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
CMS-1749-F

On October 29, 2021, the Centers for Medicare & Medicaid Services (CMS) posted for public inspection a final rule addressing routine updates to the Medicare End-Stage Renal Disease Prospective Payment System (ESRD PPS), payment updates for renal dial services to individuals with acute kidney injury (AKI) updates for the ESRD Quality Incentive Program (QIP), modifications to the ESRD Treatment Choices (ETC) Model to directly address health equity, among other policies for calendar year 2022. One application for 2022 payment of the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) is approved. The final rule also summarizes comments on requests for information on a myriad of issues related to the ESRD PPS, the ESRD QIP, and The ETC Model. The final rule will be published in the *Federal Register* on November 8, 2021.

Addenda provided by CMS on the ESRD PPS provide wage index files and facility level impact analysis. These are available at https://www.cms.gov/medicaremedicare-fee-service-paymentesrdpaymentend-stage-renal-disease-esrd-payment-regulations-and/cms-1749-f

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I. End-Stage Renal Disease Prospective Payment System

Under the ESRD PPS, a single, per-treatment payment is made to an ESRD facility for all defined renal dialysis services furnished in the treatment of ESRD in the ESRD facility or in the patient's home. Payment consists of a base rate adjusted for characteristics of both adult and pediatric patients. The adult case-mix adjusters are age, body surface area (BSA), low body mass index (BMI), onset of dialysis, and four co-morbidity categories, while the pediatric patient-level adjusters consist of two age categories and two dialysis modalities. In addition, the ESRD PPS provides for three facility-level adjustments: one for differences in area wage levels, another for facilities furnishing a low volume of dialysis treatments, and a third for facilities in rural areas.

The ESRD PPS provides four additional payment adjustments for: (1) a training add-on for home and self-dialysis modalities; (2) an additional payment for high cost outliers; (3) a transitional drug add-on payment adjustment (TDAPA) for certain new renal dialysis drugs and biological products; and (4) a TPNIES for certain qualifying new and innovative renal dialysis equipment and supplies.

II. ESRD PPS Updates for 2022

A. 2022 ESRD PPS Update

CMS finalizes a 2022 ESRD PPS base rate of $257.90, compared with the final 2021 rate of $253.13. As shown in the table below, this increase is the result of several factors: Application of the wage index budget neutrality adjustment of 0.99985 and application of the update factor of 1.9 percent. The update factor reflects an estimated increase of 2.4 percent in the ESRD bundled input price index ("market basket") and an estimated productivity adjustment of 0.5 percent. The market basket update is a notable upward revision compared to the proposed rule as the most recent forecast reflects a higher 2022 inflationary outlook.

2022 ESRD PPS Base Rate	
Base Rate Update Components	**Amount**
Final 2021 ESRD PPS Base Rate	**$253.13**
Wage index budget neutrality adjustment	0.99985
Market basket increase	+2.4%
Productivity adjustment	-0.5%

Subtotal: update factor	+1.9%
FY 2022 ESRD PPS Base Rate	**$257.90**
Note: the final 2022 base rate is calculated as (($253.13*0.99985) x 1.019 = $257.90.	

CMS finalizes an average per treatment offset amount for TPNIES for capital-related assets that are home dialysis machines of $9.50, compared with the final 2021 offset amount of $9.32. This offset reflects the application of the update factor of 1.019 to the 2021 offset amount (($9.32 x 1.019 = $9.50).

1. Wage Index

The ESRD PPS adjusts the labor-related portion of the base rate to reflect geographic differences in wage levels using wage index values based on the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. That is, the ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Social Security Act and utilize pre-rural and imputed floor hospital data that are unadjusted for occupational mix. For CY 2022, the updated wage data are from hospital cost reporting periods for FY 2018 and are listed in Addendum A (available on the CMS web page for this final rule at the link provided on page 1 of this summary). The previously adopted ESRD wage index floor of 0.5000 is applied; wage areas in Puerto Rico are currently the only ones to benefit from the floor. The labor-related share (the portion of the base rate adjusted by the wage index) continues to be 52.3 percent, based on the 2016-based ESRD market basket.

In the 2021 ESRD final rule, CMS updated the labor market areas used for the wage index adjustment using the OMB delineations described in the September 14, 2018, OMB Bulletin No. 18-04. To mitigate any negative impact from the wage index changes due to the new labor market areas, CMS provided for a 5 percent cap on decreases in any facility's wage index for 2021 when compared to 2020. No cap would be applied in 2022. For 2022, the labor-related share (the portion of the base rate adjusted by the wage index) continues to be 52.3 percent, based on the 2016-based ESRD market basket.

Table 9 in the final rule, reproduced in part in section VII of this summary, shows the impact of the adoption of the new wage area delineations by type and region of ESRD facility.

2. Outlier Policy

An ESRD facility is eligible for outlier payments if its actual or imputed Medicare Allowable Payment (MAP) per treatment for ESRD outlier services exceeds a threshold, which is equal to the facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus a fixed-dollar loss amount (FDL). ESRD outlier services are defined as specified items and services included in the ESRD PPS bundle.

For 2022, CMS did not propose any changes to the methodology used to compute the MAP amount per treatment or FDL amounts used to calculate ESRD PPS outlier payments. However, these amounts were updated using 2020 claims data. The 2022 outlier policy amounts and those for 2021 are shown in Table 1 of the final rule, reproduced below.

As shown in the table, the 2022 MAP and FDL amounts are lower than those for 2021. The MAP and FDL amounts continue to be lower for pediatric patients than for adults due to continued lower use of outlier services (particularly calcimimetics, ESAs and other injectable drugs) among the pediatric ESRD population.

Based on 2020 claims, outlier payments represented about 0.6 percent of total payments, below the 1 percent target. CMS believes the updates to the MAP and FDL amounts for 2022 will increase payments for ESRD beneficiaries requiring higher resource utilization and result in total payments closer to the 1 percent target.

Table 1: 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
FDL amount that is added to the predicted MAP to determine the outlier threshold	$44.78	$122.49	$26.02	$75.39
Patient-months 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).

Although no changes were proposed to the outlier target percentage or its methodology for computing the MAP or FDL amounts, CMS continues to receive comments from stakeholders expressing concern that the outlier policy has not been effective. Outlier payments continue to fall short of the 1 percent target. Commenters suggested 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. CMS notes that the ESRD PPS outlier policy was established to account for unusual variations in the type or amount of medically necessary care and that 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. It also notes that it did not propose any modifications to the ESRD PPS outlier policy for 2022, so it is not finalizing any changes to the methodology in this final rule.

B. Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for 2022 Payment

1. TPNIES Eligibility Criteria

In the 2020 ESRD PPS final rule,[1] CMS established transitional add-on payment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS. In the 2021 ESRD PPS final rule,[2] CMS made several changes to the TPNIES eligibility criteria and expanded the TPNIES policy to include certain capital-related assets[3] that are dialysis machines used in the home for a single patient. To be eligible for the TPNIES adjustment, the renal dialysis equipment or supply item must meet all the following requirements:

1. Has been designated by CMS as a renal dialysis service under §413.171;
2. Is new, meaning it is within 3 of the date of the FDA marketing authorization;
3. Is commercially available by January 1 of the year in which the payment adjustment would take effect;
4. Has a Healthcare Common Procedure Coding System (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;
5. Is innovative, meaning it meets the substantial clinical improvement criteria specified in § 412.87(b)(1) (criteria used by CMS for the IPPS New Technology Add-on Payment); and
6. Is not a capital-related asset, except for capital-related assets that are home dialysis machines.

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 of 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 treatment; 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 be evidence that use of the renal dialysis service to make a diagnosis affects the management of the patient; or
- The use of the new 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;

[1] 84 FR 60681 - 60698
[2] 85 FR 71410 - 71464
[3] 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).

    - A decreased number of future hospitalizations or physician visits;
    - A more rapid beneficial resolution of the disease process 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 serves previously available, the diagnosis or treatment of Medicare beneficiaries.

CMS states that evidence from published or unpublished information sources from within the U.S. or elsewhere may be sufficient to establish a substantial clinical improvement. Evidence can include clinical trials, peer reviewed journal articles, study results, meta-analyses, consensus statements, white papers, patient survey, case studies, systemic literature reviews, letters from major healthcare associations, editorials and letters to the editor, and public comments. CMS may consider other appropriate information sources.

CMS has also established a process for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. CMS will only consider a complete application received by February 1 prior to the particular year. FDA marketing authorization must occur by September 1 prior to the particular year. CMS established a workgroup of CMS medical and other staff to review the materials submitted as part of the TPNIES application, public comments, FDA marketing authorization, HCPCS application information to assess the extent the product provides substantial clinical improvement over current technologies.[4]

Payment for a TPNIES is for 2-years. Payment for the TPNIES is based on 65 percent of the price established by the Medicare Administrative Contractors (MACs), using information from the invoice and other specified sources of information. Following payment of the TPNIES, the ESRD base rate will not be modified and the renal dialysis equipment or supply will become an eligible outlier service. (§413.237).

2. Applications for the TPNIES

For 2022, CMS received two applications for the TPNIES:

- Tablo® System and
- CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System).

The applicant for the CloudCath System withdrew its application because the system did not receive FDA marketing authorization by July 6, 2021, 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 by this HCPCS Level II Code application deadline.

[4] The CMS TPNIES Work Group consists of CMS Medical Officers, senior staff, a senior technical adviser, a biomedical engineer, and contracted physicians, including nephrologists.

The summary below provides a high-level discussion of the Tablo® System. After consideration of all public comments received, CMS determined that the Tablo® System meets all of the eligibility criteria to qualify for the TPNIES for CY 2022. Readers are advised to review the final rule for more detailed information.

a. Tablo® System

Outset Medical submitted an application for the Tablo® System for CY 2022.[5] According to the applicant, the technology is a hemodialysis (HD) machine that has been designed for patient-driven self-care and minimizes device training time. The Tablo® System is comprised of (1) the Tablo® Cartridge with integrated water purification, on-demand dialysate production and a simple to use touchscreen interface; (2) a proprietary, disposable, single-use cartridge that easily clicks into place, and (3) the Tablo® Connectivity and Data Ecosystem. The system functions in a connected setting with cloud-based system monitoring, patient analytics, and clinical recordkeeping.

The applicant discussed four unique features of the Tablo® System that substantially improve the treatment of ESRD patients by removing barriers to home dialysis. First, the Tablo® System's intuitive touchscreen interface makes it easy to learn and use. Second, the Tablo® System does not have a pre-configured dialyzer, which allows the use of a broad range of dialyzer types and manufactures. The applicant states that the incumbent home device requires a separate device component and a specific dialyzer. Third, the system is an all-in-one system with an integrated water purification and on-demand dialysate production which eliminates the need for industrial water treatment rooms that are required to operate traditional HD machines. The system includes automated features, including an integrated blood pressure monitor, air removal and blood return. Fourth, the system's two-way wireless connectivity and data analytics provides the ability to continuously activate new capabilities through wireless software updates and also enables predictive preventive maintenance.

The applicant asserted that the Tablo® presents a clinical improvement over NxStage® System One (NxStage®), the current standard of home HD care, because it is easier to use and will increase the number of patients doing HD at home.

(1) Renal Dialysis Service Criterion (§413.236(b)(1))
CMS considers an in-home HD machine as equipment necessary for the provision of maintenance dialysis and meets the renal dialysis service criterion.

(2) Newness Criterion (§413.236(b)(2))
The applicant stated that the Tablo® System received FDA marketing authorization for home use on March 31, 2020.[6] CMS agrees that the Tablo® System meets the newness criterion.

[5] The applicant submitted a 2021 TPNIES application for the *Tablo® Cartridge for the Tablo® Hemodialysis System* (85 FR 71464).
[6] In the proposed rule, CMS noted that the Tablo® Cartridge was reviewed separately and has its own separate 510(k) clearance. As discussed in the CY 2021 ESRD PPS final rule, CMS determined that the cartridge did not meet the newness criterion for the TPNIES.

(3) Commercial Availability Criterion (§413.236(b)(3)
The applicant stated the Tablo® System is commercially available; it became available for home use on April 1, 2020. CMS agrees that the Tablo® System meets the commercial availability criterion.

(4) HCPCS Level II Application Criterion (§413.236(b)(2))
The applicant indicated it submitted a HCPCS Level II code application by the July 6, 2021, deadline. Based on this information, CMS agrees that the applicant has met this criterion.

(5) Innovation Criterion (§§413.236(b)(5) and 412.87(b)(1))
The applicant claimed that the Tablo® System significantly improved clinical outcomes relative to the current standard of care for home HD services, the incumbent NxStage® home dialysis machine. The applicant made the following substantial clinical improvement assertions:

- Decreased treatment frequency with adequate dialysis clearance;
- Increased adherence to dialysis treatment and retention to home therapy; and
- Improved patient quality of life.

The applicant provided the Tablo® Investigational Device Exemption (IDE) Study and secondary support from four papers and two posters. The applicant also provided comparison data from three studies directly related to the NxStage® home dialysis machine. The applicant also submitted several letters of support for the Tablo® System.

CMS summarized this information in the proposed rule. Based on the information provided, the applicant concluded that the Tablo® System improves the treatment of Medicare beneficiaries relative to the incumbent by improving outcomes, including a decreased number of treatments to achieve dialysis adequacy, which leads to greater adherence to prescribed therapy and improved quality of life.

In the proposed rule, CMS discussed several concerns with the evidence provided by the applicant. CMS was concerned that the data from the Tablo® IDE study did not support the applicant's claim that patients using the Tablo® System can achieve dialysis adequacy in as little as 3 treatments per week. CMS was also concerned with the applicant's conclusion that because the Tablo® System increases adherence to dialysis treatment and retention to home therapy it may reduce dialysis-related hospitalizations and other adverse events associated with missing treatment. CMS noted this claim was supported by unpublished information from the Tablo® IDE study (28 patients completed the study) and the use of historical comparisons to prior studies involving the incumbent. In addition, CMS noted that the applicant relied on historical comparisons in asserting that patients treated with the Tablo® System experience reduced disease burden and improved quality of life. CMS was also concerned that in the IDE study, the before-after comparisons in patients with NxStage® regarding improved sleep compared to the Tablo® System could be prone to recall bias because the information was based on recall at the time of the IDE study.

CMS received multiple comments on the substantial clinical improvement claims ranging from concerns about the claims (including from a manufacturer of a competitor device) to comments in support of the application from the applicant, clinicians, and patients.

The manufacturer of a competitor device asserted that the Tablo® System did not meet the substantial clinical improvement criterion due to lack of robust clinical evidence. The commenter discussed several criticisms about the Tablo® System IDE trial and other clinical evidence. Several commenters identified the ability to travel as a quality-of-life issue and stated that because the Tablo® System weighs approximately 200 pounds, it is not portable.

The applicant provided additional information addressing CMS' concerns, including results from an online survey conducted by a third-party research firm between July 29 and August 9, 2021. According to 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 the results indicated that more than 70 percent of the nephrologists and patients rated the Tablo® System features as a substantial clinical improvement in home HD care. Many comments from clinicians, patients, and caregivers supported the Tablo® System's TPNIES application.

After reviewing the comments and additional information provided by the applicant, CMS agrees that the Tablo® System represents an advance that substantially improves, relative to renal dialysis services previously available, the treatment of Medicare beneficiaries. CMS believes the data submitted demonstrates 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. CMS also thinks the Tablo® System may provide additional flexibility for home HD that could benefit some patients and may represent an improvement in one or more activities of daily living and an improved quality-of-life.

In response to concerns about the clinical evidence submitted, CMS states that its concerns have been sufficiently addressed by the applicant. CMS notes that it recognizes that published data may not be available and it may consider unpublished data in making a determination of substantial clinical improvement. CMS also notes that it 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 available, the diagnosis or treatment of Medicare beneficiaries. In addition, because of the additional risks due to the COVID-19 pandemic, CMS is interested in supporting technologies that expand home dialysis.

CMS concludes that the Tablo® System meets the TPNIES innovation criteria.

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

The applicant stated that the Tablo® System meets the capital related asset criterion because the Tablo® System is 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 the home. CMS agrees.

CMS concludes that the Tablo® System meets all the eligibility criteria to qualify for the TPNIES for CY 2022.

Regulatory Impact. CMS estimates that the overall TPNIES payment amounts in CY 2022 for the Tablo® System will be approximately $2.5 million, of which, approximately $490,000 will be attributed to beneficiary coinsurance amounts.

This estimate is based on the price of the Tablo® System at $40,000 being amortized over 5 useful life years using straight line depreciation which results in an annual cost of $8,000 per year. Sixty-five percent of the annual cost equals $5,200 per year. Assuming an average of 156 treatments per year for a Medicare beneficiary, the pre-adjusted per treatment payment amount equals $33.33 per treatment ($5,200/156 = $33.33 per treatment. The TPNIES amount equals an estimated $23.83 per treatment ($33.33 – the CY 2022 average per treatment offset amount of $9.50). Based on February 2021 Share Systems Data, there were approximately 6,600 Medicare beneficiaries receiving home dialysis treatment. CMS believes that 10 percent of this population will use the Tablo® System. Applying the estimated $23.83 per treatment TPNIES amount to 10 percent of this population results in approximately $2.5 million in spending.

III. 2022 Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

In the 2017 ESRD PPS final rule, CMS adopted policies to implement payment for renal dialysis services furnished to individuals with AKI, as required under section 808 of the Trade Preferences Extension Act (TPEA) of 2015 (Pub. Law 114-27). TPEA defines an individual with AKI to mean "…an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14) [ESRD PPS]." CMS established payment for AKI to equal the ESRD PPS base rate updated by the ESRD bundled market basket, minus a productivity factor, and adjusted for wages and any other amount deemed appropriate by the Secretary. For 2022 final rule, CMS is setting the AKI dialysis payment rate to equal the 2022 ESRD PPS base rate of $257.90, adjusted by the facility's wage index.

IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP) (§413.178)

A. Background

Under the ESRD QIP, facilities are assessed on a set of quality measures that currently includes nine scored, "clinical" measures (e.g., hypercalcemia) and five "reporting" measures that are not scored (e.g., medication reconciliation). Payment reductions of up to 2 percent are applied in each Program Year (PY) to facilities that fail to achieve a minimum total performance score (mTPS). Scores are calculated based on quality measure performance data from the calendar year two years prior to the PY (e.g., 2021 data will affect payments for PY 2023). Performance results are displayed publicly via *Care Compare* (Accessible at https://www.medicare.gov/care-compare/?providerType=DialysisFacility&redirect=true).

Formerly, QIP performance data were entered and submitted to CMS using the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb). In November 2020, CROWNWeb

was incorporated into the new ESRD Quality Reporting System (EQRS), along with the ESRD QIP System used for performance score reviewing and the Renal Management and Information System used for Medicare coverage determinations. Facilities access the EQRS via a secure identity management portal account.[7]

Additional information about the ESRD QIP is available on the CMS website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP.

B. Application of the Extraordinary Circumstances Exception (ECE) Policy

1. ECE Policy Exceptions Previously Granted for the COVID-19 PHE

In its September 2020 IFC, in response to the COVID-19 PHE, CMS adopted updates to the ESRD QIP's ECE policy. At that time, CMS requested comments on the updates and now responds to the comments. The policy updates established in the September 2020 IFC, and affirmed as finalized in this final rule, provide that:

- Except for Q4 2019, a facility to whom a data-reporting ECE has been granted but instead opts to submit data must notify CMS of its intention to submit data. Absent notification, the voluntarily submitted data will not be scored.
- An ESRD facility submitting QIP data timely for Q4 2019 is considered to have opted out of the Q4 data-reporting ECE granted by CMS to all ESRD facilities in March 2020. The submitted data will be scored, regardless of whether the facility notified CMS of its intention to submit data voluntarily.
- For Q1 and Q2 2020, no ESRD facility is permitted to opt out of the March 2020 data-reporting exception, even if the facility notifies CMS and voluntarily submits data.

Commenters responding to the September 2020 IFC generally supported the ECE policy updates. Most also expressed concerns about the validity of any QIP data collected during any part of 2020, and they recommended a data-reporting exception be granted for Q3 and Q4.

CMS agrees with the concerns voiced. CMS responds that elsewhere in this final rule, special QIP scoring policies are being finalized for performance year 2020 data, on which QIP Program Year (PY) 2022 payment adjustments are based. As a result of the special scoring, no payment reduction will be made under the QIP to any facility in 2022. CMS also clarifies that while the agency may provide advance notice of its intentions regarding payment adjustments through subregulatory guidance, any actual adjustments and related policy changes would be proposed through rulemaking, as was done for the PY 2022 special scoring policies.

2. ECE Due to Operational Issues Affecting the EQRS (§413.178(d)(6)(ii))

Elsewhere in this rule, CMS finalizes a special QIP scoring policy for PY 2022, proposed by the agency in response to the effects on the QIP by EQRS operational issues as well as those due to COVID-19 PHE. Critical data submission issues became apparent soon after the EQRS was

[7] Operational issues have adversely impacted some EQRS functionalities, as discussed in section IV.B.2 of the rule and section IV.B.2 of this summary.

launched in November 2020. Submission of 2020 clinical measure data was suspended beginning in January 2021 and lasted until mid-July. In the proposed rule, CMS announced a blanket extension of all remaining 2020 clinical data reporting deadlines until September 1, 2021, subsequently extended to September 15.

Commenters supported the data reporting extension and the proposed special scoring policy for PY 2022. Some requested that the reporting extension be continued until the end of 2021, citing the ongoing COVID-19 PHE and uncertainty about whether all of the EQRS operational issues have been fully resolved. CMS declines, believing the extension already issued allowed facilities sufficient time to complete their required 2020 clinical data submissions.

Using updated estimates of the total number of dialysis facilities, the total number of dialysis patients nationally, and wages for Medical Records and Health Information Technicians, CMS recalculates the estimated burden costs associated with completing EQRS data entry and submission for PY 2024 and PY 2025 to be about $28,000 per facility per year.

C. Flexibilities Proposed in Support of the CMS Response to the COVID-19 PHE

1. Measure Suppression Policy and Measure Suppression Factors for the ESRD QIP

CMS finalizes the ESRD QIP measure suppression policy for the duration of the COVID-19 PHE as proposed. The policy enables CMS to suppress one or more QIP measures and modify program scoring if the agency determines that the PHE has significantly impacted the program's measures and resulting performance scores. CMS also finalizes without modification the proposed measure suppression factors to be considered in determining whether the PHE has significantly impacted the program's measures and performance scores.

The policy and its associated factors parallel those already adopted for the agency's other value-based purchasing programs (e.g., the inpatient hospital VBP program). The finalized Measure Suppression Factors are:

1) Significant deviation in national performance on the measure during the PHE for COVID-19, which could be significantly better or worse compared to historical performance during the immediately preceding program years;
2) Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the COVID-19 PHE;
3) Rapid or unprecedented changes in:
    i. Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or
    ii. 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;
4) Significant national shortages or rapid or unprecedented changes in
    i. Healthcare personnel;
    ii. Medical supplies, equipment, or diagnostic tools or materials; or
    iii. Patient case volumes or facility-level case mix.

Commenters were supportive of the proposed measure suppression policy. Some recommended application of the policy to performance year 2021 data – for use in program year 2023 -- due to the ongoing PHE and emerging virus variants. CMS responds that the policy applies for the duration of the COVID-19 PHE. If the agency were to determine that further significant PHE impacts on the QIP had occurred, it would consider proposing additional specific measure suppression proposals for one or more future program years through rulemaking.

Most commenters were supportive of the proposed measure suppression factors. In response to suggestions for revisions, CMS states that the proposed measures are sufficiently inclusive to appropriately guide the agency in deciding whether measure suppression is indicated.

CMS reiterates that actual performance data for all suppressed measures will be confidentially reported to ESRD facilities to aid them in performance improvement. Per existing policy, PY 2022 QIP results will be publicly reported on the Care Compare but will be accompanied by caveats concerning results of suppressed measures.

2. Suppression of Specific Measures for PY 2022

Guided by the measure suppression factors finalized as described above, CMS finalizes as proposed the suppression of four clinical measures for program year 2022:

- Standardized Hospitalization Ratio (SHR), suppression factors 1 and 4;
    - The hospitalization rate for Medicare ESRD patients having COVID-19 diagnoses was seven times higher than for those without COVID-19.
- Standardized Readmission Ratio (SRR), suppression factors 1 and 4;
    - The readmission rate for Medicare ESRD patients having COVID-19 diagnoses is distorted by the much higher early mortality rate among COVID-19 patients.
- ICH CAHPS Survey Administration, suppression factor 1;
    - 95% of facilities would not meet minimum case measure thresholds for PY 2022 (based on 2020 data) compared to 58.9 percent for PY 2020 (based on 2018 data).
- Long Term Catheter Rate, suppression factor 1;
    - Long-term catheter rates were near 12 percent for 2017 through 2019 but rose to nearly 15 percent for 2020, the performance period for PY 2022.

Commenters supported suppression of all four factors. Some suggested additional measures for program year 2022 suppression: Standardized Fistula Rate, Percentage of Prevalent Patients Waitlisted (PPPW), Kt/V Dialysis Adequacy, and National Health Safety Network Bloodstream Infection (NHSN BSI).

CMS responds that data for these measures were reviewed but were found to be insufficient to determine the propriety of suppression at the time of publication of the proposed rule. CMS adds that the data remain insufficient at the time of publication of this final rule and that suppression is not yet warranted.

D. Special Scoring Methodology and Payment Policy for the ESRD QIP for PY 2022 (§§ 413.177(a) and 413.178(h))

CMS finalizes a special scoring methodology and payment policy for PY 2022 as proposed. CMS will calculate a measure rate for all of the PY 2022 QIP measures but will not score facility performance on any of those measures. Achievement and improvement points will not be calculated for any measure. CMS will not calculate an individual TPS for any facility nor establish a national mTPS for PY 2022 payment purposes. No payment reductions will be made to any ESRD facility for PY 2022 under the QIP and there will be no regulatory impact on facilities by the QIP for that year.

Commenters were supportive of the special scoring and payment policies. Some recommended also applying the policies to PY 2023. CMS states it will continue to monitor impacts of the PHE and EQRS operational issues and will propose extending the policy to future years if warranted by the data.

E. Updates to ESRD QIP Requirements Beginning with PY 2024

CMS notes that the ESRD QIP measure set for PY 2024 will contain the same 14 measures as previously finalized for PY 2023, shown in Table 2 of the rule (and included in a cumulative measure summary table in section IV.F of this summary).[8]

1. Standardized Hospitalization Ratio (SHR) Clinical Measure Update (NQF #1463)

CMS finalizes as proposed revising the SHR measure's specifications to align with measure updates as endorsed by the National Quality Forum (NQF) during its recently completed routine measure maintenance review (November 20, 2020). Use of the updated SHR measure will begin with PY 2024.

The NQF adopted updates to the measure's risk adjustment model including its prevalent comorbidity adjustment and its parameterization of existing adjustment factors. The model was further updated by the addition of Medicare Advantage (MA) patients and an MA indicator, as well as adding an indicator for time spent by a patient in a skilled nursing facility during the model's lookback period. Prior to the NQF review, the updated measure went through the standard pre-rulemaking process and was supported by the Measure Applications Partnership (MAP) for rulemaking.

Some commenters supported the SHR measure update. Others raised concerns that technical changes made to accommodate the inclusion of MA patients (e.g., limiting the source of prevalent comorbidities to inpatient claims as CMS does not have ready access to MA outpatient claims) would bias the risk adjustment model towards sicker patients.

CMS disagrees that the updated risk adjustment model would be biased towards sicker patients, citing results from its analysis of inpatient claims from both MA and Fee-for-Service (FFS) Medicare beneficiaries. The agency further responds by emphasizing this measure's importance

[8] Performance year 2021 technical specifications are available at https://www.cms.gov/files/document/esrd-measures-manual-v61.pdf and those for performance year 2022 are available at https://www.cms.gov/files/document/esrd-measures-manual-v70.pdf.

in the QIP measure set, since roughly one-third of total Medicare expenditures annually for ESRD patients are attributable to hospitalizations. CMS also notes the rapidly increasing number of beneficiaries choosing to enroll in MA rather than remain in FFS Medicare. Finally, the agency highlights the recent statutory change that permits MA beneficiaries with pre-existing ESRD diagnoses to choose MA plans; CMS expects this change to increase the ESRD patient population covered under MA.[9]

2. PY 2024 Performance Standards

a. Setting Applicable Standards

CMS finalizes as proposed to calculate PY 2024 performance standards using CY 2019 rather than 2020 data as the PY 2024 baseline year. The 2019 performance data represent the most recently available full performance year data set; the 2020 data set is incomplete due to the QIP data-reporting exception for Q1 and Q2 2020 granted because of the COVID-19 PHE to all ESRD facilities.

Most commenters were supportive of using 2019 data as the baseline year for setting PY 2024 QIP performance standards. Concern was voiced by some about using pre-pandemic data as the baseline year. CMS responds that inequitable performance scoring and payment reductions would be more likely to occur if the available 6 months of 2020 data were used for standard setting. The agency's internal analysis showed that standard setting using the partial year's data would have inconsistent effects across measures and thereby could skew achievement and improvement thresholds. CMS clarifies that the 2019 data would be used for calculation of all PY 2024 performance standards (measures, thresholds, benchmarks, and achievement and improvement points).[10]

b. Finalized PY 2024 Performance Standards

Finalized values for PY 2024 QIP clinical measure standards are provided in Table 3 of the rule. CMS notes that current policy also permits the substitution of PY 2023 values for PY 2024 values should the former be higher than those calculated for PY 2024. Values in Table 3 that are substitutions from PY 2023 are explicitly identified. Table 4 provides the standards for reporting frequency and data elements for the QIP's five reporting measures for PY 2024; these are unchanged from those already set for PY 2023. The data minimums required for scoring in PY 2024 for all 14 measures also are unchanged from PY 2023 and are provided in Table 5.

3. ESRD Facility Payment Reductions for PY 2024 under the ESRD QIP

CMS finalizes a mTPS threshold of 57 for QIP PY 2024. Facilities must meet or exceed the mTPS to avoid a payment reduction under the QIP for PY 2024. This mTPS is unchanged from

[9] Section 17006(a) of the 21st Century Cures Act, Pub. L. 114-255, amended sections 1851, 1852, and 1853 of the Act.

[10] CMS also notes that current policy would also permit the substitution of 2018 data for measures, thresholds, and benchmarks should 2019 data produce values lower than those derived from 2018 data.

the proposed rule and reflects the finalized adoption of CY 2019 data as the baseline year as described above.

Combining the finalized clinical measure standards from Table 3 of the final rule with the final mTPS of 57 leads to the estimated QIP payment reduction scale for PY 2024, as shown in Table 6 of the final rule and reproduced below.

TABLE 6 – Estimated Payment Reduction Scale for PY 2024 Based on CY 2019 Data	
Total Performance Score	**Reduction**
100 – 57	0.0%
56-47	0.5%
46-37	1.0%
36-27	1.5%
26 or lower	2.0%

CMS estimates that the finalized payment reduction scale for PY 2024 would result in an estimated $17 million in reduced payments across all facilities and add burden costs from information collection of about $215 million for the year, for a total regulatory impact of $232 million associated with the ESRD QIP. Additional details -- including the impact by ESRD size, location, and type – are provided in Section VIII of the rule (Regulatory Impact Analysis).

F. Updates for the PY 2025 ESRD QIP

For PY 2025, no new measures are proposed and the QIP measure set will be unchanged from that for PY 2024. Per established policy, 2023 will be the performance period for PY 2025 for all measures and 2021 will be the baseline period for purposes of calculating the achievement thresholds and benchmarks for all nine clinical measures and the mTPS. CMS intends to publish the numerical values for those standards in the CY 2023 ESRD PPS final rule when the 2021 data will be available. Standards for the five reporting measures will continue to be those previously finalized in the 2019 ESRD PPS final rule (83 FR 57101 through 57011).

No changes are made to previously established policies for calculation of measure scores based on achievement and improvement points for the nine clinical measures; performance scoring for the five reporting measures; measure domain groupings and their assigned weights in the TPS formula; or measure weights within each domain and the policy by which the weights of unscored measures are redistributed. The four domains, their weights, and their included measures are shown in the summary table below.

For PY 2025, CMS estimates $17 million in reduced payments across all facilities and burden costs from information collection of about $215 million for the year, for a total regulatory impact of $232 million associated with the ESRD QIP.

Summary Table: ESRD QIP Measure Sets for PYs 2021-2025[a]			
National Quality Forum #	**Measure Domain, Domain Weight, and Measure**	**PY 2021**	**PYs 2022-2025**
	Clinical Care Measure Domain (40%)		
	Kt/V Dialysis Adequacy (Comprehensive)	X	X
2979*	Standardized Transfusion Ratio (STrR) **	X	X
2977	Standardized AV Fistula Rate	X	X
2978	Long-term Catheter Rate	X	X
1454	Hypercalcemia	X	X
	Ultrafiltration Rate reporting measure	X	X
	Patient & Family Engagement Measure Domain (15%)		
0258	In-Center Hemodialysis CAHPS measure	X	X
	Care Coordination Measure Domain (30%)		
2496	Standardized Readmission Ratio (SRR)	X	X
1463	Standardized Hospitalization Ratio (SHR)***	X	X
0148*	Clinical Depression Screening and Follow-up reporting measure	X	X
	Safety Domain (15%)		
1460*	NHSN Bloodstream Infection (BSI)	X	X
	NHSN Dialysis Event reporting measure	X	X
	Percentage of Prevalent Patients Waitlisted (PPPW)		X
2988	Medication Reconciliation (MedRec) reporting measure		X

[a] Table created by HPA based on the current and prior ESRD PPS final rules.
*QIP measure is based on but differs slightly from this NQF measure
**STrR became a reporting rather than clinical measure beginning with PY 2022
***Measure will be updated for PY 2024 and subsequent years to align with changes made during NQF routine measure maintenance review in 2020.

G. Requests for Information (RFIs)

1. Closing the Health Equity Gap in CMS Quality Programs

Through this RFI CMS sought comment on possible revisions to CMS quality programs to make reporting of health disparities stemming from demographic and social risk factors more comprehensive and actionable for ESRD facilities, providers, and patients. To this end, CMS posed questions falling into three broad topic areas for potential future actions, shown below.

- Generating facility-level ESRD QIP performance reports containing results stratified by race, ethnicity, dual-eligibility status, and social risk factors;
- Improving demographic and social risk factor data collection by facilities from their dialysis patients, to include social, psychological, and behavioral data elements; and
- Creating an ESRD Facility Equity Score that would combine multiple performance measures whose results could be stratified by several social risk factors, thereby creating a single summative equity metric for use by beneficiaries.

For each of the three topic areas, CMS excerpts comments received. CMS does not respond directly to the comments, but instead states that the input received will be taken into account during the development and expansion of the agency's health equity quality measure efforts.

Many commenters were at least conceptually supportive of CMS undertaking efforts to advance health equity, though recommended that the agency monitor its efforts for unintended consequences and increased administrative burden for facilities. A sample of the comments taken from the many described by CMS in the rule is provided below.

Stratified results reporting
Many commenters supported stratification by race, ethnicity, and dual eligibility status. Some noted that differences in Medicaid eligibility across states could confound analysis and actionability of results stratified for dual eligibility status. Others emphasized the importance of performing stratification in a manner that does not exclude safety net providers. Suggestions for specific ESRD QIP measures for which stratification could be feasible and informative included SRR, SHR, STrR, PPPW, and vascular access measures.

Improving data collection
Many commenters offered general support for addressing inequities in health outcomes through improved data collection and patient outcome measurement. Some urged CMS to target data elements for collection that are highly likely to impact patient outcomes and noted that much of the information sought by CMS is already collected on Form 2728 — End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration. Others recommended the adoption of standardized screening tools to facilitate data collection with minimal added burden. Several advised against using indirect estimation to impute missing data elements. Others advised that creating too many risk factor strata could produce patient subgroups too small for meaningful analysis. Some emphasized the importance of transparency, urging CMS to clearly explain to beneficiaries why sensitive data was being sought and how CMS plans to use the data collected.

ESRD Facility Equity Score Development
Some commenters offered conceptual support for score development but requested more details. Others recommended that the score's component measures must be actionable for facilities and that the score itself be tested by the CMS Innovation Center to confirm the score is meaningful to beneficiaries. Concerns were voiced about adding to facility burden.

2. COVID-19 Vaccination Measures

CMS requested comments on formally adding two new measures to the ESRD QIP measure set through 2023 rulemaking: one to track vaccination rates among dialysis facility staff members and another to track vaccination rates among dialysis patients. Both measures were developed by the CDC and have been submitted for NQF endorsement. During the pre-rulemaking process, both measures have received support for rulemaking from the Measures Application Partnership (MAP) if NQF-endorsed.

Some commenters were supportive of adding both measures to the ESRD QIP measure set. Others voiced concerns that as the pandemic continues to evolve, the measures' specifications may need revisions. Some believed that the measures would hold facilities accountable for vaccination decisions by individuals that are beyond facilities' control.

CMS responds by emphasizing that these measures are designed to be for reporting only and actual vaccination rates would not be linked to payment reductions. The agency acknowledges that future measure specification revisions may become necessary but views timely measure adoption as providing valuable information to beneficiaries and believes it would motivate facilities to encourage their patients to become vaccinated.

3. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR® Health Level 7)

CMS requested input into the agency's planning for transformation to a fully digital quality enterprise by 2025, posing questions grouped into two categories: definition of digital quality measures and changes under consideration to advance digital quality measures. For each category, CMS excerpts comments received. CMS does not respond specifically to the comments but instead states that the input received will be taken into account during the agency's digital transformation. A sample of the comments taken from the many described by CMS in the rule is provided below.

Digital Quality Measure Definition (dQM)
Support for the definition offered by CMS was mixed and refinements to add clarity were suggested. Support was expressed for transitioning toward interoperability through dQMs to interface with FHIR-based resources. Some commenters observed that interfacing with FHIR will require extensive development of FHIR extensions and profiles, given that many ESRD-specific data elements currently are not part of meaningful use requirements. Others questioned the value of shifting to FHIR-based APIs since the utility of an ESRD-specific FHIR standard would largely be limited to quality reporting by facilities to CMS. They noted that current ESRD data submission processes already capture about 90 percent of data electronically and recommended instead that CMS incorporate interoperability standards into the EQRS.

Changes Under Consideration to Advance Digital Quality Measurement
Support was expressed by some commenters for aligning required data with interoperability standards. Others questioned the value of changing from the existing data format that meets the needs of 90 percent of the dialysis community to an interoperability format that is designed for data movement among providers outside of the dialysis community. Concern was voiced about the necessity of data aggregator availability because ESRD information from multiple sources is already aggregated for use by the dialysis community though the EQRS. Commenters also noted that most ESRD data are already submitted electronically via batch. Suggestions were offered for collaborations across governmental entities to align measures and thus reduce reporting burden.

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

A. Background

The ETC is a mandatory payment model tested under the authority of section 1115A of the Act. The purpose of the ETC Model is to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and clinicians managing dialysis patients (Managing Clinicians) to encourage greater utilization of home dialysis and kidney transplantation, support beneficiaries' choice of treatment options, reduce Medicare expenditures, and maintain or enhance the quality of care.

CMS randomly selected ESRD facilities and Managing Clinicians (MCs) as ETC Participants based on their location in Selected Geographic Areas defined as a set of 30 percent of Hospital Referral Regions (HRR) that were randomly selected to be in the ETC Model, as well as HRRs with at least 20 percent of component ZIP codes located in Maryland. All U.S. Territories were excluded from the Selected Geographic Areas.

ETC Participants are subject to two payment adjustments:

1. The Home Dialysis Payment Adjustment (HDPA) is an upward adjustment on certain payments made to ESRD facilities under the ESRD PPS on home dialysis claims, and an upward adjustment to the Monthly Capitation Payment (MCP) paid to MCs on home dialysis-related claims. The HDPA applies to claims with claim service dates between January 1, 2021, and December 31, 2023 (the initial three years of the ETC Model).

2. The Performance Payment Adjustment (PPA) creates upward or downward performance-based adjustments on all dialysis claims and MCP claims based on the ETC Participants' home dialysis rate and transplant rate during a Measurement Year (MY) which includes 12 months of performance data. Performance-based adjustments are based on the 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 (BY), and the ETC Participants improvement in relation to its own home dialysis rate and transplant rate during the BY. PPAs apply to claims with service dates between July 1, 2022, and June 30, 2027.

B. ETC Model Provisions

1. Technical Clarifications

CMS clarifies at §413.230 that the HDPA and PPA do not apply to claims from ESRD facilities that are not paid under the ESRD PPS and are instead paid through other Medicare payment systems. Also, the CROWNWeb management system used to collect data from ESRD facilities has been replaced with the ESRD Quality Reporting System (EQRS).

2. PPA Beneficiary Attribution for Living Kidney Donor Transplants

Beginning for MY3, CMS proposed to modify the methodology attributing Preemptive Living Donor Transplant (LDT) Beneficiaries to attribute the beneficiary to the MC who assists the beneficiary through the living donor transplant process. The current Preemptive LDT Beneficiary attribution methodology attributes the beneficiary to the MC with the plurality of claims from the start of the MY and the month of transplant. Attribution for those months would be made to the clinician furnishing the highest number of services to the beneficiary.

An unintended consequence of the current attribution methodology is Preemptive LDT Beneficiaries may be attributed to the nephrologist who manages their transplant and not the MC who follows them through the living donor transplant process. Because the current attribution methodology is based on visits from the beginning of a MY, if a preemptive LDT Beneficiary has a transplant early in a MY, the beneficiary may be attributed to a transplant nephrologist who had only a single visit with a beneficiary instead of the MC who had the largest share of the care of the beneficiary receiving the living donor transplant.

Beginning for MY3, CMS proposed to attribute a Preemptive LDT Beneficiary to the MC with the plurality of claims during the 365 days prior to the transplant date. If multiple MCs each have the same number of claims for the beneficiary in the time frame, the beneficiary would be attributed to the MC associated with the latest claim service date preceding the transplant. If MCs have the same number of claims and the same latest claim service date preceding the transplant, the Preemptive LDT Beneficiary would be randomly attributed to one of the MCs.

CMS proposed that the Preemptive LDT Beneficiary would be considered eligible for attribution to a MC if the 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. CMS proposed that an eligible month would refer to a month during which the Preemptive LDT Beneficiary does not meet exclusion criteria in §512.360(b).

Public commenters either supported CMS proposals or indicated that because there are few Preemptive LDT beneficiaries, the policy change will have little impact. CMS is finalizing its proposal without change.

3. PPA Home Dialysis Rate

A primary goal of the ETC Model is to support beneficiary choice by encouraging ETC Participants to support beneficiaries in selecting alternatives to in-center dialysis. In the Specialty Care Models final rule, CMS included self-dialysis in the home dialysis rate because it believes that in-center self-dialysis may provide a gradual transition from in-center to home dialysis.[11] The home dialysis rate for both MC 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 in-center self-dialysis.

[11] 85 FR 61306

Nocturnal in-center dialysis is a form of in-center dialysis conducted overnight for extended hours while the beneficiary is asleep. CMS notes that this dialysis is longer and slower than traditional in-center dialysis and is associated with positive clinical impacts. 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. Based on CMS' review of 2019 claims data, approximately 1 percent of ESRD facilities furnished nocturnal in-center dialysis.

Beginning for MY3, CMS proposed adding nocturnal in-center dialysis to the calculation of the home dialysis rate for MCs and ESRD facilities not owned in whole or in part by a large dialysis organization (LDO). CMS believes this policy will incent additional alternative renal replacement modalities under the ETC model. ESRD facilities owned by LDOs are not included in this definition because CMS believes these dialysis organizations face resource constraints in establishing nocturnal in-center programs. However, CMS proposed to include nocturnal in-center dialysis in the numerator of the home dialysis rate at one half of the total number of dialysis treatment beneficiary years to avoid disincentives for facilities to invest in a home dialysis infrastructure.

CMS acknowledges there is not a single definition of an LDO; definitions of an LDO generally focus on the number of ESRD facilities owned by the legal entity. The Comprehensive ESRD Care Model defined an LDO as a legal entity owning 200 or more ESRD facilities, and the Kidney Care Choices Model defines an LDO as a legal entity owning 35 or more ESRD facilities. CMS discusses the definitions used by academic researchers ranging from as low as owning 20 or more and as high as owning 1,000 or more ESRD facilities to consider a legal entity as an LDO.

For the ETC Model, CMS proposed to define the term ETC Large Dialysis Organization (ETC LDO) as a legal entity that owns, in whole or in part, 500 or more ESRD facilities. CMS bases this definition on the current market. It differentiates the largest organizations which own over 2,500 ESRD facilities from the smaller organizations, which own approximately 350 facilities.

Claims for nocturnal in-center dialysis would be identified with Type of Bill 072X, where the facility code is 7 and the type of care code is 2, and with the modifier UJ (specifies that a claim is for nocturnal in-center dialysis).

While commenters generally supported including in-center nocturnal dialysis in the numerator of the home dialysis rate, they objected to excluding dialysis facilities owned by LDOs from this policy noting that these facilities provide the majority of dialysis care. CMS agreed and is modifying its policy to include all dialysis facilities in its final policy on nocturnal in-center dialysis and the calculation of the home dialysis rate. This policy change mooted any comments CMS received on its definition of an LDO. Several commenters asked CMS include referrals made to nocturnal in-center dialysis program in the numerator of the home dialysis rate. CMS rejected this comment as being too administratively burdensome, but it may consider the idea in the future.

4. Performance Payment Adjustment Transplant Rate

a. Status of Organ Availability

The ETC Model is designed to encourage greater rates of transplantation. However, CMS acknowledged shortages of deceased donor organs. For this reason, CMS only considers the transplant waitlist rate and living donor transplant rate when determining the performance payment adjustment. While recent initiatives from HRSA ("Removing Financial Disincentives to Living Organ Donation" (85 FR 59438)) and CMS ("Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations" (85 FR 77898)) are intended to increase the supply of donor organs, these efforts are still in the implementation process. Accordingly, CMS does not believe that it would be appropriate to update the transplant rate to hold model participants accountable for deceased donor transplants at this time. Nevertheless, CMS intends to update the transplant rate through future rulemaking to include accountability for deceased donor transplants once the organ supply increases.

Public commenters supported not updating the transplant rate to hold model participants accountable for deceased donor transplants at this time.

b. Beneficiary Exclusions from the Transplant Rate

CMS did not originally exclude ESRD beneficiaries with cancer from attribution to an ETC participant. However, upon examining further evidence, CMS found that the majority of ESRD beneficiaries with cancer, specifically cancer in vital solid organs (heart, lung, liver, and kidney), are not considered to be eligible candidates for transplant.

The transplant rate has two components: the transplant waitlist rate and the LDT rate. Beginning for MY3, CMS 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). To be excluded, the patients must be receiving treatment for these cancers in the form of radiation or chemotherapy. These patients will be excluded from the denominator of the transplant rate for both ESRD facilities and MCs for the duration of the model.

CMS lists the diagnosis codes and procedure codes that would be used to identify patients that have been diagnosed with and are being treated for solid organ cancers (see pages 260-263 of the display copy of the final rule). Identifying beneficiaries to be excluded requires a combination of codes to capture diagnosis and active treatment. CMS proposed 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. The proposed lookback period only applied to diagnosis and not to procedure codes.

Some commenters suggested additional cancers or conditions to exclude from the transplant rate or a longer lookback period and for the lookback period to include procedure codes as well as diagnosis codes. CMS declined to make any changes for additional cancers or conditions as many transplant centers do not reject a beneficiary for transplants solely on the basis of the

conditions suggested by the commenters. In response to the request for a longer lookback period, CMS considered the comment but indicated a longer lookback period did not identify any significant difference in the number of beneficiaries that had a diagnosis for a vital solid organ cancer.

CMS agreed with commenters suggesting the 6-month lookback period should apply to procedure codes as well as diagnosis codes and is modifying the proposal to exclude beneficiaries who have had radiation or chemotherapy treatment procedures within 6 months of the beginning of the MY. CMS also made a few minor changes in the regulation text to account for some errors in the proposed rule related to the diagnosis and procedure codes for identifying qualifying cancers.

5. PPA Achievement Benchmarking

a. Background

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, CMS assesses each participant's achievement on the home dialysis rate and transplant rate in relation to achievement and improvement benchmarks with more weight assigned to achievement (maximum 2.0 points) than improvement (maximum 1.5 points). Achievement benchmarks are percentile based and reflect home dialysis and transplant rates for the model's comparison geographic areas for the BY.

In response to comments, CMS finalized the achievement benchmark policy for all years of the model but indicated that it intended to increase achievement benchmarks after MYs 1 and 2 through subsequent rulemaking. Higher benchmarks would provide an additional incentive for ETC participants to increase their rates of home dialysis and transplantation at a rate faster than would occur absent the ETC Model. CMS stated a goal of 80 percent of ETC participants receiving home dialysis or a transplant in order to receive the maximum upward payment adjustment by the final MYs.

b. Socioeconomic Factors

CMS previously acknowledged commenters' concerns that non-clinical factors, such as socioeconomic status, may impact a beneficiary's likelihood to receive home dialysis or a transplant. However, CMS did not exclude beneficiaries from attribution based on socioeconomic status. The rule acknowledges Medicare claims data showing that beneficiaries who are dually 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.

c. Achievement Benchmarking and Scoring

(1) Achievement Benchmarking and Scoring for MY3 through MY10. CMS proposed to increase the achievement benchmarks above the comparison geographic area rates during the BY

by 10 percentage points every two MYs, beginning for MY3 (e.g., 1.1 for MY3 and MY4, 1.2 for MY5 and MY6 and so forth). CMS believes that this proposed 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. The proposed rule noted that CMS is not adopting an achievement benchmark such that 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, as was included in the proposed Specialty Models rule.

Public comments both supported and opposed CMS' proposal to increase achievement benchmarks above comparison geographic areas. Below are selected comments and CMS' response.

Some commenters stated that improvement scoring creates a sufficient incentive for ETC Participants to continue to increase rates of home dialysis and transplants. Increasing achievement benchmarks over time will lead to model failure and payment reductions. CMS disagreed stating that improvement scoring is insufficient to increase rates of home dialysis and transplants. Even with an increase in achievement benchmarks, CMS believes it is possible for participants to receive positive PPAs.

Commenters indicated that lack of growth in home dialysis after the shift to the ESRD PPS bundled payment system in 2011 and between 2018 and 2021, and stable transplant waitlist rates between 2014 and 2019 are evidence that CMS has proposed an unachievable standard. CMS notes that a number of public commenters believe a 10-percentage point increase is achievable and further observes that the home dialysis rate increased by 7.9 percent among prevalent patients with ESRD from 2017 to 2018. More recently, the aggregate home dialysis rate grew by approximately 4 percent in 2020.

There were comments requesting that increases in achievement benchmarks only be for ESRD facilities owned by LDOs as ESRD facilities not owned by LDOs have limited ability to increase their home dialysis and transplant rates. CMS responded that 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.

Some commenters were concerned that setting achievement benchmarks relative to Comparison Geographic Areas may cause dialysis organizations with ESRD facilities in both Comparison Geographic Areas and Selected Geographic Areas to focus their resources on increasing rates in Selected Geographic Areas to the detriment of those in Comparison Geographic Areas. CMS responded that MCs (as opposed to ESRD facilities) have significant influence over whether ESRD beneficiaries select home dialysis or elect to be on a transplant waiting list and are less likely than ESRD facilities to practice across both types of areas. CMS further responded that it will engage in active monitoring for adverse outcomes, including behavior described by commenters, and may take remedial action if an ETC Participant takes any action that threatens the health or safety of a beneficiary or other patient.

Commenters suggested CMS use the ESRD QIP for setting achievement benchmarks under the ETC Model. CMS reiterated earlier responses in the Specialty Models rule that the ESRD QIP performance standard setting methodology does not ensure escalating performance standards over time, and it is not a methodology MCs are familiar with.

Some commenters suggested that CMS use population-weighted achievement benchmarks to account for variation in size among aggregation groups (i.e., larger aggregation groups need to have a larger number of individual beneficiaries meet the achievement thresholds than smaller aggregation groups). CMS did not propose this approach and also disagrees stating that this approach would hold smaller aggregation groups to a higher relative standard solely because they have fewer attributed beneficiary months (and vice versa for larger aggregation groups).

There were comments questioning why the home dialysis rate and transplant rate are combined and why they are not equally weighted. CMS stated 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, home dialysis rates take a greater weight than transplant rates.

Some commenters questioned why the model applies to ESRD facilities and MCs and not just MCs. These commenters said that 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. CMS clarified that the pre-emptive transplant rate is part of the transplant rate calculation only for MCs.

CMS is finalizing its proposal without change.

(2) Achievement Benchmark Stratification by Dual-Eligible and LIS Status. CMS proposed the following two strata for achievement benchmarking and scoring to recognize the higher difficulty of treating dual eligible patients or those receiving the LIS:

- ETC participants whose aggregation groups had 50 percent or more of their attributed beneficiary years for beneficiaries who were dual eligible or received the LIS.
- ETC participants with less than 50 percent of attributed beneficiary years attributed to beneficiaries who were dual-eligible or received the LIS.

CMS proposed to use Medicare administrative data to determine whether a beneficiary was dual eligible or received the LIS in a given month.

Public comments generally supported CMS' proposal while suggesting some potential modifications for CMS to consider. For instance, there were comments indicating that dual eligible and LIS-recipient status is an insufficient proxy to illuminate the diversity of underserved communities or individuals facing health disparities due to complex socioeconomic circumstances in the United States. Further, dual eligible status will vary by state making it an inconsistent proxy by which to determine socioeconomic status. Some commenters suggested different cut points than 50 percent while other commenters suggested there be more strata than

two. Some commenters suggested risk adjustment using individual patient factors instead of stratification by dual eligible status or receiving the LIS.

CMS acknowledged that Medicaid eligibility may vary by state but indicated that it remains the best proxy for identifying socioeconomically disadvantaged beneficiaries. Stratification makes it more likely ETC participants serving a high proportion of low-income beneficiaries will achieve a positive PPA that enables them to invest in caring for these beneficiaries. More strata would decrease the number of observations within each stratum, in turn decreasing statistical reliability. The 50 percent cut point is statistically appropriate, stable over time, and easily comprehendible to ETC participants. 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.

Some public comments suggested the proposed benchmarks might make dual-eligible and LIS recipients feel pressured to try a method of care that will not be successful for them. CMS responded by saying that ETC Participants are prohibited from interfering with a beneficiary's freedom of choice or access to services and will monitor for ETC Participant compliance with this requirement, including beneficiary complaints and appeals.

There were also public comments suggesting that stratification 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. CMS disagrees saying that its approach will enable not disadvantage ETC participants that serve a high proportion of dual-eligible or LIS recipients by comparing them to a substantively different beneficiary population.

CMS is finalizing its proposal without modification.

6. PPA Improvement Benchmarking and Scoring

a. Changes to Improvement Benchmarking and Scoring

An ETC participant's improvement score is measured by comparing MY performance on the home dialysis rate and transplant rate against past ETC participant performance. The percentage improvement in the ETC participant's MY performance on the home dialysis rate and the transplant rate relative to the BY rate is scored as follows:

- Greater than 10 percent improvement relative to the BY rate: 1.5 points
- Greater than 5 percent improvement relative to the BY rate: 1 point
- Greater than 0 percent improvement relative to the BY rate: 0.5 points
- Less than or equal to the BY rate: 0 points

If the BY rate is zero, an improvement score for the MY cannot be calculated. CMS proposed to add one month to the home dialysis rate and the transplant rate for the BY rate for an ETC participant's aggregation group BY when that rate is zero for MY3 through MY10. This policy will allow for an improvement score to be calculated even when the BY rate is zero. Public comments supported CMS' proposal that it is finalizing without change.

b. Incenting Improvement for Socioeconomically Disadvantaged Beneficiaries

CMS proposed a "health equity incentive" that will add 0.5 points to the ETC participant's improvement score. The health equity incentive will be awarded for a 5-percentage point or more increase in the ETC participant's aggregation group's home dialysis rate and/or transplant rate among attributed beneficiaries who are dual eligible or LIS recipients between the BY and the MY.

This policy would increase the maximum improvement score to 2 points. The health equity incentive would begin in MY3. ETC participants in aggregation groups with fewer than 11 attributed beneficiary years would be ineligible to earn the health equity incentive consistent with the low-volume threshold for the applicability of the PPA generally. CMS further proposed to amend the modality performance score (MPS) methodology to incorporate the health equity incentive.

The formula for the MPS for MY3 through MY10 would be the following:
$MPS = 2 \times (higher\ of\ the\ home\ dialysis\ achievement\ or\ (home\ dialysis\ improvement\ score + health\ equity\ incentive)) + (higher\ of\ the\ transplant\ achievement\ or\ (transplant\ improvement\ score + health\ equity\ incentive))$.

Public comments generally supported CMS' proposal while some commenters suggested that a five-percentage point increase to earn the Health Equity Incentive may not be attainable for ETC Participants. As a result, ETC Participants may not try to increase home dialysis rates and transplant rates among their beneficiaries who are dual eligible or LIS recipients. These commenters suggested alternative thresholds for awarding the Health Equity Incentive. CMS agrees with commenters' concerns that setting the threshold for awarding the Health Equity Incentive too high could undermine the intent of the policy. CMS is persuaded by the specific evidence provided by commenters that the proposed threshold was likely unachievable based on historic data and is changing it to 2.5 percentage points in the final rule.

7. PPA Reports and Data Sharing

a. Background on Beneficiary Attribution and Performance Reporting

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. This attribution is performed retrospectively after the end of the MY.

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. These rates are used to calculate the ETC participant's MPS and PPA. The PPA is then used to adjust certain Medicare payments to the ETC participant during 6-month PPA periods. The first PPA period would take place from July 1, 2022, through December 31, 2022.

CMS will notify each ETC participant of attributed beneficiaries, MPS, and PPA no later than one month before the start of the applicable PPA period. The ETC participant would be able to retrieve this data at any point during the relevant PPA period and would have 90 days from the date that CMS shares the MPS to request a targeted review. These data are needed by the ETC participant to evaluate and improve performance.

b. Sharing of Beneficiary-Identifiable Data

CMS proposed to 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: ESRD Treatment Choices (ETC) Model | CMS Innovation Center. Under the proposal, the following data, when available, would be provided:

1. The ETC participant's attributed beneficiaries' names;
2. Medicare Beneficiary Identifiers (MBIs);
3. Dates of birth;
4. Dual-eligible status; and
5. LIS-recipient status.

This beneficiary-identifiable data also would include, when available, 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.

The proposed disclosure of ETC Model beneficiary-identifiable data would be permitted by the HIPAA Privacy Rule under provisions that permit disclosures of PHI as "required by law."

The Privacy Act of 1974 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. "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. 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.

Public commenters generally supported CMS' proposals stating that it is essential for ETC participants to have access to the data elements CMS proposed to allow informed decisions and improved clinical processes. There were also comments that agreed with allowing ETC participants to request targeted review of the MPS calculation, care management or coordination, and quality improvement.

Several comments requested more frequent data sharing under the ETC Model stating that it 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. CMS replied that the

schedule it proposed for sharing data affords ETC participants sufficient time to conduct the improvement activities. 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.

One commenter suggested that CMS make available to ETC participants a list of beneficiaries who are dual eligible or LIS recipients in advance of the applicable MY explaining that sharing such data in advance would give ETC Participants a clearer understanding of their patient population. CMS responded that it 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.

Several commenters requested that CMS make claims data available to ETC participants as CMS does with other models. CMS disagreed stating that it balanced the need to make data available to improve quality of care with protecting the privacy interests of attributed beneficiaries. Only the "minimum necessary" amount of beneficiary-identifiable data, as required by the HIPAA Privacy Rule, is being shared to support the ETC Model.

CMS is finalizing its proposal without modification.

(1) Conditions for Retrieving Beneficiary-Identifiable Data.
CMS proposed only sharing data on the condition that the ETC participant observes all relevant statutory and regulatory provisions regarding appropriate data use, confidentiality and privacy of individually identifiable health information as would apply to a covered entity under HIPAA regulations. The ETC participant would also have to agree to comply with the terms of a separate data sharing agreement.

The HIPAA provisions that the ETC participant would have to observe would include, but would not be necessarily limited to:

1. Standards regarding the use and disclosure of PHI; and
2. Administrative, physical, and technical safeguards and other security provisions; and
3. Breach notification.

CMS proposed that to retrieve the beneficiary-identifiable data, the ETC participant would be required to first complete, sign, and submit a data sharing agreement with CMS (the ETC Data Sharing Agreement) at least annually. Public commenters agreed with all of these proposals that CMS is finalizing with one minor technical modification in the regulatory language for how it refers to HIPAA.

(2) Content of ETC Data Sharing Agreement.
CMS proposed that under the ETC Data Sharing Agreement, ETC Participants would agree to:

1. 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. Comply with additional privacy, security, and breach notification requirements to be specified by CMS;
3. 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; and
4. The ETC participant no longer being eligible to retrieve the beneficiary-identifiable data for misuse or disclosure that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the ETC Data Sharing Agreement. Further, the ETC participant in this circumstance could also be subject to additional sanctions and penalties available under the law.

These provisions would not prohibit the ETC participant from making any disclosure of the data otherwise required by law.

CMS considered imposing limits on how the ETC participant may use the beneficiary-identifiable data without prior written authorization from CMS to assess:

1. CMS's calculation of the MPS for a given PPA period;
2. The ETC participant's clinical care, management and coordination of care for an attributed beneficiary;
3. Certain "health care operations" of the ETC participant;
4. Quality improvement activities, and
5. Provider incentive design and implementation, to the extent these activities would constitute "health care operations" as defined under the HIPAA Privacy Rule (45 CFR 164.501).

Under the proposal, the ETC Data Sharing Agreement would include other provisions, including requirements regarding data security, retention, destruction, and breach notification. For example, the ETC Data Sharing Agreement may include:

1. 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;
2. 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;
3. How and when beneficiary-identifiable data could be retained by the ETC participant or its downstream recipients of the beneficiary-identifiable data;
4. Procedures for notifying CMS of any breach or other incident relating to the unauthorized disclosure of beneficiary-identifiable data; and
5. Provisions relating to destruction of the data.

CMS further proposed that, if one or more grounds for remedial action specified in § 512.160(a) has taken place, it may discontinue data sharing to the model participant. Remedial action may be taken 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.

CMS is modifying its proposed policy in the final rule on data sharing that will allow an ETC participant to disclose the beneficiary-identifiable data with a business associate 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. The policy places limits on the ETC participant's further disclosures of the beneficiary-identifiable data shared by CMS to a downstream recipient who is neither a covered entity nor a business associate of the ETC participant – except as otherwise required by law.

One commenter requested that CMS clarify the differences between the privacy protections required under the ETC Model and those required by HIPAA. CMS responded that the policies it is finalizing 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. The final rule is consistent with the HIPAA Privacy Rule but also establishes the following additional protections that apply to ETC participants and their business associates:

- 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.

CMS' proposal placed additional limits on how the ETC participant may use and further disclose the beneficiary-identifiable data beyond what may otherwise be permitted under the HIPAA Privacy Rule without obtaining prior written permission from CMS 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;
- 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.

Some commenters objected to 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. There were also comments requesting that CMS not require the ETC participant to obtain permission from CMS or another agency prior to any permitted data use.

CMS responded that the HIPAA Privacy Rule covers a broad array of activities most of which 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;" activities that are not applicable an ETC participant.

CMS will permit the ETC participant to use and further disclose beneficiary-identifiable data 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.

Once the ETC participant has completed its annual ETC Data Sharing Agreement, CMS does 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 consistent with the final rule, data sharing agreement or other uses CMS may authorize in writing.

One commenter recommended that CMS implement a warning system prior to deeming an ETC participant ineligible to retrieve beneficiary-identifiable data under the model as revoking the ability for the ETC participant to obtain beneficiary-identifiable data will result in the ETC participant being unable to have the data to improve care. CMS did not agree to establishing a warning system but does agree 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.

CMS indicates that it already has discretion under the regulations to apply various remedial actions short of data revocation for unauthorized disclosure of beneficiary-identifiable data. Nevertheless, CMS is finalizing § 512.390(b)(1)(iv)(D) with a modification that allows CMS to deem an ETC participant ineligible to retrieve beneficiary-identifiable 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 change is intended to give CMS more flexibility in application of the rules related to sharing of ETC data.

CMS is finalizing its proposal with the following modifications:

- It is removing language from § 512.390(b)(1)(iv)(C) 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.
- It is modifying the proposed language at § 512.390(b)(1)(iv)(D) to provide that, if an 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.

(3) Process for Retrieving the ETC Data Sharing Agreement and Beneficiary-Identifiable Data. CMS expects to provide a web-based platform for ETC participants to retrieve the beneficiary-identifiable data. If the ETC participant does not follow the process specified by CMS or agree to

the ETC Data Sharing Agreement, the ETC Participant would be unable to retrieve 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. Public commenters agreed with CMS' proposal that it is finalizing without modification.

c. CMS Sharing of Aggregate Data

In addition to the process for sharing beneficiary-identifiable data described above, CMS proposed to make aggregate data available for each PPA period (de-identified in accordance with 45 CFR 164.514(b)) using the same process as other information described above:

- 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; and
- The ETC Participant's MPS and PPA for the corresponding PPA Period.

CMS believes aggregate, de-identified data would better enable the ETC participant to see which performance rates the ETC participant might need to more generally improve its performance under the ETC Model. As the information is de-identified, the ETC participant would not have to agree to the ETC Data Sharing Agreement to retrieve aggregated data.

Public commenters generally supported CMS' proposal. One commenter requested that CMS make aggregate comparative data available quarterly so an ETC participant can compare its own performance to that of others. CMS declined to share aggregate data quarterly because accurate data is unavailable that frequently. It cannot share data more often than biannually after the end of the applicable MY. As performance benchmarks are already developed in relation to Comparison Geographic Areas, CMS believes data it is already planning to share will provide the ETC participant with insight into how it compares to other health care providers in the corresponding Comparison Geographic Area during the applicable BY.

8. Medicare Waivers and Additional Flexibilities

a. Background on Kidney Disease Patient Education Services Waiver

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 (CKD). CMS believes that kidney disease patient education services play an important role in educating patients about their disease and to help them make informed decisions on their treatment options, including options for transplantation, dialysis modalities, and vascular access.

Because kidney disease patient education services have been infrequently billed, CMS used its authority under section 1115(A)(d) of the Act to waive certain requirements for individuals and

entities that furnish and bill for kidney disease patient education services under the ETC Model. These waivers, codified at §512.397(b) allow more beneficiaries to have access to these education services and provide greater flexibility for how these education services are performed. Under the ETC Model, beneficiaries with Stage IV and Stage V CKD or in the first 6 months of starting dialysis can receive this benefit. In addition, 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 MC who is an ETC Participant. CMS also waived requirements related to the content of kidney disease education services.

b. Kidney Disease Patient Education Telehealth Waivers and Additional Flexibilities

In response to the PHE, CMS used its waiver authority under section 1135(b)(8) of the Act, to waive 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. CMS believes that allowing qualified staff to continue to furnish kidney disease patient education services via telehealth, consistent with this waiver, would increase access to kidney disease patient education.

In addition, CMS believes that removing beneficiary cost barriers for kidney disease patient education would also improve beneficiary choice of dialysis modality. CMS summarizes the evidence suggesting there is a significant relationship between household income or poverty status and prevalence of CKD.

To provide MCs who are ETC Participants additional flexibility in furnishing the kidney disease patient education services described in §410.48, CMS proposed a waiver of certain telehealth requirements solely to allow ETC Participants to furnish kidney disease patient education services via telehealth under the ETC Model. CMS also proposed a waiver to allow ETC Participants to reduce or waive the beneficiary coinsurance for kidney disease patient education services.

(1) Kidney Disease Patient Education Services Telehealth Waiver
CMS finalizes its proposal to amend §512.397 to add a waiver of certain telehealth requirements to provide qualified staff the flexibility to furnish kidney disease patient education services via telehealth, [12] with a modification of the start date. CMS modifies the effective date of these waivers from January 1, 2022 (the beginning of MY3) to beginning upon the expiration of the COVID-19 PHE.

- Waive the geographic and site of service originating site requirements in section 1834(m)(4)(B)(3) and 1834(m)(4)C) of the Act (and in 42 CFR 410.78(b)(3) and (4)) and allow for the beneficiary to be outside of a rural area and to be located anywhere.
- Waive the requirements 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 services furnished via telehealth to a beneficiary at a site not specified in §410.78(b)(3).

[12] As defined for the ETC Model at §512.310.

CMS will not waive the requirements under section 1834(m)(1) of the Act and 42 CFR 410.78(b) that telehealth services be furnished via an "interactive telecommunications system". Specifically, audio-only telehealth kidney disease patient education services would not be permitted.

In the proposed rule, CMS noted that it used the term "clinical staff" and "qualified staff" in the Specialty Care Models final rule but did not provide definitions of these terms. CMS finalizes its proposed definitions:

- "Clinical staff" means a licensed social worker or registered dietician/nutritional professional who furnishes services for which payment may be made under the PFS under the direction of, and incident to, the services of the MC who is an ETC Participant.
- "Qualified staff" means both clinical staff and any qualified person (as defined at §410.48(a)) who is an ETC Participant.[13]

Many commenters expressed support for the use of telehealth in general and for the specific proposed telehealth waivers. CMS notes that because the COVID-19 PHE and the section 1135(b)(8) waiver of geographic and site of service restrictions are still ongoing, it is modifying its proposal such that the ETC telehealth waiver policy will begin upon the expiration of the COVID-19 PHE instead of beginning in MY3.

CMS disagrees with a commenter opposed to the proposal to waive the originating site fee. The commenter stated that the originating site fee was not waived for telehealth services furnished under the section 1835(b)(8) telehealth waiver during the PHE and it would provide an incentive for ETC Participants to offer kidney disease patient education services via telehealth after the PHE. In response, CMS clarifies it 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. CMS will still pay the originating site facility fee when these education services are furnished via telehealth at a site specified in §410.78(b). CMS also notes that the proposal was designed specifically for the ETC Model and it does not believe that when an ETC Participant furnishes kidney disease patient education services at a site not specified in its regulations, the ETC Participant is generally providing administrative, clinical support or overhead for the site where the beneficiary is located. In addition, CMS is concerned that permitting the originating site facility fee for these services would likely represent too large an impact on the ETC Model's savings estimates, potentially jeopardizing CMS' ability to continue to test the model.

A few commenters recommended that CMS allow audio-only telehealth services. CMS acknowledges that not every beneficiary has access to an interactive telecommunications system, but it is also concerned that audio-only kidney disease patient education services would not be effective in educating beneficiaries. CMS notes this would not align with its focus on health equity because such a policy may result in beneficiaries of lesser means systematically receiving lower quality kidney education.

[13] Doctors, physician assistants, nurse practitioners, and clinical nurse specialists are including in the existing definition of qualified person at §410.48(a).

(2) Kidney Disease Patient Education Services Beneficiary Coinsurance Waiver

CMS discusses its concerns that cost represents a meaningful barrier for beneficiaries obtaining kidney disease education services.

Kidney disease education services can be billed using G0420 for an individual session or G0421 for a group session. The current national unadjusted payment for G0420 is $114.10 and for G0421 it is $27.22; a beneficiary coinsurance would be $22.82 for an individual session and $5.44 for a group session. If an individual receives six kidney disease patient educations (the maximum covered by Medicare), the beneficiary may be required to pay $136.92 for individual sessions or $32.64 for group sessions. In order to increase access to kidney disease patient education services, CMS believes it is important to permit ETC participants the flexibility to reduce or waive the 20 percent coinsurance requirement for these services.

Beginning January 1, 2022, CMS proposed to permit 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 certain conditions are satisfied. CMS referred to this proposal as the "kidney disease patient education services coinsurance patient incentive". CMS believed that limiting this patient incentive to beneficiaries without secondary insurance would better ensure that only beneficiaries who need cost-sharing would receive the incentive.

CMS also proposed that the kidney disease patient education 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, which require that a beneficiary obtain a referral from the physician managing the beneficiary's kidney condition.

CMS proposed that coinsurance support would be permitted for education services offered either in-person or via telehealth and for both individual and group sessions. CMS had considered limiting the coinsurance support only to individual sessions but was concerned that any cost, even if low, could be a barrier to some beneficiaries.

CMS proposed that an ETC Participant offering coinsurance support would be required to maintain records for each kidney disease patient education service for which the coinsurance was reduced or waived. The records would maintain the following: the identity of the qualified staff furnishing the service; the date the patient incentive was provided; the name of the beneficiary; evidence that the beneficiary was eligible to receive the service and did not have secondary insurance; and the amount of the patient education coinsurance patient incentive reduced or waived by the ETC Participant. CMS could suspend or terminate the ability of the ETC Participant to offer the kidney disease patient education services coinsurance patient incentive if it determined that any grounds for remedial action exist.

CMS anticipated making the determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)), would be available to protect the reduction or elimination of coinsurance. CMS expected that the CMS-sponsored model safe

harbor would 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)(4).

CMS considered prohibiting an ESRD facility or other entity from providing qualified staff or the ETC Participant with financial support to enable qualified staff or the ETC Participant to provide the coinsurance patient incentive. CMS was concerned that permitting financial support may encourage unlawful or abusive arrangements**.**

CMS considered waiving Medicare payment and pay 100 percent of the kidney disease patient education service furnished to a beneficiary lacking secondary insurance.[14] CMS was concerned this policy would likely represent too large an impact to the ETC Model's savings estimates and potentially jeopardize the ability to continue to test the ETC Model.

Given the policies proposed, CMS proposed to modify the title of §512.397 from the "ETC Model Medicare program waivers' to "ETC Model Medicare program waivers and additional flexibilities."

Many commenters agreed that cost is a barrier for some beneficiaries to obtain kidney disease patient education services and supported CMS' proposal to reduce or waive a beneficiary's coinsurance for this education furnished by qualified staff under the ETC Model in both individual and group sessions. A few commenters opposed limiting the proposal to beneficiaries without secondary insurance; a commenter expressed concern that Medicaid may not necessarily provide cost-sharing support for kidney disease patient education services. CMS acknowledges that Medicaid will not necessarily cover the coinsurance amount for dual-eligible beneficiaries' kidney disease patient education services because all Medicare Savings Programs do not cover Medicare coinsurance and Medicaid coverage of cost sharing generally varies by state. CMS modifies the proposed policy to restrict the coinsurance patient incentive to only those beneficiaries without secondary insurance that provides cost sharing support for kidney disease patient education services.

In response to comments about CMS' proposal to prohibit an ESRD facility or other from providing the ETC Participant with qualified staff or financial support for use in furnishing kidney disease patient education services, CMS discusses its concerns that these arrangements could result in program abuse by circumventing the statutory prohibition against dialysis facilities furnishing kidney disease patient education services. CMS notes that staff or resources furnished to the ETC Participant from an ESRD facility or related entity could market a specific ESRD facility to beneficiaries. CMS does not believe ETC Participants should obtain safe harbor protection for the reduction or waiver of cost-sharing on kidney disease patient education services if services are provided by personnel leased from an ESRD facility or related entity. For the finalized policy, CMS adds 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

[14] Under section 1115A(d)(1) of the Act, the Secretary may waive the copayment requirements of title 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 with respect to testing models described in section 1115(A) of the Act.

related entity. For this provision, CMS states a related entity would include any entity that is directly or indirectly owned in whole or in part by an ESRD facility.

CMS agrees with commenters 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 revenue. CMS states that the safe harbor protection for cost-sharing support furnished by ETC Participants should be contingent on the ETC Participant bearing the full cost of the copayment reduction or waiver. CMS finalizes 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.

In response to commenters recommending that CMS pay the full amount of the kidney disease patient education services furnished to a beneficiary without any secondary insurance, CMS reiterates its concern that such a policy may impact the savings estimates of the ETC Model. CMS also states that it cannot exclude the 20 percent coinsurance payment paid by CMS from the Model's cost calculations because it would need to account for these costs when determining the Model's overall impact on Medicare program expenditures. CMS may consider implementing a payment waiver in a future model. CMS understands commenters' concerns that the proposed coinsurance policy imposes an administrative burden on ETC Participants who choose to furnish the patient incentive, but it believes that the benefits to patients from reducing cost barriers will outweigh the administrative burden.

After considering public comments, CMS finalizes with modifications its proposal to add §512.397(c) which allows an ETC Participant to reduce or waive the 20 percent coinsurance obligation for kidney disease patient education services. ETC Participants can 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:

- the individual or entity that furnished the education services is qualified staff;
- the qualified staff are not leased from or otherwise provided by the ESRD facility or related entity;
- the kidney 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;
- the kidney disease patient education services were furnished in compliance with the applicable provisions of §410.48 or §512.397(b); and
- 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.

CMS also finalizes with modifications its proposal regarding documentation retention and government access to records regarding the reduction or waiver of this beneficiary cost-sharing obligation. CMS modifies §512.397(c)(2)(iii) to specify this coinsurance waiver applies to beneficiaries who are eligible to receive the kidney disease patient education service and do not

have secondary insurance that provides cost-sharing for kidney disease patient education services on the date the services were provided.

CMS finalizes its proposal at §512.397(c)(3) stating that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentive is available to protect kidney disease patient education coinsurance waivers that satisfy the requirements of safe harbor and the conditions stated in §512.397(c)(1).

(3). Revising Language Providing Other ETC Model Medicare Program Waivers

CMS finalizes its proposal to revise §512.397(b)(1) through (4) to make conforming changes to any reference to kidney disease education to "kidney disease patient education services." As discussed previously, CMS finalizes its proposal to add definitions for "clinical staff" and "qualified staff". CMS also finalizes its proposal to remove the "clinic/group practice" from the list of individuals or entities that are permitted to furnish kidney disease patient education services under the ETC Model. CMS states that the inclusion of clinic/group practices was in error as these practices are not able to furnish or bill for kidney disease patient education services under existing law and CMS did not intend for the waiver described in §512.397(b)(1) to permit anyone other than a clinician to furnish these education services.

CMS did not receive any comments about these proposals, but it did receive a few comments recommending CMS make additional changes to the kidney disease patient education services waivers to allow additional clinicians and health care sites to provide this service. A few commenters also suggested CMS create accredited curricula to ensure consistent education. CMS appreciates these comments but does not plan additional ETC Model waivers at this time.

C. Requests for Information on Topics Relevant to the ETC Model.

In the proposed rule, CMS stated these RFIs were issued solely for information and planning purposes and that CMS would not respond to questions about the policy issues raised in these RFIs.

1. Peritoneal Catheters (PD) Catheter Placement

CMS discussed concerns from numerous stakeholders about the ability to effectively get PD catheters placed in beneficiaries wanting home dialysis. PD is the most common form of home dialysis. CMS requested feedback about how it can promote placement of PD catheters under the ETC Model:

- What are the key barriers to increased placement of PD catheters?
- How can CMS promote placement of PD catheters in a timelier manner?
- Should the Innovation Center use its authority to test alternative payment structures to address the barriers to PD catheter placement as part of the ETC Model? If so, why and how?

Commenters expressed general concern that CMS continues to address barriers to home dialysis one provider type at a time rather than from a global perspective that included all the barriers and decision points that patients face, including those in earlier stages of kidney disease.

Most commenters agreed that the main barriers to PD catheter placement include lack of hospital-based catheter insertion teams, lack of operating room time, and lack of training on PD catheter placement for vascular surgeons. The majority of comments considered the largest barrier for PD catheter placement was the low reimbursement rate and made several recommendations for addressing this issue, including a separate PD catheter placement incentive under the ETC Model.

CMS will consider the input it received as it continues to test the ETC Model.

2. Beneficiary Experience Measures

The ETC Model uses two ESRD facility quality measures: Standardized Mortality Ratio (SMR) (NQF #0369) and Standardized Hospitalization Ratio (NQF #1463). CMS is considering including a measure to capture the beneficiary experience of home dialysis and requested feedback on the following:

- What domains of a patient experience of care with home dialysis would be the most useful to assess and why?
- 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?
- How would a patient experience measure be best used to further the purpose of the ETC Model?
- How should CMS use a patient experience measure to assess the quality of care to beneficiaries?
- How should CMS use a patient experience measure to incentivize improved quality of care on the ETC Model and/or for other CMS programs?

CMS is also considering publishing the quality outcomes for the ETC Model and requested feedback on the following:

- What is the frequency with which CMS should disseminate the results?
- What should be the unit of analysis for the reported data?

Commenters thought a measure to access beneficiary perception of the care they receive would be useful. The majority of commenters agreed with CMS that the current measures are not sufficient to capture the beneficiary experience with home dialysis and encouraged CMS to work with the kidney community to develop a measure endorsed by the NQF. Commenters suggested several areas that a new measure could address including ease of use of their modality/device; patient/provider burden in self administration; and communication with the care team. Several commenters suggested additional mandatory measures in the ETC Model including an advance care planning measure; access to palliative care; and timely and appropriate referral to hospice.

With regard to reporting quality outcomes, commenters supported transparency for beneficiaries attributed to ETC Participants and recommended the data should be aggregated instead of

reported at an individual ETC Participant level. Commenters also suggested that reporting occur annually, consistent with the ESRD QIP timeline.

CMS will continue to take all comments and suggestions into consideration.

VI. Requests for Information

A. Overview

This section addresses several requests for information) to inform payment reform under the ESRD PPS. Specifically, CMS solicited feedback on the following topics:

- low-volume payment adjustment,
- case-mix adjustment calculation,
- outlier payment adjustment calculation,
- pediatric dialysis payment adjustment,
- ESRD PPS and hospital cost report modifications,
- pediatric cost report modifications, and
- home dialysis for Medicare beneficiaries with acute kidney injury.

CMS notes that in the last several years, it has, in conjunction with its contractor, been conducting research, including holding three technical expert panels (TEPs), to explore possible improvements to the ESRD payment model.[15] In addition, in the 2020 ESRD PPS proposed rule (84 FR 38398 through 38400), CMS invited further comments on several 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. CMS states that it solicited comments this year so that it has time to consider them for potential proposals in the 2023 ESRD PPS proposed rule for a 2025 implementation.

B. Calculation of the Low-Volume Payment Adjustment (LVPA)

CMS reviews the statutory and regulatory background of the LVPA adjustment and its applicability to ESRD facilities.[16] Under §413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation: (1) furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month costs reports, whichever is most recent) preceding the payment year; and (2) has not opened, closed, or received a new provider number due to a change in ownership in the three cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent)

[15] The materials from the TEPs and summary reports can be found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources

[16] Section 1881(b)(14)(D)(iii) of the Act required the Secretary to establish a payment adjustment for low-volume ESRD facilities.

preceding the payment year. As established in regulations in the 2016 ESRD PPS final rule (80 FR 69001), low-volume ESRD facilities receive an LVPA adjustment factor of 23.9 percent.

ESRD facilities, the Medicare Payment Advisory Commission (MedPAC), and the Government Accountability Office have recommended that CMS make refinements to the LVPA to better target ESRD facilities that are critical to beneficiary access to dialysis care in remote or isolated areas.[17] These groups have also expressed concern that the strict treatment count introduces a "cliff-effect" that may incentivize facilities to restrict their patient caseload to remain below the 4,000 treatments per year for the LVPA threshold.[18] Stakeholders have also expressed concern that the eligibility criteria for the LVPA lacks flexibility and that the attestation process is burdensome to small facilities with limited resources. Given these concerns, CMS is seeking alternative approaches to the LVPA that would reduce burden, remove negative incentives that may cause gaming, and better target facilities that are critical for beneficiary access to ESRD services.

CMS discussed two approaches in the proposed rule: (1) a census tract methodology that would identify low volume facilities in certain geographic areas, specifically census tracts, with low demand for dialysis; and (2) a low-volume and isolated (LVI) adjustment that would identify isolated, low-volume ESRD facilities critical to beneficiary access.

The census tract methodology would involve dividing the U.S. into geographic areas based on a reasonable assessment of ESRD beneficiaries' ability or willingness to travel. Latent demand is then calculated by counting the number of ESRD beneficiaries near each facility. "Near" is defined by driving time to facilities. Latent demand is calculated by multiplying the number of beneficiaries near an ESRD facility by average number of treatments for ESRD beneficiaries.

The LVPA threshold is then applied by determining the threshold of adjusted latent demand. That is, those facilities, which fall below the threshold are LVPA eligible. As part of the TEP process, the panelists noted that this methodology appears administratively simple and could eliminate the burden associated with the LVPA attestation process for facilities and MACs. CMS notes that this methodology often results in a single facility being the only dialysis provider for a number of miles.

The LVI adjustment was recommended by MedPAC in its June 2020 report to Congress as a replacement to the LVPA and rural adjustment under the ESRD PPS. Under this methodology, the facility's distance from the nearest facility and its total treatment volume would determine whether a facility is low volume and isolated. This methodology would use a single facility-level regression approach instead of the current two-regression approach utilized by CMS. Based on a simulation using 2017 data, 575 facilities would have been eligible for the LVI verses 1,734 facilities under the current LVPA and rural adjustment methodology.

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[17] See http://www.medpac.gov/docs/default-source/reports/jun20_ch7_reporttocongress_sec.pdf and https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf

[18] https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf

CMS sought **comments** on the approaches suggested above, other alternate approaches, and support of the current LVPA methodology. In addition to any other input regarding the LVPA under the ESRD PPS, CMS requested responses to the following questions.

- Should a distinction other than census tract information be considered?
- What criteria should be used to determine the threshold(s) of adjusted latent demand (in treatment counts) which determine LVPA eligibility (for example, a threshold of high average cost per-treatment)?
- What are the concerns for facilities that would lose the LVPA under the LVI methodology?
- What are the concerns about the potential for gaming within the LVI methodology?
- To the extent that the LVI methodology captures more isolated (and most often rural) facilities, should a separate rural adjustment be maintained?

All commenters (14 responses to the LVPI RFI) supported either eliminating or revising the current LVPA or rural adjustment. Several commenters agreed with MedPAC's suggestion for the low volume and isolated (LVI) adjustment. Several commenters also opposed the census tract methodology stating that it is complex and lacks transparency.

C. Calculation of the Case-Mix Adjustments

CMS reviews the statutory and regulatory background of the case-mix adjustment within the ESRD PPS.[19] The goal of case-mix adjustment is to ensure that payment for a dialysis treatment reflects expected total treatment costs and costs that were formerly separately billable and composite rate services.

Under the current case-mix methodology, CMS uses two equations, including a patient-level equation for formerly separately billable costs and a facility-level equation for composite rate costs. Formerly separately billable services are itemized on the ESRD Facility claim, (Type of Bill: 72x) and include injectable drugs and their oral equivalents plus certain laboratory tests and supplies. Composite rate services, which are captured on the cost report, constitute approximately 90 percent of a treatment's cost and include capital, labor, and administrative costs plus certain drugs, laboratory tests, and supplies. CMS calculates the final case-mix adjusters for adults based on the weighted average of estimated coefficients from these two equations (that is, patient level and facility level equations). The regression equations and weighted averages are calculated using 2012 through 2013 claims and cost report data. Case-mix factors in the current model include age categories, body surface area (BSA), low body mass index (BMI) indicator, onset status, and comorbidities (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, and myelodysplastic syndrome). Facility adjusters include wage index, low volume status, and rural status.

Stakeholders have raised concerns that the existing case-mix adjusters may not correlate well with the current cost of dialysis treatments citing several factors:

[19] Section 1881(b)(14)(D)(i) of the Act mandates that the ESRD PPS "shall include a payment adjustment based on case mix that may take into account patient weight, body mass index, comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors".

- Current adult case-mix adjustors were calculated using old data (2012-2013 claims and cost report data);
- Current adjustors may not reflect resource-intensive patient-level services such as isolation rooms, behavioral issues, or neurocognitive issues;
- Apportioned composite rate costs are currently only observable at the facility level and do not include patient or treatment level variations; and
- Composite rate items are not individually collected on the claims, resulting in the payment not differentiating between the cost of hemodialysis verses peritoneal dialysis.

MedPAC has suggested that CMS move to a "one-equation model" or a patient-data focused model that better accounts for the variation in the cost of providing the full PPS payment bundle. CMS currently does not have sufficient data to implement this recommendation but data on dialysis treatment time (that is, time on machine) would allow for a proportionately higher amount of composite rate costs to be allocated to patients with longer dialysis treatment times. CMS has taken steps towards developing a patient-data focused model and had intended collecting time on machine data effective January 1, 2021, but later rescinded this requirement. Panelists and stakeholders believe that this one-equation model is more intuitive than the current ESRD case-mix adjusters and more accurately reflects variation in patient resource use. CMS is seeking feedback from the public on the one-equation model, keeping the current ESRD PPS case-mix adjustments or any additional approaches not yet considered.

CMS sought comments on the methodology to collect data to reflect patient-level differences in composite rate costs, including the use of a value code to collect time on machine on the claim. It also requested responses to detailed questions:

- Which of the five composite rate cost components (that is, age, BSA, BMI, onset of dialysis, comorbidities) are most likely to vary with treatment duration?
- Should new information for these cost components be collected on cost reports, for use in better inferring the composite rate costs associated with treatment duration?
- What are the advantages and disadvantages of obtaining treatment duration information from blood urea nitrogen time on dialysis through the End Stage Renal Disease Quality Reporting System (EQRS) (our new system that has replaced the Consolidated Renal Operations in a Web-enabled Network (CROWNWeb)), versus collecting treatment duration through new fields on claims?
- What challenges would be encountered in reporting treatment duration on claims, using one of the options discussed?
- Are there alternative proxies for resource utilization that can be reported at the patient/treatment level?

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. Most commenters did not support the collection of time on machine data on claims or cost reports to allocate composite rate costs. MedPAC continued to recommend that CMS develop a one-equation regression model in place of the current two-equation model currently used.

D. Calculation of the Outlier Payment Adjustment

CMS reviews the statutory and regulatory background of the outlier policy used within the ESRD PPS.[20] Under its policy, an ESRD facility will receive 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) plus the fixed-dollar loss ratio (FDL) amount, set each year by CMS. The outlier MAP and FDL amounts are estimated using the most recent, complete data set available, which are data from 2 years prior to the payment year in question. If the outlier MAP amount per treatment on the claim is above the threshold, there will be a per-treatment outlier payment equal to 80 percent of the amount exceeding the threshold.

CMS established the outlier percentage at 1.0 percent of total ESRD payments. Outlier payments for the adult population, however, have consistently constituted less than the targeted 1.0 percent of total ESRD PPS payment since such payments began in 2011. Stakeholders note that the current methodology results in underpayment to providers, as money was removed from the base rate to balance the outlier payment. MedPAC has echoed these concerns and suggested that the introduction of calcimimetics as outlier-eligible items could perpetuate the pattern of underpayment going forward.

Suggestions for outlier payment adjustment include establishing a new outlier threshold using alternative modeling approaches that account for trends in separately billable spending over time by using additional years of claims data; the current approach assumes constant utilization over time and uses a single year of claims data. Another suggestion is using a calculation of "after the fact" FDLs that would achieve the 1.0 percent outlier target for each year included in the FDL calculation – referred to as the retrospective FDL. Using three years of claims data, for example, to simulate FDLs resulted in an outlier percentage that was much closer to the 1.0 percent target than using the most recent year of data.

CMS sought comments on the approach suggested above, and to solicit information that will better inform future modifications to the methodology. It also requested responses to detailed questions about the calculation and the data it should use.

In its description of comments, CMS did not provide a detailed summary but notes that commenters continue to express 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. Commenters suggested various strategies including reducing the outlier threshold and excluding TDAPA and TPNIES payments in the outlier calculation methodology. Other suggestions included support of the use of the FDL trend using historical utilization data and the creation of a mechanism to return unpaid outlier amounts to the ESRD PPS.

[20] Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high-cost outliers. Current outlier policy was codified in the 2011 ESRD PPS final rule and codified at §413.237.

E. Calculation of the Pediatric Dialysis Payment Adjustment

CMS reviews the statutory authority and regulatory background of the pediatric dialysis payment adjustment used within the ESRD PPS.[21] Payment adjusters for pediatric dialysis vary by variables of age (< 13 and 13-17) and modality (peritoneal dialysis or hemodialysis). The pediatric adjusters currently in effect (finalized in 2016) are: (1) <13 peritoneal dialysis =1.063; (2) <13 hemodialysis =1.306; (3) 13-17 peritoneal dialysis = 1.102; and (4) 13-17 hemodialysis = 1.327.

Stakeholders continue to express concerns to CMS about the undervaluation of pediatric ESRD care, which they believe requires significantly different staffing and supply needs from those required to deliver ESRD care to adults. For example, pediatric dialysis often requires a developmental and behavioral specialist, pediatric dieticians, and social workers. In addition, the current hospital cost report (CMS Form 2552-10) does not distinguish pediatric and adult dialysis cost. CMS notes that a small number of facilities provide 95 percent of pediatric dialysis treatments (about 100) and those pediatric facilities are hospitals, mostly children's hospitals. Analysis performed by a contractor confirmed many of the stakeholders concerns and found, for example, that using finer stratification of the age groups reveals differences in cost per treatment.

CMS notes that in the December 2020 TEP, three approaches were discussed among the panelists that could potentially lead to a more accurate estimate of pediatric dialysis costs under a revised payment model: (1) the addition of pediatric-specific case-mix adjustment multipliers; (2) the creation of a separate payment bundle for pediatric ESRD treatment costs; and (3) revisions to current data collection practices. CMS notes that the creation of a separate payment bundle for pediatric ESRD treatment costs would require substantial time to determine. It would also require a statutory change. The other approaches appear to be more promising; challenges remain in collecting sufficiently detailed data to develop more accurate payment adjusters for pediatric dialysis.

CMS sought comments on pediatric dialysis payments and specifically requests responses to the following questions:

- Does the magnitude of total costs and pediatric multipliers reflect ESRD facilities' actual incurred costs? If not, what specific costs are not being reported on claims and/or cost reports?
- Is there sufficient variation in composite rate costs among pediatric patients to justify use of a proxy to distribute facility-level composite rate costs to individual treatments?
- If duration of treatment is not a valid proxy for composite rate costs per treatment, what are alternative proxies to consider?
- What, if any, are the specific concerns about incorporating pediatric patients into the estimation of multipliers for both the adult and pediatric populations?
- What are the issues facing pediatric billing and accounting staff with regard to completion of claims and cost reports? How can these problems be remedied?

[21] Section 1881(b)(14)(D)(iv)(I) of the Act provides that the ESRD PPS may include such other payments adjustments as the Secretary determines appropriate; this includes the adjustment for pediatric providers of services and renal dialysis facilities.

- Are there additional costs factors for pediatric patients that are not adequately captured on the 72X claim?

In its brief summary of comments, CMS notes that all commenters expressed concern 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 recommended that a combination of age, weight, and pediatric-specific comorbidities be used as a proxy for composite rate costs for pediatric patients.

F. Modifying the Pediatric Dialysis, ESRD PPS and Hospital Cost Reports

1. Modifying the Pediatric Cost Report

CMS highlights issues associated with obtaining pediatric specific costs for dialysis. Pediatric composite rate costs are not differentiated from adult costs on hospital cost reports, though some pediatric-specific costs are itemized on the existing free-standing cost report. Analysis done by CMS indicates that pediatric treatments are more expensive to administer than adult treatments, and that pediatric supply costs are much higher than for adult supplies. A substantial portion of facilities, however, do not differentiate between adult and pediatric costs in their cost report accounting.

CMS states that it is considering two types of changes to the cost reports: (1) changes that differentiate pediatric from adult composite rate component costs, and (2) changes that allow for further differentiation of component costs by modality and age group within the pediatric population. It is seeking stakeholder inputs on potential revisions including the addition of select direct patient care labor categories, which correspond to the type of labor typically employed by pediatric dialysis facilities, and the differentiation of pediatric supplies and equipment.

Specifically, CMS is considering adding the following staff categories to CMS Form 265-11, Worksheet S-1, Lines 21-31(Renal Dialysis Facility—Number of Employees (Full Time Equivalents)): pediatric dialysis nurses and nurse practitioners, pediatric social workers, pediatric dieticians, child life specialists, teachers, and pediatric dialysis unit coordinator. It is also considering whether additional columns should be added to this section of the cost report to differentiate pediatric home dialysis and in-facility dialysis.

CMS would also like to more clearly delineate supplies used in dialysis treatment of pediatric patients, which vary in type and size, from those used with adult dialysis patients. Categories of supplies for which there may be significantly increased cost for the pediatric population include: dialyzers, catheter kits, fistula needles, saline flushes, monitors for vitals, blood pressure cuffs and items used to occupy children during their treatment.

CMS sought comments on the potential changes to cost reports applicable to ESRD facilities treating pediatric dialysis patients. It also requested responses to detailed questions on these issues.

2. Modifying the ESRD PPS and Hospital Cost Reports

CMS reviews its audit and research efforts that provided insights into updating the Medicare Renal Cost Reports (CMS-Form-265-11). As required by section 217(e) of PAMA, CMS conducted an audit of Medicare cost reports for a representative sample of providers of services and renal dialysis facilities. Removal of certain unallowable costs reduced the average cost per treatment by an average of 1.75 percent; a total of $147.5 million of unallowable costs were removed for reasons, including unsupported documentation, lobbying expense, taxes for items not related to patient care, among other reasons.

During the 2020 ESRD PPS TEP, the data contractor engaged the panelists in a discussion regarding potential revisions to the Independent Dialysis Facility Cost Report (CMS Form 265-11).[22] CMS sought input from the public on the feasibility of implementing these suggestions in freestanding ESRD facilities. These potential reporting changes would require facilities to allocate composite rate costs across settings and modalities. This includes addressing the costs for capital-related assets that are dialysis machines, allocating direct patient labor costs, costs of supplies and laboratory services, and allocation of managerial and administrative labor costs. Taken together, modifications to the resulting cost report data would enable the determination of variation in costs across patient types (by risk groups and dialysis modalities).

CMS invited comments on the suggested changes to the Independent Facility Cost Report (CMS Form 265-11). In addition to any other input on modifying the Independent Facility Cost Report, CMS requested responses to detailed questions about operational costs ESRD facilities currently face in reporting capital costs, direct patient care labor costs, administrative and management personnel costs, and other categorical costs that are not currently reported on the cost report, such as missed treatments and isolation rooms.

3. Summary of Comments on Cost Reports

With respect to 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. This includes 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. Commenters also recommended streamlining the reporting required and making it more consistent with reporting required from the State Medicaid programs or private payers.

CMS received input from ten commenters in response to modifying the ESRD PPS and Hospital Cost Reports from a broad spectrum of perspectives. This included large, small, and non-profit dialysis organization, an advocacy organization, a coalition of dialysis organizations, a large non-profit health system, an independent commenter, and MedPAC. All supported making improvements to the cost report that will streamline reporting and improve accuracy. Commenters also recommended that CMS make timely updates to hospital cost reports to reflect

[22] See https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable- Public-Use-Files/Cost-Reports/Renal-Facility-265-2011-form.

changes to payment policies, including TDAPA and TPNIES, while balancing the burden of data collection.

G. Modifying the Site of Services Provided to Medicare Beneficiaries with Acute Kidney

CMS reviews the statutory authority and regulatory background of Medicare payment for individuals with AKI.[23] The AKI dialysis payment rate was finalized in the 2017 ESRD PPS final rule. As affirmed in that rule, payment will only be made for in-center peritoneal dialysis or hemodialysis treatments for AKI beneficiaries. It did not expect that AKI beneficiaries will dialyze at home. Stakeholders, however, continue to indicate that some patients with AKI can safely dialyze at home and have their urine and blood tests performed for the assessment of kidney function in a location closer to home. The 2020 TEP had a session on AKI and the current Medicare payment system and some panelists advocated allowing patients with AKI to be treated at home and another suggested the implementation of transitional care units to allow patients new to dialysis time to adjust to dialysis and the accompany lifestyle changes.

CMS sought comment on the differences in care for patients with AKI versus patients with ESRD and whether it has bearing on the ability of patients with AKI to perform home dialysis safely. It also requested any additional comments regarding potentially modifying site of renal dialysis services and payment for AKI in the home setting.

CMS notes that almost all comments (15 of the 16 comments received) discussed modifications of the site of service requirements, with commenters supporting payment for the AKI patients receiving dialysis in-home settings, including skilled nursing facilities.

VII. Regulatory Impact Analysis

A. Impact of Changes in ESRD PPS Payments

CMS estimates that the revisions to the ESRD PPS would increase payments to ESRD facilities by approximately $290 million in 2022. The Executive Summary of the final rule further breaks down the $290 million total as the net result of 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. These amounts are from CMS' modeling of payment rate changes holding utilization, case-mix and other variables constant.

Considering changes in utilization and other factors, Medicare program payments for ESRD facilities in 2022 are estimated to total $8.8 billion, reflecting an expected 5.8 percent decrease in fee-for-service Medicare dialysis beneficiary enrollment. (The final rule does not address the reasons for a projected enrollment decline, but it is notable that beginning in 2021, Medicare

[23] Section 1861(a)(2)(F) of the Act provides coverage for renal dialysis services to individuals with AKI on or after January 1, 2017.

ESRD beneficiaries may elect to enroll in a Medicare Advantage plan, pursuant to section 17006 of the 21st Century Cures Act (P.L. 114-255)).

Table 9 in the final rule shows the estimated impact on ESRD payments in 2022 by various types of ESRD facilities. The estimates are based on 2020 data from the Part A and Part B Common Working Files as of February 12, 2021. CMS considered using 2019 claims but its analysis showed that ESRD utilization did not change substantially during the pandemic and thus uses the most recent 2020 data for its calculations. A portion of that table is reproduced below. The omitted rows display facility impact by region, urban/rural location, and percentage of pediatric patients.

Overall, CMS estimates the combined effects of all the policies in the final rule would be an increase in payments—again, holding utilization, case mix and other factors constant—of 2.5 percent across all ESRD facilities.

Impact of Changes in 2022 Payment to ESRD Facilities (from Table 9)

Facility Type	Number of Facilities	Number of Treatments (millions)	Effect of 2022 Changes in Outlier Policy	Effect of Change in Wage Index Data	Effect of Payment Rate Update	Total Effect of 2022 Changes
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						
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[1]	380	1.7	1.1%	0.0%	2.2%	3.3%
Facility Size (Treatments)						
Less than 4,000	1,295	2.0	0.5%	-0.1%	1.9%	2.3%
4,000 to 9,999	3,158	13.1	0.6%	0.0%	1.9%	2.5%
10,000 or more	3,281	29.0	0.6%	0.0%	1.9%	2.5%

B. Estimated Impact of ESRD QIP

For 2022, CMS is finalizing its proposal to codify specialty scoring policies for PY 2022 at 42 CFR 413.178(h). Under these finalized regulations, CMS will calculate measure rates for all measures but will not calculate achievement and improvement points for any measures. It will also not calculate or award a TPS for any facility and will not reduce payment to any facility for PY 2022.

For 2024, CMS estimates that the payment reductions from not receiving the full update under the ESRD QIP program under the final rule will total $17.1 million for 1,788 facilities (about 24.3 percent of ESRD facilities). Identical estimates are provided for 2025.[24] The tables below, reproduced from the final rule, show the estimated distribution of payment reductions for 2024 and the impact by facility type. (With respect to the latter, only a portion of the table is shown here.) For about three-quarters of the facilities receiving a payment reduction, the estimated reduction is 0.5 percentage points. Only 23 facilities are estimated to receive the maximum 2 percent penalty.

Overall, CMS estimates the payment reductions will represent about 0.16 percent of payments in 2024; reductions are shown to be largest for hospital-based facilities. Costs to facilities associated with reporting of data for the ESRD QIP through CROWNWeb (now EQRS) are estimated to total $208 million for 2024 under the final rule.

Table 14: Estimated Distribution of 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%
Note: 372 facilities not scored due to insufficient data.		

Impact of QIP Payment Reductions to ESRD Facilities for 2024 (from Final Rule Table 13)

Facility Type	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction as Percent of Total ESRD Payments
All Facilities	7,345	1,788	-0.16%
Facility Type			
Freestanding	7,007	1,685	-0.15%
Hospital-based	338	103	-0.25%
Ownership Type			
Large Dialysis	5,703	1,207	-0.12%
Regional Chain	845	250	-0.20%
Independent	457	228	-0.39%
Hospital based (non-chain)	338	103	-0.25%
Facility Size (Treatments)			
Less than 4,000	1,059	201	-0.15%

[24] CMS cautions that the actual impact of the 2025 ESRD QIP may vary significantly from the values provided in the tables when the performance year data is updated for this year.

Impact of QIP Payment Reductions to ESRD Facilities for 2024 (from Final Rule Table 13)			
Facility Type	**Number of Facilities with QIP Score**	**Number of Facilities Expected to Receive a Payment Reduction**	**Payment Reduction as Percent of Total ESRD Payments**
4,000 to 9,999	2,901	605	-0.13%
10,000 or more	3,383	981	-0.17%

C. Estimated Impact of ETC Model

Table 18 in the final rule (reproduced below) summarizes the estimated impact of the ETC Model. This assumes 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. CMS estimates that 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. The final changes in this rule had a small effect on Medicare savings from the proposed rule; $10 million in savings for the net impact to Medicare spending over a 4.5-year period (shown in Table 19 in the final rule).

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

	Year of Model							
KDE Benefit 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.

CMS states that the results were generated from an average of 400 simulations. The key assumption underlying the impact estimate is that each ESRD facility or Managing Clinician's share of total maintenance dialysis provided in the home setting was assumed to grow at a maximum rate averaging 3-percentage points per year. CMS notes that this 3-percentage point per year growth rate would in effect move the average market peritoneal dialysis rate (about 10 percent) to the highest market baseline peritoneal dialysis rate (Bend Oregon HRR at about 25 percent), which it believes is a reasonable upper bound growth estimate. CMS notes that it decided to be conservative and did not include an assumption that the overall number of kidney transplants will increase.