received the LIS, based on rates in Comparison Geographic Areas for aggregation groups with 50 percent or more attributed beneficiary years during the Benchmark Year being for dual-eligible or LIS beneficiaries. There would be a second stratum for ETC Participants whose aggregation groups had less than 50 percent of their attributed beneficiary years during the MY for beneficiaries who were dual-eligible or received the LIS, based on rates in Comparison Geographic Areas for aggregation groups with less than 50 percent attributed beneficiary years during the Benchmark Year being for dual-eligible or LIS beneficiaries. We proposed to determine whether an attributed beneficiary was dual-eligible or received the LIS for a given month using Medicare administrative data. In the CY 2022 ESRD PPS proposed rule, we stated our belief that this proposal would address concerns that socioeconomic factors may impact a beneficiary's likelihood to receive alternative renal replacement modalities, lowering the transplant rate and home dialysis rates for ETC Participants who provide services to low income beneficiaries. We also stated our expectation that stratifying the achievement benchmarks as proposed would increase home dialysis rate and transplant rates for such ETC Participants.

In the CY 2022 ESRD PPS proposed rule, we considered using more than two strata, in order to increase the precision of the achievement benchmarks and the degree of similarity between ETC Participants within a given stratum. However, we noted that increasing the number of strata would decrease the number of observations within each stratum, in turn decreasing statistical reliability. Additionally, analysis of the distribution of the home dialysis rate and transplant rate demonstrates that the underlying distribution does not lend itself to more than two strata, as the distribution is not multi-modal. For this reason, we proposed only two strata.

We sought public comment on our proposal to amend § 512.370(b) to stratify achievement benchmarks based on the proportion of attributed beneficiary years for which attributed beneficiaries were dual-eligible or received the LIS, and on our proposal to create two strata for this purpose.

The following is a summary of the comments received on our proposal to stratify achievement benchmarks based on the proportion of attributed beneficiary years for which attributed beneficiaries were dual eligible or received the LIS beginning for MY3, including our policy to create two strata for this purpose, and our responses.

Comment: Two commenters expressed support for addressing socioeconomic factors that impact ETC Participant achievement. These commenters also specifically supported CMS's recognition of the two proposed categories of beneficiaries who are economically disadvantaged for this purpose, namely beneficiaries who are dual-eligible or are LIS recipients. Several commenters stated that they agree that beneficiaries who are dual eligible or LIS recipients may be less likely to dialyze at home or receive a kidney transplant.

Response: We appreciate the commenters' support.

Comment: Multiple commenters stated that they supported stratifying the achievement benchmarks based on the proportion of beneficiary years attributed to the ETC Participant's aggregation group for which attributed beneficiaries were dual-eligible or LIS recipients. Several of these commenters expressed specific reasons for their support. A few of these commenters expressed support for stratification because they agree that stratification will support the goal of not disadvantaging ETC Participants who treat a high proportion of socioeconomically disadvantaged beneficiaries. One of these commenters

stated that stratification addresses concerns that socioeconomic factors outside the ETC Participant's control may impact a beneficiary's likelihood to receive alternative renal replacement modalities.

Response: We appreciate the commenters' support.

Comment: One commenter indicated that while dually eligible and LIS-recipient beneficiaries are important groups of underserved beneficiaries, this proxy does not illuminate the diversity of underserved communities or individuals facing health disparities due to complex socioeconomic circumstances in the United States.

Response: We understand that beneficiaries face challenges and barriers to choosing alternatives to traditional in-center dialysis in particular, and to accessing healthcare generally, related to their socioeconomic circumstances. We have recognized that there is variation in rates of home dialysis and transplantation by socioeconomic status. As discussed in the CY 2022 ESRD PPS proposed rule and in this section of this final rule, we know that socioeconomic status impacts the likelihood of a beneficiary receiving home dialysis or a transplant. In order to address these socioeconomic factors that impact ETC Participant Achievement, one of our proposals is to stratify achievement benchmarks based on the proportion of attributed beneficiaries who are dually-eligible for Medicare and Medicaid or receive the LIS during the MY, in recognition that beneficiaries with lower socioeconomic status have lower rates of home dialysis and transplant than those with higher socioeconomic status.

Comment: One commenter asked that, if the Innovation Center intends to proceed with the proposal to stratify achievement benchmarks by the proportion of beneficiaries who are dual eligible or received the LIS, CMS should release information to the public regarding LIS beneficiaries so that the commenter could adequately analyze the ETC Model, and implement work plans to address the needs of this population.

Response: We generally do not share beneficiary-identifiable data related to a model tested under section 1115A of the Act with individuals or entities who are not participants in said model. However, CMS data for research is available via the Research Data Assistance Center (ResDAC). Additional information about ResDAC is available at resdac.org. A variety of aggregate data is also available directly from CMS at *data.cms.gov*, including the Mapping Medicare Disparities Tool.

Comment: One commenter supported any and all measures that incentivize care for beneficiaries who are dual-eligible or LIS recipients. However, this commenter expressed that the proposal to stratify achievement benchmarks based on the proportion of attributed beneficiary years for which attributed beneficiaries were dual eligible or received the LIS might make dual-eligible and LIS recipients feel pressured to try a method of care that will not be successful for them. This commenter stated that these patients are often not used to advocating for themselves, so an incentive to the providers may seem like a threat to the patients.

Response: We believe that addressing disparities experienced by beneficiaries who are dual-eligible or LIS recipients by stratifying the achievement benchmarks, as proposed, will encourage ETC participants to decrease disparities in renal replacement modality choice across beneficiaries of different socioeconomic status. However, we are sensitive to concerns about ETC Participants exerting undue influence on this beneficiary population, in particular. As stated in the Specialty Care Models final rule, ETC Participants are prohibited from interfering with a beneficiary's freedom of choice or access to services under 42 CFR 512.120, and CMS will monitor for ETC Participant compliance with this requirement, including beneficiary complaints and appeals (85 FR 61341 through 61343).

Comment: A few commenters expressed concern about the proposal to stratify benchmarks by the proportion of attributed beneficiaries who are dual-eligible or LIS recipients. These commenters stated that they believed this approach could unnecessarily set a lower bar for achieving access to transplant and home dialysis by conflating differences owing to social risk factors and true differences in quality of care. Two of these commenters stated that they do not believe patient income or dual eligible status should be a factor in access to home dialysis or transplant and remain concerned that benchmark stratification could possibly worsen inequities by reducing Model-specific incentives to increase access to home dialysis for all patients.

Response: As discussed in the CY 2020 ESRD PPS proposed rule and in section V.B.6.c this final rule, we believe that stratifying achievement benchmarks based on the proportion of beneficiary years attributed to the ETC Participant's aggregation group for which attributed beneficiaries were dually-eligible for Medicare and Medicaid or received the LIS, based on rates in Comparison Geographic Areas, will address concerns that socioeconomic factors may impact a beneficiary's likelihood to receive alternative renal replacement modalities, lowering the transplant rate and home dialysis rates for ETC Participants who provide services to low income beneficiaries.

We do not believe that stratifying benchmarks by dual eligible and LIS recipients would unnecessarily set a lower bar for achieving access to transplant and home dialysis for these individuals. Rather, as discussed in the CY 2020 ESRD PPS proposed rule and in section V.B.6.c of this final rule, we expect that stratifying the achievement benchmarks as proposed will increase home dialysis rate and transplant rates for those ETC Participants who provide services to low-income beneficiaries. Specifically, rather than giving ETC Participants permission to provide lower levels of care to beneficiaries, we believe this approach will enable ETC Participants to address disparities in renal replacement modality choice among beneficiaries who are dual-eligible or LIS recipients by not disadvantaging them by comparing them to a standard set including a substantively different beneficiary population. While we understand that stratification would not provide a direct financial incentive for ETC Participants to focus on reducing disparities by improving the home dialysis rate and transplant rate for beneficiaries who are dual-eligible or receive the LIS, as ETC Participants who provide services to socioeconomically disadvantaged beneficiaries are likely to have lower home dialysis rates and transplant rates, stratification makes it more likely they will achieve a positive PPA that they can invest in caring for these beneficiaries. We believe ETC Participants will be able to use additional funds received as a result of receiving a positive PPA to improve their performance dialysis rates and transplant rates for all beneficiaries, including beneficiaries who are dual eligible and recipients of LIS.

Comment: Several commenters indicated that they supported stratifying achievement benchmarks based on dual eligible and LIS recipient status, but suggested modifications to the proposed approach. Some of these commenters suggested using a different cutpoint. Of the commenters suggesting a different cutpoint, some suggested a higher cutpoint and others suggested a lower cutpoint than 50 percent of attributed beneficiary years being for attributed

beneficiaries who were dual eligible or received the LIS. One commenter suggesting a higher cutpoint stated that this approach would better enable ETC Participants serving the highest percentage of low-income patients to successfully perform in the ETC Model. Some commenters suggesting modifications had suggested using more than two strata—including suggestions of three to ten strata—or using a sliding scale. Some commenters suggesting using more than two strata stated that doing so would provide more nuance to the PPA calculation. Generally, commenters suggesting alternative cutpoints or more than two strata stated that their suggested cutpoint or number of strata was more reflective of the commenters' own analysis of available data.

Response: We appreciate the commenters support for stratifying achievement benchmarks. As discussed in the proposed rule and previously in this section of the final rule, we considered using more than two strata in order to increase the precision of the achievement benchmarks and the degree of similarity between ETC Participants within a given stratum. This would have required the use of additional cutpoints—both lower and higher than 50 percent. In response to suggestions that we use more than two strata, as described in the CY 2022 ESRD PPS proposed rule and previously in this section of this final rule, increasing the number of strata would decrease the number of observations within each stratum, in turn decreasing statistical reliability. We continue to believe that that using more than two strata would decrease statistical reliability. Additionally, as described in the CY 2022 ESRD PPS proposed rule and in this section of this final rule, our analysis of the distribution of the home dialysis rate and transplant rate demonstrated that the underlying distribution does not lend itself to more than two strata, as the distribution is not multi-modal. In response to suggestions that we use a different cutpoint between strata, we believe that 50 percent is an appropriate cutpoint based on our analysis of the data. Based on the statistical properties of the underlying distribution, the 50 percent cutpoint is statistically appropriate, stable over time, and easily comprehendible to ETC Participants.

Comment: One commenter stated that while they support stratification, CMS should adjust performance within each stratum to account for variation within the stratum.

Response: While we recognize that there will be variation within each stratum, the commenter did not articulate what adjusting performance within each stratum should entail. Therefore, we are unable to respond with specificity to the suggestion that we adjust performance within each stratum. We continue to believe that stratification addresses variation in rates of home dialysis and transplantation for beneficiaries who are dual eligible or LIS recipients, but remain open to specific feedback regarding further adjustments for potential inclusion in future rulemaking.

Comment: Several commenters expressed support for CMS' proposal to use dual eligible and LIS recipient as proxies for socioeconomic status. One of these commenters stated that they agree that these are useful metrics to identify patients who may face clinical and non-clinical challenges to electing home dialysis or receiving a transplant.

Response: We thank commenters for their support.

Comment: A few commenters stated that they agreed with the intent behind, or the need for, an approach to address how socioeconomic factors impact beneficiaries' likelihood of receiving home dialysis or a kidney transplant and how that relationship impacts ETC Participants' performance, but stated that there may be better ways to account for this than stratification of the achievement benchmark. A few of these commenters suggested that CMS incorporate risk adjustment into the achievement benchmarking methodology, either instead of or in addition to stratification. Commenters suggesting risk adjustment stated that risk adjustment is more precise, because it is applied at the beneficiary-level, rather than the aggregate level. However, one such commenter acknowledged that, while they recommend risk adjustment, stratification may also address the same underlying issues.

Response: We considered other approaches for accounting for how the socioeconomic status of an ETC Participant's attributed beneficiaries may impact an ETC Participant's performance. However, we did not contemplate using risk adjustment for this purpose. While we appreciate that risk adjustment accounts for factors at an individual beneficiary level, adopting this policy would represent a significant departure from our proposal and would present its own challenges. For instance, without sufficient protections, the use of risk adjustment can result in payment inaccuracies due to factors such as upcoding. In addition, depending on the factors being used for risk-adjustment, there may be limitations in the available data, as discussed below. After considering the comments, we continue to believe that stratification of achievement benchmarks based on dual eligible and LIS recipient status is an appropriate approach for considering socioeconomic status under the ETC Model.

Comment: A few commenters recommended that CMS also consider incorporating additional social risk factors into the achievement benchmarking methodology. One such commenter acknowledged that current data on social determinants of health necessary to develop such a methodology is limited, citing Z-code data in particular, and that in the interim, stratification may address many of the concerns related to differential rates of home dialysis and transplantation between beneficiaries of higher and lower socioeconomic status. Another commenter stated that while dual eligibility and LIS recipient status can serve as proxies for social risk factors, this is not equivalent to patient-level data on individual risk factors. This commenter also pointed out that criteria for dual eligibility vary between states, and that being a LIS recipient is dependent on the beneficiary having been enrolled in a Part D plan.

Response: As stated in the CY 2022 ESRD PPS proposed rule and this section of this final rule, we continue to acknowledge that non-clinical factors, such as socioeconomic status, may impact a beneficiary's likelihood to receive home dialysis or a transplant. However, revising the proposed policy to include additional risk adjustments in the home dialysis rate based on socioeconomic status, as suggested by some of the commenters, would be a significant departure from the policy originally proposed. We also agree with the commenter who acknowledged the current limitations in data on individual-level social determinants of health. At this time, we continue to believe stratification using the proportion of attributed beneficiaries who are dual-eligible or LIS recipients is an appropriate means of considering socioeconomic status under the ETC Model. Moreover, while we acknowledge that dual eligibility and LIS recipient status may not capture socioeconomic status in the same way for all beneficiaries—due to variation between states or the necessity of being enrolled in a Part D plan to be an LIS recipient—as stated in the CY 2022 ESRD PPS proposed rule and in section V.B.5.b of this final rule, dual eligibility and LIS recipient status are correlated with lower rates of home dialysis and transplantation. As such, ETC

Participants who have a higher proportion of attributed beneficiaries who are dual eligible or LIS recipients may be less likely to achieve high home dialysis and transplant rates than ETC Participants who have a lower proportion of attributed beneficiaries who are dual-eligible or LIS recipients. Therefore, we believe dual eligible and LIS status are appropriate proxies for socioeconomic status. If Z-codes become more widely used and more such codes become available for use into the claims process, such that Z-code data becomes appropriate for use, we may consider incorporating such data into the ETC Model methodology through future rulemaking.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.370(b)(2) to stratify achievement benchmarks based on the proportion of attributed beneficiary years for which attributed beneficiaries were dual eligible or received the LIS beginning for MY3, and to create two strata for this purpose, without modification.

6. PPA Improvement Benchmarking and Scoring

a. Background on Improvement Benchmarking and Scoring

Another part of the scoring methodology for the PPA is improvement scoring. We calculate an ETC Participant's improvement score under § 512.370(c) by comparing MY performance on the home dialysis rate and transplant rate against past ETC Participant performance. As described in the Specialty Care Models final rule, the purpose of the improvement score is to acknowledge efforts made in practice transformation to improve rates of home dialysis and transplants (85 FR 61318). The percentage improvement in the ETC Participant's MY performance on the home dialysis rate and the transplant rate relative to the Benchmark Year rate is scored as follows:

- Greater than 10 percent improvement relative to the Benchmark Year rate: 1.5 points
- Greater than 5 percent improvement relative to the Benchmark Year rate: 1 point
- Greater than 0 percent improvement relative to the Benchmark Year rate: 0.5 points
- Less than or equal to the Benchmark Year rate: 0 points

However, when the Benchmark Year rate is zero, an improvement score for the MY cannot be calculated. This is because, when calculating percent change, as used in improvement scoring, the Benchmark Year rate is the denominator. As such, we cannot calculate percent improvement for an aggregation group with a rate of zero during the Benchmark Year because the denominator of the improvement score calculation is zero, and division by zero is undefined. Thus, an aggregation group in this situation will not receive an improvement score if the Benchmark Year rate is zero, even if the aggregation group has made improvements in the home dialysis rate and/or the transplant rate between the Benchmark Year and MY.

b. Incentivizing Improvement for Socioeconomically Disadvantaged Beneficiaries

As described in the CY 2022 ESRD PPS proposed rule and in section V.B.5.b of this final rule, beneficiaries who are dual-eligible or receive the LIS are less likely than beneficiaries who are not dual-eligible and do not receive the LIS to dialyze at home or receive a kidney transplant. As described in the CY 2022 ESRD PPS proposed rule and previously in this section of the final rule, we proposed to stratify achievement benchmarks by the proportion of attributed beneficiary years for beneficiaries who are dual-eligible or LIS recipients to avoid disadvantaging ETC Participants who provide care for a high proportion of these beneficiaries. However, we noted that the proposed stratification would not provide a direct financial incentive for ETC Participants to focus on reducing disparities by improving the home dialysis rate and transplant rate for beneficiaries who are dual-eligible or receive the LIS. In the CY 2022 ESRD PPS proposed rule, we stated our interest in creating that incentive as part of the ETC Model, as these beneficiaries may require additional support from ETC Participants to pursue home dialysis and transplant as alternative renal replacement modalities (86 FR 36384).

c. Changes to Improvement Benchmarking and Scoring

(1) Revised Improvement Calculation

As described previously, when the Benchmark Year rate for an aggregation group is zero, the aggregation group cannot receive an improvement score, even if the aggregation group has made improvements in the home dialysis rate and transplant rate between the Benchmark Year and MY. To address this issue, we proposed to amend § 512.370(c)(1) to change the improvement calculation such that the aggregation group's Benchmark Year rate cannot be zero. Specifically, for MY3 through MY10, we proposed to add one beneficiary month to the numerator of the home dialysis rate and the transplant rate for the Benchmark Year rate for an ETC Participant's aggregation group Benchmark Year when that rate is zero (86 FR 36384). CMS did not propose to change the denominator of the Benchmark Year rate calculations because doing so would negate the purpose of mathematically correcting ETC Participants' improvement scoring. In the CY 2022 ESRD PPS proposed rule, we stated that CMS does not expect that adding a beneficiary month to the numerator of the Benchmark Year rate calculations, as proposed, would affect the improvement scoring enough to change the number of points awarded to the ETC Participant, and has the advantage that it would enable an improvement score to be calculated, even when the Benchmark Year rate is zero.

The following is a summary of the comments received on our proposal to modify the calculation of the an ETC Participant's Benchmark Year home dialysis rate and transplant rate to prevent it from being zero, such that an improvement score can be calculated, and our responses.

Comment: A few commenters stated that they support the proposal to add one beneficiary month to the numerator of the home dialysis rate and the transplant rate for the Benchmark Year rate for an ETC Participant's aggregation group Benchmark Year when that rate is zero.

Response: We appreciate commenters' support for this proposal.

Comment: One commenter suggested that CMS change the improvement scoring methodology to allow ETC Participants to attain the top tier of scoring—2 points—through improvement alone.

Response: As stated in the Specialty Care Models final rule (85 FR 61322), while we acknowledge the importance of incentivizing improvement over time, we do not award full points for improvement for consistency with other CMS programs and initiatives employing similar improvement scoring methodologies. Additionally, with the introduction of the Health Equity Incentive, as described in the CY 2022 ESRD PPS proposed rule and in section V.B.6.c.(2) of this final rule, ETC Participants are able to, beginning for MY3, attain the full 2 points for improvement if they demonstrate greater than 10 percent improvement relative to the Benchmark Year rate and earn the Health Equity Incentive.

Final Rule Action: After considering public comments, we are finalizing our

proposal in our regulation at § 512.370(c)(1) to add one beneficiary month to the numerator of the ETC Participant's Aggregation Group's home dialysis rate and transplant rate for the Benchmark Year when calculating the ETC Participant's improvement score beginning for MY3, without modification.

(2) Health Equity Incentive

To incentivize ETC Participants to decrease disparities in the home dialysis rate and transplant rate between beneficiaries who are dual-eligible or LIS recipients and those who are not, we proposed to add a Health Equity Incentive to the improvement scoring methodology (86 FR 36385). We proposed to define the Health Equity Incentive at § 512.310 as the amount added to the ETC Participant's improvement score calculated as described in § 512.370(c)(1) if the ETC Participant's aggregation group demonstrated sufficient improvement on the home dialysis rate or transplant rate for attributed beneficiaries who are dual-eligible or LIS recipients between the Benchmark Year and the MY. We proposed that this improvement on the home dialysis rate or transplant rate would be based on the performance of the ETC Participant's aggregation group.

As noted in the CY 2022 ESRD PPS proposed rule and previously in this section of the final rule, socioeconomic factors impact a beneficiary's receipt of alternative renal replacement modalities. Beneficiaries with limited resources may require more assistance from ESRD facilities and Managing Clinicians to use alternative renal replacement modalities. In the CY 2022 ESRD PPS proposed rule, we stated our belief that our proposal to add a Health Equity Incentive would benefit these beneficiaries and improve scoring for home dialysis rate and transplant rate for ETC Participants that serve disproportionately high numbers of beneficiaries with lower socioeconomic status. To earn the Health Equity Incentive, ETC Participants would have to demonstrate sufficiently significant improvement on the home dialysis rate or transplant rate among their attributed beneficiaries who are dual eligible or receive the LIS between the Benchmark Year and the MY. ETC Participants who earn the Health Equity Incentive would receive a 0.5-point increase on their improvement score, thus increasing the maximum improvement score to 2 points. In the CY 2022 ESRD PPS proposed rule, we stated our belief that the proposed Health Equity Incentive would benefit attributed beneficiaries who are dual eligible or receive the LIS, by encouraging ETC Participants to address disparities in access to alternative renal replacement modalities among these beneficiaries. We also stated our belief that providing this incentive for ETC Participants to increase their home dialysis and transplant rate among their dual eligible or LIS beneficiary population would ultimately reduce this disparity in access for the beneficiaries in question. Therefore, we stated our belief that this incentive to reduce socioeconomic disparities in access to alternative renal replacement modalities would be an improvement to the PPA scoring methodology.

We proposed to amend § 512.370(c) to add the Health Equity Incentive to the improvement scoring methodology, beginning for MY3. We proposed that the Health Equity Incentive would be equal to 0.5 points, which would be added to the ETC Participant's improvement score for the home dialysis rate or for the transplant rate, calculated as described in § 512.370(c)(1), such that the maximum improvement score would increase from 1.5 points to 2 points for ETC Participants that earn the Health Equity Incentive. Therefore, for those ETC Participants that earn the Home Equity Incentive, we proposed that the ETC Participant's improvement score for the home dialysis rate and for the transplant rate would be the sum of the improvement score calculated as described in § 512.370(c)(1) and the Health Equity Incentive. We noted in the CY 2022 ESRD PPS proposed rule that the Health Equity Incentive would allow ETC Participants to increase their improvement score, and thereby increase their payment adjustment.

We proposed to award the Health Equity Incentive to an ETC Participant if the ETC Participant's aggregation group's home dialysis rate and/or transplant rate among attributed beneficiaries who are dual-eligible or LIS recipients increases by 5 or more percentage points from the Benchmark Year to the MY. We stated our belief in the CY 2022 ESRD PPS proposed rule that 5-percentage points is the correct threshold for awarding the Health Equity Incentive based on our analysis of Medicare claims. Five percentage points is one standard deviation above the average difference between the home dialysis rate and the transplant rate for attributed beneficiaries who are dual-eligible or LIS recipients and those beneficiaries who are not dual-eligible or LIS recipients, rounded to the nearest integer. In the CY 2022 ESRD PPS proposed rule, we noted that we anticipate improvement in home dialysis and transplant rates among dual-eligible or LIS recipients between the MY and the Benchmark Year, but that we expect that attaining the proposed threshold for earning the Health Equity Incentive would generally require significant effort on the part of the ETC Participant.

We proposed that an ESRD Beneficiary or Pre-emptive LDT Beneficiary would be considered to be dual-eligible or a LIS recipient for a given month if at any point during the month the beneficiary was dually eligible for Medicare and Medicaid or a LIS recipient. We proposed to determine whether an attributed beneficiary was dual-eligible or received the LIS using Medicare administrative data.

We proposed to modify § 512.370(c) such that the improvement benchmarking and scoring methodology for MY1 and MY2 would be specified at § 512.370(c)(1), and the improvement benchmarking and scoring methodology for MY3 through MY10, described earlier, would be specified at § 512.370(c)(2). We sought comment on the proposal to modify § 512.370(c) accordingly.

In the CY 2022 ESRD PPS proposed rule, we considered using a rolling approach to setting the threshold for earning the Health Equity Incentive, such that the threshold would be recalculated every other MY, to reflect changes in underlying disparities. Under this approach, we would calculate the threshold as one standard deviation above the average difference between the home dialysis rate and the transplant rate for attributed beneficiaries who are dual-eligible or LIS recipients and those beneficiaries who are not dual-eligible or LIS recipients, rounded to the nearest integer. We would calculate this threshold either using data from the Benchmark Year, such that ETC Participants would know the threshold for earning the Health Equity Incentive in advance of the MY, or using data from the MY, such that the threshold for earning the Health Equity Incentive would accurately reflect the magnitude of the disparity observed during the MY. However, we stated our belief that setting a threshold for earning the Health Equity Incentive applicable for all MYs, beginning for MY3, would be more appropriate. We noted that this approach would be in keeping with the intent of the proposed Health Equity Incentive, which is to provide ETC Participants a financial incentive to focus on decreasing the disparity in the home dialysis and transplant rates between beneficiaries who are dual-eligible or LIS recipients, and those who

are not. We further stated our belief that providing ETC Participants clear information about what they need to achieve to earn the Health Equity Incentive in advance would best enable them to work towards the goal.

We proposed that ETC Participants in aggregation groups that fall below a low-volume threshold would be ineligible to earn the Health Equity Incentive (86 FR 36386). Specifically, we proposed that an ETC Participant in an aggregation group with fewer than 11 attributed beneficiary years comprised of months in which ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries are dual eligible or LIS recipients during either the Benchmark Year or the MY would be ineligible to earn the Health Equity Incentive. We selected this particular low-volume threshold for consistency with the low-volume threshold for the applicability of the PPA generally, as specified at § 512.385. We stated our belief that it is necessary to apply a low volume threshold in determining whether an ETC Participant has earned the Home Equity Incentive to ensure statistical reliability of the home dialysis rate and transplant rate calculations. This statistical reliability provides consistency in the home dialysis rate and transplant rate calculations. Therefore, similar results are produced under consistent conditions when applying a low volume threshold to ETC Participants. We proposed a low-volume threshold specific to attributed beneficiaries who are dual-eligible or receive the LIS because whether an ETC Participant has earned the Health Equity Incentive is being assessed on this subset of attributed beneficiaries.

We proposed to amend the Modality Performance Score (MPS) methodology to incorporate the Health Equity Incentive. To that end, we proposed to modify § 512.370(d) such that the calculation of the MPS for MY1 and MY2 is specified at § 512.370(d)(1), and the calculation of the MPS for MY3 through MY10 is specified at § 512.370(d)(2). We proposed that the formula for the MPS for MY3 through MY10 would be the following:

Modality Performance Score
= 2 × (*Higher of the home dialysis achievement or* (*home dialysis improvement score* + *Health Equity Bonus* †))
+ (*Higher of the transplant achievement or* (*transplant improvement score* + *Health Equity Bonus* †))

† The Health Equity Incentive is applied to the home dialysis improvement score or transplant improvement score only if earned by the ETC Participant and provided that the ETC Participant is not ineligible to receive the Home Equity Incentive as described in proposed § 512.370(c)(2)(iii).

We sought comment on our proposed definition for the Health Equity Incentive at § 512.310 and our proposal to amend § 512.370(c) to add the Health Equity Incentive to the improvement scoring methodology for the home dialysis rate and the transplant rate. We also sought comment on our proposal to set the threshold for earning the Health Equity Incentive at 5-percentage points improvement from the Benchmark Year to the MY.

The following is a summary of the comments received on the proposal to introduce the Health Equity Incentive to the improvement scoring methodology beginning for MY3, and our responses.

Comment: Many commenters expressed support for the concept of addressing socioeconomic disparities in access to alternative renal replacement modalities through the ETC Model. A few commenters highlighted that particular groups that tend to experience healthcare disparities—including patients of lower socioeconomic status and patients from racial and ethnic minorities—make up a significant portion of dialysis patients.

Response: We appreciate the commenters' support.

Comment: One commenter stated that the racial and ethnic disparities in access to home dialysis care have long existed, but that the COVID–19 pandemic has exacerbated them. According to the commenter, increased access to home dialysis modalities would give those historically disadvantaged patients the chance to avoid potentially dangerous contact with COVID–19 infected individuals by reducing visits to a dialysis clinic or doctor's office. The commenter stated that, for all of these important reasons, they strongly support CMS's efforts to advance home dialysis through the ETC Model.

Response: We agree with the commenter that COVID–19 pandemic has highlighted one of the benefits of home dialysis—that dialyzing at home reduces the risk that an individual patient is exposed to COVID–19 or other communicable diseases in the course of their dialysis care—and we agree that beneficiaries should have equal access to this modality for this and other reasons.

Comment: A few commenters expressed concerns about the impact of the ETC Model on health disparities. One commenter expressed concern about certain design aspects of the ETC Model that could have unintended effects that perpetuate existing kidney health disparities. Another commenter stated that CMS is not providing additional resources to ETC Participants to give extra assistance to disadvantaged patients.

Response: We believe that the ETC Model will improve access to alternative renal replacement modalities, including home dialysis and transplantation, for all types of beneficiaries. We further believe the Model will not cause any unintended effects that perpetuate existing kidney health disparities. Indeed, with the introduction of achievement benchmark stratification and the Health Equity Incentive, as described in the CY 2022 ESRD PPS proposed rule and sections V.B.5.c.(2) and V.B.6.c.(2) of this final rule, respectively, we are testing ways to directly address socioeconomic disparities in access to alternative renal replacement modalities. We believe the proposed Health Equity Incentive, in particular, will benefit attributed beneficiaries who are dual eligible or receive the LIS, by encouraging ETC Participants to address disparities in access to alternative renal replacement modalities among these beneficiaries.

Comment: The majority of commenters generally supported the Health Equity Incentive. Most of these commenters supported the Health Equity Incentive proposal without providing any additional recommendations.

Response: We appreciate commenters' support.

Comment: Several commenters stated that they supported creating a Health Equity Incentive, but indicated that it is important that the thresholds for earning the Health Equity Incentive are achievable for ETC Participants.

Response: We agree that it is important for the thresholds for earning the Health Equity Incentive to be achievable for ETC Participants. We believe that this is the case. First, by establishing the thresholds for all MYs, starting for MY3, through this rulemaking, ETC Participants will have clear information in advance about what they need to achieve to earn the Health Equity Incentive to enable them to work towards the goal of increasing access to home dialysis and transplant for beneficiaries who are dual eligible and LIS recipients for the remaining duration of the ETC Model test. Second, as described in greater detail below, we are modifying our proposal such that we would award the Health Equity Incentive to an ETC Participant if the ETC Participant's aggregation group's home dialysis rate and/or transplant rate among attributed beneficiaries who are dual eligible or LIS recipients increases

by at least 2.5 percentage points from the Benchmark Year to the MY, which we believe will be a more attainable threshold for ETC Participants than the proposed threshold of 5 percentage points.

Comment: Several commenters expressed specific support for our proposal that the Health Equity Incentive would be worth 0.5 improvement points.

Response: We appreciate the commenters support.

Comment: Several commenters stated that they supported the introduction of the Health Equity Incentive, but recommended that we set a lower threshold for ETC Participants to earn the Health Equity Incentive. These commenters stated that they believed that a five-percentage point increase to earn the Health Equity Incentive is too high, and may not be attainable for ETC Participants. A few of these commenters stated that setting the threshold too high would be discouraging—that ETC Participants would not try to increase home dialysis rates and transplant rats among their beneficiaries who are dual eligible or LIS recipients because they would not believe attaining a five-percentage point increase would be possible. One commenter stated that a lower threshold would mean that more ETC Participants would earn the incentive, which would result in higher payments and therefore more resources for those participants to support disadvantaged beneficiaries choosing alternative renal replacement modalities. One commenter stated that a 5-percentage point increase from year to year is likely an unachievable goal based on historic data. Several commenters suggested alternative methods for awarding the Health Equity Incentive. A few of these commenters suggested a lower percentage point threshold, such as 1.25-percentage points. Others suggested alternative methodologies, such as a percentage or percentage point increase over the Benchmark Year rate, or a percent increase instead of a percentage point increase.

Response: We appreciate commenters' suggestions of alternative methods for awarding the Health Equity Incentive. We agree with commenters' concerns that setting the threshold for awarding the Health Equity Incentive too high could undermine the intent of the policy. As stated in the CY 2022 ESRD PPS proposed rule (86 FR 36385) and in this section of this final rule, 5 percentage points is equal to one standard deviation above the average difference between the home dialysis rate and the transplant rate for attributed beneficiaries who are dual-eligible or LIS recipients and those beneficiaries who are not dual-eligible or LIS recipients, rounded to the nearest integer. We also stated our expectation that attaining the proposed threshold for earning the Health Equity Incentive would generally require significant effort on the part of the ETC Participant. However, we are persuaded by the specific evidence provided by commenters that our proposed threshold was likely unachievable based on historic data. As such, we agree with commenters that we should lower the threshold for awarding the Health Equity Incentive.

After considering the alternatives suggested by commenters, we continue to believe that a percentage-point increase is appropriate for awarding the Health Equity Incentive. However, rather than a 5-percentage point increase, we believe that at 2.5-percentage point increase is more appropriate. Specifically, we believe that a 2.5 percentage point threshold presents a more achievable goal than the 5-percentage point increase described in the proposed rule. However, as compared to the 1.25 percentage point increase suggested by the commenters, we believe using a 2.5 percentage point increase as the threshold for earning the Health Equity Incentive will incentivize ETC Participants to make substantial reductions in disparities between their Beneficiaries who are dual eligible or LIS recipients and those who are not over the course of the ETC Model.

Comment: One commenter stated that the Health Equity Incentive should be considered for other value-based care models.

Response: If we adopt the Health Equity Incentive for one or more other models, we would do so by amending that model's governing documentation, which may involve notice and comment rulemaking.

Comment: A few commenters encouraged CMS to explore and consider adding additional characteristics or social drivers of health disparities in addition to dual eligibility and LIS status as part of the Health Equity Incentive calculation under the ETC Model. A few of these commenters suggested that we do so now, and one of these commenters suggested that we do so pending further study and analysis. One commenter suggested that we include race as part of the Health Equity Incentive calculation.

Response: We appreciate the suggestion that we consider including other factors in the Health Equity Incentive calculation under the ETC Model. However, we agree with the commenter who suggested that we consider adding additional characteristics or social drivers of health disparities only after further study and analysis. Thus, while we are only awarding the Health Equity Incentive on the basis of improvement among beneficiaries who are dual eligible or LIS recipients at this time, we may consider additional factors for the future after we complete research and analysis on those factors. Any additional factors would be incorporated through subsequent rulemaking.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.370(c) to add the Health Equity Incentive to the improvement scoring methodology, with one modification. Specifically, we are modifying our regulation at §§ 512.370(c)(2)(i) and (c)(2)(ii) to change the threshold for earning the Health Equity Incentive from a 5-percentage point increase to a 2.5-percentage point increase in the ETC Participant's home dialysis rate and transplant rate, respectively, among attributed beneficiaries who are dual-eligible or LIS recipients from the Benchmark Year to the MY. We are also finalizing our proposed definition of Health Equity Incentive at § 512.310 without modification.

7. PPA Reports and Data Sharing

a. Background on Beneficiary Attribution and Performance Reporting

Under the ETC Model, as described in 42 CFR 512.360, CMS attributes ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries to an ETC Participant for each month during a MY based on the beneficiary's receipt of services during that month. CMS performs this attribution for a MY retrospectively, after the end of the MY. As described in § 512.365, each ETC Participant's performance is assessed based on the transplant rate and home dialysis rate among the population of beneficiaries attributed to the ETC Participant. As described in 42 CFR 512.370 and 42 CFR 512.380, these rates are used to calculate the ETC Participant's MPS and, in turn, the ETC Participant's PPA. The PPA is then used to adjust certain Medicare payments of the ETC Participant during 6-month PPA periods, with the first PPA Period taking place from July 1, 2022, through December 31, 2022. As described in 42 CFR 512.390(a), CMS will notify each ETC Participant, in a form and manner determined by CMS, of the ETC Participant's attributed beneficiaries, MPS, and PPA for a PPA Period no later

than one month before the start of the applicable PPA Period.

In order to ensure ETC Participants have timely access to these ETC Model reports, in the CY 2022 ESRD PPS proposed rule (86 FR 36386 through 36391), we proposed to add a new paragraph (b) to § 512.390 to establish a process for CMS to share certain beneficiary-identifiable and aggregate data with ETC Participants pertaining to their participation in the ETC Model. As we stated in the CY 2022 ESRD PPS proposed rule, CMS believes that ETC Participants need this data to successfully coordinate the care of their ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries; to succeed under the ETC Model; and to assess CMS's calculations of the individual ETC Participant's PPA for a given PPA Period. Specifically, we stated CMS believes that ETC Participants must have a clear understanding of the beneficiaries CMS has attributed to them under the ETC Model and how each attributed beneficiary has factored into the ETC Participant's home dialysis rate, transplant waitlist rate, and living donor transplant rate, to better identify care coordination and care management opportunities, and to have the opportunity to seek targeted review of CMS's calculation of the MPS. We noted that the purpose of the targeted review process, established under current § 512.390(b), which we would redesignate as paragraph (c), is to determine whether an incorrect PPA has been applied during the PPA Period. We stated that CMS additionally believes that timely access to this data is important and proposed to require CMS to make this data available twice a year, prior to each PPA Period in an MY.

In the following sections of this final rule, we describe the process that we proposed for CMS to share and for ETC Participants to retrieve certain beneficiary-identifiable attribution data and performance data, as well as the protections that we proposed to apply to this data under a data sharing agreement with CMS. We also describe our proposed process for sharing certain aggregate, de-identified performance data with ETC Participants.

b. CMS Sharing of Beneficiary-Identifiable Data

We proposed to establish a process in new § 512.390(b)(1) under which CMS would share certain beneficiary-identifiable data with ETC Participants regarding their attributed beneficiaries and performance under the ETC Model. We proposed that, in accordance with the timing of the notification requirement described in § 512.390(a), CMS would be required to make the beneficiary-identifiable data pertaining to a given PPA Period available for retrieval by ETC Participants no later than 1 month before the start of that PPA Period. The ETC Participant would be able to retrieve this data at any point during the relevant PPA Period, but, in accordance with current § 512.390(b)(1), which would be redesignated as paragraph (c)(1), the ETC Participant would have 90 days from the date that CMS shares the MPS, including the data CMS used in calculating the MPS, to request a targeted review. We proposed that CMS would notify ETC Participants of the availability of the beneficiary-identifiable data for a relevant PPA Period and the process for retrieving that data, through the ETC listserv and through the ETC Model website, available at *https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model*.

Regarding the specific beneficiary-identifiable data that CMS would be required to share with ETC Participants, we proposed in § 512.390(b)(1)(ii)(A) to include, when available, the following data for each PPA Period: The ETC Participant's attributed beneficiaries' names, Medicare Beneficiary Identifiers (MBIs), dates of birth, dual-eligible status, and LIS recipient status. We stated in the CY 2022 ESRD PPS proposed rule that we believe that the patient's name, MBI, and date of birth constitute the minimum elements to enable an ETC Participant to properly identify an attributed beneficiary, and to confirm the identity of an attributed beneficiary during any communications with a beneficiary or a beneficiary's caregiver, as appropriate and allowable. In addition, we stated the ETC Participant needs to be aware of each attributed beneficiary's dual-eligible status and LIS recipient status to understand how each attributed beneficiary contributed to how CMS calculated the ETC Participant's Health Equity Incentive, if finalized. We proposed in § 512.390(b)(1)(ii)(B) that this beneficiary-identifiable data also would include, when available, data regarding the ETC Participant's performance under the ETC Model, including, for each attributed beneficiary, as applicable, the number of months the beneficiary was attributed to the ETC Participant, received home dialysis, self-dialysis, or nocturnal in-center dialysis, or was on a transplant waitlist; and the number of months that have passed since the beneficiary has received a living donor transplant, as applicable. We stated that we believe that sharing these data elements would help the ETC Participant understand and, as appropriate, seek targeted review of CMS's calculation of the ETC Participant's MPS, and otherwise understand how CMS adjusted the ETC Participant's Medicare payments by the PPA.

In the CY 2022 ESRD PPS proposed rule (86 FR 36387), we stated that we recognized there are sensitivities surrounding the disclosure of individually-identifiable (beneficiary-specific) health information, and we noted that a number of laws place constraints on the sharing of individually identifiable health information. We noted that, for example, section 1106 of the Act generally bars the disclosure of information collected under the Act without consent unless a law (statute or regulation) permits for the disclosure. In this instance, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule permits this proposed disclosure of individually identifiable health information by us to ETC Participants if this proposed disclosure is required by law. We explained that under the HIPAA Privacy Rule, covered entities (defined as health care plans, health care providers that submit certain transactions electronically, and health care clearinghouses) are barred from using or disclosing protected health information (PHI) in a manner that is not explicitly permitted or required under the HIPAA Privacy Rule, without the individual's authorization. The Medicare FFS program, a ''health plan'' function of the Department, is subject to the HIPAA Privacy Rule limitations on the disclosure of PHI, without an individual's authorization. ETC Participants are also covered entities, provided they are health care providers as defined by 45 CFR 160.103 and they or their agents electronically engage in one or more HIPAA standard transactions, such as for claims, eligibility, or enrollment transactions.

As we discussed in the CY 2022 ESRD PPS proposed rule, the proposed disclosure of ETC Model beneficiary-identifiable data would be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI as ''required by law.'' Under 45 CFR 164.512(a)(1), a covered entity may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.[275] We proposed to establish

[275] Under 45 CFR 164.103, ''Required by law'' means ''a mandate contained in law that compels

a requirement under § 512.390(b)(1) for CMS to share this data with ETC Participants.

In the CY 2022 ESRD PPS proposed rule, we further noted that the Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act applies when Federal agencies maintain systems of records by which information about an individual is retrieved by use of one of the individual's personal identifiers (name, Social Security number, or any other codes or identifiers that are assigned to the individual). The Privacy Act generally prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply, 5 U.S.C. 552a(b). ''Routine uses'' are an exception to this general principle. A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the **Federal Register** about the applicable system of records describing to whom the disclosure will be made and the purpose for the disclosure. We stated in the CY 2022 ESRD PPS proposed rule that we believe that the proposed data disclosures are consistent with the purposes for which the data discussed in this rule was collected, and thus, should not run afoul of the Privacy Act, provided we ensure that an appropriate Privacy Act system of records ''routine use'' is in place prior to making any disclosures. The systems of records from which CMS would share data are the Medicare Integrated Data Repository (''IDR''), system of records number 09–70–0571, and the Health Resources and Services Administration (''HRSA'') Organ Procurement and Transplantation Network (''OPTN'')/ Scientific Registry of Transplant Recipients (''SRTR'') Data System, system of records number 09–15–0055.

In the CY 2022 ESRD PPS proposed rule, we expressed that establishing a regulatory requirement for CMS to share the beneficiary-identifiable data described previously would be appropriate for the ETC Model for several reasons. First, we stated that we believe that all ETC Participants not only desire but need this data to know which beneficiaries CMS has attributed to them (and thus is holding them financially accountable for such beneficiaries' individual contributions to the ETC Participant's performance measures described in 42 CFR part 512, subpart C, with the proposed modifications described in this proposed rule, if finalized), and for each ETC Participant to understand the basis by which CMS computed their MPS. Second, we stated that CMS believes that all ETC Participants, regardless of size, would have the capability of managing and meaningfully using the shared data. We noted that we would provide the data in a form and manner that CMS believes is user-friendly. In addition, the ETC Participant would be able to review the beneficiary-identifiable data along with the aggregated data, which should help the ETC Participant understand the data CMS would share with the ETC Participant. Finally, we stated that CMS believes that any other approach to making beneficiary-identifiable data available, including the alternative proposal considered by CMS and described later in this section, would impose additional operational burdens on CMS and administrative burdens on both CMS and the ETC Participants without producing any meaningful privacy or security benefit.

In the CY 2022 ESRD PPS proposed rule, we noted that we considered an alternative proposal for making beneficiary-identifiable data available to ETC Participants based on the data sharing policies currently used in many models tested under section 1115A of the Act, which would involve ETC Participants formally requesting the data from CMS before CMS could share the data. In particular, ETC Participants would have the opportunity to request the ''minimum necessary'' PHI for their own ''health care operations'' as defined in 45 CFR 164.501 and CMS would be permitted to disclose the requested data based on the HIPAA Privacy Rule provisions that permit disclosures of PHI for the recipient's health care operations purposes as described in 45 CFR 164.506(c)(4). We stated that under this alternative approach, ETC Participants that request this information would have to attest to compliance with specific HIPAA requirements in addition to, or as part of, the data sharing agreement described in section V.B.7.b.c of the CY 2022 ESRD PPS proposed rule and the next section of this final rule.

In the CY 2022 ESRD PPS proposed rule, we stated that after considering this option, we believed that having the ETC Participant request the data from CMS would add steps in the process that would cause administrative burden for both CMS and ETC Participants, and operational cost and burden for CMS. We also stated that we further believed that adding these steps would not produce a meaningful privacy or security benefit based on the specific circumstances of this ETC Model. We noted that both this option and the proposed approach would require that the ETC Participant complete and sign a data sharing agreement, and both would allow an ETC Participant to decline receiving beneficiary-identifiable data by declining to complete or sign a data sharing agreement. As such, we stated that there would be no meaningful privacy or security benefits that this option would create that were not already realized by the proposed approach to data sharing in the ETC Model. We also anticipated that all ETC Participants would want and need, and overwhelmingly would request, the data described previously, would be capable of handling such data, and would take the steps necessary to obtain the data. In addition, we stated that under an alternative approach based on the HIPAA provisions for the ETC Participant's ''health care operations,'' CMS would only be able to disclose the beneficiary-identifiable data for a purpose listed in paragraph (1) or (2) of the definition of ''health care operations'' in 45 CFR 164.501. However, we noted that we also believe it is crucial that an ETC Participant has the opportunity to understand how CMS calculated the ETC Participant's PPA for a PPA Period, and have the information needed to request a targeted review of CMS's MPS calculation if the ETC Participant believes CMS made an error.

Given the policies we were proposing for data sharing, we also proposed to modify the title of § 512.390 from ''Notification and targeted review'' to ''Notification, data sharing, and targeted review.'' We proposed this change so that the section title would more accurately reflect the contents of the section.

We solicited public comment on our proposal to require, under proposed § 512.390(b)(1), that CMS make available certain beneficiary-identifiable attribution and performance data for retrieval by ETC Participants no later than one month prior to the start of each PPA Period, and on our considered alternative to this proposal.

The following is a summary of the comments received on our proposal to require that CMS make available certain beneficiary identifiable attribution and performance data for retrieval by ETC Participants no later than one month prior to the start of each PPA Period, and our responses.

an entity to make a use or disclosure of protected health information and that is enforceable in a court of law.'' It includes, among other things, ''statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.''

Comment: We received many comments in support of the need for data sharing under the ETC Model. One commenter asserted that it is essential for ETC Participants to have access to the data elements CMS described in the CY 2022 ESRD PPS proposed rule to allow ETC Participants to make informed decisions and implement changes to clinical processes that permit improvement over time. Another commenter stated that the availability of beneficiary-level data under the ETC Model would be helpful in caring for and providing appropriate care to ESRD Beneficiaries. Another commenter stated that the data CMS proposed to share would assist ETC Participants in establishing targeted interventions to increase rates of the contemplated dialysis modalities and transplant waitlisting, and that it would help ETC Participants decrease health disparities.

Response: We thank the commenters for their support.

Comment: One commenter expressed agreement with the expected uses of beneficiary-identifiable data by ETC Participants that CMS described in the CY 2022 ESRD PPS proposed rule, including requesting targeted review of the MPS calculation, care management or coordination, and quality improvement.

Response: We appreciate this comment. We continue to believe that requesting targeted review of the MPS calculation, care management or coordination, and quality improvement constitute appropriate uses of the beneficiary-identifiable data that CMS would share with ETC Participants, and we are pleased this commenter agrees with these expected uses.

Comment: We received some comments regarding the timing and frequency of data sharing under the ETC Model. Some commenters expressed support for our proposal to share data prior to each PPA Period. A few commenters proposed that CMS share data more frequently than proposed. A couple commenters proposed that CMS share the data described in the CY 2022 ESRD PPS proposed rule on a quarterly basis. Another commenter proposed that CMS share the data on as close to a real-time basis as possible, suggesting either a quarterly or a monthly basis. This commenter asserted that sharing data on a quarterly or monthly basis would help ensure that the data is not outdated, and that it could better help guide interventions by ETC Participants to increase home dialysis and transplant rates.

A couple commenters recommended that CMS share the data on a monthly basis. One such commenter maintained that, for an ETC Participant to meaningfully track its performance, the ETC Participant should have access to monthly reports detailing its attributed beneficiary population. The same commenter also suggested that they anticipate that sharing data on a monthly basis would impose minimal burden on CMS, that such data sharing frequency would allow CMS and ETC Participants to address potential errors through targeted reviews on a smaller scale and on a rolling basis, and that more timely access to data would better support ETC Participants in increasing transplant waitlisting and monitoring their performance.

Response: We thank the commenters for their feedback. While we agree, in general, that having access to more timely data would incur many benefits for CMS and ETC Participants alike, including the ones identified by commenters, we believe that the schedule we proposed for sharing data affords ETC Participants sufficient time to conduct the activities for which CMS proposed allowing the ETC Participant to use the data, namely: To assess CMS's calculations underlying the ETC Participant's MPS, and to conduct care management, care coordination, and quality improvement activities. In addition, we believe that sharing data biannually, no later than one month ahead of each PPA Period, gives ETC Participants sufficient opportunity to track or monitor their performance and otherwise increase transplant waitlisting. Further, as described in § 512.360 of our regulations, CMS conducts beneficiary attribution for each month of a MY retrospectively after the end of each MY. Accordingly, CMS would not necessarily have accurate beneficiary-identifiable data to share with the ETC Participant on a monthly or quarterly basis to the extent that a beneficiary's attribution status can change during a given MY. In other words, CMS is unable to share accurate, final beneficiary-identifiable data on the ETC Participant's attributed beneficiaries more often than biannually, after the end of the applicable MY.

In addition, because we conduct beneficiary attribution retrospectively, we disagree with the commenter's suggestion that sharing data monthly would impose minimal burden on CMS. Sharing data monthly or quarterly would in effect require CMS to conduct beneficiary attribution monthly or quarterly, even though CMS is basing its MPS calculations on beneficiary attribution run only biannually, which would impose more than minimal burden on CMS. We similarly disagree with the commenter's suggestion that sharing data more frequently would enable CMS and ETC Participants to address potential errors through targeted reviews on a smaller scale and on a rolling basis. CMS did not propose any changes to when CMS computes the MPS or applies it to determine the ETC Participant's PPA. Because CMS will still be applying the PPA according to the schedule provided in § 512.355, sharing data more frequently than proposed would not give CMS and ETC Participants the ability to address potential errors through targeted reviews on a smaller scale or on a rolling basis.

For the same reasons, we disagree with the commenter's concern that, under CMS's proposal to share beneficiary-identifiable data prior to each PPA Period, the data shared would be outdated. Under § 512.365, CMS calculates the ETC Participant's MPS based on the ETC Participant's performance during a given MY. Any beneficiary-identifiable data shared during an MY would not necessarily be accurate because a beneficiary's attribution status can change during an MY. In other words, to share beneficiary-identifiable data more frequently would require CMS to share data that is not yet final and may be inaccurate. Thus, unlike the data we proposed to share under § 512.390(b)(1), an ETC Participant could not use this interim data to assess CMS's calculation of the MPS.

Comment: One commenter suggested that CMS make available to ETC Participants a list of beneficiaries who are dual-eligible or LIS recipients prospectively (which, in the context of the ETC Model, we interpret to mean in advance of the applicable MY), explaining that sharing such data in advance would give ETC Participants a clearer understanding of their patient population as it will be analyzed by CMS. The commenter also stated that neither the commenter nor healthcare providers are able to fully model the impact of CMS's proposal to stratify achievement benchmarks based on the proportion of beneficiaries who are dual-eligible or LIS recipients, as they do not have access to public information regarding ESRD Beneficiaries' LIS eligibility.

Response: As noted previously, under § 512.360, CMS conducts beneficiary attribution retrospectively in the ETC Model, and thus data on the dual eligibility and LIS recipient status of each attributed beneficiary will not be available for CMS to share with ETC Participants prospectively in advance of the MY. Any beneficiary-identifiable

data we could share in advance of an MY would include at least a few beneficiaries that, when we conduct attribution for the MY at the end of that MY, would not be attributed to the ETC Participant, or at least not attributed to the ETC Participant for all months of the MY. Because we conduct beneficiary attribution monthly, attribution is subject to change, and the benefits that the commenter asserts could be gained by CMS sharing dual-eligible and LIS-eligible status data in advance of an MY would likely be undermined by the fact that such data may not be complete or accurate. In other words, CMS cannot know in advance of an MY which beneficiaries, or more specifically, which beneficiary-months, will count for the purpose of conducting attribution and calculating performance; we can only know this after the MY has ended. For this reason, we believe that limiting beneficiary-identifiable data sharing to after the MY, but prior to its corresponding PPA Period—in advance of when the ETC Participant's payments will be adjusted—best ensures that CMS is sharing the most accurate beneficiary-identifiable data as relevant to the ETC Participant's attributed beneficiaries and performance under the ETC Model, while providing the ETC Participant the opportunity to understand and, as needed, request a targeted review of the calculation of the MPS under § 512.390(b) of our regulations. Finally, dual-eligibility and LIS-eligibility data shared prior to a PPA Period could also be viewed as prospective in nature. Specifically, while a beneficiary's attribution status is subject to change during and between MYs, such data will provide ETC Participants with a rough estimate of their population of attributed beneficiaries who are dual-eligible and LIS recipients for the upcoming MY.

Regarding the commenter's concern that neither the commenter nor healthcare providers are able to fully model the impact of CMS's proposal to stratify achievement benchmarks based on the proportion of beneficiaries who are dual-eligible or LIS recipients, CMS declines to make beneficiary-identifiable LIS-eligibility data publicly available, or to share with the ETC Participant beneficiary-identifiable LIS-eligibility data on ESRD Beneficiaries who are not attributed to the ETC Participant, as such policies would raise privacy concerns. If the commenter is instead expressing concern that there does not exist publicly available aggregate data regarding ESRD beneficiaries who are LIS-eligible, such broad data dissemination is beyond the scope of this rulemaking for the ETC Model.

Comment: Several commenters provided feedback on the data elements CMS proposed to share with ETC Participants. One commenter expressed support for the data elements that CMS proposed to provide under the ETC Model, noting that, even without claims data, the data CMS proposed to provide would assist ETC Participants in establishing targeted interventions to increase the rates of home dialysis, self-dialysis, and nocturnal in-center dialysis modalities, as well as transplant waitlist rates. The same commenter also recommended that CMS make claims data available to ETC Participants, as claims data would better assist ETC Participants in establishing appropriate care coordination and quality improvement initiatives, thereby improving care for beneficiaries. The commenter also noted that CMS has deemed claims data necessary to share with participants under other models tested under section 1115A of the Act, and that CMS should take the same position here.

Response: We agree that making certain beneficiary-identifiable data available under the ETC Model will help ETC Participants conduct care coordination and quality improvement activities, and realize the goals of the ETC Model of promoting beneficiary choice of renal replacement modality. We believe that our proposal struck the appropriate balance between sharing enough data to ensure that ETC Participants understand which beneficiaries were attributed to them during a given MY for purposes of care management and coordination and quality improvement, providing treatment to the subject beneficiary, and to assess CMS's calculation of the corresponding MPS, while also remaining sensitive to the privacy interests of attributed beneficiaries and sharing only the ''minimum necessary'' amount of beneficiary-identifiable data, as required by the HIPAA Privacy Rule, to support the ETC Model for the purposes we described in the CY 2022 ESRD PPS proposed rule. In most other models tested under section 1115A of the Act under which CMS has made available beneficiary-identifiable Medicare claims data, CMS shares such data only when formally requested by model participants for certain ''health care operations,'' and only after such model participants attest to meeting specific HIPAA requirements, including that the particular claims data requested meet the ''minimum necessary'' for their respective ''health care operations.'' These disclosures are based on the HIPAA Privacy Rule provisions that permit disclosures of PHI for the recipient's health care operations purposes as described in 45 CFR 164.506(c)(4) and § 164.501.

For the ETC Model, we proposed to establish a requirement under § 512.390(b)(1) for CMS to share the beneficiary-identifiable data described in the CY 2022 ESRD PPS proposed rule with ETC Participants. Our proposal did not include a process whereby ETC Participants could request the beneficiary-identifiable data for their ''health care operations.'' As we explained in the CY 2022 ESRD PPS proposed rule (86 FR 36388), having the ETC Participant formally request the beneficiary-identifiable data from CMS would add steps in the process that would cause administrative burden for both CMS and ETC Participants, and operational cost and burden for CMS. We also noted that adding these steps would not produce a meaningful privacy or security benefit based on the specific circumstances of this ETC Model. We agree that Medicare claims data likely would help many ETC Participants' care coordination and quality improvement efforts. However, we do not believe, at this time, that making claims data available is appropriate given the nature of this model, which is focused on making payment adjustments related to relatively specific outcomes, namely increasing rates of home dialysis and transplant. We believe that the data elements we proposed to share with ETC Participants are sufficient to position ETC Participants to meaningfully conduct care coordination and quality improvement activities to increase rates of home dialysis, self-dialysis, nocturnal in-center dialysis, and transplant waitlisting. Moreover, we do not believe that Medicare claims data are necessary for ETC Participants to assess CMS's calculations underlying the payment adjustments made under the ETC Model.

Comment: One commenter recommended that CMS add the following data elements to the beneficiary-identifiable data that CMS would be required to share with ETC Participants: ''Modality attribution status,'' the name of the transplant center at which the beneficiary is listed on the transplant waitlist, and the date on which the beneficiary joined their respective waitlist.

Response: We thank the commenter for this feedback. We believe our proposed data elements capture two of the commenter's three suggested data elements. Specifically, we believe our proposal to provide data on the number

of months the beneficiary was attributed to the ETC Participant, received home dialysis, self-dialysis, or nocturnal in-center dialysis, or was on a transplant waitlist; and the number of months that have passed since the beneficiary has received a living donor transplant, as applicable, sufficiently capture a beneficiary's ''modality attribution status'' (which we interpret to mean the dialysis modality that CMS understands the beneficiary to be receiving) and, even if indirectly, provides the date (or an approximation thereof) that the beneficiary was placed on a transplant waitlist.

CMS did not propose to provide the name of the transplant center at which the beneficiary is listed on the transplant waitlist, and CMS does not believe, at this time, that it is appropriate to make such information available. An ETC Participant should be able to obtain such information from the subject beneficiary, as we anticipate that an ETC Participant would first talk to a beneficiary, and likely obtain the beneficiary's explicit consent, prior to contacting a transplant center on his or her behalf. That said, we may consider this suggestion for future rulemaking related to the ETC Model.

Comment: One commenter suggested that CMS provide more granular data on attributed beneficiaries, and suggested that CMS include the following elements: ''Patient ID,'' ''Date (year/month),'' ''Modality,'' and ''Status (active or not active on transplant list.''

Response: CMS believes that its proposed data elements under § 512.390(b)(1)(ii) capture all of the elements the commenter suggested. CMS proposed sharing the beneficiary's name and MBI, which CMS believes would serve as a ''Patient ID.'' CMS also proposed sharing the number of months a beneficiary was attributed to the ETC Participant, home dialysis months, self-dialysis months, nocturnal in-center dialysis months, transplant waitlist months, and months following a living donor transplant. We believe these data elements capture the ''Date (year/month),'' ''Modality,''modality, and ''Status (active or not active on transplant list'' elements suggested by the commenter. ''Date (year/month)'' could be ascertained by the number of months a beneficiary was attributed to the ETC Participant; ''Modality'' could be ascertained by the beneficiary's data regarding home dialysis months, self-dialysis months, and nocturnal in-center dialysis months; and ''Status (active or not active on transplant list)'' could be ascertained by the transplant waitlist months or months following a living donor transplant.

Comment: Two commenters expressed support for CMS's proposal to provide beneficiary-identifiable data to ETC Participants without establishing a process for ETC Participants to request it. Both commenters asserted that the approach described in the CY 2022 ESRD PPS proposed rule of requiring CMS by law to make available the beneficiary-identifiable data identified in the CY 2022 ESRD PPS proposed rule, rather than allowing ETC Participants to request the data, would decrease burden on both CMS and ETC Participants.

Response: We thank the commenters for their support. We agree that the proposed approach of requiring CMS by law to make available the described beneficiary-identifiable data would reduce burden on both CMS and ETC Participants, and that it is otherwise appropriate for sharing beneficiary-identifiable data under the ETC Model.

Final Rule Action: After considering public comments, we are finalizing our proposal to require in our regulation at § 512.390(b)(1) that CMS make available for retrieval by ETC Participants certain beneficiary-identifiable data no later than one month before the start of each PPA Period, without modification. This beneficiary-identifiable data will include, when available: The ETC Participant's attributed beneficiaries' names, Medicare Beneficiary Identifiers, dates of birth, dual eligible status, and LIS recipient status; and data regarding the ETC Participant's performance under the ETC Model, including, for each attributed beneficiary, as applicable: The number of months the beneficiary was attributed to the ETC Participant, home dialysis months, self-dialysis months, nocturnal in-center dialysis months, transplant waitlist months, and month following a living donor transplant. As we stated in the CY 2022 ESRD PPS proposed rule, an appropriate Privacy Act system of records ''routine use'' will need to be in place prior to the disclosure of this data.

(1) Conditions for Retrieving Beneficiary-Identifiable Data

Given the sensitive nature of the beneficiary-identifiable data that CMS would be required to share under our proposal, in the CY 2022 ESRD PPS proposed rule (86 FR 36388), we proposed certain conditions for ETC Participants to be able to retrieve this data and certain protections that would govern use of the data following retrieval. First, we proposed that CMS would only share the beneficiary-identifiable data on the condition that the ETC Participant observes all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information as would apply to a covered entity under the HIPAA regulations and agrees to comply with the terms of a separate data sharing agreement. Although we stated that we expected ETC Participants are covered entities and must comply with the HIPAA regulations directly, we proposed to include this provision to ensure an ETC Participant would abide by those rules with respect to the data, even if, for example, the ETC Participant is a hybrid entity under HIPAA and the component requesting the data has not been designated as a health care component under 45 CFR 164.105. We proposed that the HIPAA provisions that the ETC Participant would have to observe would include, but would not be necessarily limited to, standards regarding the use and disclosure of PHI; administrative, physical, and technical safeguards and other security provisions; and breach notification.

We proposed that, if an ETC Participant wishes to retrieve the beneficiary-identifiable data, the ETC Participant would be required to first complete, sign, and submit—and thereby agree to the terms of—a data sharing agreement with CMS, which we would call the ETC Data Sharing Agreement. We proposed that this agreement would include certain protections and limitations on the ETC Participant's use and further disclosure of the beneficiary-identifiable data, and would be provided in a form and manner specified by CMS, which we discussed in more detail in later sections of the CY 2022 ESRD PPS proposed rule and describe below. We also stated that this agreement would potentially require the ETC Participant to make certain attestations, for example, if required under the applicable Privacy Act system of records notice. We proposed that an ETC Participant that wishes to retrieve the beneficiary-identifiable data would be required to complete and submit a signed ETC Data Sharing Agreement at least annually. We stated that we believe that it is important for the ETC Participant to complete and submit a signed ETC Data Sharing Agreement at least annually so that CMS has up-to-date information that the ETC Participant wishes to retrieve the beneficiary-identifiable data, attestations (if required), and information on the designated data custodian(s). As described in greater detail in the CY 2022 ESRD PPS proposed rule (86 FR 36388—36389),

we proposed that a designated data custodian would be the individual(s) that an ETC Participant would identify as responsible for ensuring compliance with all privacy and security requirements and for notifying CMS of any incidents relating to unauthorized disclosures of beneficiary-identifiable data.

In the CY 2022 ESRD PPS proposed rule, we stated our belief that it is important for the ETC Participant to first complete and submit a signed ETC Data Sharing Agreement before it retrieves any beneficiary-identifiable data to help protect the privacy and security of any beneficiary-identifiable data shared by CMS with the ETC Participant. As described in section V.B.7.b of the CY 2022 ESRD PPS proposed rule and previously in this final rule, there are important sensitivities surrounding the sharing of this type of individually identifiable health information, and CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with ETC Participants would be further protected in an appropriate fashion.

In the CY 2022 ESRD PPS proposed rule, we considered an alternative under which ETC Participants would not need to complete and submit a signed ETC Data Sharing Agreement, but we concluded that, if we proceeded with this option, we would not have adequate assurances that the ETC Participants would appropriately protect the privacy and security of the beneficiary-identifiable data that we are proposing to share with them. We also considered, in the CY 2022 ESRD PPS proposed rule, an alternative under which the ETC Participant would need to complete and submit a signed ETC Data Sharing Agreement only once for the duration of the ETC Model. However, we concluded that this similarly would not give CMS adequate assurances that the ETC Participant would protect the privacy and security of the beneficiary-identifiable data from CMS. We concluded in the CY 2022 ESRD PPS proposed rule that it is critical that we have up-to-date information and designated data custodians, and that requiring the ETC Participant to submit an ETC Data Sharing Agreement at least annually would represent the best means of achieving this goal.

We solicited public comment on our proposal to require, in § 512.390(b)(1)(iii), that the ETC Participant agree to comply with all applicable laws and the terms of the ETC Data Sharing Agreement as a condition of retrieving the beneficiary-identifiable data, and on our proposal in § 512.390(b)(1)(iv) that the ETC Participant would need to submit the signed ETC Data Sharing Agreement at least annually if the ETC Participant wishes to retrieve the beneficiary-identifiable data.

The following is a summary of the comments received on our proposals regarding the conditions for retrieving beneficiary-identifiable data, and our responses.

Comment: Some commenters expressed support for our proposal to require an ETC Participant to complete an ETC Data Sharing Agreement prior to CMS making the beneficiary-identifiable data described in the CY 2022 ESRD PPS proposed rule available to the ETC Participant. One such commenter noted that CMS's proposals strike a good balance between crucial privacy goals and ETC Participants' need to assess their performance under the Model. Another commenter claimed that the proposed process would be consistent with the process CMS followed in the Comprehensive ESRD Care (CEC) Model and is following in the Kidney Care Choices (KCC) Model Options.

Response: We agree that requiring an ETC Participant to complete an ETC Data Sharing Agreement prior to CMS making the beneficiary-identifiable data described in the CY 2022 ESRD PPS proposed rule available to the ETC Participant strikes an appropriate balance between the important goals of making ETC Participants aware of which beneficiaries CMS has attributed to them and enabling ETC Participants to understand the basis by which CMS computed their MPS, while protecting the privacy interests of attributed beneficiaries. We clarify, however, that the process CMS followed in the CEC Model and is following in the KCC Model Options is different from the process CMS proposed for the ETC Model. In the CEC Model CMS offered model participants the opportunity to request beneficiary-identifiable data for their ''health care operations,'' in accordance with HIPAA Privacy Rule provisions at 45 CFR 164.506(c)(4), contingent upon the participants making certain attestations and agreeing to certain privacy and security protections as part of the participation agreements for those models. CMS is taking this same approach with the KCC Model Options. For the ETC Model, we proposed that CMS would be required by law to provide certain beneficiary-identifiable data to ETC Participants, in accordance with the HIPAA Privacy Rule provisions at 45 CFR 164.512(a), contingent upon the ETC Participant annually signing an ETC Data Sharing Agreement.

Comment: One commenter expressed specific support for CMS's proposal to require an ETC Participant to complete an ETC Data Sharing Agreement on an annual basis. A couple of commenters recommended that CMS require the ETC Participant to complete an ETC Data Sharing Agreement only once during the Model. One such commenter further suggested that CMS require an ETC Participant to complete a subsequent ETC Data Sharing Agreement if material changes occur requiring a new agreement, rather than requiring an ETC Participant to complete an ETC Data Sharing Agreement annually. This commenter stated that this approach would align with the approach the Innovation Center takes in certain other alternative payment models, and that annual completion of an ETC Data Sharing Agreement would be overly burdensome for ETC Participants.

Response: We believe that it is appropriate to require the ETC Participant to complete an ETC Data Sharing Agreement on an annual basis. It is critical that CMS guarantees, to the best of its ability, that it always has an up-to-date, completed ETC Data Sharing Agreement from each ETC Participant that wishes to obtain the beneficiary-identifiable data CMS described in the CY 2022 ESRD PPS proposed rule. We believe that requiring the ETC Participant to complete an ETC Data Sharing Agreement annually, rather than only when material changes occur, would better ensure that CMS achieves this goal. Even if CMS were to articulate specific elements of what constitutes a ''material change,'' such a policy would require that an ETC Participant appropriately identify when such a change as occurred and timely notify CMS, and would require CMS to conduct additional monitoring and outreach activities to ensure compliance. Such an approach imposes additional and substantial burden on CMS in the context of the ETC Model, which includes approximately 7,000 ETC Participants, and this burden is disproportionate to the burden imposed on ETC Participants by completing an ETC Data Sharing Form annually. We believe that requiring the ETC Participant to complete an ETC Data Sharing Agreement annually strikes a reasonable balance between ensuring, to the extent possible, that CMS has up-to-date information, while minimizing the administrative burden imposed on a given ETC Participant in completing the form.

While CMS has not required the annual completion of a data sharing agreement in every alternative payment model, the ETC Model importantly

differs from other section 1115A models insofar as participation in the ETC Model changes in a different way than other models. ESRD facilities and Managing Clinicians located in a Selected Geographic Area are required to participate in the ETC Model under § 512.325(a). As such, participation in the ETC Model can fluctuate between MYs when ESRD facilities or Managing Clinicians move in or out of a Selected Geographic Area. This element of the ETC Model differs from many voluntary section 1115A models, such as the CEC Model or Primary Care First, where individuals or entities apply to participate, and accepted individuals or entities continue to participate until the section 1115A model ends or the participant or CMS terminates the participation agreement. The potential fluctuation in participation between MYs creates a need for CMS to require the ETC Participant to complete a data sharing agreement more frequently than it permits or requires in other section 1115A models, and we believe that requiring an ETC Participant to complete the data sharing agreement annually is sufficiently frequent to ensure that CMS has up-to-date data sharing agreements in place.

In addition, other alternative payment models generally provide, within their respective participation agreements, terms and conditions relating to data protection, uses and disclosures, retention, and destruction, and those participation agreements are often amended, which typically requires model participants to complete new data request and attestation forms during the model's performance period. Our CY 2022 ESRD PPS proposed rule indicated that the specific terms relating to privacy, security, data retention, breach notification, and data destruction, which are found for other section 1115A models in the models', governing documentation would be found in the ETC Data Sharing Agreement, and we believe it is important that ETC Participants review these terms at least once a year, including in completing an annual ETC Data Sharing Agreement.

In addition, the ETC Model includes a larger number of participants than many other section 1115A models; as described in the Specialty Care Models final rule, this larger scale is necessary to obtain the minimum sample size needed to produce robust and reliable evaluation results (85 FR 61280). With so many participants receiving beneficiary-identifiable data, CMS believes that the privacy interests of beneficiaries would be best protected by requiring the ETC Participant to complete an ETC Data Sharing Agreement annually, helping CMS to ensure that the ETC Data Sharing Agreement submitted by an ETC Participant is reasonably up-to-date. Moreover, CMS believes that completing an ETC Data Sharing Agreement represents a low burden for an ETC Participant. As discussed later in this final rule, the ETC Data Sharing Agreement form will be available on the same web-based platform as the beneficiary-identifiable and aggregate data, which the ETC Participant likely would be accessing at least twice a year to obtain data when available at least 30 days prior to a PPA Period.

Comment: One commenter recommended that CMS follow its approach in the Kidney Care Choices Model of requiring, in the commenter's words, ''eligible signatories for the ETC Data Sharing Agreement.''

Response: We thank the commenter for this feedback. We agree that it is important that the individual who signs the ETC Data Sharing Agreement has the authority to bind the ETC Participant to its terms and conditions. We believe this is standard for any binding agreement, and thus we do not believe we must specify this in our regulations.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.390(b)(1)(iii) and § 512.390(b)(1)(iv) to require that the ETC Participant observe all applicable laws regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information as would apply to a covered entity under the HIPAA regulations, and agree to comply with the terms of the ETC Data Sharing Agreement, to be signed at least annually, as a condition of receiving the beneficiary identifiable data, with one modification. Specifically, we are making a technical change at § 512.390(b)(1)(iii) to replace the phrase ''HIPAA regulations'' with ''regulations found at 45 CFR parts 160 and 164 promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended'' to clarify the applicable regulations, as the regulations initially promulgated under HIPAA have been amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act, and may be amended by other statutes in the future.

(2) Content of ETC Data Sharing Agreement Provisions for Beneficiary-Identifiable Data

We proposed in new § 512.390(b)(iv) that, under the ETC Data Sharing Agreement, ETC Participants would agree to certain terms, namely: (1) To comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA regulations and the requirements of the ETC Model set forth in 42 CFR part 512; (2) to comply with additional privacy, security, and breach notification requirements to be specified by CMS in the ETC Data Sharing Agreement; (3) to contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the ETC Participant or performs a similar function for the ETC Participant, to the same terms and conditions to which the ETC Participant is itself bound in its data sharing agreement with CMS as a condition of the downstream recipient's receipt of the beneficiary-identifiable data retrieved by the ETC Participant under the ETC Model; and (4) that if the ETC Participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the ETC Data Sharing Agreement, the ETC Participant would no longer be eligible to retrieve the beneficiary-identifiable data and may be subject to additional sanctions and penalties available under the law. In the CY 2022 ESRD PPS proposed rule (86 FR 36389), we stated that we believe these terms for sharing beneficiary-identifiable data with ETC Participants are appropriate and important, as CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with ETC Participants would be further protected by the ETC Participant, and any business associates of the ETC Participant, in an appropriate fashion. We stated that we believe that these proposals would allow CMS to accomplish that.

CMS solicited public comment on the additional privacy, security, breach notification, and other requirements that we would include in the ETC Data Sharing Agreement. As we noted in the CY 2022 ESRD PPS proposed rule, CMS has these types of agreements in place as part of the governing documents of other models tested under section 1115A of the Act and in the Medicare Shared Savings Program. In these agreements, CMS typically requires the identification of data custodian(s) and imposes certain requirements related to administrative, physical, and technical safeguards relating to data storage and transmission; limitations on further use and disclosure of the data; procedures for responding to data incidents and breaches; and data destruction and

retention. We proposed that these provisions would be imposed in addition to any restrictions required by law, such as those provided in the HIPAA privacy, security, and breach notification regulations. We additionally proposed that these provisions would not prohibit the ETC Participant from making any disclosure of the data otherwise required by law.

We noted in the CY 2022 ESRD PPS proposed rule that we were considering limiting the use of beneficiary-identifiable data for specific purposes, either alone or in combination. We noted that, for example, in the ETC Data Sharing Agreement, CMS considered imposing limits on how the ETC Participant may use the beneficiary-identifiable data without prior written authorization from CMS to specific purposes, such as assessing CMS's calculation of the MPS for a given PPA Period, the ETC Participant's clinical care or ''treatment'' (as that term is defined at 45 CFR 164.501) of an attributed beneficiary, and certain ''health care operations'' (as that term is defined at 45 CFR 164.501) of the ETC Participant. As noted previously in the CY 2022 ESRD PPS proposed rule and this final rule, CMS believes that ETC Participants would require this data to be able to request a targeted review of CMS's calculation of the MPS as it relates to a given PPA Period, as understanding and being able to seek review of CMS's calculation of the MPS, and thus the reason CMS adjusted the ETC Participant's Medicare payments in the manner it did, is critical for the ETC Model. In the CY 2022 ESRD PPS proposed rule, we noted that importantly, there is no other source of this information outside of CMS. In addition to potentially limiting use to reviewing how CMS calculated the ETC Participant's MPS, we stated in the CY 2022 ESRD PPS proposed rule that we were considering limiting, in the ETC Data Sharing Agreement, use of the beneficiary-identifiable data without prior written authorization from CMS to use for clinical treatment purposes. We stated our belief that this beneficiary-identifiable data would be important in helping the ETC Participant determine which of its ESRD Beneficiaries are not on the transplant waitlist or have not received a living donor transplant, to inform how the ETC Participant engages in clinical care of the subject ESRD Beneficiary.

In addition to the previous two uses, we stated in the CY 2022 ESRD PPS proposed rule that we also were considering limiting, in the ETC Data Sharing Agreement, the ETC Participant's use of the beneficiary-identifiable data without prior written authorization from CMS to care management and coordination, quality improvement activities, and provider incentive design and implementation, to the extent these activities would constitute ''health care operations'' that fall within the first and second paragraphs of the definition of that phrase under the HIPAA Privacy Rule (45 CFR 164.501). As it relates to case management and coordination and quality improvement activities, we stated in the CY 2022 ESRD PPS proposed rule that CMS believes that this beneficiary-identifiable data would help the ETC Participant to conduct the important task of identifying which ESRD Beneficiaries are not currently on the transplant waitlist and thus better enable the ETC Participant to engage those beneficiaries, as clinically appropriate, about the process of signing up for the transplant waitlist, thereby improving the ETC Participant's performance on the transplant waitlist rate, and increasing the likelihood that the subject ESRD Beneficiaries would receive a transplant. In addition, we noted our belief that sharing this data with the ETC Participant would help the ETC Participant to conduct the important task of identifying which ESRD Beneficiaries are receiving dialysis in-center, and to consider whether furnishing kidney disease patient education services or otherwise making such beneficiaries aware of the possibility of receiving home dialysis, self-dialysis, or nocturnal in-center dialysis, as clinically appropriate in the ESRD Beneficiary's individual situation.

We sought public comment on how an ETC Participant might need to, and want to, use the beneficiary-identifiable data retrieved from CMS under the ETC Model to accomplish the goals of the ETC Model in accordance with applicable law.

We also sought public comment on what further disclosures of the beneficiary-identifiable data might be appropriate to permit or prohibit under the ETC Data Sharing Agreement. For example, we stated in the CY 2022 ESRD PPS proposed rule that CMS considered prohibiting, in the ETC Data Sharing Agreement, any further disclosure, not otherwise required by law, of the beneficiary-identifiable data described previously in this section of the CY 2022 ESRD PPS proposed rule to anyone who is not a HIPAA covered entity or business associate, as defined in 45 CFR 160.103, or to an individual practitioner in a treatment relationship with the subject ESRD Beneficiary or Pre-emptive LDT Beneficiary, or that practitioner's business associates. Such a prohibition would be similar to that imposed by CMS in other models tested under section 1115A of the Act in which CMS shares beneficiary-identifiable data with model participants. In the alternative, we noted, CMS also considered including more restrictive prohibitions in the ETC Data Sharing Agreement, which would limit further discloses to only some, one, or none of the categories of individuals or entities described above.

We explained in the CY 2022 ESRD PPS proposed rule that we considered all of these possibilities because there exist important legal and policy limitations on the sharing of the beneficiary-identifiable data discussed previously in the CY 2022 ESRD PPS proposed rule, and CMS must consider carefully the ways in which and reasons for which we would provide access to this data for purposes of the ETC Model. We stated that we believe that some ETC Participants may require the assistance of business associates, such as contractors, to perform data analytics or other functions using this beneficiary-identifiable data to support the ETC Participant's review of CMS's MPS calculations, care management and coordination, quality improvement activities, or clinical treatment of attributed beneficiaries. We further noted that we believe that this beneficiary-identifiable data may be helpful for any HIPAA covered entities who are in a treatment relationship with the subject ESRD Beneficiary or Pre-emptive LDT Beneficiary.

We sought public comment on how an ETC Participant might need to, and want to, disclose the beneficiary-identifiable data to other individuals and entities to accomplish the goals of the ETC Model, in accordance with applicable law.

Under our proposal, the ETC Data Sharing Agreement would include other provisions, including requirements regarding data security, retention, destruction, and breach notification. For example, we considered including, in the ETC Data Sharing Agreement, a requirement that the ETC Participant designate one or more data custodians who would be responsible for ensuring compliance with the privacy, security and breach notification requirements for the data set forth in the ETC Data Sharing Agreement; various security requirements like those found in other models tested under section 1115A of the Act, but no less restrictive than those provided in the relevant Privacy Act system of records notices; how and when beneficiary-identifiable data could be retained by the ETC Participant or its downstream recipients of the

beneficiary-identifiable data; procedures for notifying CMS of any breach or other incident relating to the unauthorized disclosure of beneficiary-identifiable data; and provisions relating to destruction of the data. We noted that these are only examples, and are not the only terms CMS would potentially include in the ETC Data Sharing Agreement.

We solicited public comment on this proposal that CMS, by adding § 512.390(b)(1)(iv)(B), would impose certain requirements in the ETC Data Sharing Agreement related to privacy, security, data retention, breach notification, and data destruction.

Finally, as described previously in section V.B.7.b(2) of this final rule, we proposed, at § 512.390(b)(1)(iv)(D), that the ETC Data Sharing Agreement would include a term providing that if the ETC Participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the ETC Data Sharing Agreement, the ETC Participant would no longer be eligible to retrieve beneficiary-identifiable data under proposed § 512.390(b)(1)(i) and may be subject to additional sanctions and penalties available under law. We also proposed to make conforming amendments to 42 CFR 512.160. Section 512.160(b) outlines the remedial actions available under the RO Model and ETC Model, and paragraph (b)(8), in particular provides that, if CMS determines that one or more grounds for remedial action specified in § 512.160(a) has taken place, CMS may discontinue the provision of data sharing and reports to the model participant. We proposed to add a new § 512.160(a)(9) to specify that, for the ETC Model only, CMS may take remedial action if the model participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the applicable data sharing agreement. We noted that this proposed change would align the regulatory provision on remedial action with the remedial action we would include in the ETC Data Sharing Agreement.

We solicited public comment on this proposal, to prohibit the ETC Participant from obtaining beneficiary-identifiable data pertaining to the ETC Model if the ETC Participant fails to comply with applicable laws and regulations, the terms of the ETC Model, or the ETC Data Sharing Agreement.

The following is a summary of the comments received on additional privacy, security, breach notification, and other requirements that we proposed to include in the ETC Data Sharing Agreement, and our responses.

Comment: One commenter expressed general support for having strong safeguards to protect sensitive beneficiary information and to ensure the data's appropriate use.

Response: We appreciate this comment. We agree that it is critical that any data sharing policy we finalize for the ETC Model have strong safeguards designed to protect sensitive beneficiary information and to ensure, to the best of our ability, the appropriate use of the data by ETC Participants and their downstream users.

Comment: One commenter expressed support for allowing an ETC Participant to disclose the beneficiary-identifiable data shared by CMS under the ETC Model with other covered entities in a treatment relationship with ESRD Beneficiaries, and with the ETC Participant's business associates. The commenter noted that this proposal would allow the data to be used in quality improvement activities by ETC Participants, and that many clinicians partner with third-party data vendors as business associates under the HIPAA rules, since such vendors have expertise in the field of data analytics and in analyzing trends and identifying areas for quality improvement.

Response: CMS agrees that it is appropriate to allow an ETC Participant to disclose the beneficiary-identifiable data shared by CMS under the ETC Model with other covered entities in a treatment relationship with ESRD Beneficiaries, to help ensure that other covered entities who furnish care to ESRD Beneficiaries have the benefit of this important information related to the subject beneficiary's kidney care. In addition, CMS agrees that many clinicians contract with third parties for analytics support, and that such support can assist clinicians in conducting quality improvement activities. As we describe later in this section of the final rule, CMS is finalizing a data sharing policy that will allow an ETC Participant to disclose the beneficiary-identifiable data shared by CMS under the ETC Model with a business associate of the ETC Participant, so long as the ETC Participant contractually binds the business associate to the same terms and conditions to which the ETC Participant is itself bound in its ETC Data Sharing Agreement with CMS as a condition of the business associate's receipt of the beneficiary-identifiable data. The policy we are finalizing places limits on the ETC Participant's further disclosures of the beneficiary-identifiable data shared by CMS. Specifically, the policy we are finalizing requires that any non-covered entity with whom the ETC Participant discloses beneficiary-identifiable data made available to the ETC Participant under the ETC Model must be a business associate of the ETC Participant—and cannot be a downstream recipient who is neither a covered entity nor a business associate of the ETC Participant—except as otherwise required by law. CMS is making this modification because it believes that limiting downstream recipients of beneficiary-identifiable data shared under the ETC Model to those who have a business associate agreement in place with the ETC Participant, and that business associate agreement adopts the terms required under this regulation, will best safeguard the privacy and security interests of beneficiaries.

Comment: One commenter expressed support for the data shared to be protected by existing Federal privacy and confidentiality laws, but requested that CMS clarify the differences between the privacy protections required under the ETC Model and those required by HIPAA.

Response: It is critical to clarify that the policies we are finalizing in this section of the final rule are for the ETC Model only and are not intended to modify the HIPAA Privacy Rule or change existing legal obligations under the HIPAA Privacy Rule or other privacy laws. By finalizing our proposal in this final rule, we are establishing a requirement under § 512.390(b)(1) for CMS to share beneficiary-identifiable data in a manner that is consistent with the HIPAA Privacy Rule, 45 CFR 164.512(a). We are also establishing additional protections for the beneficiary-identifiable data shared with ETC Participants under the ETC Model that they must, in turn, impose on any business associates. These additional requirements and safeguards include, but are not limited to, the annual completion and submission of an ETC Data Sharing Agreement; specific instructions relating to breach notification and data retention and destruction; and the identification of one or more data custodians who will be responsible for ensuring compliance with the privacy, security, and breach notification requirements set forth in the ETC Data Sharing Agreement. Further, under our final policy, we are placing additional limits on how the ETC Participant may use and further disclose the beneficiary-identifiable identifiable data received from CMS under the ETC

Model, beyond what may otherwise be permitted under the HIPAA Privacy Rule. In particular, ETC Participants will be limited to using and further disclosing the beneficiary-identifiable data under the ETC Model for the following purposes (other than disclosures otherwise required by law), without obtaining prior written permission from CMS: The ETC Participant's ''health care operations'' that fall within the first and second paragraphs of the definition of that phrase under the HIPAA Privacy Rule (45 CFR 164.501), to the extent they relate to care management and coordination, quality improvement activities, and provider incentive design and implementation; for clinical care or ''treatment'' (as that term is defined in 45 CFR 164.501) of the subject beneficiary; and for assessing CMS's calculations underlying the MPS for the relevant PPA Period. We believe these uses and bases for further disclosure represent the only appropriate uses and bases for further disclosure for the beneficiary-identifiable data made available to the ETC Participant under the Model, and the only appropriate uses for business associates to whom the ETC Participant discloses such data, for the reasons we provide below in response to other comments.

Comment: One commenter recommended that CMS not impose additional restrictions on data sharing beyond those required by the HIPAA Privacy Rule, and asserted that an ETC Participant should be able to use the beneficiary-identifiable data for the same ''treatment'' and ''health care operations'' activities permitted under HIPAA. Another commenter similarly suggested that CMS not impose additional limitations on an ETC Participant's use or further disclosure of the beneficiary-identifiable data beyond those imposed by existing law, and additionally recommended that CMS not require the ETC Participant to obtain permission from CMS or another agency prior to any permitted data use.

Response: We agree that an ETC Participant should be able to use the beneficiary-identifiable data made available by CMS under the ETC Model for the ''treatment'' (as that term is defined in 45 CFR 164.501) of the subject beneficiary, and we are finalizing our proposal to allow an ETC Participant to use such data for treatment. We believe it is important that an ETC Participant be able to use such data to inform their direct care of the beneficiary, especially as it relates to discussing renal replacement modalities and transplantation.

The definition of ''health care operations'' in the HIPAA Privacy Rule at 45 CFR 164.501 covers a broad array of activities, most of which we believe are not relevant or necessary for purposes of the ETC Participant's performance in the Model. For example, an ETC Participant would not need to perform ''underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits[,]'' as described in the third paragraph of the definition. In addition, other uses and disclosures generally allowed under HIPAA without obtaining individual authorization, such as ''payment,'' are not relevant to the ETC Participant's performance in the Model. To appropriately safeguard the beneficiary-identifiable data, we will limit the permitted uses and further disclosures of the PHI shared under the ETC Model to the ETC Participant's ''health care operations'' that fall within the first and second paragraphs of the definition of that phrase under the HIPAA Privacy Rule (45 CFR 164.501), to the extent they relate to care management and coordination, quality improvement activities, and provider incentive design and implementation; treatment of the subject beneficiary; assessing CMS's calculations of the ETC Participant's MPS; and as otherwise required by law. In addition, under our final policy, we will permit the ETC Participant to use and further disclose beneficiary-identifiable retrieved under the ETC Model for assessing CMS's calculations underlying the MPS, which sufficiently covers the ETC Participant's need to use such data for ''[b]usiness planning and development'' as permitted under the fifth paragraph of the ''health care operations'' definition.

Moreover, we agree that it is not desirable to require an ETC Participant to obtain permission from CMS or another agency prior to engaging in any particular use or further disclosure of the beneficiary-identifiable data. Once the ETC Participant has completed its annual ETC Data Sharing Agreement, we do not expect the ETC Participant will need to obtain additional permission from CMS or another agency to use or further disclose the beneficiary-identifiable data in the ways we describe in this final rule or will describe in the ETC Data Sharing Agreement, or that CMS may otherwise authorize in writing.

Comment: One commenter recommended that CMS implement a warning system prior to deeming an ETC Participant ineligible to retrieve beneficiary-identifiable data under the ETC Model, because without access to the beneficiary-identifiable data that CMS proposed to make available to ETC Participants under the Model, an ETC Participant would be unable to identify its dual-eligible or LIS-eligible beneficiaries, or trends in the data for the purpose of conducting quality improvement. The commenter additionally asserted that rendering an ETC Participant ineligible to retrieve such data would lead to a decrease in the quality of care provided, negatively affecting both ETC Participants and attributed beneficiaries. The commenter further suggested that an instance of noncompliance with the relevant requirements under the proposed regulation at § 512.390(b) or the ETC Data Sharing Agreement could arise due to an inadvertent error.

Response: We thank the commenter for this feedback. As we noted in the CY 2022 ESRD PPS proposed rule and in this section of this final rule, there are important sensitivities surrounding the sharing of this type of individually identifiable health information, and we must ensure to the best of our ability that any beneficiary-identifiable data shared with ETC Participants would be further protected in an appropriate fashion. Further, errors or other conduct resulting in the improper disclosure of beneficiary-identifiable data, inadvertent or otherwise, threaten the privacy interests of attributed beneficiaries. However, we also understand that not every improper use, disclosure, or other handling of beneficiary-identifiable data shared under the ETC Model would equally threaten the privacy interests of attributed beneficiaries. We agree with the commenter that we should retain a level of discretion in responding to instances of noncompliance.

However, we disagree that we should implement an explicit warning system prior to deeming an ETC Participant ineligible to retrieve beneficiary-identifiable data under the ETC Model. If CMS believed that a given instance of noncompliance warranted a warning, CMS would have discretion under § 512.160 to impose various remedial actions, including but not limited to notifying the ETC Participant of the violation. We also have the discretion under § 512.160 to require the ETC Participant to provide additional information to CMS or its designees; subject the model participant to additional monitoring, auditing, or both; or to require the ETC Participant to submit a corrective action plan. In other words, CMS already has the authority impose remedial actions less severe than discontinuing data sharing, if CMS

determines the situation so warranted, without implementing an explicit warning system that would impose burden and limit CMS's discretion. Accordingly, we decline to implement an explicit warning system prior to deeming an ETC Participant ineligible to retrieve beneficiary-identifiable data under the Model.

Instead, we are finalizing § 512.390(b)(1)(iv)(D) with a modification to grant CMS more discretion in determining whether an ETC Participant's misuse or improper disclosure of beneficiary-identifiable data warrants CMS deeming an ETC Participant ineligible to retrieve beneficiary-identifiable data during performance of the Model. Under this modification, CMS may deem an ETC Participant ineligible to retrieve such data for any amount of time, meaning it could be for the entire period of the Model or for a shorter time, or CMS could impose a lesser remedial action. This language would better align with our proposal to add a new § 512.160(a)(9) to specify that, for the ETC Model only, CMS may take remedial action under § 512.160(b) if CMS determines that the model participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the applicable data sharing agreement.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.390(b)(iv)(A)–(D) related to additional privacy, security, breach notification, and other requirements that we would include in the ETC Data Sharing Agreement, with modification. First, we are modifying our proposal at § 512.397(b)(iv)(C) to remove language related to downstream recipients who perform a similar function or service to that of a business associate, to clarify that the ETC Participant may only further disclose beneficiary-identifiable data made available under the ETC Model to business associates of the ETC Participant. Second, we are modifying our proposed policy that an ETC Participant that misuses or discloses the beneficiary-identifiable data retrieved under the ETC Model in a manner that violates any applicable statutory or regulatory requirements, or that is otherwise noncompliant with the provisions of the ETC Data Sharing Agreement, would be automatically ineligible to retrieve beneficiary-identifiable data under the ETC Model. Instead, we are finalizing a policy that would give CMS discretion to take appropriate remedial action in the instance that an ETC Participant engages in such misuse or improper disclosure. Specifically, we are modifying the proposed language at § 512.390(b)(1)(iv)(D) to provide that, if an ETC Participant wishes to retrieve the beneficiary identifiable data specified in § 512.390(b)(1)(ii), the ETC Participant agrees, in signing and completing the ETC Data Sharing Agreement, that if the ETC Participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements, or that is otherwise non-compliant with the provisions of the data sharing agreement, CMS may deem the ETC Participant ineligible to retrieve the beneficiary-identifiable data under § 512.390(b)(1)(i) for any amount of time, and the ETC Participant may be subject to additional sanctions and penalties available under the law. We are otherwise finalizing our proposal to include privacy, security, breach notification, and other requirements in the ETC Data Sharing Agreement.

(3) Process for Retrieving the ETC Data Sharing Agreement and Beneficiary-Identifiable Data

In the CY 2022 ESRD PPS proposed rule (86 FR 36390), we proposed that we would make the ETC Data Sharing Agreement and beneficiary-identifiable data available in a form and manner specified by CMS. We stated that we expected to provide a web-based platform for ETC Participants to use to retrieve the beneficiary-identifiable data. We noted that CMS would provide ETC Participants further information about this web-based platform through the ETC listserv and the ETC Model website at a date to be determined by CMS, but at least 1 month before the first PPA Period begins on June 1, 2022. We also stated that we expect that CMS would notify ETC Participants of each opportunity to retrieve a new set of beneficiary-identifiable data and the process for accessing the web-based platform to receive the data through the ETC listserv and on the ETC Model website. Under this proposal, the ETC Participant would be required to use the form and manner specified by CMS (which we expect will be a web-based platform) to retrieve the data. We proposed that if the ETC Participant did not use the form and manner specified by CMS or did not agree to the ETC Data Sharing Agreement, the ETC Participant would be unable to retrieve the beneficiary-identifiable data described previously in this section of the CY 2022 ESRD PPS proposed rule. We proposed that ETC Participants would be permitted to retrieve this data at any point during the relevant PPA Period. In the CY 2022 ESRD PPS proposed rule, we considered establishing certain periods of time within a PPA Period during which the ETC Participant would be able to retrieve the data, but we concluded that permitting the ETC Participant to obtain the data at any point during the relevant PPA Period would be relatively operationally low-burden for CMS while providing additional flexibility to the ETC Participant.

We stated that we believe that it is important that the ETC Participant complete and submit its signed ETC Data Sharing Agreement, and retrieve the beneficiary-identifiable data, in the same form and manner (which we expect to be a web-based platform).

In the alternative, we considered providing the beneficiary-identifiable data to ETC Participants via paper mail rather than through a web-based platform, but we concluded that making the data available through a web-based platform would reduce administrative burden on both CMS and the ETC Participants. We also concluded that making this beneficiary-identifiable data available through a web-based platform would allow CMS to provide the data in a manner that is more secure than if CMS were to make the data available through paper mail. As we explained in the CY 2022 ESRD PPS proposed rule, by using a web-based platform, to be further described by CMS through the ETC listserv and the ETC Model website, CMS would help ensure that only authorized users would be able to obtain the data, and would be able to implement a two-factor authentication to help ensure that no one other than an ETC Participant would have access to the data. In addition, we concluded that it would be more efficient to provide the ETC Data Sharing Agreement and the beneficiary-identifiable data itself through the same form and manner (which we expect to be a web-based platform), rather than using two different processes and that using a web-based platform would be more efficient than paper mail. For these reasons, we stated that we believe the best option would be for us to use only the web-based platform both for providing the ETC Data Sharing Agreement and for sharing data pertaining to the ETC Model.

We solicited public comment on our proposal to require the ETC Participant to complete and submit a signed ETC Data Sharing Agreement before the ETC Participant could retrieve the beneficiary-identifiable data, and on our

proposal that the ETC Participant would be required to retrieve the beneficiary-identifiable data in the same form and manner as the ETC Participant receives and submits the ETC Data Sharing Agreement. We also solicited comment regarding our expectation that we will use a web-based platform, rather than paper mail, for these purposes.

The following is a summary of the comments received on our proposed process for retrieving the ETC Data Sharing Agreement and beneficiary-identifiable data, and our responses.

Comment: Two commenters expressed support for CMS making the beneficiary-identifiable data available to the ETC Participant via a web-based platform. One such commenter expressed opposition to the alternative process that CMS considered; namely, to share the beneficiary-identifiable data via paper mail, as data sent via paper mail would be inconvenient to both CMS and ETC Participants. The commenter also stated that sharing the beneficiary-identifiable data by paper mail would increase the risk of the data being viewed by the wrong parties, and that mailing data would be contradictory to CMS's initiatives promoting interoperability.

Response: We agree that a web-based platform is an appropriate process for sharing beneficiary-identifiable data in the ETC Model, and is a more appropriate process than sharing such data through paper mail. We believe, as we expressed in the CY 2022 ESRD PPS proposed rule, that making the data available through a web-based platform would reduce administrative burden on both CMS and ETC Participants, and that a web-based platform would be more secure than making the data available through paper mail. We agree with the commenter's concern that sharing data via paper mail would increase the risk of a data breach compared to sharing data via a web-based platform. While we do not believe sharing data via paper mail would necessarily contradict CMS's efforts promoting interoperability, we do believe that sharing data via paper mail would make it more burdensome for ETC Participants to ingest the data in a software that could exchange information with other healthcare providers or suppliers, or business associates, as appropriate.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.390(b) that an ETC Participant must obtain an ETC Data Sharing Agreement, sign and complete an ETC Data Sharing Agreement, and retrieve beneficiary identifiable data all in a form and manner to be specified by CMS, without modification. As stated in the CY 2022 ESRD PPS proposed rule, we expect that ''form and manner'' will be via a web-based platform, and CMS will provide ETC Participants further information about this web-based platform via the ETC listserv and ETC Model website at least one month before the first PPA Period begins on June 1, 2022.

e. CMS Sharing of Aggregate Data

In addition to the proposed process for sharing beneficiary-identifiable data described previously in this section, we proposed in § 512.390(b)(2) that CMS would make available certain aggregate data for retrieval by the ETC Participant, in a form and manner to be specified by CMS, no later than one month before each PPA Period. We proposed that this aggregate performance data, would include, when available, the following information for each PPA Period, de-identified in accordance with 45 CFR 164.514(b): The ETC Participant's performance scores on the home dialysis rate, transplant waitlist rate, living donor transplant rate, and, if finalized, Health Equity Incentive; the ETC Participant's aggregation group's scores on the home dialysis rate, transplant waitlist rate, living donor transplant rate, and, if finalized, Health Equity Incentive; information on how the ETC Participant's and ETC Participant's aggregation group's scores relate to the achievement benchmark and improvement benchmark (that is, whether the ETC Participant met or exceeded the threshold for each such benchmark); and the ETC Participant's MPS and PPA for the corresponding PPA Period. We stated in the CY 2022 ESRD PPS proposed rule (86 FR 36391) that we believe sharing this aggregate, de-identified data with the ETC Participant would be important to help the ETC Participant better understand its performance in the ETC Model relative to its aggregation group and to the achievement and improvement benchmarks against which CMS is measuring the ETC Participant's performance. We stated that whereas the beneficiary-identifiable data described previously in the CY 2022 ESRD PPS proposed rule and this section of the final rule would indicate which ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries the ETC Participant could devote greater resources to, CMS believes this aggregate, de-identified data would better enable the ETC Participant to see which performance rates the ETC Participant might need to improve to more generally improve its performance under the ETC Model.

We proposed that CMS would make this data available to the ETC Participant for retrieval in a form and manner to be specified by CMS no less than one month prior to each PPA Period. We stated that we expected that CMS would make this data available to the ETC Participant on the same web-based platform on which CMS would be providing the beneficiary-identifiable data described previously in this section. We proposed that the ETC Participant would be required to use the form and manner specified by CMS to retrieve this aggregate data, but would not have to agree to the ETC Data Sharing Agreement to retrieve this aggregated data, as it is not beneficiary-identifiable. We noted our belief that using a web-based platform for sharing this aggregate data would be appropriate for the same reasons it would be appropriate for sharing the beneficiary-identifiable data. By using a web-based platform, CMS would help ensure that only authorized users would be able to obtain the data, and would be able to implement a two-factor authentication to help ensure that no one other than an ETC Participant would have access to the data. In addition, we stated, because CMS would be providing the ETC Data Sharing Agreement and beneficiary-identifiable data on the same web-based platform, we believe it would be convenient for the ETC Participant if CMS shared the aggregate data on the same web-based platform.

In the alternative, we considered sending this aggregate data to the ETC Participant via paper mail. However, CMS concluded in the CY 2022 ESRD PPS proposed rule that it would be more convenient to the ETC Participant to retrieve this data from a web-based platform rather than via paper mail, and that sending this data via paper mail would represent significant administrative and operational burdens for CMS.

We solicited public comment on our proposal to share aggregate data generally, to share aggregated data in the same form and manner we are proposing to use for sharing beneficiary-identifiable data. We also solicited public comment on our expectation to use a web-based platform for this purpose, as well as our considered alternative to share the aggregate data via paper mail.

The following is a summary of the comments received on our proposed process for sharing aggregate data, and our responses.

Comment: Some commenters expressed support for our proposal to

share aggregate data. One such commenter stated that aggregate data will help an ETC Participant determine its previous rates for different dialysis modalities, and allow the ETC Participant to focus on increasing rates of the dialysis modalities measured for payment adjustments under the ETC Model. The commenter further noted that without knowledge of the ETC Participant's current rates on the different modalities, the ETC Participant would have difficulty understanding when the ETC Participant's actions have resulted in positive change. Another commenter noted that many small ETC Participants may lack the resources to perform detailed analytics with the beneficiary-identifiable data, and that the proposed aggregate data would thus be helpful for such ETC Participants. The same commenter additionally noted that the proposed aggregate data would be useful for ETC Participants that can and do perform detailed analytics with the beneficiary-identifiable data to help validate the results of such analytics.

Response: We agree that sharing the aggregate data, as proposed, would prove helpful for ETC Participants, regardless of the individual ETC Participant's analytics capacity. We also agree that such data can be used to compare the ETC Participant's previous home dialysis and transplant rates, and performance with current rates and performance, and thus can help signal to the ETC Participants when interventions are producing positive results.

Comment: One commenter expressed support for our proposal to not require the ETC Participant to sign an ETC Data Sharing Agreement to obtain aggregate data from CMS.

Response: We agree; we do not believe an ETC Data Sharing Agreement is necessary to protect the aggregate data because it will be fully de-identified in accordance with HIPAA requirements under 45 CFR 164.514(b) and will not contain any beneficiary-identifiable data.

Comment: One commenter recommended that CMS make available aggregate comparative data to ETC Participants quarterly to allow an ETC Participant to assess where it stands on its home dialysis rate and transplant rate in terms of ranking relative to other ETC Participants' performance.

Response: We appreciate this comment. For the same reason that we are not making beneficiary-identifiable data available on a more frequent cadence as discussed in section V.B.7.b of this final rule, we are not making aggregate data available on a more frequent cadence. Specifically, we believe that the proposed schedule for sharing aggregate data affords the ETC Participant sufficient time to derive benefit, such as monitoring the ETC Participant's performance over the course of the ETC Model from the aggregate data. Further, as described in § 512.360, CMS conducts beneficiary attribution for each month retrospectively after the end of each MY, at which time CMS calculates the ETC Participant's MPS. Accordingly, CMS would not have aggregate data to share with the ETC Participant on a quarterly basis; CMS is unable to share aggregate data on the ETC Participant's performance more often than biannually, after the end of the applicable MY.

In addition, we do not believe it is necessary for CMS to release aggregate comparative data to ETC Participants at this time. As described in § 512.370(b), to assess the ETC Participant's achievement score, CMS assesses the ETC Participant performance at the aggregation group level against benchmarks constructed among aggregation groups of ESRD facilities and Managing Clinicians located in Comparison Geographic Areas during the Benchmark Year. The beneficiary-identifiable data we proposed to share includes the ETC Participant's MPS, and the aggregate data we proposed to share includes information on how the ETC Participant's and the ETC Participant's aggregation group's scores relate to the achievement benchmark and improvement benchmark. In this way, the data CMS is already planning to share will provide the ETC Participant with insight into how the ETC Participant and the ETC Participant's aggregation group performed relative to other health care providers in the corresponding Comparison Geographic Area during the applicable Benchmark Year.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.390(b)(2) to share aggregate data and to specify the aggregate data that CMS would share and the process by which CMS would make available and the ETC Participant would obtain such aggregate data, without modification. Specifically, we are finalizing our proposal to require CMS to share make aggregate data available for retrieval by the ETC Participant, in a form and manner to be specified by CMS, no later than one month before each PPA Period. This de-identified data includes, when available, the ETC Participant's performance scores on the home dialysis rate, transplant waitlist rate, living donor transplant rate, and the Health Equity Incentive; the ETC Participant's aggregation group's scores on the home dialysis rate, transplant waitlist rate, and living donor transplant rate, and the Health Equity Incentive; information on how the ETC Participant's and ETC Participant's aggregation group's scores relate to the achievement benchmark and improvement benchmark; and the ETC Participant's MPS and PPA for the corresponding PPA Period.

8. Medicare Waivers and Additional Flexibilities

a. Background on Kidney Disease Patient Education Services Waiver

Pursuant to section 1861(ggg)(1) of the Act and § 410.48 of our regulations, Medicare Part B covers outpatient, face-to-face kidney disease patient education services provided by certain qualified persons to beneficiaries with Stage IV chronic kidney disease. As noted in the Specialty Care Models final rule, kidney disease patient education services play an important role in educating patients about their kidney disease and to help them make informed decisions on the appropriate type of care and/or dialysis needed for them (85 FR 61337). In addition, we noted in the Specialty Care Models final rule that kidney disease patient education services are designed to educate and inform beneficiaries about the effects of kidney disease, their options for transplantation, dialysis modalities, and vascular access (85 FR 61337). Because kidney disease patient education services have been infrequently billed, we found it necessary for purposes of testing the ETC Model to waive select requirements of kidney disease patient education services authorized in section 1861(ggg)(1) of the Act and in the implementing regulation at 42 CFR 410.48. Specifically, to broaden the availability of kidney disease patient education services under the ETC Model, we have used our authority under section 1115A(d) of the Act to waive certain requirements for individuals and entities that furnish and bill for kidney disease patient education services. We codified these waivers at § 512.397(b). These include waivers to allow more types of beneficiaries to have access to kidney disease patient education services, as well as greater flexibility in how the kidney disease patient education services are performed. For instance, CMS waived the requirement that kidney disease patient education services are covered only for Stage IV chronic kidney disease (CKD) patients to permit beneficiaries to receive kidney disease patient education

services if they are diagnosed with CKD Stage V or are in the first 6 months of starting dialysis to receive the benefit. CMS also waived the requirements in section 1861(ggg)(2)(A)(i) of the Act and § 410.48(a) and (c)(2)(i) of the applicable regulations pertaining to the definition of ''qualified person'' such that registered dieticians/nutrition professionals, licensed clinical social workers, or a clinic/group practice may furnish kidney disease patient education services under the direction of, and incident to the services of a Managing Clinician who is an ETC Participant.

Finally, CMS waived two requirements relating to the content of kidney disease patient education services furnished to a beneficiary. CMS waived the requirement under § 410.48(d)(1) of our regulations that the content of kidney disease patient education services include the management of co-morbidities, including delaying the need for dialysis, when such services are furnished to beneficiaries with CKD Stage V or ESRD, unless such content is relevant for the beneficiary. In addition, CMS waived the requirement under § 410.48(d)(5)(iii) of our regulations that an outcomes assessment designed to measure beneficiary knowledge about chronic kidney disease and its treatment be performed during one of the kidney disease patient education services, requiring instead that such outcomes assessment is performed within 1 month of the final kidney disease patient education services session furnished by qualified staff.

b. Kidney Disease Patient Education Services Telehealth Waiver and Additional Flexibilities

Many changes took place in 2020 and early 2021 due to the COVID–19 PHE. Legislation enacted to address the PHE for COVID–19 provided the Secretary with new authorities under section 1135(b)(8) of the Act to waive or modify Medicare telehealth payment requirements during the PHE for COVID–19. We established several flexibilities to accommodate these changes in the delivery of care. Through waiver authority under section 1135(b)(8) of the Act, in response to the PHE for COVID–19, we temporarily waived the geographic and site of service originating site restrictions in section 1834(m)(4)(C) of the Act. For example, CMS waived the rural area requirement at section 1834(m) of the Act to allow for telehealth services, including kidney disease patient education services that can be furnished via telehealth, to be furnished to beneficiaries in any geographic area, regardless of location and in their homes, for the duration of the PHE. These waivers are set to terminate at the end of the COVID–19 PHE.

In the CY 2022 ESRD PPS proposed rule, we stated that we believe that, once the PHE ends, these waivers removing the geographic and site of service originating site restrictions for kidney disease patient education services furnished via telehealth would be necessary solely for purposes of testing the ETC Model (86 FR 36392). Except under very limited circumstances, under section 1834(m) of the Act and its implementing regulations, the originating site where the beneficiary is located at the time a telehealth service is furnished is limited to certain, mostly rural, geographic locations and a site of service that is one of certain types of health care facilities. We also stated our belief that allowing qualified staff to furnish kidney disease patient education services via telehealth, regardless of the beneficiary's geographic area or the site of the beneficiary, and regardless of the site of service of the practitioner, would increase access to kidney disease patient education services for a few reasons. First, some beneficiaries may not have access to reliable transportation, especially those beneficiaries who suffered economically during the ongoing PHE, but may have access to the technology necessary for practitioners to furnish kidney disease patient education services. Moreover, some beneficiaries, even those with reliable transportation, may be more comfortable receiving kidney disease patient education services via telehealth rather than appearing in person after over a year of social distancing, even when it becomes safe according to Federal guidance for such beneficiaries to enter physical spaces with other individuals. We noted that this is especially likely to be the case for instances in which a practitioner would furnish kidney disease patient education services in a group session rather than an individual session. We further noted that increasing access to kidney disease patient education services is consistent with one of the main goals of the ETC Model, insofar as we believe that education, as delivered through kidney disease patient education services, helps improve beneficiary choice of dialysis modality.

In addition, we stated that we believe that removing beneficiary cost barriers for kidney disease patient education services would be helpful. As we demonstrate below in this final rule, there is a significant relationship between household income or poverty status and kidney disease, and removing or mitigating cost barriers to access to kidney disease patient education services would likely increase the number of beneficiaries who would be willing to receive kidney disease patient education services.

We therefore proposed that, starting in MY3, kidney disease patient education services may be furnished to certain beneficiaries via telehealth in a manner that is more flexible than that required under existing telehealth requirements. In addition, we proposed to permit the reduction or waiver of coinsurance for the kidney disease patient education services, starting in MY3.

(1) Kidney Disease Patient Education Services Telehealth Waiver

CMS proposed to amend § 512.397 to add a waiver of certain telehealth requirements to provide qualified staff, as we proposed to define for purposes of the ETC Model at § 512.310 as described below, the flexibility to furnish kidney disease patient education services via telehealth for the reasons described above (86 FR 36392). Specifically, we proposed to waive the geographic and site of service originating site requirements in sections 1834(m)(4)(B) and 1834(m)(4)(C) of the Act, and in our regulations at 42 CFR 410.78(b)(3) and (4), for kidney disease patient education services furnished via telehealth. We stated, in the CY 2022 ESRD PPS proposed rule, that we believe the kidney disease patient education services telehealth waiver would allow more Medicare beneficiaries to receive kidney disease patient education services via telehealth by removing the originating site restrictions, thus allowing for the beneficiary to be located anywhere, and including at a site not specified in § 410.78(b)(3) of our regulations; and by allowing for the beneficiary to be located outside of a rural area. We also proposed to waive the requirement in section 1834(m)(2)(B) of the Act and 42 CFR 414.65(b) such that CMS would not pay an originating site facility fee for kidney disease patient education services furnished via telehealth to a beneficiary at a site not specified in § 410.78(b)(3) of our regulations under this proposed waiver, if finalized. However, we did not propose to waive the requirement under section 1834(m)(1) of the Act and 42 CFR 410.78(b) that telehealth services be furnished via an ''interactive telecommunications system,'' as that term is defined in § 410.78(a)(3) to mean multimedia communications equipment

that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Accordingly, we proposed that we would continue to require that the kidney disease patient education services furnished via telehealth be provided through an interactive telecommunications system; audio-only telehealth services would not be permitted.

We proposed that kidney disease patient education services could be furnished via telehealth only by qualified staff. We noted, in the CY 2022 ESRD PPS proposed rule, that we used the terms ''clinical staff'' and ''qualified staff'' in the Specialty Care Models final rule, but did not provide definitions of these terms. For clarity, we proposed to define ''clinical staff'' and ''qualified staff'' in 42 CFR 512.310. We proposed to define ''clinical staff'' to mean a licensed social worker or registered dietician/nutrition professional who furnishes services for which payment may be made under the physician fee schedule under the direction of and incident to the services of the Managing Clinician who is an ETC Participant. We proposed to define the term clinical staff in this manner to describe those clinicians who are authorized to furnish kidney disease patient education services only pursuant to the waiver specified at § 512.390(b)(1)—namely licensed social workers and registered dieticians/nutrition professionals. The remaining clinicians currently specified in § 512.390(b)(1)—doctors, physician assistants, nurse practitioners, and clinical nurse specialists—fall within the existing definition of qualified person at 42 CFR 410.48(a). We therefore proposed to define ''qualified staff'' to mean both clinical staff and any qualified person (as defined at § 410.48(a) of our regulations) who is an ETC Participant.

We sought comment on our proposal to waive the originating site requirements for telehealth services to allow qualified staff to furnish kidney disease patient education services via telehealth to a beneficiary regardless of where the beneficiary is geographically located such that kidney disease patient education services could be furnished via telehealth regardless of the beneficiary's location, including at a site not specified in § 410.78(b)(3) of our regulations. We further sought comment on our proposal to waive the originating site facility fee requirements such that CMS would not pay an originating site facility fee for kidney disease patient education services furnished via telehealth to a beneficiary at a site not specified in § 410.78(b)(3) of our regulations.

The following is a summary of the comments received on our proposed definitions of ''qualified staff'' and ''clinical staff,'' as well as our proposal to waive certain requirements for furnishing kidney disease patient education services such that they can be furnished via telehealth, and our responses.

Comment: A few commenters expressed support for the proposed definitions of ''clinical staff'' and ''qualified staff.'' One such commenter reasoned that these definitions would provide clarity on which clinicians are authorized to furnish kidney disease patient education services pursuant to the waivers implemented in the ETC Model.

Response: We agree that the proposed definitions of ''clinical staff'' and ''qualified staff'' add clarity regarding the types of staff authorized to furnish kidney disease patient education services under the ETC Model waivers implemented in § 512.397(b) of our regulations.

Comment: Many commenters expressed support for the use of telehealth in general, noting that telehealth is particularly good for kidney patients, especially kidney patients who live in rural areas or otherwise face barriers to accessing care. In addition, many commenters expressed support for the specific telehealth waiver in the CY 2022 ESRD PPS proposed rule. Two such commenters reasoned that the proposed telehealth waiver would materially increase attributed beneficiaries' access to kidney disease patient education services. A few commenters who expressed support reasoned that the proposed telehealth waiver would address some barriers to access such services for attributed beneficiaries, such as lack of reliable transportation, lack of childcare, inability to take time away from work, and other socioeconomic barriers, and would afford attributed beneficiaries the choice to receive kidney disease patient education services in a location of their choice. Several commenters referenced the positive experience with and benefits of increased access to telehealth during the PHE. A few commenters expressed support for the proposed telehealth waiver because they believed it would increase the utilization of kidney disease patient education services, which they deem an important benefit.

One commenter expressed support for the proposed telehealth waiver because they believe it will both allow more beneficiaries to receive kidney disease patient education services and advance health equity. Another commenter expressed support for the proposed telehealth waiver because they believe it would help address the challenge of increasing rates of kidney disease in rural areas.

Response: We appreciate the comments and support. We agree with the reasons cited by commenters in support of telehealth generally and the proposed telehealth waiver specifically. However, because the COVID–19 PHE and the section 1135(b)(8) waiver of geographic and site of service restrictions for telehealth originating sites in section 1834(m)(4)(C) of the Act are still ongoing, as described in greater detail below, we are modifying our proposal such that the proposed ETC telehealth waiver policy will apply beginning upon the expiration of the COVID–19 PHE, rather than beginning in MY3 as proposed.

Comment: One commenter expressed support for CMS's proposal to waive the requirements in Section 1834(m)(2)(B) of the Act and 42 CFR 414.65(b) so that CMS does not pay an originating site facility fee for kidney disease patient education services furnished via telehealth at a site not specified in § 410.78(b)(3) of our regulations.

Response: We appreciate the commenter's support.

Comment: One commenter expressed opposition to CMS's proposal to waive the originating site fee when telehealth services are offered under the ETC Model's telehealth waiver for kidney disease patient education services furnished via telehealth at a site not specified in § 410.78(b)(3) of our regulations. The commenter stated that the originating site fee was not waived for telehealth services furnished under the section 1135(b)(8) telehealth waiver in effect during the COVID PHE. The commenter also stated that the inclusion of the originating site fee provides an incentive for ETC Participants to offer kidney disease patient education services via telehealth to a broader population. The commenter further noted that, consistent with the proposed incentives to increase access to alternative renal replacement modalities for dual-eligible and LIS-eligible beneficiaries under the ETC Model, allowing ETC Participants to receive the originating site fee for services furnished under the Model's telehealth waivers could assist in increasing access to kidney disease patient education services for dual-eligible and LIS-eligible beneficiaries.

Response: While we appreciate the comment, we respectfully disagree.

First, to clarify, CMS did not propose to waive the originating site fee altogether when telehealth services are offered under the ETC Model's telehealth waiver for kidney disease patient education services. That is, CMS will still pay the originating site facility fee when kidney disease patient education services are furnished via telehealth at a site specified in § 410.78(b)(3) of our regulations. This is true even if the originating site is located in a geographic area not described in § 410.78(b)(4) of our regulations, as we have waived the geographic requirements in § 410.78(b)(4) for purposes of kidney disease patient education services furnished by qualified staff via telehealth in accordance with this section, regardless of the location of the beneficiary or qualified staff.

Second, while our proposal to implement a telehealth waiver under the ETC Model was informed by the section 1135(b)(8) telehealth waiver in effect during the COVID PHE, our proposed waiver was designed specifically for purposes of the ETC Model. We do not believe it is appropriate, under the ETC Model, for CMS to pay an originating site facility fee to an ETC Participant when an ETC Participant furnishes kidney disease patient education services to a beneficiary via telehealth at a site not specified in § 410.78(b)(3) of our regulations. We anticipate that when an ETC Participant is furnishing kidney disease patient education services to a beneficiary via telehealth at an originating site not specified in § 410.78(b)(3), the site will be the home of a beneficiary, or caregiver, family member, or friend of the beneficiary, or otherwise at a site not maintained by the ETC Participant. We believe this because, relative to many other Medicare services, renal replacement therapy (in particular home dialysis) require the involvement of a caregiver and other family and friends for support, both directly in assisting the beneficiary in learning how to perform home dialysis, and indirectly in preparing a beneficiary's residence for home dialysis (such as ensuring that there is adequate space available for equipment).

When an ETC Participant is furnishing kidney disease patient education services to a beneficiary via telehealth at an originating site not specified in § 410.78(b)(3), the ETC Participant is generally not providing administrative, clinical support, or overhead for the site where the beneficiary is located. Not paying an originating site facility fee under these circumstances is consistent with Medicare payment policy generally, as CMS does not pay an originating site facility fee for telehealth services furnished at an originating site that is the home of an individual.

While CMS does pay the originating site facility fee if the originating site is a patient's home that has been made provider-based to a hospital during the COVID–19 PHE, such a site is not technically considered the patient's home. Additionally, this policy was adopted in recognition of the changes in practice patterns adopted during the PHE for infection control purposes. CMS clarified that, during the COVID–PHE, if applicable requirements are met, a patient's home may be considered a provider-based department of a hospital (HOPD) in recognition that when a physician or other practitioner who ordinarily practices in the HOPD furnishes a telehealth service to a patient who is located in the home, the hospital would often still provide some administrative and technical support for the service (85 FR 27565). We do not believe this policy is appropriate for the ETC Model, as the ETC Model's telehealth waiver will not become effective until the COVID–19 PHE expires, as described elsewhere in this final rule.

Third, for calendar year 2021, the payment amount for the originating site facility fee is 80% of $27.02, or $21.62. It is possible (and indeed, we hope that) the telehealth waiver will increase clinically appropriate furnishing of kidney disease patient education services. We are concerned that paying the originating site facility fee for services furnished via telehealth at an originating site not specified in § 410.78(b)(3) would likely represent too large an impact on the ETC Model's savings estimates, potentially jeopardizing our ability to continue to test the model. In addition, we are concerned that permitting the originating site facility fee for kidney disease patient education services furnished via telehealth to a beneficiary at a site not specified in § 410.78(b)(3) of our regulations would increase the 20 percent coinsurance owed by a beneficiary when not reduced or waived by an ETC Participant pursuant to § 512.390(c). The increased coinsurance obligation may dissuade a beneficiary from accessing this important service.

For these reasons, we are finalizing our proposed waiver of the requirement in section 1834(m)(2)(B) of the Act and 42 CFR 414.65(b) such that CMS will not pay an originating site facility fee for kidney disease patient education services furnished via telehealth to a beneficiary at a site not specified in § 410.78(b)(3) of our regulations.

Comment: One commenter expressed support for CMS's proposal to not waive the requirement under section 1834(m)(1) of the Act and 42 CFR 410.78(b) that telehealth services be furnished via an ''interactive telecommunications system,'' as that term is defined in § 410.78(a)(3) to mean multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

Response: We agree that it is appropriate to continue to require that kidney disease patient education services furnished via telehealth be provided through an interactive telecommunications system, such that audio-only telehealth services are not permitted. We are concerned that audio-only kidney disease patient education services would not be effective in meaningfully educating beneficiaries on kidney disease given the complexity of the subject matter. We believe it is important that telehealth kidney disease patient education services include, or at least have the opportunity to include, images, demonstrations, and other visual cues to most effectively accomplish the objectives of kidney disease patient education services.

Comment: A few commenters expressed concern regarding our proposal to not waive the requirement under section 1834(m)(1) of the Act and 42 CFR 410.78(b) that telehealth services be furnished via an interactive telecommunications system, and recommended that CMS allow the provision of audio-only telehealth services for kidney disease patient education services. Two such commenters reasoned that not every beneficiary has access to interactive telecommunications systems, and one of whom further suggested that requiring the use of video systems would preclude those beneficiaries who may most need access to kidney disease patient education services from benefiting from the proposed telehealth waiver.

The same commenter additionally suggested that CMS should give ETC Participants the opportunity to determine how many beneficiaries would take advantage of audio-only kidney disease patient education services sessions to allow CMS to determine whether such services would represent an effective method of providing beneficiary education. Another commenter suggested that allowing audio-only telehealth services

for kidney disease patient education services would align with other proposed changes to the ETC Model, which, the commenter points out, include a significant focus on health equity.

Response: We do not believe waiving the requirement that telehealth services be furnished via an interactive telecommunications system is necessary to test the ETC Model, either Model-wide or on an ETC Participant-specific basis. We believe that the telehealth waiver, as proposed, will accomplish the goal of increasing access to kidney disease patient education services, and we are interested in learning whether this goal is realized through this particular proposed waiver. While we share the concerns raised by commenters that not every beneficiary has access to an interactive telecommunications system, we are also concerned that audio-only kidney disease patient education services would not be effective in meaningfully educating beneficiaries on kidney disease. As such, we do not agree, at this time, that allowing audio-only telehealth services for kidney disease patient education services would align with CMS's focus on health equity insofar as such a policy may result in beneficiaries of lesser means systematically receiving lower quality kidney education. However, CMS will monitor the extent to which there are barriers in access to interactive telecommunciations systems among attributed beneficiaries. Based on our experience testing this telehealth waiver in the ETC Model, we may consider waiving the requirement that telehealth services be furnished via an interactive telehealth communications system, or other waivers or initiatives necessary to mitigate or eliminate barriers to accessing interactive telehealth communications systems, at a later time, either as part of the ETC Model test or in another initiative.

Final Rule Action: After considering public comments, we are finalizing our proposal in our regulation at § 512.397(b)(5) to waive geographic and site of service originating site requirements in section 1834(m)(4)(B) and 1834(m)(4)(C) of the Act and § 410.78(b)(3) and (4) of our regulations for the purposes of kidney disease patient education services furnished by qualified staff via telehealth in accordance with § 512.397, regardless of the location of the beneficiary or qualified staff, and the requirement in section 1834(m)(2)(B) of the Act and § 414.65(b) of our regulations that CMS pay a facility fee to the originating site with respect to telehealth services furnished to a beneficiary in accordance with § 512.397 at an originating site that is not one of the locations specified in § 410.78(b)(3), with modification. Specifically, we are modifying our proposed regulatory text at § 512.397(b)(5) to change the date on which these waivers become effective. We are modifying both instances of the phrase, ''Beginning January 1, 2022,'' proposed in § 512.397(b)(5) to the phrase ''Beginning the upon the expiration of the Public Health Emergency (PHE) for the COVID–19 pandemic[.]''

(2) Kidney Disease Patient Education Services Beneficiary Coinsurance Waiver

Available data and scholarly research suggest that there is a significant relationship between socioeconomic status and prevalence of CKD. For example, evidence suggests that CKD is more prevalent among individuals with lower income.[276] In addition, at least one study suggests that as an individual's CKD severity increases (for example, from CKD III to CKD IV), the likelihood of the CKD patient falling into poverty increases.[277] In light of this research, we stated in the CY 2022 ESRD PPS proposed rule that CMS believes that cost represents a meaningful barrier for beneficiaries in accessing kidney disease patient education services (86 FR 36393). While we also stated that there does not appear to be any research that explicitly investigates to what extent cost barriers preclude access to kidney disease patient education services, the identified relationship between household income or poverty status and prevalence of CKD suggests that cost is an important factor when considering a beneficiary's access to kidney disease patient education services.

Under section 1833 of the Act, the amounts paid by Medicare for kidney disease patient education services are equal to 80 percent of the applicable payment amount; beneficiaries are thus subject to a 20 percent coinsurance for kidney disease patient education services. Kidney disease patient education services can be billed under G0420 for an individual session, or under G0421 for a group session. The current national unadjusted payment for G0420 under the CY 2021 Physician Fee Schedule is $114.10; for G0421, it is $27.22. As such, a beneficiary would be required to pay $22.82 for an individual session of kidney disease patient education services or $5.44 for kidney disease patient education services furnished to a group, which may be higher or lower depending on certain factors, such as the geographic location of the beneficiary. Medicare covers up to six kidney disease patient education services for an individual beneficiary during that beneficiary's lifetime, meaning that a beneficiary may be required to pay $136.92 if six individual kidney disease patient education services are clinically appropriate for that beneficiary, or $32.64 if six group kidney disease patient education services are clinically appropriate for that beneficiary.

In the CY 2022 ESRD PPS proposed rule, we stated that we believe that it is necessary, for purposes of testing the ETC Model, to permit ETC Participants the flexibility to reduce or waive the 20 percent coinsurance requirement for kidney disease patient education services. We also stated that we believe this patient incentive would increase the provision of kidney disease patient education services to beneficiaries, given the relationship between income or poverty and prevalence of CKD, and the relationship between kidney disease patient education services and progression of CKD. In the CY 2022 ESRD PPS proposed rule, we stated that CMS had determined that, if this proposal were finalized, this CMS-sponsored patient incentive would advance the ETC Model's goal of increasing access to kidney disease patient education services, and to making beneficiaries more aware of their choices in preparing for kidney treatment, including the choice of receiving home dialysis, self-dialysis, or nocturnal in-center dialysis, rather than traditional in-center dialysis.

Accordingly, we proposed at § 512.397(c) to permit, beginning January 1, 2022, ETC Participants to reduce or waive the beneficiary coinsurance obligations for kidney disease patient education services furnished to an eligible beneficiary who does not have secondary insurance on the date the kidney disease patient education services are furnished if

[276] Table 1.2 in United States Renal Data System, *2020 Annual Report, Chronic Kidney Disease: Chapter 1, CKD in the General Population,* available at *https://adr.usrds.org/2020/chronic-kidney-disease/1-ckd-in-the-general-population* (indicating that the prevalence of CKD in those above the poverty line is 14.4 percent while the prevalence of CKD in those below the poverty line is 17.4 percent. *See also* McClellan, W.M., et al., *Poverty and Racial Disparities in Kidney Disease: The REGARDS Study, Am. J Nephrol,* 2010, Volume 32, Issue 1, pages 38–46, available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2914392/* (providing data suggesting that lower household income is associated with higher prevalence of CKD).

[277] Morton, R.L, et al., *Impact of CKD on Household Income,* Kidney International Reports, Volume 3, Issue 3, 2018, pages 610–618, available at *https://www.sciencedirect.com/science/article/pii/S2468024917304795?via%3Dihub.*

certain conditions are satisfied. We refer to this patient incentive herein as the ''kidney disease patient education services coinsurance patient incentive.'' We stated in the CY 2022 ESRD PPS proposed rule that we expected to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) would be available to protect cost-sharing support that is furnished in compliance with ETC Model requirements with respect to kidney disease patient education services. We noted that if CMS were to make such a determination, the safe harbor for CMS-sponsored model patient incentives would protect an ETC Participant, as that term is defined at § 512.310, who offers a reduction or waiver of coinsurance for kidney disease patient education services to beneficiaries who are eligible to receive kidney disease patient education services, including those eligible pursuant to the waiver described in § 512.397(b)(2), and who do not have secondary insurance on the date that the kidney disease patient education services were furnished.

We proposed that the kidney disease patient education services coinsurance patient incentive would be available to the ETC Participant for kidney disease patient education services furnished by an individual or entity who is qualified staff. We stated that this proposal would align with the individuals who may furnish kidney disease patient education services under § 512.397(b) of this subpart, which are we replacing in its entirety to standardize certain terms and add clarity, as described in greater detail in the CY 2022 ESRD PPS proposed rule and in section VIII.b.3 of this final rule.

We proposed to limit the kidney disease patient education services coinsurance patient incentive to beneficiaries who do not have secondary insurance, because secondary insurance typically provides cost-sharing support of the type CMS proposed in the CY 2022 ESRD PPS proposed rule. In the CY 2022 ESRD PPS proposed rule, we stated that we also believe that limiting the kidney disease patient education services coinsurance patient incentive to beneficiaries without secondary insurance would better ensure that only beneficiaries who need cost-sharing support would receive it, rather than permitting cost-sharing support for all beneficiaries for whom kidney disease patient education services are clinically appropriate.

We also proposed that the kidney disease patient education services coinsurance patient incentive would be available only for kidney disease patient education services that were furnished in compliance with the applicable provisions of § 410.48 of our regulations, which includes a requirement that a beneficiary obtain a referral from the physician (as defined in section 1861(r)(1) of the Act) managing the beneficiary's kidney condition in order for the beneficiary to be eligible to receive kidney disease patient education services. We proposed to include this requirement because we waived some but not all provisions of § 410.48, and because, as stated in the CY 2022 ESRD PPS proposed rule, we believe that the requirement that the beneficiary receive a referral from their physician is important for ensuring that kidney disease patient education services are furnished only to beneficiaries for whom it is clinically appropriate.

We proposed that such coinsurance support would be permitted for the kidney disease patient education services offered either in-person or via telehealth, and that it would be permitted for both individual sessions and group sessions. However, in the CY 2022 ESRD PPS proposed rule we considered limiting the coinsurance support to kidney disease patient education services that are furnished to an individual beneficiary, rather than allowing the coinsurance support for such services furnished either individually or to a group. We noted that the cost burden on beneficiaries who receive kidney disease patient education services in a group setting is much lower than it is on beneficiaries who receive kidney disease patient education services individually. However, as we stated in the CY 2022 ESRD PPS proposed rule, we are concerned that any cost barrier to kidney disease patient education services, even if low, represents a meaningful barrier to some beneficiaries who would otherwise elect to receive such services. We solicited comments on this issue.

We proposed that an ETC Participant that offers coinsurance support for kidney disease patient education services would be required to maintain records of certain information. Specifically, we proposed that an ETC Participant that offers the kidney disease patient education services coinsurance patient incentive would be required to maintain records of the following: The identity of the qualified staff who furnished the kidney disease patient education services for which the coinsurance was reduced or waived; the date the kidney disease patient education services coinsurance patient incentive was provided; the identity of the beneficiary to whom the kidney disease patient education services coinsurance patient incentive was provided; evidence that the beneficiary who received the kidney disease patient education services coinsurance patient incentive was eligible to receive the kidney disease patient education services and did not have secondary insurance; and the amount of the kidney disease patient education services coinsurance patient incentive reduced or waived by the ETC Participant. We proposed to require an ETC Participant that offers this kidney disease patient education services coinsurance patient incentive to maintain and provide the government with access to these records in accordance with 42 CFR 512.135(b) and (c).

We further proposed in proposed 42 CFR 512.160(b)(6)(ii) that, for the ETC Model only, CMS could suspend or terminate the ability of an ETC Participant to offer the kidney disease patient education services coinsurance patient incentive if CMS determined that any grounds for remedial action exist pursuant to § 512.160(a).

We stated in the CY 2022 ESRD PPS proposed rule that, in lieu of a waiver of certain fraud and abuse provisions in sections 1128A and 1128B of the Act, CMS may determine that the anti-kickback statute safe harbor CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect the reduction or waiver of coinsurance for kidney disease patient education services permitted under the ETC Model final rule, if issued. We stated in the CY 2022 ESRD PPS proposed rule that we expect to determine that the CMS-sponsored model safe harbor will be available to protect the reduction or waiver of coinsurance that satisfies the requirements of such safe harbor and the provisions of proposed § 512.397(c)(1). We proposed that, if we make this determination, we would specify in regulation text at § 512.397(c)(4) that the safe harbor is available.

We also considered, in the CY 2022 ESRD PPS proposed rule, prohibiting on an ESRD facility or other entity from providing qualified staff or the ETC Participant with financial support to enable such qualified staff or ETC Participant to provide the kidney disease patient education services coinsurance patient incentive. As we stated in the CY 2022 ESRD PPS proposed rule, CMS is concerned that permitting such financial support may encourage unlawful or abusive

arrangements designed to induce or reward referrals for Federal health care program business. We solicited comments on whether this prohibition is necessary to safeguard against fraud and abuse or if other laws effectively provide sufficient protection.

We also considered waiving Medicare payment requirements such that CMS would pay the full amount of the kidney disease patient education services furnished to a beneficiary who does not have secondary insurance, rather than just 80 percent of the amount. Under section 1115A(d)(1) of the Act, the Secretary may waive such requirements of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii) of the Act, and certain provisions of section 1934 of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act respect to testing models described in section 1115A(b) of the Act. As we stated in the CY 2022 ESRD PPS proposed rule, this is the authority under which we would waive such Medicare payment requirements. We stated that, under such a policy, Medicare would pay 100 percent of the payment amount for kidney disease patient education services furnished by Managing Clinicians who are ETC Participants to beneficiaries who do not have secondary insurance, and such beneficiaries would have no cost-sharing obligation for that benefit. However, in the CY 2022 ESRD PPS proposed rule, we determined that this policy would likely represent too large an impact to the ETC Model's savings estimates, and thus would potentially jeopardize our ability to continue to test the ETC Model, if such a policy were finalized.

Given the proposed policies related to programmatic waivers and additional flexibilities available under the ETC Model, we proposed to modify the title of § 512.397 from ''ETC Model Medicare program waivers'' to ''ETC Model Medicare program waivers and additional flexibilities.'' We proposed this change so that the section title would more accurately reflect the contents of the section if our proposed kidney disease patient education services coinsurance patient incentive is finalized.

We solicited public comments on our proposal to allow qualified staff, as we proposed to define the term under § 512.310, to offer coinsurance support for kidney disease patient education services to beneficiaries who are eligible for such services, including those eligible under § 512.397(b)(2), and who do not have secondary insurance on the date the kidney disease patient education services are furnished. We also solicited comment on our proposal to require the ETC Participant to maintain and provide the government with access to records regarding the use of the kidney disease patient education services coinsurance patient incentive.

The following is a summary of the comments received on our proposal to allow qualified staff to offer coinsurance support for kidney disease patient education services to beneficiaries who do not have secondary insurance and our responses.

Comment: Many commenters expressed that cost is a barrier for at least some beneficiaries in accessing kidney disease patient education services.

We also received many comments expressing support for our proposal to allow an ETC Participant to reduce or waive a beneficiary's coinsurance for kidney disease patient education services furnished by qualified staff, in accordance with § 512.397(b)(1), under the ETC Model. One commenter expressed support for the proposal noting that many kidney patients have limited resources, and may choose to forgo education to dedicate such resources to obtaining medications and medical care. Another commenter similarly expressed support because they believe the proposed coinsurance patient incentive would increase access to kidney disease patient education services by removing cost barriers. Yet another commenter expressed support for the proposal, noting that coinsurance payments can burden beneficiaries, particularly those in the most underserved communities. The same commenter also expressed a belief that the proposal will advance the ETC Model's goal of increasing access to kidney disease patient education services, and of making beneficiaries more aware of their choices in preparing for kidney treatment, including the choice to receive home dialysis, self-dialysis, or nocturnal in-center dialysis, rather than traditional in-center dialysis.

Response: We agree with the reasons the commenters provided for their support, which is why we proposed and are now finalizing a policy allowing an ETC Participant to reduce or waive a beneficiary's coinsurance for kidney disease patient education services furnished by qualified staff, in accordance with § 512.397(b)(1), under the ETC Model.

Comment: A few commenters expressed opposition to our proposal to limit the proposed coinsurance patient incentive to beneficiaries without secondary insurance. One such commenter expressed that offering the coinsurance patient incentive to more beneficiaries would improve uptake of kidney disease patient education services, which is important given both the historically low percentage of eligible beneficiaries who have been provided kidney disease patient education services, and the important of pre-dialysis education to help beneficiaries make informed treatment decisions. Another commenter stated that, unless CMS can guarantee that Medicaid would cover the coinsurance amount for dually-eligible beneficiaries, the coinsurance patient incentive should be broadened to cover dual-eligible and LIS-eligible beneficiaries, reasoning that such a proposal would ensure these groups' access to appropriate education.

Response: We proposed to restrict the coinsurance patient incentive to only those beneficiaries without secondary insurance because secondary insurance typically covers this type of cost sharing. That is, providing cost sharing support would be redundant for beneficiaries with secondary coverage. Because a beneficiary's secondary insurance will likely cover cost sharing for kidney disease patient education services, we believe our proposed policy would generally succeed in increasing access to beneficiaries by removing cost barriers for those who are obligated to pay cost sharing because it is not covered by their insurance. However, the commenter who expressed concern that Medicaid may not necessarily provide cost-sharing support for kidney disease patient education services raises an important point.

Medicaid will not necessarily cover the coinsurance amount for dual-eligible beneficiaries' kidney disease patient education services, because not all Medicare Savings Programs cover Medicare coinsurance and Medicaid coverage of cost sharing generally varies by State. In some states, Medicaid would cover the cost sharing for kidney disease patient education services, while in other states it would not. In light of this State variation, and to further our stated goal of providing cost sharing support to beneficiaries who are obligated to pay cost sharing because it is not covered by their insurance, we are finalizing a policy that restricts the coinsurance patient incentive to only those beneficiaries without secondary insurance that provides cost sharing support for kidney disease patient education services.

Comment: Two commenters suggested that CMS include both individual and group kidney disease patient education services sessions in the coinsurance patient incentive. One such commenter

reasoned that, while group kidney disease patient education services sessions have minimal costs, even nominal costs can quickly add up for beneficiaries with a chronic condition, especially for beneficiaries with kidney disease, who often see multiple providers and fill multiple prescriptions each month.

Response: We agree with the commenters that, even if the coinsurance amount for group kidney disease patient education services sessions is minimal, these costs can indeed present meaningful barriers to some beneficiaries, including the beneficiaries with multiple chronic conditions and beneficiaries with kidney disease. In light of these comments, we are finalizing our proposed kidney disease patient education services coinsurance patient incentive policy to permit cost sharing support for individual or group kidney disease patient education services sessions alike.

Comment: A few commenters requested clarification relating to our statement in the CY 2022 ESRD PPS proposed rule that we are considering prohibiting an ESRD facility or other entity from providing the ETC Participant with qualified staff or financial support that the ETC Participant would use in furnishing kidney disease patient education services and the proposed cost sharing support. Two such commenters requested clarification specifically on whether ESRD facilities or other entities could enter into arrangements with ETC Participants to provide certain services at fair market value, and proposed that CMS permit such arrangements so long as the services were indeed provided at fair market value. These commenters reasoned that ESRD facilities sometimes provide physician practices with clinical staff under a personal services or other similar arrangement that complies with the Anti-Kickback Statute, the physician self-referral law, and other requirements. The commenters noted that such arrangements often occur when the dialysis facility maintains staff with pertinent expertise, such as expertise with educating patients about chronic kidney disease. These comments expressed a belief that a dialysis facility providing staffing at fair market value would not constitute providing ''financial support'' as CMS expressed concern about in the CY 2022 ESRD PPS proposed rule, so long as the arrangement complies with all applicable fraud and abuse requirements.

Another commenter asserted that the CY 2022 ESRD PPS proposed rule did not clarify whether CMS is considering prohibiting ESRD facilities from providing qualified staff to ETC Participants without compensation, or whether CMS is considering prohibiting dialysis facilities from entering into a payment contract with ETC Participants to provide such services. The commenter expressed the belief that providing staff without compensation would be inappropriate and inconsistent with current fraud and abuse laws, but suggested that a prohibition on contractual payment arrangements between dialysis facilities and ETC Participants for the purpose of providing qualified staff to deliver kidney disease patient education services runs counter to CMS's goals in proposing the kidney disease patient education services coinsurance patient incentive. The commenter expressed the belief that current fraud and abuse rules, combined with the requirements CMS currently imposes relating to kidney disease patient education services, offer sufficient protection against potentially problematic arrangements.

Response: We thank the commenters for their feedback and information. We understand that ESRD facilities and other entities sometimes enter into arrangements with clinicians or other parties to provide certain services. We recognize that some ETC Participants may wish to furnish kidney disease patient education services using staff or other resources furnished under a contractual arrangement with an ESRD facility or other entity. We are concerned, however, that even if such arrangements are structured to comply with all applicable fraud and abuse laws, they could nevertheless result in program abuse. Specifically, such arrangements could operate to circumvent the statutory prohibition against dialysis facilities furnishing kidney disease patient education services. For example, the staff or resources furnished to the ETC Participant from an ESRD facility or related entity could be used to market a specific ESRD facility or chain of ESRD facilities to beneficiaries who may need to choose a dialysis facility in the future.

We do not believe ETC Participants should obtain safe harbor protection for the reduction or waiver of cost-sharing on kidney disease patient education services if such services were furnished by personnel leased from an ESRD facility or related entity. Accordingly, we are adding a provision at § 512.397(c)(1)(ii) to require that the qualified staff furnishing the kidney disease patient education services for which an ETC Participant reduces or waives cost sharing must not be leased from or otherwise provided by an ESRD facility or related entity. For purposes of this provision, a related entity would include any entity that is directly or indirectly owned in whole or in part by an ESRD facility. We believe this aligns with the statutory intent to prohibit ESRD facilities from furnishing kidney disease patient education services.

Comment: Two commenters advocated that CMS should prohibit ESRD facilities from effectively making up the financial difference an ETC Participant would experience by waiving or reducing a beneficiary's coinsurance amount for kidney disease patient education services. One commenter recommended that CMS not finalize a prohibition on an ESRD facility or other entity from providing financial support to enable ETC Participants to reduce or eliminate cost sharing for kidney disease patient education services. This commenter believed that such financial support arrangements should be permitted as long as they comply with all applicable law.

Response: We agree that ESRD facilities should not be permitted to pay ETC Participants in an effort to offset the financial impact of the ETC Participant's lost cost-sharing revenues. We question whether the receipt of any such remuneration could comply with applicable fraud and abuse laws. Such arrangements, including those in which an entity other than an ESRD facility reimburses the ETC Participant for lost cost-sharing revenues, could result in inappropriate referrals of Federal health care program business, patient steering, corruption of medical judgment, and other abuses. Indeed, the receipt of any such remuneration could implicate and potentially violate the Federal Anti-Kickback statute (42 U.S.C. 1320a–7b(b)), and by extension the False Claims Act (31 U.S.C. 3729–3733 and 42 U.S.C. 1320a–7b(g)).

Moreover, we do not believe that permitting such arrangements is necessary to test the model. We are testing a narrowly-tailored exception to the usual prohibition against the reduction or waiver of beneficiary cost-sharing obligations. Permitting any individual or entity other than the ETC Participant to finance cost-sharing support is beyond the scope of the policy we are testing. Accordingly, we are persuaded that safe harbor protection for cost-sharing support furnished by ETC Participants to beneficiaries for kidney disease patient education services should be contingent

on the ETC Participant bearing the full cost of the copayment reduction or waiver. That is, the copayment reduction or waiver may not be financed by a third party, including but not limited to an ESRD facility or related entity. Therefore, we are finalizing at § 512.397(c)(1)(v) a new safeguard that requires the ETC Participant to bear the full cost of any cost-sharing reduction or waiver for kidney disease patient education services.

We note that we did not propose and are not finalizing any provision that would offer safe harbor protection for any arrangement between an ETC Participant and an ESRD facility or other entity. Under this final rule, the only arrangements that may qualify for protection under the safe harbor for CMS-sponsored model patient incentives are arrangements between the ETC Participant and the beneficiary for whom the ETC Participant reduced or waived the kidney disease patient education services coinsurance amount, provided that the arrangements comply with the requirements of the safe harbor as set forth at 42 CFR 1001.952(ii)(2) and the provisions of 512.397(c)(1).

Comment: Several commenters, including some commenters who expressed support for CMS's proposed coinsurance patient incentive policy, suggested that CMS instead waive Medicare payment requirements such that CMS would pay the full amount of the kidney disease patient education services furnished to a beneficiary who does not have secondary insurance, rather than just 80 percent of the amount. One such commenter expressed concern that ETC Participants will not have the financial resources to forgo all or a portion of a beneficiary's coinsurance and will therefore be unable to use the flexibility afforded under this patient incentive to reduce the financial burden of beneficiaries. Two such commenters expressed concern that while waiving coinsurance would serve to increase beneficiary use of kidney disease patient education services, ETC Participants and their qualified staff may lack willingness to provide kidney disease patient education services at a rate that, according to the commenters, would not adequately cover their costs, and that this would diminish the availability of kidney disease education to beneficiaries. Further, these commenters suggested that CMS providing the full payment amount for kidney disease patient education services would alleviate CMS's stated concern that the proposed coinsurance patient incentive could incentivize improper financial assistance from ESRD facilities and other entities. These commenters suggested that, to counterbalance CMS's stated concern that such payment waivers would result in additional Medicare costs under the ETC Model, CMS could exclude the 20 percent coinsurance amounts that CMS would cover under this alternative proposal from ETC cost calculations during the ETC Model period to determine whether this limited additional investment results in improved beneficiary quality of care and an overall cost of care reduction. Two commenters stated that CMS should pay the full amount of the kidney disease patient education services furnished to a beneficiary who does not have secondary insurance because, according to the commenters, the requirements needed to qualify for the coinsurance patient incentive are overly onerous and may present an additional barrier to access to kidney disease patient education services.

Response: We considered this alternative policy in the CY 2022 ESRD PPS proposed rule, but concluded that it would represent too large an impact to the ETC Model's potential savings (86 FR 36394–36395). We believe that the policy we are finalizing, wherein an ETC Participant may reduce or waive cost sharing for kidney disease patient education services, strikes the appropriate balance in providing a new tool for ETC Participants to engage beneficiaries while also helping support the success of the Model. While a policy under which Medicare pays the full amount of the kidney disease patient education services amount, rather than 80 percent of the amount, may result in the highest number of beneficiaries receiving kidney disease patient education services, we believe that the kidney disease patient education services coinsurance patient incentive will result in more beneficiaries receiving kidney disease patient education services compared to the status quo, and will do so without detracting from the savings estimates of the ETC Model.

Moreover, we disagree with the commenters who suggested that CMS could exclude the 20 percent coinsurance payment paid by CMS from the Model's cost calculations. We cannot exclude the 20 percent coinsurance payment paid by CMS from the Model's cost calculations. If we implemented the payment waiver as recommended by the commenters, CMS would need to account for these costs when determining the Model's overall impact on Medicare program expenditures. However, CMS may consider implementing a payment waiver like the alternative we considered in the CY 2022 ESRD PPS proposed rule in a future model or initiative to determine whether such an investment results in improved beneficiary quality of care and an overall cost of care reduction.

Finally, we understand the commenters' concern that the proposed kidney disease patient education services coinsurance patient incentive imposes an administrative burden on ETC Participants who choose to furnish the patient incentive, but we believe that the benefits of reducing cost barriers to kidney disease patient education services through furnishing the kidney disease patient education services coinsurance patient incentive will outweigh this administrative burden. Commenters have expressed that beneficiaries who undergo kidney disease education are more likely to choose home dialysis, and to the extent this is the case, an ETC Participant that furnishes the coinsurance patient incentive might recover the direct and indirect (administrative) costs associated with cost-sharing waivers for such services if the ETC Participant qualifies for a positive PPA. In addition, while we agree that the alternative policy considered in the CY 2022 ESRD PPS proposed rule would alleviate the fraud and abuse concerns we articulated in that rule, we have concluded that existing law and the safeguards finalized in this rule provide sufficient protection against such fraud and abuse.

Final Rule Action: After considering public comments, we are finalizing with modification our proposal to add § 512.397(c) regarding an ETC Participant's ability to reduce or waive the 20 percent coinsurance obligation for kidney disease patient education services. Specifically, we are adding § 512.390(c)(1), which permits ETC Participants to reduce or waive beneficiary cost sharing for kidney disease patient education services furnished on or after January 1, 2022 if the following conditions are satisfied: (i) The individual or entity that furnished the kidney disease patient education services is qualified staff; (ii) the qualified staff are not leased from or otherwise provided by an ESRD facility or related entity; (iii) the kidney disease patient education services were furnished to a beneficiary described in § 410.48(b) or § 512.397(b)(2) who did not have secondary insurance that provides cost-sharing support for kidney disease patient education services on the date the services were furnished; (iv) the kidney disease patient education services were furnished in compliance with the applicable provisions of § 410.48 and § 512.397(b); and (v) the

ETC Participant bears the full cost of the waiver or reduction of the 20 percent coinsurance requirement under section 1833 of the Act and such reduction or waiver is not financed by a third party, including but not limited to an ESRD facility or related entity.

Under new § 512.397(c)(2), we are finalizing with modification our proposed requirements regarding documentation retention and government access to records regarding the reduction or waiver of beneficiary cost-sharing obligations for kidney disease patient education services furnished under the ETC model. Specifically, we are modifying § 512.397(c)(2)(iii) to read, ''Evidence that the beneficiary who received the kidney disease patient education services coinsurance waiver was eligible to receive the kidney disease patient education services under the ETC Model and did not have secondary insurance that provides cost-sharing support for kidney disease patient education services on the date the services were furnished.''

Lastly, we are finalizing without change our proposal to include at § 512.397(c)(3) a provision stating that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives is available to protect kidney disease patient education coinsurance waivers that satisfy the requirements of such safe harbor and the conditions set forth in § 512.397(c)(1).

(3) Revising Language Providing Other ETC Model Medicare Program Waivers

We proposed to revise § 512.397(b)(1) through (4) in their entirety to accomplish a few goals (86 FR 36395). First, we proposed to make conforming changes throughout § 512.397(b) to the manner in which CMS discusses kidney disease patient education services. Currently, § 512.397(b) includes references to ''KDE services,'' ''the KDE benefit,'' ''KDE sessions,'' and, simply, ''KDE.'' CMS would change all of these references to ''kidney disease patient education services'' for clarity and to conform with the term used elsewhere in our regulations.

In addition, we proposed to make conforming changes through § 512.397(b) to the manner in which CMS discusses the individuals who are permitted to furnish kidney disease patient education services under the ETC model programmatic waivers. Specifically, as discussed previously, CMS proposed to add definitions for ''clinical staff'' and ''qualified staff'' in the CY 2022 ESRD PPS proposed rule, as CMS believes clarifying how CMS discusses these individuals in § 512.397(b) will enhance clarity. Finally, we proposed to remove the ''clinic/group practice'' from the list of individuals or entities that are permitted to furnished kidney disease patient education services under the ETC Model programmatic waivers, and to remove the waiver of 42 CFR 410.48(c)(2)(i) from § 512.397(b)(1) of this part. We stated in the CY 2022 ESRD PPS proposed rule that we believe that its inclusion of clinic/group practices previously was in error, and we noted that a clinic/group practice is not able to furnish or bill for kidney disease patient education services under existing law and that CMS did not intend for the waiver described in § 512.397(b) to permit anyone other than a clinician to furnish kidney disease patient education services. Because the waiver of the requirements under 42 CFR 410.48(c)(2)(i) was implemented only to broaden the ''qualified person'' that could furnish kidney disease patient education services pursuant to § 512.397(b)(1) to include a clinic/group practice, we proposed to remove references to 42 CFR 410.48(c)(2)(i) in § 512.397(b)(1) of this part.

We solicited public comments on these proposed changes to § 512.397(b) to make conforming and clarifying changes to the manner in which CMS discusses kidney disease patient education services and the individuals who are permitted to furnish kidney disease patient education services under the ETC Model waivers described in § 512.397(b), and to our proposed removal of ''clinic/group practice'' from the list of individuals or entities who may, under the ETC Model waivers described in § 512.397(b), furnish kidney disease patient education services.

CMS did not receive any comments regarding the proposed conforming and clarifying changes to § 512.397(b) of our regulations. However, we did receive some comments suggesting that CMS make additional changes to the kidney disease patient education services waivers in § 512.397(b). The following is a summary of those comments and our responses.

Comment: We received a few comments asking CMS to further increase the scope of the kidney disease patient education services waivers, specifically in order to allow additional clinicians and healthcare sites to furnish kidney disease patient education services, including ESRD facilities, home dialysis nurses, and Certified Nephrology Nurses (CNNs).

Response: While we understand the commenters' interest in increasing even further the types of clinicians and entities that may furnish kidney disease patient education services under the ETC Model, we believe that our current policy provides sufficient flexibility to test the Model. Accordingly, we are not updating § 512.397(b) at this time to add additional types of clinicians and entities that may furnish kidney disease patient education services under the Model.

Comment: We received several comments urging CMS not to grant a waiver to allow ESRD facilities to be able to bill for kidney disease patient education services, due to concerns about potential quality of education and the entrenchment of the existing dialysis market structure.

Response: We do not believe that a waiver of the requirement preventing ESRD facilities from billing for kidney disease patient education services is necessary for testing the model. ESRD facilities are already required to provide information to beneficiaries about their treatment modality options in the ESRD facility conditions for coverage at § 494.70(a)(7) and to develop and implement a plan of care that addresses the patient's modality of care, at § 494.90(a)(7), and the costs for doing so are already included in the payment for the ESRD PPS bundled payment. Accordingly, we are not modifying § 512.397(b) to permit ESRD facilities to furnish kidney disease patient education services under the Model at this time.

Comment: We received a few comments expressing concern about the quality of education that beneficiaries receive as part of kidney disease patient education services and urging that CMS create accredited curricula to ensure consistent education.

Response: We appreciate this feedback and are monitoring utilization of kidney disease patient education services to see potential effects on care. We believe that the required content for kidney disease patient education services, as set forth in 42 CFR 410.48(d), shows the minimum of what must be covered but urge interested stakeholders to consider creating a curriculum that could be used by Managing Clinicians and other qualified staff to administer kidney disease patient education services.

Comment: A few commenters suggested that CMS use its waiver authority to authorize referrals for kidney disease patient education services issued by nurse practitioners. Two such commenters also proposed that CMS use its waiver authority to additionally authorize physician assistants and clinical nurse specialists

to issue referrals for kidney disease patient education services.

Response: As required under 42 CFR 410.48(b)(2), Medicare Part B covers kidney disease patient education services only if the beneficiary obtains a referral from the physician managing the beneficiary's kidney condition. We did not consider issuing a waiver to broaden the categories of clinicians who could issue referrals for kidney disease patient education services in the CY 2022 ESRD PPS proposed rule. Moreover, we currently have no evidence to suggest that the waiver suggested by the commenters would be necessary solely for purposes of testing the model, as would be required to issue such a waiver under section 1115A(d)(1) of the Act. In addition, we do not currently have, and no commenter provided, evidence that broadening the categories of clinicians who could issue a referral for kidney disease patient education services would continue to ensure clinical appropriateness. As such, we will continue to require that the physician managing the beneficiary's kidney condition refer a beneficiary for kidney disease patient education services in order for Medicare to pay for such services as required under 42 CFR 410.48(b)(2). However, we will continue to consider the commenters' suggestions, and we may consider broadening the categories of clinicians who may issue a referral for kidney disease patient education services in future rulemaking.

Final Rule Action: After considering public comments, we are finalizing our proposal to make conforming and clarifying changes to our regulation at § 512.397(b), without modification. After considering public comments, we will not be altering the curriculum for kidney disease patient education services or allowing any additional types of Medicare providers or suppliers to furnish and bill kidney disease patient education services beyond clinical staff and qualified staff at this time.

C. Requests for Information on Topics Relevant to the ETC Model

1. Peritoneal Dialysis Catheter Placement—Request for Information (RFI)

Through the CY 2022 ESRD PPS proposed rule (86 FR 36395), we sought input on how we can test and use Medicare payment policy, under the ETC Model, to promote placement of PD catheters. Specifically, we sought feedback on the following questions:

a. What are the key barriers to increased placement of PD catheters?

b. How can CMS promote placement of PD catheters in a more timely manner?

c. Should the Innovation Center use its authority to test alternative payment structures to address the barriers to PD catheter placement as a part of the ETC Model? If so, why and how?

For the complete discussion of this RFI, see the CY 2022 ESRD PPS proposed rule, 86 FR 39395 through 39396.

Comments: Commenters expressed general concern that CMS continues to address barriers to home dialysis one provider type at a time rather than holistically as an extended series of barriers and decision points that patients face beginning when they are in earlier stages of kidney disease.

Most commenters agreed with the main barriers to PD catheter placement described in the RFI, including the lack of availability of hospital-based catheter insertion teams to perform PD catheter placements, lack of appropriate operating room time, and a lack of training on PD catheter placement for vascular surgeons. But the commenters suggested additional barriers for CMS's consideration.

First, commenters noted that the COVID–19 pandemic has limited the ability of health care providers to perform elective procedures on a timely basis. According to the commenters, hospital operating rooms effectively halted PD catheter implantation in many hospitals for several months. Rural facilities were particularly hit because these communities rely on surgeons who travel in from larger communities and have limited availability. One commenter noted that incentivizing, or disincentivizing, providers through payment changes or Innovation Center models would not fix the core issue for rural dialysis facilities unless there are enough scheduled patients to make a trip financially feasible. This commenter suggested that as an alternative, CMS should consider methods to reduce the prevalence of ESRD in the long term with a specific focus on rural areas. While this approach may not create immediate savings, reducing the rate of ESRD would significantly benefit CMS in the years to come.

A commenter noted that many of the candidates for prospective PD catheter placement are either not yet eligible for Medicare or are uninsured, and that there is little incentive for hospitals or other facility settings to address the lack of availability of vascular surgeons to perform PD catheter placements, lack of appropriate operating room time, and a lack of training on PD catheter placement for vascular surgeons. Another commenter noted a concern regarding the number of physicians trained to perform PD catheter placement as many of the more experienced PD catheter physician providers are in the later stages of their careers and there are not replacement providers in the pipeline when they retire.

The majority of commenters mentioned the largest barrier for PD catheter placement is low reimbursement, making it difficult to encourage new surgeons and other physicians to become adept at PD catheter implantation. One commenter specifically mentioned that many of the standalone vascular access centers have closed because of the reduction of CMS payments to vascular access surgeons. Unlike the transplant surgeons, who may be incentivized to increase rates of transplantation through increased revenue resulting directly from increasing the number of transplants performed, there are no other direct or indirect incentives for vascular surgeons or vascular access centers to increase rates of, PD catheter placements that can work outside the model to address these concerns. Accordingly, commenters suggested that it would be appropriate to create a separate PD catheter placement incentive under the ETC Model.

As the ETC Model currently seeks to change payment incentives only for ETC Participants (ESRD facilities and Managing Clinicians in Selected Geographic Areas) and, doesn't provide direct incentives for vascular access surgeons to work with ETC Participants, commenters strongly urged CMS to thoughtfully consider to what extent ETC Participants can influence increased rates of PD catheter placement. Despite the importance of dialysis access procedures to patients, commenters noted that ETC Participants currently have little influence on surgeons and hospitals performing dialysis access procedures in a fee-for-service structure. This factor limits the ability of ETC Participants to increase home dialysis utilization, which is contingent on timely and high-quality PD catheter placement. Commenters also urged CMS to consider establishing an incentive payment of at least $360.62 to surgeons and other access specialists in the ETC Model to achieve this goal.

Several commenters suggested that a voluntary track or option could be added to the ETC Model under which ETC Participants would receive a payment increase per PD placement (of at least an additional $360.62 per PD catheter procedure) to equalize the

reimbursement between PD catheter insertion and vascular placement within the Model. A voluntary track would allow participants to opt-in to further test broader and more comprehensive incentive payments. This track would allow for comparison of rates of PD catheter placement within and outside the model, to evaluate whether the payment increase within the Model increased the rate of PD catheter placement. Others didn't think the incentive could be tested in the current model because ETC Participants have no ability to influence the behavior of surgeons or interventionalists who place PD catheters. However, these commenters noted they would be supportive of the incentive in another context.

Several commenters suggested that the Innovation Center should pilot bonus or increased payments for PD catheter placement outside of the ESRD PPS and MCP. These commenters recommended that the Innovation Center consider testing a bonus incentive payment for vascular surgeons, hospitals, and surgical centers that would increase reimbursement for PD catheter placement commensurate with reimbursement provided for AV Fistula reimbursement. According to the commenters, this incentive payment should not be budget neutral to the ESRD PPS or the MCP, but instead should be viewed in the broader context of physician, hospital, and outpatient surgical center reimbursement systems.

Other commenters suggested financial options with less detail. One commenter suggested that CMS can encourage the placement of PD catheters by not only maintaining the reimbursement levels for office based placed catheters but increasing the reimbursement to levels that are on par with Ambulatory Surgery Center settings. Another commenter suggested paying PD catheter placement over time—that is, adding longevity payments so the surgeon gets payments for patients staying on PD at 90 days and 180 days—to align interests across nephrologists and PD providers. Another commenter suggested a bonus payment per diagnostic related group (DRG) of new ESRD dialysis starts in the hospital who are leaving with a PD catheter, including urgent PD. Lastly, another commenter suggested that PD catheter placement be designed as an urgent procedure to be prioritized by the hospital under emergent procedures.

There were also several comments related to use of Innovation Center authority. The first such comment suggested that CMS propose including as ETC Participants those surgeons who bill for dialysis vascular access procedures including PD catheter placement identified based on certain CPT codes (for example, 36818, 36819, 36820, 36821, 36825, 36830, 36831, 36832, 36833, 36838, 49324, 49418, 49421). According to the commenter, including these surgeons in the model would provide an incentive for the surgeons to partner with other providers to ensure the timely placement, repair, and revision of vascular accesses for patients with ESRD. The second such comment had concerns with RVUs in the PFS and suggested the Innovation Center has authority to supplement, beyond the PFS, payments to surgeons that increase access to and availability of procedures that are ''gateways.'' Another such comment urged the Innovation Center to address PD catheter placement and consider possible alternate payment structures such as retroactive payment for successful placement of PD catheters that are proven to have been successful over time or establishment of a bonus structure similar to the Kidney Transplant Bonus under the KCC Model; the commenter also suggested that such innovations should include pediatric patients. The same commenter also urged CMS to not exclude pediatric patients from innovative policies to promote PD catheter placement.

Response: We plan to continue working with other agencies and stakeholders to coordinate and to inform our decisions regarding the potential for incorporating peritoneal dialysis into the ETC Model and any related quality measurement and reporting requirements. While we stated that we would not be responding to specific comments submitted in response to this RFI in the CY 2022 ESRD PPS final rule, we will actively consider all input as we continue testing the ETC Model. Any updates to specific program requirements related to peritoneal dialysis and quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

2. Beneficiary Experience Measure—Request for Information

While a beneficiary experience measure is not currently included in the ETC Model, in the CY 2022 ESRD PPS proposed rule (86 FR 36396), we sought comment on the inclusion of a measure to capture the beneficiary experience of home dialysis care. We invited public comment on any aspect of a patient experience measure. We noted that questions to consider include the following:

a. What domains of a patient experience of care with home dialysis would be the most useful to assess and why?

b. Would you prefer the measure to be newly developed or an update to an existing measure? If an update, which existing measure should be updated?

c. How would a patient experience measure be best used to further the purpose of the ETC Model?

d. How should CMS use a patient experience measure to assess the quality of care of beneficiaries?

e. How should CMS use a patient experience measure to incentivize improved quality of care in the ETC Model and/or for other CMS programs?

CMS also considered publishing the quality outcomes for the ETC Model. We invited public comment on any aspect of reporting quality data, and specifically sought input on the following:

f. What is the frequency with which CMS should disseminate the results?

g. What should be the unit of analysis for the reporting data?

For the complete discussion of this RFI, see the CY 2022 ESRD PPS proposed rule, 86 FR 39396.

Comments: Commenters were appreciative that CMS solicited feedback and there was overwhelming support for inclusion of a measure assessing beneficiary experience on home dialysis in the ETC Model. In general, the commenters thought the inclusion of a measure to assess beneficiary perceptions of the care they receive would be useful to inform changes that can improve the patient's health and well-being. Commenters concurred with CMS that the current ICH CAHPS is not sufficient to capture the beneficiary experience of home dialysis patients and strongly encouraged CMS to work with the kidney community to develop a useful measure that is endorsed by the National Quality Forum (NQF).

A few commenters continued to recommend that CMS continue to develop and improve the ICH CAHPS, with a particular focus on adding a home dialysis survey to allow the patient experience to be compared across settings.

However, more commenters recommended that the agency not update an existing measure, such as ICH CAHPS or the Patient Activation Measure (PAM), and instead develop an entirely new instrument and include questions that are most meaningful to patients. A commenter noted that measuring the patient experience of dialysis in a home setting includes components of in-center dialysis, home

health, and home medical equipment, in addition to topics that are unique to this care setting and patient population. No existing survey touches on all aspects of this distinctive experience. Commenters asked CMS to consider including topics specific to dialysis care at home, such as patient training on equipment, supplies, and safety, and communication with and access to the patient's care team. According to commenters, CMS could convene a Technical Expert Panel (TEP) to develop and test a tool to measure the patient voice in their treatment with home dialysis that would include satisfaction, patient activation, quality of life and economic impact of the treatment at home.

Several commenters commented there are already private-sector efforts to develop a survey tool to measure home dialysis patient experience. Commenters encouraged CMS to work closely with these efforts, and to actively support the psychometric testing and validation necessary to ensure that there is a valid and reliable instrument that can be utilized broadly across providers in assessing the experience of home dialysis patients. Commenters specifically mentioned that any Innovation Center effort should complement and not replicate potential efforts to leverage the Home Dialysis Care Experience (Home-DCE) instrument developed and initially tested by the University of Washington. Commenters further expressed hope that this measure will eventually be tested more broadly and be submitted to NQF for endorsement and use in the CMS ESRD QIP.

Several commenters mentioned that the survey response rate for ICH CAHPS has declined significantly in recent years. Therefore, the commenters recommended that any patient experience measure CMS uses should impose minimal burden on patients and providers. In addition, commenters noted that there is a critical need to develop and implement a patient experience tool that does not further health inequities. Lastly, commenters recommended that any home dialysis patient experience measure CMS implements should be relevant to other CMS programs, such as the ESRD QIP.

Some commenters suggested that a new measure should address the following areas: Ease of use of their modality/device; patient/provider burden in self administration or helping support a loved one; sense of support from the care team.; sense of respect and value from the care team; and communication with the care team. One commenter recommended including three specific questions in a new home dialysis patient experience measure. The first is ''if the patient previously received in-center dialysis, does the patient have better quality of life on home dialysis?'' The second is ''is the patient on home dialysis more able to engage in activities of daily living (ADLs)?'' The final question is ''are dialysis facility staff supportive for patients on home dialysis?''

Some commenters suggested additional mandatory measures in the ETC Model. Commenters suggested an advance care planning measure specifically because it is critical for patients and clinicians to define goals of care. Commenters also suggested measures regarding palliative care access and utilization because there is mounting evidence that ESRD patients who have access to or are enrolled in palliative care programs have better outcomes and have more support for treatment choices. Lastly, commenters suggested a measure specific to timely and appropriate referral to hospice to encourage timely and appropriate referral to hospice. The commenters recommended that this measure should also provide documentation of include evidence of goals of care and advance care planning.

With regard to reporting quality outcomes, commenters supported transparency for beneficiaries attributed to ETC Participants. Commenters suggested that reporting of quality outcomes occur annually in order to be consistent with the ESRD QIP timeline. Commenters also recommended the quality outcomes be available via a website, as well as posted at each facility in the ETC Participant's aggregation group. Specifically, because the ETC Model is focused on aggregation at the HRR level, commenters recommended that the data should be at that aggregated level rather than at the individual ETC Participant level.

Response: We appreciate all the comments and interest in this topic and believe that this input is very valuable in the continuing development of the quality measurement efforts for the ETC Model. We will continue to take all concerns, comments, and suggestions into consideration.

VI. Requests for Information

A. Informing Payment Reform Under the ESRD PPS

Over the last several years, CMS, in conjunction with its contractor, has been conducting research, including holding three technical expert panels (TEPs), to explore possible improvements to the ESRD payment model. Additionally, in the CY 2020 ESRD PPS proposed rule (84 FR 38398 through 38400), CMS invited further comment on a number of topics, including expanding the outlier policy to include composite rate drugs, laboratory tests and supplies; reporting the length of each dialysis session directly on the ESRD claim; patient characteristics which contribute significantly to the cost of dialysis care; and improving the quality of facility-level data as reflected in the Medicare cost report. Stakeholders have asked CMS to explore a refined case-mix adjustment model for the ESRD PPS, stating that the existing case mix adjustors may not correlate well with the current cost of dialysis treatment.

Accordingly, in the CY 2022 ESRD PPS proposed rule (86 FR 36398 through 36409), CMS included a detailed request for information (RFI) on several topics in order to inform payment reform under the ESRD PPS. Those topics included six focal areas: (1) The LVPA payment methodology; (2) calculations for the case-mix adjustment; (3) the calculation for the outlier payment adjustment; (4) the current pediatric dialysis payment model; (5) modifications to the pediatric, the ESRD PPS and the hospital cost report; and (6) payment for home dialysis for Medicare beneficiaries with acute kidney injury. For each topic, we provided background information, reviewed current issues and stakeholder concerns, described suggestions that we received, and included specific requests for information. Although we are not presenting that information again in this final rule, we refer readers to the complete discussion in the CY 2022 ESRD PPS proposed rule, 86 FR 36396 through 36409.

We received numerous public comments in response to our RFI on payment reform under the ESRD PPS, including from large, small, and non-profit dialysis organizations; an advocacy organization; a coalition of dialysis organizations; a large non-profit health system; an independent commenter; and MedPAC. A high level description of these comments is included below. We will provide more detailed information about the commenters' recommendations in a future posting on the CMS website located at the following link: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.*

1. Calculation of the Low-Volume Payment Adjustment (LVPA)

Of the fourteen responses to the LVPA RFI, all commenters supported either eliminating or revising the current LVPA or rural adjustment. One small dialysis organization within a large non-profit health system responded that they are reliant upon the LVPA and the rural adjustment, and support both adjustments, albeit with modifications. Several commenters agreed with MedPAC's suggestion for the low volume and isolated (LVI) adjustment. Several commenters opposed the census tract methodology with some stating that it is complex and lacks transparency.

2. Calculation of the Case-Mix Adjustments

In response to the RFI for current case-mix methodology, several commenters recommended changes or removal of the case-mix adjusters, including refinement of the age and weight (BSA and BMI) adjustments and removal of the comorbidity adjustments, based on declining frequency of claims containing comorbidities. Commenters expressed their belief that the comorbidity categories no longer protect beneficiary access and no longer correlate with increased costs. Numerous commenters expressed support for the current onset of dialysis adjustment. Most commenters did not support the collection of time on machine data on claims or cost reports to allocate composite rate costs. MedPAC recommended that CMS develop a one-equation regression model in place of the current two-equation model currently used as the basis for the ESRD PPS.

3. Calculation of the Outlier Adjustment

In response to the current RFI for the calculation of the outlier payment adjustment, several commenters recommended changes to the outlier policy, expressing concerns about the current outlier policy because it continues to achieve less than the target amount of outlier payments equal to 1.0 percent of total PPS payments. They suggested various strategies for addressing the outlier policy, including reducing the outlier threshold, and excluding TDAPA and TPNIES payments in the outlier calculation methodology. Several commenters supported the use of the FDL trend using historical utilization data. Commenters also recommended the creation of a mechanism to return unpaid outlier amounts to the ESRD PPS.

4. Calculation of the Pediatric Dialysis Payment Adjustment

In the response to RFI for calculation of pediatric dialysis payment adjustment, all the commenters expressed that the total costs of ESRD care delivered to pediatric dialysis patients are not covered by the current ESRD bundled payment and existing pediatric multipliers. Several commenters stated that they did not believe that using duration of treatment is a valid proxy for composite rate costs. Some commenters recommended that a combination of age, weight and pediatric-specific comorbidities be used as a proxy for composite rate costs for pediatric patients. A few commenters recommended streamlining the reporting for claims and cost reports.

5. Modifying the Pediatric Dialysis, ESRD PPS and Hospital Cost Reports

In the responses to RFI for modifying the pediatric cost report, commenters supported updating the pediatric cost report to allow facilities to include costs that cannot be currently reported on the cost report. Specific recommendations included breakdown of patient age groups, pediatric-specific dialysis supplies, additional overhead at hospital outpatient dialysis facilities, psychosocial support, specialized pharmacy needs and costs unique to the pediatric population for home dialysis.

Several commenters noted that, despite best efforts to educate reporting and billing staff, hospitals often triage their cost reporting obligations, focusing on those that affect payment over those that do not; they stated that this is particularly true with pediatric dialysis costs. In order to improve reporting, the commenters recommended streamlining the reporting required and making it more consistent with reporting required from the State Medicaid programs or the private payers.

In the responses to RFI for modifying the ESRD PPS and Hospital Cost Reports, we received input from ten commenters consisting of large, small, and non-profit dialysis organizations; an advocacy organization; a coalition of dialysis organizations; a large non-profit health system; an independent commenter; and MedPAC. All the commenters expressed support for making improvements to the cost report that will streamline reporting and improve accuracy of information collected that informs payment policy. Additionally, commenters recommended CMS consider modifying hospital cost report reporting instructions to ensure complete, consistent, and accurate data reporting as well as make timely updates to reflect changes to payment policies, including the TDAPA and TPNIES. These commenters cautioned CMS that prior to making changes, CMS should weigh the burden of data collection against the benefit to the system in collecting it.

6. Modifying Site of Services Provided to Medicare Beneficiaries With Acute Kidney Injury (AKI)

The responses to the RFI for modifying site of service provided to Medicare beneficiaries included numerous requests to allow payment for home dialysis for patients with AKI. Of the 16 total comments received on this topic, 15 discussed modification of the site of service requirements, with commenters supporting payment for AKI patients receiving dialysis in home settings, including skilled nursing facilities. Several commenters favored modification of the site of service requirements in concert with payment of home dialysis for AKI patients when deemed appropriate by health care providers.

7. CMS Response to Public Comments

We appreciate the public input and comments on suggested refinements to the ESRD PPS in response to our RFI in the CY 2022 ESRD PPS proposed rule. We will take all of these comments into consideration for possible future rulemaking.

VII. 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, the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) 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.

We solicited public comment on each of these issues for the following sections

of this document that contain information collection requirements (ICRs):

B. Requirements in Regulation Text

In sections V through V.B of this final rule, we are revising the regulatory text for the ETC Model. However, the changes do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This final rule does not impose any new information collection requirements in the regulation text, as specified above. However, there are changes in some currently approved information collections. The following is a discussion of these information collections.

1. ESRD QIP—Wage Estimates (OMB Control Numbers 0938–1289 and 0938–1340)

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates. In the CY 2016 ESRD PPS final rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to CROWNWeb (now EQRS) and NHSN, as well as compiling and submitting patient records for the purpose of data validation studies, rather than a Registered Nurse, whose duties are centered on providing and coordinating care for patients. We stated that the median hourly wage of a Medical Records and Health Information Technician is $21.20 per hour.[278] We also stated that fringe benefit and overhead are calculated at 100 percent. Therefore, using these assumptions, we estimated an hourly labor cost of $42.40 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP. We 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. We stated that these are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, we stated that there is no practical alternative and we believe that these are reasonable estimation methods.

We used this updated wage estimate, along with updated facility and patient counts to re-estimate the total information collection burden in the ESRD QIP for PY 2024 that we discussed in the CY 2021 ESRD QIP final rule (85 FR 71473 through 71474) and to estimate the total information collection burden in the ESRD QIP for PY 2025. We provided the re-estimated information collection burden associated with the PY 2024 ESRD QIP and the newly estimated information collection burden associated with the PY 2025 ESRD QIP in section VII.C.3 of the proposed rule.

2. Estimated Burden Associated With the Data Validation Requirements for PY 2024 and PY 2025 (OMB Control Numbers 0938–1289 and 0938–1340)

In the CY 2020 ESRD PPS final rule, we finalized a policy to adopt the CROWNWeb data validation methodology that we previously adopted for the PY 2016 ESRD QIP as the methodology we would use to validate CROWNWeb data for all payment years, beginning with PY 2021 (83 FR 57001 through 57002). Although, as noted in section IV.B.2. of the proposed rule, we are now using EQRS to report data that was previously reported in CROWNWeb, the data validation methodology remains the same. Under this methodology, 300 facilities are selected each year to submit 10 records to CMS, and we reimburse these facilities 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. In the proposed rule, we updated these estimates using a newly available wage estimate of a Medical Records and Health Information Technician. In the CY 2020 ESRD PPS final rule, we estimated that it would take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimated that the total combined annual burden for these facilities would be 750 hours (300 facilities × 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit these data, we estimate that the aggregate cost of the EQRS data validation each year would be approximately $31,800 (750 hours × $42.40), or an annual total of approximately $106.00 ($31,800/300 facilities) per facility in the sample. The burden cost increase associated with these requirements will be revised in the information collection request (OMB control number 0938–1289).

In the CY 2021 ESRD PPS final rule, we finalized our policy to reduce the number of records that a facility selected to participate in the NHSN data validation must submit to a CMS contractor, beginning with PY 2023 (85 FR 71471 through 71472). Under this finalized policy, a facility is required to submit records for 20 patients across any two quarters of the year, instead of 20 records for each of the first two quarters of the year. The burden associated with this policy is the time and effort necessary to submit the requested records to a CMS contractor. Applying our policy to reduce the number of records required from each facility participating in the NHSN validation, we estimated that it would take each facility approximately 5 hours to comply with this requirement. If 300 facilities are asked to submit records each year, we estimated that the total combined annual burden hours for these facilities per year would be 1,500 hours (300 facilities × 5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar staff would submit these data, using the newly available wage estimate of a Medical Records and Health Information Technician, we estimate that the aggregate cost of the NHSN data validation each year would be approximately $63,600 (1,500 hours × $42.40), or a total of approximately $212 ($63,600/300 facilities) per facility in the sample. While the burden hours estimate will not change, the burden cost updates associated with these requirements will be revised in the information collection request (OMB control number 0938–1340).

3. EQRS Reporting Requirements for PY 2024 and PY 2025 (OMB Control Number 0938–1289)

To determine the burden associated with the EQRS reporting requirements (previously known as the CROWNWeb reporting requirements), we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to EQRS for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into EQRS, and the number of facilities submitting data to EQRS. In the CY 2021 ESRD PPS final rule, we estimated that the burden associated with CROWNWeb (now

[278] *https://www.bls.gov/oes/current/oes292098.htm.* Accessed on June 7, 2021.

EQRS) reporting requirements for the PY 2024 ESRD QIP was approximately $208 million (85 FR 71400).

As discussed in section IV.C. and section IV.D. of this final rule, we are finalizing our proposed measure suppressions that would apply for PY 2022 and updates to the scoring methodology and payment reductions for the PY 2022 ESRD QIP. In the proposed rule, we also announced an extension of EQRS reporting requirements for facilities due to systems issues. However, we believe that none of the policies finalized in this final rule would affect our estimates of the annual burden associated with the Program's information collection requirements, as facilities are still expected to continue to collect measure data during this time period. We are not finalizing any changes that would affect the burden associated with EQRS reporting requirements for PY 2024 or PY 2025. However, we have re-calculated the burden estimate for PY 2024 using updated estimates of the total number of dialysis facilities, the total number of patients nationally, and wages for Medical Records and Health Information Technicians or similar staff as well as a refined estimate of the number of hours needed to complete data entry for EQRS reporting. Consistent with our approach in the CY 2021 ESRD PPS final rule (85 FR 71474), in the proposed rule we estimated that the amount of time required to submit measure data to EQRS was 2.5 minutes per element and did not use a rounded estimate of the time needed to complete data entry for EQRS reporting. We are further updating these estimates in this final rule. There are 229 data elements for 532,931 patients across 7,717 facilities. At 2.5 minutes per element, this yields approximately 658.94 hours per facility. Therefore, the PY 2024 burden is 5,085,050 hours (658.94 hours × 7,717 facilities). Using the wage estimate of a Medical Records and Health Information Technician, we estimate that the PY 2024 total burden cost is approximately $215 million (5,085,050 hours × $42.40). There is no net incremental burden change from PY 2024 to PY 2025 because we are not changing the reporting requirements for PY 2025.

VIII. Regulatory Impact Analysis

A. Impact Analysis

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980; Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 801(2)).

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

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. We solicit comments on the regulatory impact analysis provided.

2. Statement of Need

a. ESRD PPS

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 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.

This rule finalizes updates to the ESRD PPS for CY 2022, as required by section 1881(b)(14)(F) of the Act. The routine updates include the CY 2022 wage index values, the wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. Failure to publish this final rule will result in ESRD facilities not receiving appropriate payments in CY 2022 for renal dialysis services furnished to ESRD beneficiaries, as required by section 1881(b)(14)(F) of the Act.

b. AKI

This rule also finalizes updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI, as required by section 1834(r) of the Act, as added by section 808(b) of the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) enacted on June 29, 2015. Failure to publish this final rule will result in ESRD facilities not receiving appropriate payments in CY 2022 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

c. ESRD QIP

Section 1881(h)(1) of the Act requires a payment reduction of up to 2 percent for eligible dialysis facilities that do not meet or exceed the mTPS established with respect to performance standards for the ESRD QIP each year. This final rule finalizes updates for the ESRD QIP, including the adoption of a measure suppression policy and the suppression of several ESRD QIP measures under that measure suppression policy, updates regarding the scoring methodology and payment reductions for the PY 2022 ESRD QIP, an update to the SHR measure, and an update to the PY 2024 performance standards.

d. ETC Model

The ETC Model is a mandatory Medicare payment model tested under the authority of section 1115A of the

Act, which authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of such programs.

This final rule will refine the methodology for setting and updating achievement and improvement benchmarks for participating ESRD facilities and Managing Clinicians serving the ESRD population over the remaining years of the ETC Model, among other changes. As described in detail in section V.B of this final rule, we believe it is necessary to adopt certain changes to the ETC Model. Notwithstanding the changes, we continue to anticipate improvement in quality of care for beneficiaries and reduced expenditures under the ETC Model inasmuch as the Model is designed to create incentives for Managing Clinicians and ESRD facilities to support beneficiaries, along with their families and caregivers, in choosing the optimal kidney replacement modality.

B. Overall Impact

1. ESRD PPS

We estimate that the final revisions to the ESRD PPS will result in an increase of approximately $290 million in payments to ESRD facilities in CY 2022, which includes the amount associated with updates to the outlier thresholds, payment rate update, updates to the wage index, and TPNIES payment.

2. AKI

We estimate that the updates to the AKI payment rate will result in an increase of approximately $1 million in payments to ESRD facilities in CY 2022.

C. Detailed Economic Analysis

In this section, we discuss the anticipated benefits, costs, and transfers associated with the changes in this final rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this final rule.

1. Benefits for ESRD PPS and AKI

Under the CY 2022 ESRD PPS and AKI payment, ESRD facilities will continue to receive payment for renal dialysis services furnished to Medicare beneficiaries under a case-mix adjusted PPS. We continue to expect that making prospective payments to ESRD facilities will enhance the efficiency of the Medicare program. Additionally, we expect that updating ESRD PPS and AKI payments by 1.9 percent based on the final CY 2022 ESRD PPS market basket update less the final CY 2022 productivity adjustment will improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services.

2. Costs

a. ESRD PPS and AKI

We do not anticipate the provisions of this final rule regarding ESRD PPS and AKI rates-setting will create additional cost or burden to ESRD facilities.

b. ESRD QIP

For PY 2024 and PY 2025, we have re-estimated the costs associated with the information collection requirements under the ESRD QIP with updated estimates of the total number of dialysis facilities. We note that the estimated total number of patients nationally, wages for Medical Records and Health Information Technicians or similar staff, and the estimated number of hours needed to complete data entry for EQRS reporting are the same as they were in the proposed rule. We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for the EQRS validation study (previously known as the CROWNWeb validation study), the NHSN validation study, and EQRS reporting. As discussed in section IV.C. and section IV.D. of this final rule, we are finalizing our proposed measure suppressions that would apply for PY 2022 and updates to the scoring methodology and payment reductions for the PY 2022 ESRD QIP. We also announced an extension of EQRS reporting requirements for facilities due to systems issues in the proposed rule. However, we believe that none of the policies finalized in this final rule would affect our estimates of the annual burden associated with the Program's information collection requirements, as facilities are still expected to continue to collect measure data during this time period.

We also finalized the payment reduction scale using more recent data for the measures in the ESRD QIP measure set. We estimate approximately $215 million in information collection burden, which includes the cost of complying with this rule, and an additional $17 million in estimated payment reductions across all facilities for PY 2024.

For PY 2025, we estimate that the proposed revisions to the ESRD QIP would result in $215 million in information collection burden, and $17 million in estimated payment reductions across all facilities, for an impact of $232 million as a result of the policies we have previously finalized and the policies we have finalized in this final rule.

c. ETC Model

We estimate that the changes to the ETC Model will increase the Model's projected direct savings from payment adjustments alone by $5 million over the duration of the Model. We estimate that the Model will generate $28 million in direct savings related to payment adjustments over 6.5 years with the adopted changes, and would generate $23 million in savings in the absence of the finalized changes.

3. Transfers for ESRD PPS and AKI

We estimate that the finalized updates to the ESRD PPS and AKI payment rate will result in a total in increase of approximately $290 million in payments to ESRD facilities in CY 2022, which includes the amount associated with updates to the outlier thresholds, and updates to the wage index. This estimate includes an increase of approximately $1 million in payments to ESRD facilities in CY 2022 due to the finalized updates to the AKI payment rate, of which approximately 20 percent is increased beneficiary co-insurance payments. We estimate approximately $230 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately $60 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary co-insurance payments as a result of this final rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final 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 this year's proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's rule in detail, and it is 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 final rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the May, 2020 mean (average) wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $114.24 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes119111.htm.* Assuming an average reading speed of 250 words per minute, we estimate that it will take approximately 300 minutes (5 hours) for the staff to review half of this final rule, which is approximately 75,000 words. For each entity that reviews the rule, the estimated cost is $571.20 (5 hours × $114.24). Therefore, we estimate that the total cost of reviewing this regulation is $163,363.20 ($571.20 × 286).

5. Impact Statement and Table

a. CY 2022 End-Stage Renal Disease Prospective Payment System

(1) 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 2021 to estimated payments in CY 2022. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2021 and CY 2022 contain similar inputs.

Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this final rule, we used CY 2020 data from the Part A and Part B Common Working Files as of February 12, 2021, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2020 claims to 2021 and 2022 using various updates. The updates to the ESRD PPS base rate are described in section II.B.1.d of this final rule. Table 9 shows the impact of the estimated CY 2022 ESRD PPS payments compared to estimated payments to ESRD facilities in CY 2021.

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TABLE 9: Impacts of the Changes in Payments to ESRD Facilities for CY 2022[1]

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Effect of 2022 Changes in Outlier Policy (C)	Effect of 2022 Changes in Wage Index (D)	Effect of 2022 Changes in Payment Rate Update (E)	Effect of Total 2022 Final Changes (F)
All Facilities	7,761	44.1	0.6%	0.0%	1.9%	2.5%
Type						
Freestanding	7,381	42.4	0.6%	0.0%	1.9%	2.5%
Hospital based	380	1.7	1.1%	0.0%	2.2%	3.3%
Ownership Type						
Large dialysis organization	5,733	33.0	0.6%	0.0%	1.8%	2.4%
Regional chain	1,167	6.8	0.6%	0.1%	2.1%	2.8%
Independent	475	2.5	0.6%	-0.1%	2.1%	2.6%
Hospital based[2]	380	1.7	1.1%	0.0%	2.2%	3.3%
Unknown	6	0.0	0.6%	-0.4%	1.8%	2.0%
Geographic Location						
Rural	1,276	6.4	0.6%	0.0%	1.9%	2.5%
Urban	6,485	37.8	0.6%	0.0%	1.9%	2.5%
Census Region						
East North Central	1,217	5.8	0.6%	-0.2%	1.9%	2.2%
East South Central	613	3.3	0.8%	-0.4%	1.9%	2.3%
Middle Atlantic	870	5.2	0.7%	-0.2%	2.0%	2.5%
Mountain	431	2.4	0.4%	0.0%	1.9%	2.2%
New England	202	1.3	0.5%	-0.6%	1.9%	1.8%
Pacific[3]	961	6.4	0.4%	0.5%	1.9%	2.8%
Puerto Rico and Virgin Islands	52	0.3	0.5%	-0.7%	1.9%	1.6%
South Atlantic	1,806	10.6	0.6%	0.3%	1.9%	2.8%
West North Central	504	2.3	0.6%	0.0%	1.9%	2.5%
West South Central	1,105	6.6	0.6%	-0.3%	1.9%	2.2%
Facility Size						
Less than 4,000 treatments	1,295	2.0	0.5%	-0.1%	1.9%	2.3%
4,000 to 9,999 treatments	3,158	13.1	0.6%	0.0%	1.9%	2.5%
10,000 or more treatments	3,281	29.0	0.6%	0.0%	1.9%	2.5%
Unknown	27	0.0	0.8%	-0.4%	2.2%	2.5%
Percentage of Pediatric Patients						
Less than 2%	7,659	43.8	0.6%	0.0%	1.9%	2.5%
Between 2% and 19%	38	0.2	0.6%	0.1%	1.9%	2.6%
Between 20% and 49%	13	0.0	0.2%	0.4%	2.0%	2.6%

More than 50%	51	0.0	0.3%	0.1%	1.9%	2.3%

[1] The Tablo® System will be paid for using the TPNIES under the ESRD PPS for CY 2022. We estimate approximately $2.5 million in spending, of which, approximately $490,000 would be attributed to beneficiary coinsurance amounts.
[2] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the changes to the outlier payment policy described in section II.B.1.c of this final rule is shown in column C. For CY 2022, the impact on all ESRD facilities as a result of the changes to the outlier payment policy will be a 0.6 percent increase in estimated payments. All ESRD facilities are anticipated to experience a positive effect in their estimated CY 2022 payments as a result of the outlier policy changes.

Column D shows the effect of the annual update to the wage index, as described in section II.B.1.b of this final rule. That is, this column reflects the update from the CY 2021 ESRD PPS wage index using 2018 OMB delineations as finalized in the CY 2021 ESRD PPS final rule, with a basis of the FY 2022 pre-floor, pre-reclassified IPPS hospital wage index data in a budget neutral manner. The total impact of this change is 0.0 percent; however, there are distributional effects of the change among different categories of ESRD facilities. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 0.7 percent decrease to a 0.5 percent increase due to the annual update to the ESRD PPS wage index.

Column E shows the effect of the final CY 2022 ESRD PPS payment rate update as described in section II.B.1.a of this final rule. The ESRD PPS payment rate update is 1.9 percent, which reflects the ESRDB market basket percentage increase factor for CY 2022 of 2.4 percent and the productivity adjustment of 0.5 percent.

Column F reflects the overall impact, that is, the effects of the outlier policy changes, the updated wage index, and the payment rate update. We expect that overall ESRD facilities will experience a 2.5 percent increase in estimated payments in CY 2022. The categories of types of facilities in the impact table show impacts ranging from a 1.6 percent increase to a 3.3 percent increase in their CY 2022 estimated payments.

(2) 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 2022, we estimate that the ESRD PPS will have zero impact on these other providers.

(3) Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2022 will be approximately $8.8 billion. This estimate considers a projected decrease in fee-for-service Medicare dialysis beneficiary enrollment of 5.8 percent in CY 2022.

(4) 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 2.5 percent overall increase in the CY 2022 ESRD PPS payment amounts, we estimate that there will be an increase in beneficiary co-insurance payments of 2.5 percent in CY 2022, which translates to approximately $60 million.

(5) Alternatives Considered

CY 2022 Impacts: 2019 Versus 2020 Claims Data

Each year CMS uses the latest available ESRD claims to update the outlier threshold, budget neutrality factor, and payment rates. Due to the COVID–19 PHE, we compared the impact of using CY 2019 claims against CY 2020 claims to determine if there was any substantial difference in the results that would justify potentially deviating from our longstanding policy to use the latest available data. Analysis suggested that ESRD utilization did not change substantially during the pandemic, likely due to the patients' vulnerability and need for these services. Consequently, we finalized our proposal to use the CY 2020 data because it does not negatively impact ESRD facilities and keeps with our longstanding policy to make updates using the latest available ESRD claims data (86 FR 36414).

Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Application: The Tablo® System—Home Dialysis Machine

As discussed in section II.C.1.a. of the preamble of this final rule, we are approving 1 technology for TPNIES for CY 2022, the Tablo® System. We have provided an estimated impact for the purposes of the Regulatory Impact Analysis, as follows. A Tablo® System that was priced at $40,000 and amortized over 5 useful life years using straight line depreciation would equal $8,000 per year ($40,000/5 = $8,000). Sixty-five percent of the annual cost would equal $5,200 per year ($8,000 * .65 = $5,200 per year). The pre-adjusted per treatment payment amount would equal $33.33 per treatment ($5,200/156 = $33.33 per treatment). The TPNIES amount would therefore equal an estimated $23.92 per treatment ($33.33 – the CY 2022 average per treatment offset amount of $9.50 = $23.83).

Based on February 2021 Shared Systems Data, there were approximately 6,600 Medicare beneficiaries receiving home hemodialysis treatment. If we estimated that this entire population were to use the Tablo® System in CY2022, there would be 1,029,600 treatments (6,600 Medicare beneficiaries * 156 treatments per year = 1,029,600 treatments). Applying the estimated $23.83 per treatment TPNIES amount to the estimated 1,029,600 treatments would result in approximately $25 million in spending ($23.83 * 1,029,600 = $24,535,368). If, for example, 1 percent of this population were to use the Tablo® System in CY 2022, there would be 10,296 treatments (66 Medicare beneficiaries * 156 treatments per year = 10,296 treatments). Applying the $23.83 per treatment TPNIES amount to the 10,296 treatments would result in approximately $246,280 in

spending ($23.83 * 10,296 = $245,354). We believe that 10 percent of this population is a more reasonable estimate. If the estimated 10 percent were to use the Tablo® System in CY 2022, there would be 102,960 treatments (660 Medicare beneficiaries * 156 treatments per year = 102,960 treatments). Applying the estimated $23.83 per treatment TPNIES amount to the 102,960 treatments would result in approximately $2.5 million in spending ($23.83 * 102,960 = $2,453,537), of which, approximately $490,000 would be attributed to beneficiary coinsurance amounts.

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

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated payments in CY 2021 to estimated payments in CY 2022. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the estimates of payments in CY 2021 and CY 2022 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this final rule, we used CY 2020 data from the Part A and Part B Common Working Files as of February 12, 2021, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2020 claims to 2021 and 2022 using various updates. The updates to the AKI payment amount are described in section III.B of this final rule. Table 10 shows the impact of the estimated CY 2022 payments for renal dialysis services furnished to individuals with AKI compared to estimated payments for renal dialysis services furnished to individuals with AKI in CY 2021.

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TABLE 10: Impacts of the Changes in Payments for Renal Dialysis Services Furnished to Individuals with AKI for CY 2022

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Effect of 2022 Changes in Wage Index (C)	Effect of 2022 Changes in Payment Rate Update (D)	Effect of Total 2022 Final Changes (E)
All Facilities	5,290	315.1	0.0%	1.9%	1.9%
Type					
Freestanding	5,162	309.7	0.0%	1.9%	1.9%
Hospital based	128	5.5	0.1%	1.9%	2.0%
Ownership Type					
Large dialysis organization	4,273	260.7	0.0%	1.9%	1.9%
Regional chain	718	37.7	0.1%	1.9%	2.0%
Independent	170	11.3	-0.1%	1.9%	1.8%
Hospital based[1]	128	5.5	0.1%	1.9%	2.0%
Unknown	1	0.0	-0.3%	1.9%	1.6%
Geographic Location					
Rural	875	49.4	0.0%	1.9%	1.9%
Urban	4,415	265.7	0.0%	1.9%	1.9%
Census Region					
East North Central	885	56.5	-0.2%	1.9%	1.7%
East South Central	429	22.9	-0.3%	1.9%	1.5%
Middle Atlantic	590	34.2	-0.3%	1.9%	1.6%
Mountain	305	19.4	-0.1%	1.9%	1.8%
New England	142	6.5	-0.7%	1.9%	1.2%
Pacific[2]	659	49.1	0.6%	1.9%	2.5%
Puerto Rico and Virgin Islands	3	0.0	0.0%	1.9%	1.9%
South Atlantic	1,245	76.7	0.2%	1.9%	2.1%
West North Central	343	16.5	0.0%	1.9%	1.9%
West South Central	689	33.3	-0.3%	1.9%	1.6%
Facility Size					
Less than 4,000 treatments	602	23.8	-0.2%	1.9%	1.7%
4,000 to 9,999 treatments	2,187	122.0	-0.1%	1.9%	1.8%
10,000 or more treatments	2,495	169.1	0.1%	1.9%	2.0%
Unknown	6	0.2	0.5%	1.9%	2.4%
Percentage of Pediatric Patients					
Less than 2%	5,288	315.1	0.0%	1.9%	1.9%
Between 2% and 19%	0	0.0	0.0%	0.0%	0.0%
Between 20% and 49%	0	0.0	0.0%	0.0%	0.0%
More than 50%	2	0.0	-1.3%	1.9%	0.5%

[1] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[2] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of AKI dialysis

treatments (in thousands). Column C shows the effect of the final CY 2022 wage indices. Column D shows the effect of the CY 2022 ESRD PPS payment rate update. The ESRD PPS payment rate update is 1.9 percent, which reflects the ESRDB market basket percentage increase factor for CY 2022 of 2.4 percent and the productivity adjustment of 0.5 percent.

Column E reflects the overall impact, that is, the effects of the updated wage index and the payment rate update. We expect that overall ESRD facilities will experience a 1.9 percent increase in estimated payments in CY 2022. The categories of types of facilities in the impact table show impacts ranging from an increase of 0.0 percent to 2.5 percent in their CY 2022 estimated payments.

(2) Effects on Other Providers

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

(3) Effects on the Medicare Program

We estimate approximately $60 million will be paid to ESRD facilities in CY 2022 as a result of patients with AKI 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 and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

(4) 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 will continue to be responsible for a 20 percent coinsurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

(5) 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 is inappropriate. We continue to 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.

c. ESRD QIP

(a). Effects of the PY 2022 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to prevent reductions in the quality of ESRD dialysis facility services provided to beneficiaries. Although the general methodology that we use to determine a facility's TPS is described in our regulations at 42 CFR 413.178(e), we are finalizing our proposal to codify special scoring policies for PY 2022 at 42 CFR 413.178(h). Under these finalized regulations, we will calculate measure rates for all measures but will not calculate achievement and improvement points for any measures. We will also not calculate or award a TPS for any facility. Finally, we will not reduce payment to any facility for PY 2022.

We believe there will be no effects of the PY 2022 ESRD QIP on ESRD Facilities resulting from these finalized policies because no facilities will receive a TPS or payment reductions for PY 2022.

(b). Effects of the PY 2024 ESRD QIP on ESRD Facilities

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2024 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2024, as codified in our regulations at 42 CFR 413.177.

For the PY 2024 ESRD QIP, we estimate that, of the 7,717 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 24.3 percent or 1,788 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2024. We are presenting an estimate for the PY 2024 ESRD QIP to update the estimated impact that was provided in the CY 2021 ESRD PPS final rule (85 FR 71481 through 71483). As a result of our finalized policies, the total estimated payment reductions for all the 1,788 facilities expected to receive a payment reduction in PY 2024 would decrease from $18,247,083.76 to approximately $17,104,030.59. Facilities that do not receive a TPS do not receive a payment reduction.

Table 11 shows the overall estimated distribution of payment reductions resulting from the PY 2024 ESRD QIP.

TABLE 11: Estimated Distribution of PY 2024 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5,557	75.66%
0.5%	1,338	18.22%
1.0%	357	4.86%
1.5%	70	0.95%
2.0%	23	0.31%

*372 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2024, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there

were available data from EQRS and Medicare claims. Payment reduction estimates are calculated using the most recent data available (specified in Table 12) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 12.

TABLE 12: Data Used to Estimate PY 2024 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SRR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SHR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
PPPW	Jan 2018-Dec 2018	Jan 2019-Dec 2019
Kt/V Dialysis Adequacy Comprehensive	Jan 2018-Dec 2018	Jan 2019-Dec 2019
VAT		
Standardized Fistula Ratio	Jan 2018-Dec 2018	Jan 2019-Dec 2019
% Catheter	Jan 2018-Dec 2018	Jan 2019-Dec 2019
Hypercalcemia	Jan 2018-Dec 2018	Jan 2019-Dec 2019

For all measures except the SHR clinical measure, the Standardized Readmission Ratio (SRR) clinical measure, and the STrR reporting measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, in order to be included in the facility's TPS. For the STrR reporting measure, facilities were required to have at least 10 patient-years at risk in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that were consistent with the finalized polices outlined in sections IV.E. and IV.F. of this final rule. Facility reporting measure scores were estimated using available data from CY 2019. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2024 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2019 and December 2019 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 13 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2024. The table also details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2024 ESRD QIP, the actual impact of the PY 2024 ESRD QIP may vary significantly from the values provided here.

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TABLE 13: Estimated Impact of QIP Payment Reductions to ESRD Facilities for PY 2024

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,717	43.4	7,345	1,788	-0.16%
Facility Type:					
Freestanding	7,339	41.7	7,007	1,685	-0.15%
Hospital-based	378	1.7	338	103	-0.25%
Ownership Type:					
Large Dialysis	5,886	33.6	5,703	1,207	-0.12%
Regional Chain	887	5.3	845	250	-0.20%
Independent	515	2.8	457	228	-0.39%
Hospital-based (non-chain)	378	1.7	338	103	-0.25%
Unknown	51	0.0	2	0	-0.00%
Facility Size:					
Large Entities	6,773	38.9	6,548	1,457	-0.13%
Small Entities[1]	893	4.5	795	331	-0.33%
Unknown	51	0.0	2	0	-0.00%
Rural Status:					
1) Yes	1,268	6.3	1,234	203	-0.09%
2) No	6,449	37.1	6,111	1,585	-0.17%
Census Region:					
Northeast	1,060	6.4	993	256	-0.16%
Midwest	1,716	7.9	1,654	426	-0.17%
South	3,506	20.1	3,356	906	-0.17%
West	1,374	8.5	1,283	166	-0.08%
US Territories[2]	61	0.4	59	34	-0.39%
Census Division:					
Unknown	9	0.1	8	4	-0.37%
East North Central	1,213	5.6	1,163	351	-0.21%
East South Central	609	3.2	591	134	-0.13%
Middle Atlantic	859	5.1	801	224	-0.17%
Mountain	428	2.3	404	52	-0.08%
New England	201	1.3	192	32	-0.10%
Pacific	946	6.2	879	114	-0.08%
South Atlantic	1,794	10.4	1,700	493	-0.19%
West North Central	503	2.3	491	75	-0.10%
West South Central	1,103	6.5	1,065	279	-0.17%
US Territories[2]	52	0.3	51	30	-0.40%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,248	2.4	1,059	201	-0.15%
4,000-9,999 treatments	2,905	11.9	2,901	605	-0.13%
Over 10,000 treatments	3,384	28.9	3,383	981	-0.17%
Unknown	180	0.2	2	1	-0.25%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.
[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

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(c). Effects of the PY 2025 ESRD QIP on ESRD Facilities

For the PY 2025 ESRD QIP, we estimate that, of the 7,717 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 24.3 percent or 1,788 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2025. The total payment reductions for all the 1,788 facilities expected to receive a payment reduction is approximately $17,104,030.59. Facilities that do not receive a TPS do not receive a payment reduction. Table 14 shows the overall estimated distribution of payment reductions resulting from the PY 2025 ESRD QIP.

TABLE 14: Estimated Distribution of PY 2025 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	5,557	75.66%
0.5%	1,338	18.22%
1.0%	357	4.86%
1.5%	70	0.95%
2.0%	23	0.31%

*Note: 372 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction in PY 2025, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 14) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 15.

TABLE 15: Data Used to Estimate PY 2025 ESRD QIP Payment Reductions

Measure	**Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds**	**Performance period**
ICH CAHPS Survey	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SRR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SHR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
PPPW	Jan 2018-Dec 2018	Jan 2019-Dec 2019
Kt/V Dialysis Adequacy Comprehensive	Jan 2018-Dec 2018	Jan 2019-Dec 2019
VAT		
Standardized Fistula Ratio	Jan 2018-Dec 2018	Jan 2019-Dec 2019
% Catheter	Jan 2018-Dec 2018	Jan 2019-Dec 2019
Hypercalcemia	Jan 2018-Dec 2018	Jan 2019-Dec 2019

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR reporting measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For SHR and SRR, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, in order to be included in the facility's TPS. For the STrR reporting measure, facilities were required to have at least 10 patient-years at risk in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that incorporates the policies outlined in section IV.E. and IV.F. of this final rule. Facility reporting measure scores were estimated using available data from CY 2019. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2025 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2019 and December 2019 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 16 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2025. The table details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2025 ESRD QIP, the actual impact of the PY 2025 ESRD QIP may vary significantly from the values provided here.

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TABLE 16: Estimated Impact of QIP Payment Reductions to ESRD Facilities for PY 2025

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,717	43.4	7,345	1,788	-0.16%
Facility Type:					
Freestanding	7,339	41.7	7,007	1,685	-0.15%
Hospital-based	378	1.7	338	103	-0.25%
Ownership Type:					
Large Dialysis	5,886	33.6	5,703	1,207	-0.12%
Regional Chain	887	5.3	845	250	-0.20%
Independent	515	2.8	457	228	-0.39%
Hospital-based (non-chain)	378	1.7	338	103	-0.25%
Unknown	51	0.0	2	0	-0.00%
Facility Size:					
Large Entities	6,773	38.9	6,548	1,457	-0.13%
Small Entities[1]	893	4.5	795	331	-0.33%
Unknown	51	0.0	2	0	-0.00%
Rural Status:					
1) Yes	1,268	6.3	1,234	203	-0.09%
2) No	6,449	37.1	6,111	1,585	-0.17%
Census Region:					
Northeast	1,060	6.4	993	256	-0.16%
Midwest	1,716	7.9	1,654	426	-0.17%
South	3,506	20.1	3,356	906	-0.17%
West	1,374	8.5	1,283	166	-0.08%
US Territories[2]	61	0.4	59	34	-0.39%
Census Division:					
Unknown	9	0.1	8	4	-0.37%
East North Central	1,213	5.6	1,163	351	-0.21%
East South Central	609	3.2	591	134	-0.13%
Middle Atlantic	859	5.1	801	224	-0.17%
Mountain	428	2.3	404	52	-0.08%
New England	201	1.3	192	32	-0.10%
Pacific	946	6.2	879	114	-0.08%
South Atlantic	1,794	10.4	1,700	493	-0.19%
West North Central	503	2.3	491	75	-0.10%
West South Central	1,103	6.5	1,065	279	-0.17%
US Territories[2]	52	0.3	51	30	-0.40%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,248	2.4	1,059	201	-0.15%
4,000-9,999 treatments	2,905	11.9	2,901	605	-0.13%
Over 10,000 treatments	3,384	28.9	3,383	981	-0.17%
Unknown	180	0.2	2	1	-0.25%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.
[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

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(d). Effects on Other Providers

The ESRD QIP is applicable to dialysis facilities. We are aware that several of our measures impact other providers. For example, with the introduction of the SRR clinical measure in PY 2017 and the SHR 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 exploring various methods to assess the impact these measures have on hospitals and other facilities, such as through the impacts of the Hospital Readmissions Reduction Program and the Hospital-Acquired Condition Reduction Program, and we intend to continue examining the interactions between our quality programs to the greatest extent feasible.

(e). Effects on the Medicare Program

For PY 2025, we estimate that the ESRD QIP would contribute approximately $17,104,030.59 in Medicare savings. For comparison, Table 17 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2025. This includes our finalized PY 2022 scoring and payment proposals as described in section IV.D. of this final rule.

TABLE 17: Estimated Payment Reductions Payment Years 2018 through 2025

Payment year	Estimated payment reductions
PY 2025	$17,104,030.59
PY 2024	$17,104,030.59
PY 2023	$15,770,179 (85 FR 71483)
PY 2022	$0[279]
PY 2021	$32,196,724 (83 FR 57062)
PY 2020	$31,581,441 (81 FR 77960)
PY 2019	$15,470,309 (80 FR 69074)
PY 2018	$11,576,214 (79 FR 66257)

(f). Effects on Medicare Beneficiaries

The ESRD QIP is applicable to dialysis facilities. Since the Program's inception, there is evidence on improved performance on ESRD QIP measures. As we stated in the CY 2018 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 (82 FR 50795). 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. We are in the process of monitoring and evaluating trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more. However, in future years we are interested in examining these impacts through the analysis of available data from our existing measures.

(g). Alternatives Considered

In section IV.D. of this final rule, we are finalizing a special rule to modify the scoring methodology such that no facility will receive a payment reduction for PY 2022. Under this special rule for PY 2022, we will calculate measure rates for all measures for that payment year, but will not use those measure rates to generate an achievement or improvement score, domain scores, or a TPS. We considered retaining our current scoring policy for PY 2022. However, we concluded that this was not feasible because of the EQRS system issues described in section IV.B.2., and additionally, due to the impact of the COVID–19 PHE on some of the PY 2022 ESRD QIP measures, as described more fully in section IV.C. of this final rule. This approach will help to ensure that a facility would not be penalized due to extraordinary circumstances beyond the facility's control.

d. ETC Model

(1). Overview

Under the ESRD PPS under Medicare Part B, 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. Under the Physician Fee Schedule, medical management of an ESRD beneficiary receiving dialysis by a physician or other practitioner is paid through the MCP. The ETC Model is a mandatory payment model designed to test payment adjustments to certain dialysis and dialysis-related payments, as discussed in the Specialty Care Models final rule (85 FR 6114), for ESRD facilities and for Managing Clinicians for claims with dates of service from January 1, 2021 to June 30, 2027. The requirements for the ETC Model are set forth in 42 CFR part 512, subpart C. The changes in this final rule (discussed in detail in section V.B of this final rule) will impact model payment adjustments for PPA Period 3, starting in July 1, 2023.

Under the current ETC Model, there are two payment adjustments designed to increase rates of home dialysis and kidney transplant waitlisting through financial incentives. The HDPA is an upward payment adjustment on certain home dialysis claims for ESRD facilities, as described in the final rule in §§ 512.340 and 512.350, and to certain home dialysis-related claims for Managing Clinicians, as described in the final rule in §§ 512.345 and 512.350, during the initial 3 years of the ETC Model.

The PPA is an upward or downward payment adjustment on certain dialysis and dialysis-related claims submitted by ETC Participants, as described in the final rule in §§ 512.375(a) and 512.380 for ESRD facilities and §§ 512.375(b) and 512.380 for Managing Clinicians, which will apply to claims with claim service dates beginning on July 1, 2022 and increase in magnitude over the duration of the Model. We will assess each ETC Participant's home dialysis rate, as described in the final rule in § 512.365(b), and ETC transplant waitlist rate, as described in § 512.365(c), for each Measurement Year (MY). The ETC Participant's transplant waitlist rate, will be aggregated, as described in § 512.365(e), and the ETC Participant's home dialysis rate will be aggregated, as described in § 512.365(e). The ETC Participant will receive a Modality Performance Score (MPS) based on the weighted sum of the higher of the ETC Participant's achievement score or improvement score for the home dialysis rate and the higher of the ETC Participant's achievement score or improvement score for the transplant waitlist rate, as described in § 512.370(d).

For MY1 and MY2 (January 1, 2021 through July 6, 2022), the achievement scores will be calculated in relation to a set of benchmarks based on the historical rates of home dialysis and inclusion on the transplant waitlist among ESRD facilities and Managing Clinicians located in Comparison Geographic Areas. The improvement scores will be calculated in relation to a set of benchmarks based on the ETC Participant's own historical performance. The ETC Participant's MPS for a MY will determine the magnitude of its PPA during the corresponding 6-month PPA Period, which will begin 6 months after the end of the MY. An ETC Participant's MPS will be updated on a rolling basis every 6 months.

As mentioned in section IV.C.2.b(1) of the Specialty Care Models final rule (85 FR 61351), the intention was to increase achievement benchmarks over time through subsequent notice and

[279] As discussed in section IV.D of this final rule, we are finalizing our proposed special scoring methodology and payment policy for PY 2022. Under this policy, we will not apply any payment reductions to ESRD facilities for PY 2022.

comment rulemaking. In the CY 2022 ESRD PPS proposed rule, the changes listed with bullets were proposed for MY3 (beginning January 1, 2022) through the final MY of ETC Model (MY10).

- Include nocturnal in-center dialysis in the home dialysis rate calculation for Managing Clinicians and ESRD facilities not owned in whole or in part by an ETC LDO.
- Modify the PPA achievement benchmarking methodology:

++Stratify the home dialysis and transplant rate benchmark by the proportion of beneficiaries who are dual-eligible for Medicare and Medicaid, or, receive the Low-Income Subsidy (LIS), resulting in two strata.

++Increase the home dialysis and transplant rate benchmarks by 10 percent for each MY couplet (that is, 1.10 for MY3 and MY4, 1.20 for MY5 and MY6, 1.30 for MY7 and MY8, and 1.40 for MY9 and MY10).

- Modify the PPA improvement benchmarking methodology:

++Health Equity Incentive: Participants can earn 0.5 improvement points in addition to their improvement score for a 5 percentage point increase in the home dialysis rate or transplant rate among dual eligible or LIS recipient beneficiaries.

++Modify improvement calculation to ensure that the Benchmark Year rate cannot be zero, such that improvement is calculable for all participants.

In this final rule, we finalized all of the changes proposed in the CY 2022 ESRD PPS proposed rule, with certain modifications. The two such modifications most likely to affect the impact estimate for the ETC Model are:

- Modify the home dialysis rate calculation by including nocturnal dialysis in the numerator of the home dialysis rate calculation for all ESRD facilities, rather than only those ESRD facilities not owned in whole or in part by an ETC LDO.
- Modify the methodology for the Health Equity Incentive by reducing the threshold to earn the additional 0.5 improvement points from a 5-percentage point increase to a 2.5-percentage point increase from the Benchmark Year to the MY.

More detail on these changes are provided in sections V.B.3.c and V.B.6.c.(2) of this final rule. The ETC Model is not a total cost of care model. ETC Participants will still bill FFS Medicare, and items and services not subject to the ETC Model's payment adjustments will continue to be paid as they will in the absence of the Model.

(2). Data and Methods

A stochastic simulation was created to estimate the financial impacts of the changes to the ETC Model relative to baseline expenditures, where baseline expenditures were defined as data from CYs 2018 and 2019 without the changes applied. The simulation relied upon statistical assumptions derived from retrospectively constructed ESRD facilities' and Managing Clinicians' Medicare dialysis claims, transplant claims, and transplant waitlist data reported during 2018 and 2019, the most recent years with complete data available. Both datasets and the risk-adjustment methodologies for the ETC Model were developed by the CMS Office of the Actuary (OACT).

The ESRD facilities and Managing Clinicians datasets were restricted to the following eligibility criteria. Beneficiaries must be residing in the United States, 18 years of age or older, and enrolled in Medicare Part B. Beneficiaries enrolled in Medicare Advantage or other cost or Medicare managed care plans, who have elected hospice, are receiving dialysis for acute kidney injury (AKI) only, with a diagnosis of dementia, who are receiving dialysis in a nursing facility, or reside in a skilled nursing facility were excluded. In addition, beneficiaries who have a diagnosis of and are receiving treatment with chemotherapy or radiation for a vital solid organ cancer were excluded from the transplant rate calculations. Diagnosis of a vital solid organ cancer was defined as a beneficiary that had a claim with any of 39 ICD–10–CM codes ranging from C22.0 through C79.02. Treatment of a vital solid organ cancer was defined as a beneficiary with a claim with any of 2,087 radiation administration ICD–10–PCS codes, 19 chemotherapy administration CPT codes, or 41 radiation administration CPT codes. Last, the HRR was matched to the claim service facility ZIP Code™ or the rendering physician ZIP Code for ESRD facility and Managing Clinician, respectively.[280]

For the modeling exercise used to estimate changes in payment to providers and suppliers and the resulting savings to Medicare, OACT maintained the previous method to identify ESRD facilities with common ownership, the low-volume exclusion threshold, and the aggregation assumptions as CMS is not making changes to these model policies. To clarify OACT's methodology, the ESRD facilities' data were aggregated to the CMS Certification Number (CCN) level for beneficiaries on dialysis identified by outpatient claims with Type of Bill 072X to capture all dialysis services furnished at or through ESRD facilities. Beneficiaries receiving home dialysis services were defined as condition codes 74 and 76 (§ 512.340). Condition code 75 was removed from the home dialysis definition because that billing code is no longer in use. Condition code 80 was removed because we want to exclude beneficiaries who received home dialysis furnished in a SNF or nursing facility. Beneficiaries receiving in-center dialysis services were defined using condition code 71. Two new variables were created: In-center self-dialysis, condition code 72 (§ 512.365) and in-center nocturnal dialysis, based on any of the claims' lines 1–5 HCPCS codes equal to the ''UJ'' modifier. Self-care in training and ESRD self-care retraining, condition codes 73 and 87, respectively, were only included in the denominator for the home dialysis rate calculation. For consistency with the exclusion in § 512.385(a), after grouping within each HRR, aggregated ESRD facilities with less than 132 total attributed beneficiary months during a given MY were excluded. When constructing benchmarks, for consistency with the methodology for aggregating performance for purposes of the PPA calculation, we aggregated all ESRD facilities owned in whole or in part by the same dialysis organization located in the same HRR.

The Managing Clinicians' performance data were aggregated to the Tax Identification Number (TIN) level (for group practices) and the individual National Provider Identifier (NPI) level (for solo practitioners). For purposes of calculating the home dialysis rate, beneficiaries on home dialysis were identified using outpatient claims with CPT® codes 90965 and 90966 (§ 512.345). Beneficiaries receiving in-center dialysis were identified by outpatient claims with CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962 (§ 512.360). Last, following the low-volume threshold described in § 512.385(b), after grouping within each HRR, Managing Clinicians with less than 132 total attributed beneficiary months during a given MY were excluded.

The Scientific Registry of Transplant Recipients (SRTR) transplant waitlist data were obtained from the Center for Clinical Standards and Quality (CCSQ). To construct the transplant waitlist rate, the numerator was based on per-patient counts and included every addition to the waitlist for a patient in any past year. The waitlist counts for the

[280] ZIP Code is a trademark owned by the United States Postal Service.

numerator included waitlists for kidney transplants, alone or with another organ, active and inactive records, multi-organ listings, and patients that have subsequently been removed from the waitlist. The denominator was a unique count of prevalent dialysis patients as of the end of the year. Only patients on dialysis as of December 31st for the selected year were included. Facility attribution was based on the facility the patient was admitted to on the last day of the year.

For MY1 and MY2, the home dialysis score and transplant score for the PPA were calculated using the following methodology for the ESRD facilities and Managing Clinicians. ETC Participant behavior for each year was simulated by adjusting the ETC Participant's baseline home dialysis (or transplant) rate for a simulated statistical fluctuation and then summing with the assumed increase in home dialysis (or transplant) rate multiplied by a randomly generated improvement scalar. The achievement and improvement scores were assigned by comparing the ETC Participant's simulated home dialysis (or transplant) rate for the MY to the percentile distribution of home dialysis (or transplant) rates in the prior year. Last, the MPS was calculated using the weighted sum of the higher of the achievement or improvement score for the home dialysis rate and the transplant waitlist rate. The home dialysis rate constituted two-thirds of the MPS, and the transplant rate one-third of the MPS.

For MY3 through MY10, the home dialysis rate calculation accounts for modifications in this final rule compared to the CY 2022 ESRD PPS proposed rule. The revisions include changing the numerator for the home dialysis rate from the home dialysis beneficiary months to the home dialysis beneficiary months + 0.5 (in-center self-dialysis beneficiary months) + 0.5* (nocturnal in-center dialysis beneficiary months), such that 1-beneficiary year is comprised of 12-beneficiary months for all ETC Participants.

The number of beneficiaries on in-center self-dialysis who met the eligibility criteria for the ETC Model was very small, ranging from 102 to 277 over the period 2012–2019 and decreasing 89.9 percent to 22 beneficiaries in 2020 (based on preliminary 2020 data at CMS). With such a small sample size, the growth rate vacillated significantly. In addition, the in-center nocturnal dialysis UJ modifier code did not become effective until January 1, 2017; therefore, there were insufficient data to generate growth rate assumptions. The in-center nocturnal dialysis beneficiary growth rate decreased by 91.3 percent in 2020. As a solution to these data limitations, to simulate the impact of incorporating in-center self-dialysis and in-center nocturnal dialysis for the purpose of the savings to Medicare estimate, the simulation assumed any given ESRD facility or Managing Clinician will have a one percent chance of receiving an increased achievement score due to this policy.

The overall process for generating achievement and improvement scoring followed modeling from section VI.C.2 of the Specialty Care Models final rule (85 FR 61352), with the exception of the following changes proposed in the CY 2022 ESRD PPS proposed rule, which we are finalizing in this final rule.

Beginning for MY3 and beyond, the achievement benchmarking methodology included two modifications. First, the home dialysis rate and transplant waitlist rate benchmarks were increased by a total of 10 percent relative to ESRD facilities and Managing Clinicians not selected for participation, every two MYs. To clarify, no changes to the achievement benchmarking methodology were made to MYs 1 and 2. The latter MY couplets' achievement benchmarking included the following preset benchmark updates:

- MYs 3 and 4: Comparison Geographic Area percentiles*1.10,
- MYs 5 and 6: Comparison Geographic Area percentiles*1.20,
- MYs 7 and 8: Comparison Geographic Area percentiles*1.30, and
- MYs 9 and 10: Comparison Geographic Area percentiles*1.40.

The percentiles represented the 30th, 50th, 75th, and 90th percentile of the home dialysis rate and transplant rate for ESRD facilities and Managing Clinicians not selected for participation. The preset benchmark updates method provides greater certainty to ETC Participants than the rolling updates described in section IV.C.2.b(3) of the Specialty Care Models final rule (85 FR 61353).

Second, we incorporated two proxies for socioeconomic status, dual eligibility status or receipt of the Low Income Subsidy (LIS), as part of the achievement benchmarking starting for MY3 and beyond. Dual eligibility status was defined as a Medicare beneficiary with any of the following full-time dual type codes: 02 = Eligible is entitled to Medicare Qualified Medicare Beneficiary (QMB) and Medicaid coverage including prescription drugs, 04 = Eligible is entitled to Medicare Specified Low-Income Medicare Beneficiary (SLMB) and Medicaid coverage including prescription drugs, or 08 = Eligible is entitled to Medicare Other dual eligible with Medicaid coverage including prescription drugs. Separately, a yes/no indicator was created for any beneficiary that was either deemed or determined by the Social Security Administration (SSA) to be receiving the LIS. The home dialysis rate and transplant waitlist rate achievement benchmarks were then stratified by the proportion of attributed beneficiaries who are dual-eligible or receive the LIS. Two strata were created with a cutpoint of approximately 50 percent for participants with any dual-eligible or LIS recipient beneficiaries and those who do not have beneficiaries meeting these two socioeconomic status proxies.

Third, a Health Equity Incentive was added to improvement scoring starting in MY3. For the purpose of the estimates in this Regulatory Impact Analysis, we incorporated a random variable to simulate each ETC Participant's baseline variation and behavioral improvement for each MY. If the participant's simulated improvement behavior in MY3 through MY10 was greater than 2.5 percent, then the participant received a 0.5-point increase on their improvement score, allowing for a maximum of 2.0 total points. The threshold for receiving the Health Equity Incentive was reduced from the 5-percentage point threshold proposed in the CY 2022 ESRD PPS proposed rule to a 2.5-percentage point threshold in this final rule.

For all MYs, the transplant waitlist benchmarks were annually inflated by approximately 3-percentage points growth. This was a modification from section VI.C.2 of the Specialty Care Models final rule (85 FR 61352), where the waitlist benchmarks were annually inflated by approximately 2-percentage points growth observed during years 2017 through 2019 in the CCSQ data, to project rates of growth. The additional 1 percentage point growth in this final rule was included to account for uncertainty from the COVID–19 PHE disruption and section 17006 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255), which amended the Act to increase enrollment options for individuals with ESRD into Medicare Advantage. To clarify, applying the 3-percentage point annual growth from the median transplant waitlist rate across HRR condensed facilities grew from 8 percent in 2017 to 11 percent in 2018 to 14 percent in 2019 (that is, not a growth rate of 1.03 percent per year).

To assess the impact of the COVID–19 PHE on the kidney transplant waitlist, we analyzed data from the

United Network for Organ Sharing (UNOS).[281] The UNOS data suggest that the number of new patients added to the kidney transplant waitlist steadily decreased between the weeks of March 15, 2020 through May 10, 2020, when between 16 to 81 percent of patients listed on the weekly kidney transplant waitlist became inactive due to COVID–19 precautions. During July through December 2020, the number of new patients added to the kidney transplant waitlist increased to near pre-pandemic levels with an average of less than 3 percent of patients listed as inactive due to COVID–19. Anomalous dips in the number of new patients added to the kidney transplant waitlist were observed during the weeks of November 22, 2020 and December 27, 2020, which correspond with Federal holidays in addition to a period that Americans were asked to social distance to slow the spread of COVID–19. Continuing into the first quarter of 2021, new additions to the kidney transplant waitlist remained at approximately pre-pandemic rates. Therefore, we assume that the number of new patients added to the waitlist will not decrease as a result of the pandemic and the linear 2-percentage point growth rate for the transplant waitlist calculated using years 2017 through 2019 CCSQ data remains a reasonable assumption for baseline growth going forward. In the final rule, we also included a 1 percent increase to the standard error to account for a new variation assumption to address how year-over-year changes could fluctuate at the ESRD facility or Managing Clinician level, which was potentially exacerbated by the exclusion criteria (that is, residents of a nursing facility, receiving dialysis in a skilled nursing facility, dialysis for AKI only) applied to the updated model data source used for estimates in this final rule.

No changes were made to the payment structure for the HDPA calculation in the final rule (§ 512.350). As such, the HDPA was calculated using the home dialysis and home dialysis-related payments adjusted by decreasing amounts (3, 2, and 1 percent) during each of the first 3 years of the Model.

The kidney disease patient education services utilization and cost data were identified by HCPCS codes G0420 and G0421, to capture face-to-face individual and group training sessions for chronic kidney disease beneficiaries on treatment modalities. The home dialysis training costs for incident beneficiaries on home dialysis for Continuous Ambulatory Peritoneal Dialysis (CAPD) or Continuous Cycler-Assisted Peritoneal Dialysis (CCPD) were defined using CPT® codes 90989 and 90993 for complete and incomplete training sessions, respectively.

Data from CY 2019 were used to project baseline expenditures (that is, expenditures before the proposed changes were applied) and the traditional FFS payment system billing patterns were assumed to continue under current law.

(3). Medicare Estimate—Primary Specification, Assume Preset Benchmark Updates

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[281] UNOS. 2021. COVID–19 and Solid Organ Transplants. Transplant and Waitlist Data Visualizations. *https://unos.org/covid/.*

TABLE 18. Estimates of Medicare Program Savings (Rounded $M) for ETC MODEL

	Year of Model							
	2021	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**6.5 Year Total***
Net Impact to Medicare Spending	15	9	-2	-10	-12	-18	-9	-28
Overall PPA Net & HDPA	14	7	-4	-12	-15	-21	-12	-43
Clinician PPA Downward Adjustment		-1	-2	-2	-3	-4	-2	-13
Clinician PPA Upward Adjustment		0	1	1	1	1	1	5
Clinician PPA Net		0	-1	-1	-2	-2	-1	-8
Clinician HDPA	0	0	0					0
Facility Downward Adjustment		-9	-21	-25	-31	-39	-21	-146
Facility Upward Adjustment		5	12	15	18	20	10	80
Facility PPA Net		-3	-9	-10	-13	-19	-11	-65
Facility HDPA	14	10	6					30
Total PPA Downward Adjustment		-9	-22	-28	-34	-42	-23	-159
Total PPA Upward Adjustment		6	13	16	19	21	11	86
Total PPA Net		-4	-10	-12	-15	-21	-12	-73
Total HDPA	14	10	6					30
Kidney Disease Patient Education Services Costs	0	1	1	1	1	1	1	5
HD Training Costs	1	1	1	1	2	2	2	10

*Totals may not sum due to rounding and from beneficiaries that have dialysis treatment spanning multiple years. Negative spending reflects a reduction in Medicare spending. The Kidney Disease Patient Education Services Costs are less than $1M each year, but are rounded up to $1M to show what years they apply to. Similarly, the HD Training Costs are less than $1M for years 2021-2024, but are rounded up to $1M to indicate that costs were applied those years.

TABLE 19: Difference from the Proposed Rule (86 FR 36425) (Rounded $M)

	Year of Model							
	2021	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**4.5 Year Total***
Net Impact to Medicare Spending			1	2	2	3	2	10
Overall PPA Net & HDPA			1	2	2	3	2	10
Total PPA Downward Adjustment			1	1	1	1	1	4
Total PPA Upward Adjustment			0	1	1	2	1	5
Total PPA Net			1	2	2	3	2	10
Total HDPA								0

* Model changes effective for MY 3. Payments adjusted beginning in PPA Period 3, effective July 1, 2023 going forward. No changes to the HDPA. No changes to the Kidney Disease Patient Education Services Costs or the HD Training Costs. See Table 18 for additional footnotes.

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Table 18 summarizes the estimated impact of the ETC Model when assuming preset benchmark updates where the achievement benchmarks for each year are set using the average of the home dialysis rates for year *t*-1 and year *t*-2 for the HRRs randomly selected for participation in the ETC Model. We estimate the Medicare program will save a net total of $43 million from the PPA and HDPA between January 1, 2021 and June 30, 2027, less $15 million in increased training and education expenditures. Therefore, the net impact to Medicare spending is estimated to be $28 million in savings. In Table 18 and Table 19, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase. The results for both tables were generated from an average of 400 simulations under the assumption that benchmarks are rolled forward with a 1.5-year lag.

Table 19 is provided to isolate the total impact of the changes in this final rule for years 2023 going forward by calculating the difference from our final estimates in Table 18 less totals from the

estimates reported in Table 18 of the CY 2022 ESRD PPS proposed rule (86 FR 36425) that used the same years of data, but without the changes from the CY 2022 ESRD PPS proposed rule to this final rule. To clarify, the CY 2022 ESRD PPS proposed rule estimates are not the estimates reported in Table 19 of the Specialty Care Models final rule (85 FR 61354); the final rule used data from CYs 2016 and 2017 and this final rule used the most recent data available, from CYs 2018 and 2019. There was no impact reported in years 2021 and 2022 since the payment adjustments were not effective until MY3. In addition, the changes did not apply to the HDPA or the Kidney Disease Patient Education Services Costs and HD Training Costs. As expected, Table 19 shows that the changes had a small effect on Medicare savings; a reduction of $10 million in savings for the net impact to Medicare spending over the 4.5-year period can be attributed to the changes in this final rule from the CY 2022 ESRD PPS proposed rule.

As was the case in the Specialty Care Models final rule (85 FR 61353), the projections do not include the Part B premium revenue offset because the payment adjustments under the ETC Model will not affect beneficiary cost-sharing. Any potential effects on Medicare Advantage capitation payments were also excluded from the projections. This approach is consistent with how CMS has previously conveyed the primary FFS effects anticipated for an uncertain model without also assessing the potential impact on Medicare Advantage rates.

Returning to Table 18, as anticipated, the expected Medicare program savings were driven by the net effect of the Facility PPA; a reduction in Medicare spending of $65 million over the period from July 1, 2022 through June 30, 2027. In comparison, the net effect of the Clinician PPA was only $8 million in Medicare savings. This estimate was based on an empirical study of historical home dialysis utilization and transplant waitlist rates for Medicare FFS beneficiaries that CMS virtually attributed to ESRD facilities and to Managing Clinicians based on the plurality of associated spending at the beneficiary level. We analyzed the base variation in those facility/practice level measures and simulated the effect of the payment policy assuming providers and suppliers respond by marginally increasing their share of patients utilizing home dialysis. Random variables were used to vary the effectiveness that individual providers and suppliers might show in such progression over time and to simulate the level of year-to-year variation already noted in the base multi-year data that was analyzed. The uncertainty in the projection was illustrated in sections VII.C.2.b.(3)(a) and VII.C.2.b.(3)(b) of the Specialty Care Models final rule (85 FR 61354), respectively, through alternate scenarios assuming that the benchmarks against which ETC Participants are measured were to not be updated. In those sensitivity analyses, we analyzed a modified version of the model that included a fixed benchmark for the home dialysis and transplant waitlist rates as well as a separate sensitivity analysis that assumed a rolling benchmark for the home dialysis rate and a fixed benchmark for the transplant waitlist rate.

For this final rule, we are continuing with the approach applied in the CY 2022 ESRD PPS proposed rule by modeling a preset benchmark growth rate in this rule but continue to incorporate sensitivity to a range of potential behavioral changes for the home dialysis rate and transplant waitlist rate for ETC facilities and Managing Clinicians assumed to participate in the model. Kidney disease patient education services on treatment modalities and home dialysis (HD) training for incident dialysis beneficiaries are relatively small outlays and were projected to represent only relatively modest increases in Medicare spending each year.

The key assumptions underlying the impact estimate are that each aggregation group's share of total maintenance dialysis provided in the home setting was assumed to grow by up to an assumed maximum growth averaging 3-percentage points per year. Factors underlying this assumption about the home dialysis growth rate include: known limitations that may prevent patients from being able to dialyze at home, such as certain common disease types that make peritoneal dialysis impractical (for example, obesity); current equipment and staffing constraints; and the likelihood that a patient new to maintenance dialysis starts dialysis at home compared to the likelihood that a current dialysis patient who dialyzes in center switches to dialysis at home. In any given trial of the simulation, the maximum growth rate was chosen from a uniform distribution of 0 to 5-percentage points per year. Preliminary data from CMS show that the growth rate for home dialysis was 3.9 percent in CY 2020 for beneficiaries meeting the eligibility criteria for the ETC Model. This growth rate is within range to what was observed prior to the establishment of the Advancing American Kidney Health initiative in 2019 and it also shows that the COVID–19 PHE did not cause the home dialysis growth assumption to become invalid. The 3-percentage point per year average max growth rate will, in effect, move the average market peritoneal dialysis rate (about 10 percent) to the highest market baseline peritoneal dialysis rate (for example, Bend, Oregon HRR at about 25 percent), which we believe is a reasonable upper bound on growth over the duration of the ETC Model for the purposes of this actuarial model.

Aggregation groups were assumed to achieve anywhere from zero to 100 percent of such maximum growth in any given year. Thus, the average projected growth for the share of maintenance dialysis provided in the home was 1.5-percentage points per year (expressed as the percentage of total dialysis). In contrast, we do not include an official assumption that the overall number of kidney transplants will increase and provide justification for this assumption in sections VI.C.2.b.(4) and VI.C.2.b.(5) of the Specialty Care Models final rule (85 FR 61355). However, as part of the sensitivity analysis for the savings calculations for the model, we laid out a different savings scenario if the ETC Learning Collaborative described in VI.C.2.b.(6) of the Specialty Care Models final rule (85 FR 61355) were to be successful in decreasing the discard rate of deceased donor kidneys and increasing the utilization rate of deceased donor kidneys that have been retrieved.

(4). Sensitivity Analysis: Medicare Savings Estimate—Results for the 10th and 90th Percentiles

Using the primary specification for the Medicare estimate with preset benchmark updates for home dialysis and transplant waitlist rates, we compared the results for the top 10th and 90th percentiles of the 400 individual simulations to the average of all simulation results reported in Table 18. Since the impact on Medicare spending for the ETC Model using the present benchmark updates is estimated to be in savings rather than losses, the top 10th and 90th percentiles represent the most optimistic and conservative projections, respectively. The overall net PPA and HDPA for the top 10th and 90th percentiles using the present benchmark updates method are $102 million in savings and $9 million in losses (encompassing the mean estimate of $43 million in savings in Table 18). The overall uncertainty of the impact of the model is further illustrated in Table 19, the change from the CY 2022 ESRD

PPS proposed rule, where the mean $10 million dollars in savings reported for the Overall PPA Net & HDPA has $64 million in savings and $97 million in losses, for the top 10th and 90th percentiles, respectively.

(5). Effects on the Home Dialysis Rate

The two changes in this final rule have the potential to increase ETC Participants' home dialysis rate, therefore reducing the overall savings to Medicare estimate. First, this final rule modifies the home dialysis rate equation by adding 0.5 multiplied by the sum of the self-dialysis beneficiary months and the in-center nocturnal dialysis beneficiary months to the numerator such that 1-beneficiary year is comprised of 12-beneficiary months for Managing Clinicians and all ESRD facilities, regardless of ownership.

However, less than 1 percent of beneficiaries eligible for attribution into the ETC Model were receiving either self-dialysis or nocturnal in-center dialysis in CY 2019. In addition, in CY 2020, the annual growth rate decreased by 89.9 and 91.3 percent for beneficiaries receiving self-dialysis or in-center nocturnal dialysis, respectively. The sharp decline in these dialysis modalities is potentially in response to the COVID–19 pandemic. The low historical take-up for self-dialysis and shortage of historical years for in-center nocturnal dialysis (that is, a nocturnal dialysis claims line instruction became effective in 2017) result in these modifications having an insignificant impact on the savings to Medicare.

The second change in this final rule that has the potential to generate higher PPA scores for a limited subset of providers and therefore a small negative impact on estimated savings for the Model is the Health Equity Incentive. The Health Equity Incentive proposed in the CY 2022 ESRD PPS proposed rule (86 FR 36427) would have rewarded ETC Participants with an additional 0.5 points to their improvement score who improved the home dialysis rate (or transplant rate) among their attributed beneficiaries who are dual eligible or receive the LIS by at least 5 percentage points between the Benchmark Year to the MY. In this final rule, the threshold to earn the 0.5 improvement points was reduced to a 2.5-percentage point increase from the Benchmark Year to the MY. The $10 million decrease in the savings to Medicare estimate in this final rule relative to the CY 2022 ESRD PPS proposed rule was primarily due to the change in the Health Equity Incentive threshold.

(6). Effects on Kidney Transplantation

Kidney transplantation is considered the optimal treatment for most ESRD beneficiaries. The PPA includes a one-third weight on the ESRD facilities' or Managing Clinician's transplant waitlist rate, with the ultimate goal of increasing the rate of kidney transplantation. However, the changes in this final rule do not impact our decision in the CY 2022 ESRD PPS proposed rule or the Specialty Care Models final rule to not include an assumption that the overall number of kidney transplants will increase. The number of ESRD patients on the kidney transplant waitlist has for many years far exceeded the annual number of transplants performed. Transplantation rates have not increased to meet such demand because of the limited supply of deceased donor kidneys. The U.S. Renal Data System [282] reported 22,393 kidney transplants in 2018 compared to a kidney transplant waiting list [283] of over 98,000. Refer to section VI.C.2.b(4) in the Specialty Care Models final rule (85 FR 61355) for a detailed justification for our assumption that the overall number of kidney transplants will not increase in response to ESRD facilities and Managing Clinicians participating in the ETC Model.

(7). Effects of the Transplant Rate

The ETC Model continues to include the transplant rate described in the Specialty Care Models final rule (§ 512.365).

The change in this final rule that has the potential to generate higher scores for a limited subset of ETC Participants and therefore a small reduction in the estimated savings for the Model relative to the CY 2022 ESRD PPS proposed rule is the modification to the Health Equity Incentive threshold. By lowering the threshold for earning the Health Equity Incentive threshold in this final rule relative to the threshold proposed in the CY 2022 ESRD PPS proposed rule, more ETC Participants have the potential to earn the additional 0.5 points to their improvement score.

(8). Effects on Kidney Disease Patient Education Services and HD Training Add-Ons

The changes to the ETC Model finalized in this final rule relative to the Specialty Care Models final rule do not impact the findings reported for the effects of the ETC Model on the Kidney Disease Patient education services and HD training add-ons described in section VI.C.2.b(6) in the Specialty Care Models final rule (85 FR 61356–57).

(9). Effects on Medicare Beneficiaries

The changes in this final rule relative to the CY 2022 ESRD PPS proposed rule could incentivize ESRD facilities and Managing Clinicians serving dual eligible or LIS recipient Medicare beneficiaries to potentially improve access to care for those beneficiaries. The final rule's changes could also marginally improve uptake of the in-center nocturnal dialysis treatment modality since this dialysis method was not directly incentivized (that is, accounted for in the home dialysis rate for all ESRD facilities) under the ETC Model. The changes made to the final rule may have marginally increased uptake of in-center nocturnal dialysis for ESRD facilities owned in whole or in part by an ETC LDO relative to the CY 2022 ESRD PPS proposed rule, which had proposed to exclude ESRD facilities owned in whole or in part by an ETC LDO from the in-center nocturnal dialysis policy.

As noted in section VI.C.3.B of the Specialty Care Models final rule (85 FR 61357), we continue to anticipate that the ETC Model will have a negligible impact on the cost to beneficiaries receiving dialysis. Under current policy, Medicare FFS beneficiaries are generally responsible for 20 percent of the allowed charge for services furnished by providers and suppliers. This policy will remain the same for most beneficiaries under the ETC Model. However, we will waive certain requirements of title XVIII of the Act as necessary to test the PPA and HDPA under the ETC Model and to hold beneficiaries harmless from any effect of these payment adjustments on cost sharing. In addition, the Medicare beneficiary's quality of life has the potential to improve if the beneficiary elects to have home dialysis, or nocturnal in-center dialysis, as opposed to in-center dialysis. Studies have found that home dialysis patients experienced improved quality of life as a result of their ability to continue regular work schedules or life plans; as well as better overall, physical, and psychological health in comparison to other dialysis options.

(10). Alternatives Considered

Throughout this final rule, we have identified our policies and alternatives that we have considered, and provided information as to the likely effects of

[282] United States Renal Data System. 2020. ''ADR Reference Table E6 Renal Transplants by Donor Type.'' *https://adr.usrds.org/2020/reference-tables.*

[283] Organ Procurement and Transplantation Network. 2021. ''Current US Waiting List, Overall by Organ.'' *https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#.*

these alternatives and the rationale for each of our policies.

This final rule addresses a model specific to ESRD. It provides descriptions of the requirements that we will waive, identifies the performance metrics and payment adjustments to be tested, and presents rationales for our changes, and where relevant, alternatives that we considered. We carefully considered the alternatives to this final rule, including the degree that benchmark targets should be prospectively updated to provide greater transparency to ETC Participants while preserving the expectation for model net savings for the program. For context related to alternatives previously considered when establishing the ETC Model we refer readers to the Specialty Cares Models final rule (85 FR 61114) for more information on policy-related stakeholder comments, our responses to those comments, and statements of final policy preceding the limited modifications proposed here.

D. Accounting Statement

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 20, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this final rule.

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TABLE 20: Accounting Statement: Classification of Estimated Transfers and Costs/Savings	
ESRD PPS and AKI (CY 2022)	
Category	**Transfers**
Annualized Monetized Transfers	$230 million
From Whom to Whom	Federal government to ESRD providers
Category	**Transfers**
Increased Beneficiary Co-insurance Payments	$60 million
From Whom to Whom	Beneficiaries to ESRD providers
ESRD QIP for PY 2022	
Category	**Transfers**
Annualized Monetized Transfers	$0
From Whom to Whom	Federal government to ESRD providers.
ESRD QIP for PY 2024	
Category	**Transfers**
Annualized Monetized Transfers	-$17 million
From Whom to Whom	Federal government to ESRD providers.
ESRD QIP for PY 2025	
Category	**Transfers**
Annualized Monetized Transfers	-$17 million
From Whom to Whom	Federal government to ESRD providers
ETC Model for Jan 1, 2023 through June 30, 2027 Impacts of Changes in the Final Rule	
Category	**Transfers**
Annualized Monetized Transfers	-$2.00 million
From Whom to Whom	Federal government to ESRD facilities and Managing Clinicians

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

E. Regulatory Flexibility Act Analysis (RFA)

The Regulatory Flexibility Act (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 11 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 $41.5 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 website at *http://www.sba.gov/content/small-business-size-standards* (Kidney Dialysis Centers are listed as 621492 with a size standard of $41.5 million).

When viewed as individual entities, as opposed to being a part of a LDO, there are approximately 1,295 (~17 percent of total number of ESRD facilities) ESRD facilities that provide fewer than 4,000 treatments per year. With a low volume payment adjustment, each facility generates revenue from dialysis treatments of ~$1.26 million per year per facility. This is shown in the Table 21.

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TABLE 21: Revenue Table for Low Volume ESRD Facilities for CY 2022 ESRD PPS Final Rule

ESRD Facility size based on # of dialysis treatments	# of low volume ESRD Facilities per Table 9	% of total number of ESRD facilities	~Individual ESRD facility revenue per treatment (including low volume adjustment)	~Annual total treatment revenue per ESRD facility based on 3999 treatments or less	~Total annual treatment revenue to all low volume ESRD facilities
< 4000	1,295	~17%	$320	$1.28 M	$1.6B

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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 11 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 9. Using the definitions in this ownership category, we consider 515 facilities that are independent and 378 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by LDOs and regional chains would have total revenues of more than $41.5 million in any year when the total revenues for all locations are combined for each business (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 1.3 percent increase in payments for CY 2022. An independent facility (as defined by ownership type) is estimated to receive a 1.1 percent increase in payments for CY 2022.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for $52 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the ESRD QIP, we estimate that of the 1,788 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2024 ESRD QIP, 331 are ESRD small entity facilities. We present these findings in Table 11 (''Estimated Distribution of PY 2024 ESRD QIP Payment Reductions'') and Table 13 (''Estimated Impact of QIP Payment Reductions to ESRD Facilities for PY 2024'').

For ETC Model, this final rule includes as ETC Participants Managing Clinicians and ESRD facilities required to participate in the Model pursuant to § 512.325(a). We assume for the purposes of the regulatory impact analysis that the great majority of Managing Clinicians are small entities and that the greater majority of ESRD facilities are not small entities. Throughout the final rule we describe how the adjustments to certain payments for dialysis services and dialysis-related services furnished to ESRD beneficiaries may affect Managing Clinicians and ESRD facilities participating in the ETC Model. The great majority of Managing Clinicians are small entities by meeting the SBA definition of a small business (having minimum revenues of less than $8 million to $41.5 million in any 1 year, varying by type of provider and highest for hospitals) with a minimum threshold for small business size of $41.5 million (*https://www.sba.gov/document/support--table-size-standards http://www.sba.gov/content/small-businesssize-standards*). The great majority of ESRD facilities are not small entities, as they are owned, partially or entirely by entities that do not meet the SBA definition of small entities.

The HDPA in the ETC Model is a positive adjustment on payments for specified home dialysis and home dialysis-related services. The PPA in the ETC Model, which includes both positive and negative adjustments on payments for dialysis services and dialysis-related services, excludes aggregation groups with fewer than 132 attributed beneficiary-months during the relevant year.

The aggregation methodology groups ESRD facilities owned in whole or in part by the same dialysis organization within a Selected Geographic Area and Managing Clinicians billing under the same TIN within a Selected Geographic Area. This aggregation policy increases the number of beneficiary months, and thus statistical reliability, of the ETC Participant's home dialysis and transplant rate for ESRD facilities that are owned in whole or in part by the same dialysis organization and for Managing Clinicians that share a TIN with other Managing Clinicians.

Taken together, the low volume threshold exclusions and aggregation policies previously described, coupled with the fact that the ETC Model will affect Medicare payment only for select services furnished to Medicare FFS beneficiaries; we have determined that the provisions of the final rule will not have a significant impact on spending for a substantial number of small entities (defined as greater than 5 percent impact).

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

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is

located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this final rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 122 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 122 rural hospital-based dialysis facilities will experience an estimated 1.0 percent increase in payments.

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

F. Unfunded Mandates Reform Act Analysis (UMRA)

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 2021, that threshold is approximately $158 million. This final rule does not mandate any requirements for State, local, or tribal governments in the aggregate, or by the private sector. 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.

G. Federalism

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

H. Congressional Review Act

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

IX. 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 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*.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 28, 2021.

List of Subjects

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

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

■ 1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 2. Section 413.177 is amended by revising paragraph (a) introductory text to read as follows:

§ 413.177 Quality incentive program payment.

(a) With respect to renal dialysis services as defined under § 413.171, except for those renal dialysis services furnished during payment year 2022, in the case of an ESRD facility that does not earn enough points under the program described at § 413.178 to meet or exceed the minimum total performance score (as defined at § 413.178(a)(8)) established by CMS for a payment year (as defined at § 413.178(a)(10)), payments otherwise made to the facility under § 413.230 for renal dialysis services during the payment year will be reduced by up to 2 percent as follows:

* * * * *

■ 3. Section 413.178 is amended by adding paragraph (h) to read as follows:

§ 413.178 ESRD quality incentive program.

* * * * *

(h) *Special rule for payment year 2022.* (1) CMS will calculate a measure rate for all measures specified by CMS under paragraph (c) of this section for the PY 2022 ESRD QIP but will not score facility performance on any of those measures or calculate a TPS for any facility under paragraph (e) of this section.

(2) CMS will not establish a mTPS for PY 2022.

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 4. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315(a), and 1395hh.

■ 5. Section 512.160 is amended by adding paragraph (a)(9) and revising paragraph (b)(6) to read as follows:

§ 512.160 Remedial action.

(a) * * *

(9) For the ETC Model only, has misused or disclosed the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the applicable data sharing agreement.

(b) * * *

(6) In the ETC Model only:

(i) Terminate the ETC Participant from the ETC Model.

(ii) Suspend or terminate the ability of the ETC Participant, pursuant to § 512.397(c), to reduce or waive the coinsurance for kidney disease patient education services.

* * * * *

■ 6. Section 512.310 is amended by adding definitions for ''Clinical staff'', ''Health Equity Incentive'', and

''Qualified staff'' in alphabetical order to read as follows:

§ 512.310 Definitions.

* * * * *

Clinical staff means a licensed social worker or registered dietician/nutrition professional who furnishes services for which payment may be made under the physician fee schedule under the direction of and incident to the services of the Managing Clinician who is an ETC Participant.

* * * * *

Health Equity Incentive means the amount added to the ETC Participant's improvement score, calculated as described in § 512.370(c)(1), if the ETC Participant's aggregation group demonstrated sufficient improvement on the home dialysis rate or transplant rate for attributed beneficiaries who are dual eligible or Medicare Low Income Subsidy (LIS) recipients between the Benchmark Year and the MY.

* * * * *

Qualified staff means both clinical staff and any qualified person (as defined at § 410.48(a) of this chapter) who is an ETC Participant.

* * * * *

■ 7. Section 512.360 is amended by revising paragraph (c)(2)(ii) introductory text and adding paragraph (c)(2)(iii) to read as follows:

§ 512.360 Beneficiary population and attribution.

* * * * *

(c) * * *

(2) * * *

(ii) For MY1 and MY2, a Pre-emptive LDT Beneficiary who is not excluded based on the criteria in paragraph (b) of this section is attributed to the Managing Clinician with whom the beneficiary has had the most claims between the start of the MY and the month in which the beneficiary received the transplant for all months between the start of the MY and the month of the transplant.

* * * * *

(iii) For MY3 through MY10, a Pre-emptive LDT Beneficiary who is not excluded based on the criteria in paragraph (b) of this section is attributed to the Managing Clinician who submitted the most claims for services furnished to the beneficiary in the 365 days preceding the date in which the beneficiary received the transplant.

(A) If no Managing Clinician has had the most claims for a given Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of claims for that beneficiary in the 365 days preceding the date of the transplant, the Pre-emptive LDT Beneficiary is attributed to the Managing Clinician associated with the latest claim service date at the claim line through date during the 365 days preceding the date of the transplant.

(B) If no Managing Clinician had the most claims for a given Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of claims for that beneficiary in the 365 days preceding the date of the transplant, and more than one of those Managing Clinicians had the latest claim service date at the claim line through date during the 365 days preceding the date of the transplant, the Pre-emptive LDT Beneficiary is randomly attributed to one of these Managing Clinicians.

(C) The Pre-emptive LDT Beneficiary is considered eligible for attribution under this paragraph (c)(2)(iii) if the Pre-emptive LDT Beneficiary has at least 1-eligible month during the 12-month period that includes the month of the transplant and the 11 months prior to the month of the transplant. An eligible month refers to a month during which the Pre-emptive LDT Beneficiary not does not meet exclusion criteria in paragraph (b) of this section.

■ 8. Section 512.365 is amended by revising paragraphs (b)(1)(ii), (b)(2)(ii), (c)(1)(i)(A), (c)(1)(ii)(A), (c)(2)(i)(A), and (c)(2)(ii)(A)(*1*) and (*2*) to read as follows:

§ 512.365 Performance assessment.

* * * * *

(b) * * *

(1) * * *

(ii) For MY1 and MY2, the numerator is the total number of home dialysis treatment beneficiary years plus one half the total number of self dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. For MY3 through MY10, the numerator is the total number of home dialysis treatment beneficiary years, plus one half the total number of self dialysis treatment beneficiary years, plus one half the total number of nocturnal in center dialysis beneficiary years for attributed ESRD Beneficiaries during the MY.

(A) Home dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home, such that 1-beneficiary year is comprised of 12-beneficiary months. Months in which an attributed ESRD Beneficiary received maintenance dialysis at home are identified by claims with Type of Bill 072X and condition codes 74 or 76.

(B) Self dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received self dialysis in center, such that 1-beneficiary year is comprised of 12-beneficiary months. Months in which an attributed ESRD Beneficiary received self dialysis are identified by claims with Type of Bill 072X and condition code 72.

(C) Nocturnal in center dialysis beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received nocturnal in center dialysis, such that 1-beneficiary year is comprised of 12-beneficiary months. Months in which an attributed ESRD Beneficiary received nocturnal in center dialysis are identified by claims with Type of Bill 072X and modifier UJ.

* * * * *

(2) * * *

(ii) For MY1 and MY2, the numerator is the total number of home dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY plus one half the total number of self dialysis treatment beneficiary years. For MY3 through MY10, the numerator is the total number of home dialysis treatment beneficiary years, plus one half the total number of self dialysis treatment beneficiary years, plus one half the total number of nocturnal in center dialysis beneficiary years for attributed ESRD Beneficiaries during the MY.

(A) Home dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home, such that 1-beneficiary year is comprised of 12-beneficiary months. Months in which an attributed ESRD Beneficiary received maintenance dialysis at home are identified by claims with CPT codes 90965 or 90966.

(B) Self-dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received self dialysis in center, such that 1-beneficiary year is comprised of 12-beneficiary months. Months in which an attributed ESRD Beneficiary received self dialysis are identified by claims with Type of Bill 072X and condition code 72.

(C) Nocturnal in center dialysis beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received nocturnal in center dialysis, such that 1-beneficiary year is comprised of 12-beneficiary

months. Months in which an attributed ESRD Beneficiary received nocturnal in center dialysis are identified by claims with Type of Bill 072X and modifier UJ.

* * * * *

(c) * * *

(1) * * *

(i) * * *

(A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY1 and MY2, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month. For MY3 through MY10, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY.

(*1*) An attributed ESRD Beneficiary had a diagnosis of vital solid organ cancer in an MY if the beneficiary had any of the following diagnosis codes on any claim during the MY or the 6 months prior to the start of the MY: C22.0, C22.1, C22.2, C22.3, C22.4, C22.7, C22.8, C22.9, C34.10–C34.12, C34.2, C34.30–C34.32, C34.80–C34.82, C34.90–C34.92, C38.0, C38.8, C46.50–C46.52, C64.1, C64.2, C64.2, C78.00–C78.02, C78.7, C79.00–C79.02, C7A.090, C7A.093, or C7B.02.

(*2*) An attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer during the MY if the beneficiary had a claim with any of the following procedure codes on any claim during the MY or the 6 months prior to the start of the MY:

(*i*) CPT® 96401–96402, 96405–96406, 96409, 96411, 96413, 96415–96417, 96420, 96422–26423, 96425, 96440, 96446, 96549, 77373, 77401–77402, 77407, 77412, 77423, 77424–77425, 77520, 77522–77523, 77525, 77761–77763, 77770–77772, 77778, 77789, 77799, 79005, 79101, 79200, 79300, 79403, 79440, 79445, 79999.

(*ii*) ICD–10–PCS® DB020ZZ, DB021ZZ, DB022ZZ, DB023Z0, DB023ZZ, DB024ZZ, DB025ZZ, DB026ZZ, DB1297Z, DB1298Z, DB1299Z, DB129BZ, DB129CZ, DB129YZ, DB12B6Z, DB12B7Z, DB12B8Z, DB12B9Z, DB12BB1, DB12BBZ, DB12BCZ, DB12BYZ, DB22DZZ, DB22HZZ, DB22JZZ, DBY27ZZ, DBY28ZZ, DBY2FZZ, DBY2KZZ, DB070ZZ, DB071ZZ, DB072ZZ, DB073Z0, DB073ZZ, DB074ZZ, DB075ZZ, DB076ZZ, DB1797Z, DB1798Z, DB1799Z, DB179BZ, DB179CZ, DB179YZ, DB17B6Z, DB17B7Z, DB17B8Z, DB17B9Z, DB17BB1, DB17BBZ, DB17BCZ, DB17BYZ, DB27DZZ, DB27HZZ, DB27JZZ, DBY77ZZ, DBY78ZZ, DBY7FZZ, DBY7KZZ, DF000ZZ, DF001ZZ, DF002ZZ, DF003Z0, DF003ZZ, DF004ZZ, DF005ZZ, DF006ZZ, DF1097Z, DF1098Z, DF1099Z, DF109BZ, DF109CZ, DF109YZ, DF10B6Z, DF10B7Z, DF10B8Z, DF10B9Z, DF10BB1, DF10BBZ, DF10BCZ, DF10BYZ, DF20DZZ, DF20HZZ, DF20JZZ, DFY07ZZ, DFY08ZZ, DFY0CZZ, DFY0FZZ, DFY0KZZ, DT000ZZ, DT001ZZ, DT002ZZ, DT003Z0, DT003ZZ, DT004ZZ, DT005ZZ, DT006ZZ, DT1097Z, DT1098Z, DT1099Z, DT109BZ, DT109CZ, DT109YZ, DT10B6Z, DT10B7Z, DT10B8Z, DT10B9Z, DT10BB1, DT10BBZ, DT10BCZ, DT10BYZ, DT20DZZ, DT20HZZ, DT20JZZ, DTY07ZZ, DTY08ZZ, DTY0CZZ, DTY0FZZ, DW020ZZ, DW021ZZ, DW022ZZ, DW023Z0, DW023ZZ, DW024ZZ, DW025ZZ, DW026ZZ, DW1297Z, DW1298Z, DW1299Z, DW129BZ, DW129CZ, DW129YZ, DW12B6Z, DW12B7Z, DW12B8Z, DW12B9Z, DW12BB1, DW12BBZ, DW12BCZ, DW12BYZ, DW22DZZ, DW22HZZ, DW22JZZ, DWY27ZZ, DWY28ZZ, DWY2FZZ, DW030ZZ, DW031ZZ, DW032ZZ, DW033Z0, DW033ZZ, DW034ZZ, DW035ZZ, DW036ZZ, DW1397Z, DW1398Z, DW1399Z, DW139BZ, DW139CZ, DW139YZ, DW13B6Z, DW13B7Z, DW13B8Z, DW13B9Z, DW13BB1, DW13BBZ, DW13BCZ, DB13BYZ, DW23DZZ, DW23HZZ, DW23JZZ, DWY37ZZ, DWY38ZZ, DWY3FZZ, DW050ZZ, DW051ZZ, DW052ZZ, DW053Z0, DW053ZZ, DW054ZZ, DW055ZZ, DW056ZZ, DWY57ZZ, DWY58ZZ, DWY5FZZ, DWY5GDZ, DWY5GFZ, DWY5GGZ, DWY5GHZ, DWY5GYZ.

* * * * *

(ii) * * *

(A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY1 and MY2, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month. For MY3 through MY10, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a diagnosis of vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*1*) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*2*) of this section.

* * * * *

(2) * * *

(i) * * *

(A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY1 and MY2, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month. For MY3 through MY10, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD

Beneficiary had a diagnosis of vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*1*) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*2*) of this section.

* * * * *

(ii) * * *

(A) * * *

(*1*) Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY1 and MY2, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month. For MY3 through MY10, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a vital solid organ cancer diagnosis are identified as described in paragraph (c)(1)(i)(A)(*1*) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*2*) of this section.

(*2*) MY1 and MY2, Pre-emptive LDT beneficiary years included in the denominator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the living donor transplant. For MY3 through MY10, Pre-emptive LDT beneficiary years included in the denominator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the living donor transplant, excluding beneficiaries who had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a vital solid organ cancer diagnosis are identified as described in paragraph (c)(1)(i)(A)(*1*) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*2*) of this section. Pre-emptive LDT Beneficiaries are identified using information about living donor transplants from the SRTR Database and Medicare claims data.

* * * * *

■ 9. Section 512.370 is amended by revising paragraphs (b), (c), and (d) to read as follows:

§ 512.370 Benchmarking and scoring.

* * * * *

(b) *Achievement scoring.* CMS assesses ETC Participant performance at the aggregation group level on the home dialysis rate and transplant rate against achievement benchmarks constructed based on the home dialysis rate and transplant rate among aggregation groups of ESRD facilities and Managing Clinicians located in Comparison Geographic Areas during the Benchmark Year. Achievement benchmarks are calculated as described in paragraph (b)(1) of this section and, for MY3 through MY10, are stratified as described in paragraph (b)(2) of this section.

(1) *Achievement benchmarks.* CMS uses the following scoring methodology to assess an ETC Participant's achievement score.

TABLE 1 TO § 512.370(b)(1)—ETC MODEL SCHEDULE OF PPA ACHIEVMENT BENCHMARKS BY MEASUREMENT YEAR

MY1 and MY2	MY3 and MY4	MY5 and MY6	MY7 and MY8	MY9 and MY10	Points
90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.4 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	2
75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the. Benchmark Year)	1.2 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.4 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.5
50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.4 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1
30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.4 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	0.5
<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.4 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	0

(2) *Stratifying achievement benchmarks.* For MY3 through MY10, CMS stratifies achievement benchmarks based on the proportion of beneficiary years attributed to the aggregation group for which attributed beneficiaries are dual eligible or LIS recipients during the MY. An ESRD Beneficiary or Pre-emptive LDT Beneficiary is considered to be dual eligible or a LIS recipient for a given month if at any point during the month the beneficiary was dual eligible

or an LIS recipient based on Medicare administrative data. CMS stratifies the achievement benchmarks into the following two strata:

(i) *Stratum 1:* 50 percent or more of attributed beneficiary years during the MY are for beneficiaries who are dual eligible or LIS recipients.

(ii) *Stratum 2:* Less than 50 percent of attributed beneficiary years during the MY are for beneficiaries who are dual eligible or LIS recipients.

(c) *Improvement scoring.* CMS assesses ETC Participant improvement on the home dialysis rate and transplant rate against benchmarks constructed based on the ETC Participant's aggregation group's historical performance on the home dialysis rate and transplant rate during the Benchmark Year to calculate the ETC Participant's improvement score, as specified in paragraph (c)(1) of this section. For MY3 through MY10, CMS assesses ETC Participant improvement on the home dialysis rate and transplant rate for ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, who are dual eligible or LIS recipients to determine whether to add the Health Equity Incentive to the ETC Participant's improvement score, as specified in paragraph (c)(2) of this section.

(1) *Improvement score calculation.* CMS uses the following scoring methodology to assess an ETC Participant's improvement score.

(i) Greater than 10 percent improvement relative to the Benchmark Year rate: 1.5 points

(ii) Greater than 5 percent improvement relative to the Benchmark Year rate: 1 point

(iii) Greater than 0 percent improvement relative to the Benchmark Year rate: 0.5 points

(iv) Less than or equal to the Benchmark Year rate: 0 points

(v) For MY3 through MY10, when calculating improvement benchmarks constructed based on the ETC Participant's aggregation group's historical performance on the home dialysis rate and transplant rate during the Benchmark Year, CMS adds one beneficiary month to the numerator of the home dialysis rate and adds one beneficiary month to the numerator of the transplant rate, such that the Benchmark Year rates cannot be equal to zero.

(2) *Health Equity Incentive.* CMS calculates the ETC Participant's aggregation group's home dialysis rate and transplant rate as specified in §§ 512.365(b) and 512.365(c), respectively, using only attributed beneficiary years comprised of months during the MY in which ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, are dual eligible or LIS recipients. CMS also calculates the threshold for earning the Health Equity Incentive based on the ETC Participant's aggregation group's historical performance on the home dialysis rate and transplant rate during the Benchmark Year, using only attributed beneficiary years comprised of months during the Benchmark Year in which ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, are dual eligible or LIS recipients. An ESRD Beneficiary or Pre-emptive LDT Beneficiary is considered to be dual eligible or a LIS recipient for a given month if at any point during the month the beneficiary was dual eligible or a LIS recipient. CMS determines whether a beneficiary was dual eligible or a LIS recipient based on Medicare administrative data.

(i) The ETC Participant earns the Health Equity Incentive for the home dialysis rate improvement score if the home dialysis rate for the MY, calculated as specified in this paragraph (c)(2), is at least 2.5-percentage points higher than the home dialysis rate for the Benchmark Year, calculated as specified in this paragraph (c)(2). If the ETC Participant earns the Health Equity Incentive for the home dialysis rate improvement score, CMS adds 0.5 points to the ETC Participant's home dialysis rate improvement score, calculated as specified in paragraph (c)(1) of this section, unless the ETC Participant is ineligible to receive the Home Equity Incentive as specified in paragraph (c)(2)(iii) of this section.

(ii) The ETC Participant earns the Health Equity Incentive for the transplant rate improvement score if the home dialysis rate for the MY, calculated as specified in this paragraph (c)(2), is at least 2.5-percentage points higher than the transplant rate for the Benchmark Year, calculated as specified in this paragraph (c)(2). If the ETC Participant earns the Health Equity Incentive for the transplant rate improvement score, CMS adds 0.5 points to the ETC Participant's transplant rate improvement score, calculated as specified in paragraph (c)(1) of this section, unless the ETC Participant is ineligible to receive the Home Equity Incentive as specified in paragraph (c)(2)(iii) of this section.

(iii) An ETC Participant in an aggregation group with fewer than 11-attributed beneficiary years comprised of months in which ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, are dual eligible or LIS recipients, during either the Benchmark Year or the MY is ineligible to earn the Health Equity Incentive.

(d) *Modality Performance Score.* (1) For MY1 and MY2, CMS calculates the ETC Participant's MPS as the higher of ETC Participant's achievement score or improvement score for the home dialysis rate, together with the higher of the ETC Participant's achievement score or improvement score for the transplant rate, weighted such that the ETC Participant's score for the home dialysis rate constitutes ⅔ of the MPS and the ETC Participant's score for the transplant rate constitutes ⅓ of the MPS. CMS uses the following formula to calculate the ETC Participant's MPS for MY1 and MY2:

Modality Performance Score = 2 × (*Higher of the home dialysis achievement or improvement score*) + (*Higher of the transplant achievement or improvement score*)

(2) For MY3 through MY10, CMS calculates the ETC Participant's MPS as the higher of the ETC Participant's achievement score for the home dialysis rate or the sum of the ETC Participant's improvement score for the home dialysis rate calculated as specified in paragraph (c)(1) of this section and, if applicable, the Health Equity Incentive, calculated as described in paragraph (c)(2)(i) of this section, together with the higher of the ETC Participant's achievement score for the transplant rate or the sum of the ETC Participant's improvement score for the transplant rate calculated as specified in paragraph (c)(1) of this section and, if applicable, the Heath Equity Incentive, calculated as described in paragraph (c)(2)(ii) of this section, weighted such that the ETC Participant's score for the home dialysis rate constitutes ⅔ of the MPS and the ETC Participant's score for the transplant rate constitutes ⅓ of the MPS. CMS uses the following formula to calculate the ETC Participant's MPS for MY3 through MY10:

Modality Performance Score = 2 × (*Higher of the home dialysis achievement or* (*home dialysis improvement score* + *Health Equity Bonus* †)) + (*Higher of the transplant achievement or* (*transplant improvement score* + *Health Equity Bonus*†))

† The Health Equity Incentive is applied to the home dialysis improvement score or transplant improvement score only if earned by the ETC Participant.

■ 10. Section 512.390 is amended by revising the section heading, redesignating paragraph (b) as (c) and adding new paragraph (b).

The revision and addition read as follows:

§ 512.390 Notification, data sharing, and targeted review.

* * * * *

(b) *Data sharing with ETC Participants.* CMS shares certain beneficiary-identifiable data as described in paragraph (b)(1) of this section and certain aggregate data as described in paragraph (b)(2) of this section with ETC Participants regarding their attributed beneficiaries and performance under the ETC Model.

(1) *Beneficiary-identifiable data.* CMS shares beneficiary-identifiable data with ETC Participants as follows:

(i) CMS will make available certain beneficiary-identifiable data for retrieval by ETC Participants no later than one month before the start of each PPA Period, in a form and manner specified by CMS. ETC Participants may retrieve this data at any point during the relevant PPA Period.

(ii) This beneficiary-identifiable data includes, when available, the following information for each PPA Period:

(A) The ETC Participant's attributed beneficiaries' names, Medicare Beneficiary Identifiers, dates of birth, dual eligible status, and LIS recipient status.

(B) Data regarding the ETC Participant's performance under the ETC Model, including, for each attributed beneficiary, as applicable: the number of months the beneficiary was attributed to the ETC Participant, home dialysis months, self-dialysis months, nocturnal in-center dialysis months, transplant waitlist months, and months following a living donor transplant.

(iii) CMS shares this beneficiary-identifiable data on the condition that the ETC Participants observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information as would apply to a covered entity under the regulations found at 45 CFR parts 160 and 164 promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended, and comply with the terms of the data sharing agreement described in paragraph (b)(1)(iv) of this section.

(iv) If an ETC Participant wishes to retrieve the beneficiary-identifiable data specified in paragraph (b)(1)(ii) of this section, the ETC Participant must complete and submit, on at least an annual basis, a signed data sharing agreement, to be provided in a form and manner specified by CMS, under which the ETC Participant agrees:

(A) To comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA regulations and the requirements of the ETC Model set forth in this part.

(B) To comply with additional privacy, security, breach notification, and data retention requirements specified by CMS in the data sharing agreement.

(C) To contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the ETC Participant to the same terms and conditions to which the ETC Participant is itself bound in its data sharing agreement with CMS as a condition of the business associate's receipt of the beneficiary-identifiable data retrieved by the ETC Participant under the ETC Model.

(D) That if the ETC Participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the data sharing agreement, CMS may deem the ETC Participant ineligible to retrieve beneficiary-identifiable data under paragraph (b)(1)(i) of this section for any amount of time, and the ETC Participant may be subject to additional sanctions and penalties available under the law.

(2) *Aggregate data.* CMS shares aggregate performance data with ETC Participants as follows:

(i) CMS will make available certain aggregate data for retrieval by the ETC Participant, in a form and manner to be specified by CMS, no later than one month before each PPA Period.

(ii) This aggregate data includes, when available, the following information for each PPA Period, de-identified in accordance with 45 CFR 164.514(b):

(A) The ETC Participant's performance scores on the home dialysis rate, transplant waitlist rate, living donor transplant rate, and the Health Equity Incentive.

(B) The ETC Participant's aggregation group's scores on the home dialysis rate, transplant waitlist rate, and living donor transplant rate, and the Health Equity Incentive.

(C) Information on how the ETC Participant's and ETC Participant's aggregation group's scores relate to the achievement benchmark and improvement benchmark.

(D) The ETC Participant's MPS and PPA for the corresponding PPA Period.

* * * * *

■ 11. Section 512.397 is amended by revising the section heading and paragraph (b) and adding paragraph (c) to read as follows:

§ 512.397 ETC Model Medicare program waivers and additional flexibilities.

* * * * *

(b) CMS waives the following requirements of title XVIII of the Act solely for purposes of testing the ETC Model:

(1) CMS waives the requirement under section 1861(ggg)(2)(A)(i) of the Act and § 410.48(a) of this chapter that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish kidney disease patient education services to allow kidney disease patient education services to be provided by clinical staff (as defined at § 512.310) under the direction of and incident to the services of the Managing Clinician who is an ETC Participant. The kidney disease patient education services may be furnished only by qualified staff (as defined at § 512.310).

(2) CMS waives the requirement that kidney disease patient education services are covered only for Stage IV chronic kidney disease (CKD) patients under section 1861(ggg)(1)(A) of the Act and § 410.48(b)(1) of this chapter to permit beneficiaries diagnosed with CKD Stage V or within the first 6 months of starting dialysis to receive kidney disease patient education services.

(3) CMS waives the requirement that the content of kidney disease patient education services include the management of co-morbidities, including for the purpose of delaying the need for dialysis, under § 410.48(d)(1) of this chapter when such services are furnished to beneficiaries with CKD Stage V or ESRD, unless such content is relevant for the beneficiary.

(4) CMS waives the requirement that an outcomes assessment designed to measure beneficiary knowledge about CKD and its treatment be performed as part of a kidney disease patient education service under § 410.48(d)(5)(iii) of this chapter, provided that such outcomes assessment is performed by qualified staff within one month of the final kidney disease patient education service.

(5) Beginning the upon the expiration of the Public Health Emergency (PHE) for the COVID–19 pandemic, CMS waives the geographic and site of service originating site requirements in sections 1834(m)(4)(B) and 1834(m)(4)(C) of the Act and § 410.78(b)(3) and (4) of this chapter for purposes of kidney disease patient education services furnished by qualified staff via telehealth in accordance with this section, regardless of the location of the beneficiary or

qualified staff. Beginning the upon the expiration of the Public Health Emergency (PHE) for the COVID–19 pandemic, CMS also waives the requirement in section 1834(m)(2)(B) of the Act and § 414.65(b) of this chapter that CMS pay a facility fee to the originating site with respect to telehealth services furnished to a beneficiary in accordance with this section at an originating site that is not one of the locations specified in § 410.78(b)(3) of this chapter.

(c)(1) For kidney disease patient education services furnished on or after January 1, 2022, an ETC Participant may reduce or waive the 20 percent coinsurance requirement under section 1833 of the Act if all of the following conditions are satisfied:

(i) The individual or entity that furnished the kidney disease patient education services is qualified staff.

(ii) The qualified staff are not leased from or otherwise provided by an ESRD facility or related entity.

(iii) The kidney disease patient education services were furnished to a beneficiary described in § 410.48(b) or § 512.397(b)(2) who did not have secondary insurance that provides cost-sharing support for kidney disease patient education services on the date the services were furnished.

(iv) The kidney disease patient education services were furnished in compliance with the applicable provisions of § 410.48 and § 512.397(b).

(v) The ETC Participant bears the full cost of the reduction or waiver of the 20 percent coinsurance requirement under section 1833 of the Act. The reduction or waiver of the 20 percent coinsurance requirement under section 1833 of the Act shall not be financed by a third party, including but not limited to an ESRD facility or related entity.

(2) The ETC Participant must maintain and provide the government with access to records of the following information in accordance with § 512.135(b) and (c):

(i) The identity of the qualified staff who furnished the kidney disease patient education services for which the coinsurance was reduced or waived and the date such services were furnished.

(ii) The identity of the beneficiary who received the kidney disease patient education services for which the coinsurance was reduced or waived.

(iii) Evidence that the beneficiary who received the kidney disease patient education services coinsurance waiver was eligible to receive the kidney disease patient education services under the ETC Model and did not have secondary insurance that provides cost-sharing support for kidney disease patient education services.

(iv) The amount of the kidney disease patient education coinsurance reduction or waiver provided by the ETC Participant.

(3) The Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect the kidney disease patient education coinsurance waivers that satisfy the requirements of such safe harbor and paragraph (c)(1) of this section.

Dated: October 28, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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