DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

[CMS–1830–P]

RIN 0938–AV52

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would update and revise the End-Stage Renal Disease (ESRD) Prospective Payment System for calendar year 2026. This rule also proposes to update the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. In addition, this rule proposes to update requirements for the ESRD Quality Incentive Program and to terminate and modify requirements for the ESRD Treatment Choices Model.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by August 29, 2025.

ADDRESSES: In commenting, please refer to file code CMS–1830–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1830–P, P.O. Box 8010, Baltimore, MD 21244–8010.

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

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1830–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

FOR FURTHER INFORMATION CONTACT:

ESRDPayment@cms.hhs.gov or Abigail Ryan 410–786–4343 for issues related to the ESRD Prospective Payment System (PPS) and coverage and payment for renal dialysis services furnished to individuals with acute kidney injury (AKI).

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

ESRDQIP@cms.hhs.gov, for issues related to the ESRD Quality Incentive Program (QIP).

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

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov*. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at *https://www.regulations.gov/*.

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Deregulation Request for Information (RFI):

On January 31, 2025, President Trump issued Executive Order (E.O.) 14192 ''Unleashing Prosperity Through Deregulation,'' which states the Administration policy to significantly reduce the private expenditures required to comply with Federal regulations to secure America's economic prosperity and national security and the highest possible quality of life for each citizen. We would like public input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other interested parties participating in the Medicare program. CMS has made available an RFI at *https://www.cms.gov/medicare-regulatory-relief-rfi*. Please submit all comments in response to this RFI through the provided weblink.

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I. Executive Summary

A. Purpose

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

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

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule proposes updates to the ESRD PPS for CY 2026. This rule also proposes to modify the eligibility timeframe for the transitional drug add-on payment adjustment (TDAPA) and to establish a new payment adjustment for ESRD facilities in certain non-contiguous states and territories to promote efficient allocation of payments.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This proposed rule proposes to update the AKI dialysis payment rate for CY 2026.

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

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act. The Program establishes incentives for facilities to achieve high quality performance on measures with the goal of improving outcomes for ESRD beneficiaries. Beginning with PY 2027, this proposed rule proposes to remove the Facility Commitment to Health Equity reporting measure, the Screening for Social Drivers of Health reporting measure, and the Screen Positive Rate for Social Drivers of Health reporting measure from the ESRD QIP measure set. In addition, this proposed rule proposes to update the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) clinical measure beginning with PY 2028. Finally, this proposed rule requests public comment on several topics relevant to the ESRD QIP.

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

The ETC Model is a mandatory Medicare payment model tested under section 1115A of the Act. The ETC Model is operated by the Center for Medicare and Medicaid Innovation (Innovation Center). The ETC Model tests the use of payment adjustments to encourage greater utilization of home dialysis and kidney transplants, to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures. The ETC Model was finalized as part of a final rule published in the **Federal Register** on September 29, 2020, titled ''Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' (85 FR 61114), referred to herein as the ''Specialty Care Models final rule.'' Subsequently, the ETC Model has been updated four times in the annual ESRD PPS final rules for calendar year (CY) 2022 (86 FR 61874), CY 2023 (87 FR 67136), CY 2024 (88 FR 76344), and CY 2025 (89 FR 89084).

Per model evaluation reports, ETC Model performance since 2021 has continued to show that the model is not having a statistically significant impact on the use of home dialysis modalities, transplant waitlisting, and living donor transplantation. In this rule, we are proposing to terminate the ETC Model as of December 31, 2025 and also to modify the duration during which CMS will apply payment adjustments described in 42 CFR part 512, subpart C for a specific time period.

B. Summary of the Major Provisions

1. ESRD PPS

- *Proposed update to the ESRD PPS base rate for CY 2026:* The proposed CY 2026 ESRD PPS base rate is $281.06, an increase from the CY 2025 ESRD PPS base rate of $273.82. This proposed amount reflects the application of the wage index budget neutrality adjustment factor (1.00872), the budget neutrality factor for the proposed non-contiguous areas payment adjustment (NAPA) (0.99859) as discussed in section II.B.8. of this proposed rule, and a proposed ESRD Bundled (ESRDB) market basket update of 1.9 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $281.06 (($273.82 × 1.00872 × 0.99859) × 1.019 = $281.06).
- *Proposed annual update to the wage index:* We adjust the ESRD PPS wage index on an annual basis using the most current mean hourly wage data for occupations related to the furnishing of renal dialysis services from the Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS) program and occupational mix data from the most recent full CY of freestanding ESRD facility Medicare cost reports. This wage index uses the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2026, we are proposing updates to the wage index based on this methodology and the latest available data.
- *Proposed annual update to the outlier policy:* We are proposing to update the outlier policy based on the most current data and established

methodology. Accordingly, we are proposing to update the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2026 using the latest available CY 2024 claims data. We are proposing to update the ESRD outlier services fixed dollar loss (FDL) amount for pediatric patients using the latest available CY 2024 claims data and to update the FDL amount for adult patients using the latest available claims data from CY 2022, CY 2023, and CY 2024. For pediatric beneficiaries, the FDL amount would decrease from $234.26 to $148.38, and the MAP amount would decrease from $59.60 to $44.09, as compared to CY 2025 values. For adult beneficiaries, the FDL amount would decrease from $45.41 to $12.74, and the MAP amount would decrease from $31.02 to $22.07. The 1.0 percent target for outlier payments was not achieved in CY 2024, as outlier payments represented approximately 0.8 percent of total Medicare payments.

- *Proposed update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2026:* The proposed CY 2026 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is $10.41. This proposed offset amount reflects the application of the proposed ESRDB market basket update of 1.9 percent ($10.22 × 1.019 = $10.41). There are no capital-related assets set to receive the TPNIES in CY 2026 for which this offset would apply.
- *Proposed update to the post-TDAPA add-on payment adjustment amounts:* We calculate the post-TDAPA add-on payment adjustment in accordance with 42 CFR 413.234(g). The proposed post-TDAPA add-on payment adjustment amount for Korsuva® is $0.2633 per treatment, which would be included in the calculation of the total post-TDAPA add-on payment adjustment for each quarter in CY 2026. The proposed post-TDAPA add-on payment adjustment amount for DefenCath® is $1.4780 per treatment, which would be included in the calculation for the third and fourth quarter of CY 2026.
- Proposed *update to the timeframe for TDAPA eligibility:* We are proposing to modify the timeframe for TDAPA eligibility to provide that a new renal dialysis drug or biological product must have been approved by the Food and Drug Administration (FDA) within the past 3 years at the time of submission of the TDAPA application. This would be consistent with the timeframe used for TPNIES eligibility. This proposed eligibility timeframe would apply for all new drugs and biological products for which a TDAPA application is submitted on or after January 1, 2028.
- *Proposed non-contiguous areas payment adjustment (NAPA):* We are proposing a new payment adjustment for ESRD facilities in certain high-cost, non-contiguous states and territories to account for certain non-labor costs which are not captured in the ESRD PPS wage index. As proposed, this payment adjustment would apply to ESRD PPS claims submitted by ESRD facilities in Alaska, Hawaii, and the U.S. Pacific Territories of Guam, American Samoa, and the Northern Mariana Islands. We are also proposing that the NAPA would be budget neutral and a corresponding budget neutrality factor of 0.99859 would be applied to the CY 2026 ESRD PPS base rate.

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

- *Proposed update to the dialysis payment rate for individuals with AKI:* We are proposing an update to the AKI dialysis payment rate for CY 2026. The proposed CY 2026 payment rate is $281.06, which is the same as the proposed CY 2026 ESRD PPS base rate.

3. ESRD QIP

We are proposing to remove the Facility Commitment to Health Equity reporting measure beginning with PY 2027, the Screening for Social Drivers of Health reporting measure beginning with PY 2027, and the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027. Beginning with PY 2028, we are proposing to update the ICH CAHPS clinical measure. We are proposing to reduce the length of the ICH CAHPS Survey by removing 23 questions which we have identified as appropriate for removal. We are also including requests for information (RFIs) on several topics relevant to the ESRD QIP. We are requesting information on the current state of health information technology (IT) use in dialysis facilities, including electronic health records, to further ongoing CMS efforts to facilitate successful adoption and integration of Fast Healthcare Interoperability Resources® (FHIR®) and FHIR-based technologies and standardized data for patient assessment instruments. We are also requesting feedback on potential measurement concepts that could be developed into ESRD QIP measures in the future, such as measures of interoperability, well-being, nutrition, and physical activity.

4. ETC Model

We are proposing to terminate the ETC Model and modify the duration during which CMS would apply the payment adjustments described in 42 CFR part 512, subpart C to claims with claim service dates beginning on or after January 1, 2021, and ending on or before December 31, 2025. We discuss our reasons for proposing to terminate the model and the changes to the regulation required to implement the proposed termination.

C. Summary of Costs and Benefits

In section VIII.C.5. of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected entities and beneficiaries. Table 1 summarizes the impacts of each proposed provision in this CY 2026 ESRD PPS proposed rule.

TABLE 1—ESTIMATED TOTAL COSTS/TRANSFERS

Proposals	Estimated total costs/transfers
Proposed CY 2026 ESRD PPS updates.	The overall economic impact of this proposed rule is an estimated increase of approximately $160 million in aggregate payments to ESRD facilities in CY 2026. This includes estimated expenditures of approximately $27 million associated with the post-TDAPA add-on payment adjustment.
Proposed CY 2026 AKI dialysis payment rate update.	We estimate that the aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to individuals with AKI, at the proposed CY 2026 ESRD PPS base rate, would increase by $1 million.
Proposed PY 2027 and PY 2028 QIP updates.	We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are proposing, the overall economic impact of the PY 2027 ESRD QIP would be approximately $146.8 million. We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are proposing, the overall economic impact of the PY 2028 ESRD QIP would be approximately $143.1 million.
Proposed ETC Model termination.	We estimate that, as a result of the termination of the ETC Model, as proposed in this rule, the net Federal impact would be approximately $1 million in savings.

1. Impacts of the Proposed Updates to the ESRD PPS

The impact table in section VIII.C.5.a. of this proposed rule displays the estimated change in Medicare payments to ESRD facilities in CY 2026 compared to estimated Medicare payments in CY 2025. The overall impact of the proposed CY 2026 payment changes, if finalized, is projected to be a 1.9 percent increase in Medicare payments. Hospital-based ESRD facilities would have an estimated 1.5 percent increase in Medicare payments compared with freestanding ESRD facilities with an estimated 1.9 percent increase. We estimate that the aggregate Medicare payments under the ESRD PPS would increase by approximately $160 million in CY 2026 compared to CY 2025 as a result of the proposed payment policies in this rule. Because of the projected 1.9 percent overall payment increase, we estimate there would be an increase in beneficiary coinsurance payments of 1.9 percent in CY 2026, which translates to approximately $30 million. For CY 2026, we estimate total payments associated with the post-TDAPA add-on payment adjustment would be $27.6 million.

Section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. Under this authority, CMS implemented § 413.234 to establish the TDAPA, a transitional drug add-on payment adjustment for certain new renal dialysis drugs and biological products, § 413.236 to establish the TPNIES, a transitional add-on payment adjustment for certain new and innovative equipment and supplies, and § 413.234(g) to establish the post-TDAPA add-on payment adjustment. The TDAPA, the TPNIES, and the post-TDAPA add-on payment adjustment are not budget neutral.

As discussed in section II.D. of this proposed rule, because we did not receive any applications for the TPNIES in CY 2025, no new items were approved for the TPNIES for CY 2025 (89 FR 89162). Therefore, there are no continuing TPNIES payments for CY 2026. In addition, since we did not receive any applications for the TPNIES for CY 2026, there will be no new TPNIES payments for CY 2026. As discussed in section II.E. of this proposed rule, the TDAPA payment periods for DefenCath®, Vafseo®, and the oral-only phosphate binders sevelamer carbonate, sevelamer hydrochloride, sucroferric oxyhydroxide, lanthanum carbonate, ferric citrate, and calcium acetate will continue into CY 2026. As described in section VIII.C.5.b. of this proposed rule, we estimate that the combined total TDAPA payment amounts for these drugs in CY 2026 would be approximately $480 million, of which, $100 million would be attributed to beneficiary coinsurance amounts.

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

The impact table in section VIII.C.5.c. of this proposed rule displays the estimated change in Medicare payments to ESRD facilities for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for such services in CY 2025. The overall impact of the proposed CY 2026 changes is projected to be a 1.8 percent increase in Medicare payments for individuals with AKI. Hospital-based ESRD facilities would have an estimated 1.6 percent increase in Medicare payments compared with freestanding ESRD facilities that would have an estimated 1.8 percent increase. The overall impact reflects the effects of the proposed Medicare ESRD PPS payment rate update and the proposed CY 2026 ESRD PPS wage index. We estimate that the aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to individuals with AKI, at the proposed CY 2026 ESRD PPS base rate, would increase by $1 million in CY 2026 compared to CY 2025.

3. Impacts of the PY 2027 and PY 2028 ESRD QIP

We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are proposing, the overall economic impact of the PY 2027 ESRD QIP would be approximately $146.8 million. The $146.8 million estimate for PY 2027 includes $124.7 million in costs associated with the collection of information requirements and approximately $22.1 million in payment reductions across all facilities. We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are proposing, the overall economic impact of the PY 2028 ESRD QIP would be approximately $143.1 million. The $143.1 million estimate for PY 2028 includes $124.7 million in costs associated with the collection of information requirements and approximately $18.4 million in payment reductions across all facilities.

4. Impacts of the Proposed Termination of the ETC Model

We estimate that, as a result of the termination of the ETC Model, as proposed in this rule, the net Federal impact would be approximately $1 million in savings.

II. Calendar Year (CY) 2026 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, CMS implemented the ESRD PPS, a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Act, as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148), established that beginning with CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

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

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1,2016. Section 632(c) of ATRA required

[1] As discussed in the CY 2019 ESRD PPS final rule (83 FR 56922), we began using the term ''biological products'' instead of ''biologicals'' under the ESRD PPS to be consistent with FDA nomenclature. We use the term ''biological products'' in this proposed rule except when referencing specific language in the Act or regulations.

the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket percentage increase should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis drugs and biological products cannot be made under the ESRD PPS bundled payment prior to January 1, 2025. Effective January 1, 2025, all oral-only renal dialysis drugs and biological products are paid for under the ESRD PPS.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single per-treatment payment is made to an ESRD facility for all the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to an individual for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definition of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies.

The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, and four comorbidity categories (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, and myelodysplastic syndrome). A different set of case-mix adjusters are applied for the pediatric population. Pediatric patient-level adjusters include two age categories (under age 13, or age 13 to 17) and two dialysis modalities (that is, peritoneal or hemodialysis) (§ 413.235(a) and (b)(1)).

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

There are six additional payment adjustments under the ESRD PPS. The ESRD PPS provides adjustments, when applicable, for: (1) a training add-on for home and self-dialysis modalities (§ 413.235(c)); (2) an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care (§ 413.237); (3) a TDAPA for certain new renal dialysis drugs and biological products (§ 413.234(c)); (4) a TPNIES for certain new and innovative renal dialysis equipment and supplies (§ 413.236(d)); (5) a transitional pediatric ESRD add-on payment adjustment (TPEAPA) of 30 percent of the per-treatment payment amount for renal dialysis services furnished to pediatric ESRD patients for CYs 2024 through 2026 (§ 413.235(b)(2)); and (6) a post-TDAPA add-on payment adjustment for certain new renal dialysis drugs and biological products after the end of the TDAPA period (§ 413.234(g)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule appeared in the August 12, 2010, issue of the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011, in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

Most recently, we published a final rule, which appeared in the November 12, 2024, issue of the **Federal Register**, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model,'' referred to herein as the ''CY 2025 ESRD PPS final rule.'' In that rule (89 FR 89084 through 89213), we updated the ESRD PPS base rate, wage index, and outlier policy for CY 2025 and we updated the CBSA delineations used for the wage index according to Office of Management and Budget (OMB) Bulletin No. 23–01. We also finalized a new ESRD PPS wage index methodology, a phase out of the rural adjustment for ESRD facilities that were re-designated from a rural to an urban area as a result of the new CBSA delineations, an expansion of the ESRD PPS outlier list to include all drugs and biological products that were formerly part of the composite rate, an updated methodology for calculating certain inflation factors used when determining the adult fixed dollar loss (FDL) amount, and an update to the low-volume payment adjustment (LVPA) to include two tiers such that ESRD facilities with fewer than 3000 treatments in 2 of the 3 preceding years would receive a higher LVPA payment. Additionally, in the CY 2025 ESRD PPS final rule, we discussed the inclusion of oral-only drugs into the ESRD PPS bundled payment and finalized monthly TDAPA amounts for claims which utilize phosphate binders. For further detailed information regarding these updates and policy changes, see 89 FR 89084.

B. Proposed Provisions of the CY 2026 ESRD PPS

1. Proposed CY 2026 ESRD Bundled (ESRDB) Market Basket Percentage Increase; Productivity Adjustment; and Labor-Related Share

a. Background

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase and reduced

by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. Section 1881(b)(14)(F)(i) of the Act also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD bundled (ESRDB) input price index using CY 2008 as the base year (75 FR 49151 through 49162). We subsequently revised and rebased the ESRDB input price index to a base year of CY 2012 in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136). In the CY 2019 ESRD PPS final rule (83 FR 56951 through 56964), we finalized a rebased ESRDB input price index to reflect a CY 2016 base year. In the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154), we finalized a revised and rebased ESRDB input price index to reflect a CY 2020 base year.

Although ''market basket'' technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term ''ESRDB market basket'', as used in this document, refers to the ESRDB input price index.

The ESRDB market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

b. Proposed CY 2026 ESRD Market Basket Update

We are proposing to use the 2020-based ESRDB market basket as finalized in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154) to compute the CY 2026 ESRDB market basket percentage increase based on the best available data. Consistent with historical practice, we propose to estimate the ESRDB market basket percentage increase based on IHS Global Inc.'s (IGI) forecast using the most recently available data at the time of rulemaking. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets. As discussed in section II.B.1.b.(3). of this proposed rule, we are calculating the proposed ESRDB market basket update for CY 2026 based on the proposed ESRDB market basket percentage increase and the proposed productivity adjustment, following our longstanding methodology.

(1) Proposed CY 2026 ESRDB Market Basket Percentage Increase

Based on IGI's first quarter 2025 forecast of the 2020-based ESRDB market basket, the proposed CY 2026 ESRDB market basket percentage increase is 2.7 percent. We are proposing that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase), we would use such data, if appropriate, to determine the CY 2026 ESRDB market basket percentage increase in the final rule.

(2) Proposed CY 2026 Productivity Adjustment

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRDB market basket percentage increase shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year (FY), year, cost reporting period, or other annual period), hereafter referred to as the ''productivity adjustment''.

The Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the United States economy. As we noted in the CY 2023 ESRD PPS final rule (87 FR 67155), the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act previously was published by BLS as private nonfarm business MFP. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term ''multifactor productivity'' with ''total factor productivity'' (TFP). BLS noted that this is a change in terminology only and would not affect the data or methodology.[2] As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business TFP; however, as mentioned previously, the data and methods are unchanged. We refer readers to *https://www.bls.gov/productivity/* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on CMS's website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information*. In addition, in the CY 2022 ESRD PPS final rule (86 FR 61879), we noted that effective for CY 2022 and future years, we would be changing the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment.

Based on IGI's first quarter 2025 forecast, the proposed productivity adjustment for CY 2026 (the 10-year moving average growth of TFP for the period ending CY 2026) is 0.8 percentage point. Furthermore, we are proposing that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the productivity adjustment), we would use such data, if appropriate, to determine the CY 2026 productivity adjustment in the final rule.

(3) Proposed CY 2026 ESRDB Market Basket Update

In accordance with section 1881(b)(14)(F)(i) of the Act, we are proposing to base the CY 2026 ESRDB market basket percentage increase on IGI's first quarter 2025 forecast of the 2020-based ESRDB market basket. We propose to then reduce the ESRDB market basket percentage increase by the proposed productivity adjustment for CY 2026 based on IGI's first quarter 2025 forecast. Therefore, the proposed CY 2026 ESRDB market basket update is equal to 1.9 percent (proposed 2.7 percent ESRDB market basket percentage increase reduced by a proposed 0.8 percentage point productivity adjustment). Furthermore, as noted previously, we are proposing that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase or

[2] Total Factor Productivity in Major Industries—2020. Available at *https://www.bls.gov/news.release/prod5.nr0.htm*.

productivity adjustment), we would use such data, if appropriate, to determine the CY 2026 ESRD market basket percentage increase and productivity adjustment in the final rule.

(4) Proposed ESRD Labor-Related Share

We define the labor-related share as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. For the CY 2026 ESRD PPS payment update, we are proposing to continue using a labor-related share of 55.2 percent, which was finalized in the CY 2023 ESRD PPS final rule (87 FR 67153 through 67154).

2. Proposed CY 2026 ESRD PPS Wage Indices

a. Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, we established a policy to adjust the labor-related portion of the ESRD PPS base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. As discussed in detail later in this section, we later implemented an ESRD PPS specific wage index methodology in the CY 2025 ESRD PPS final rule (89 FR 89108 through 89117). Under current policy, we use OMB's CBSA-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. We most recently updated the CBSA delineations in the CY 2025 ESRD PPS final rule (89 FR 89117) to the OMB delineations as described in OMB Bulletin No. 23–01, beginning with the CY 2025 ESRD PPS wage index.[3]

[3] *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.*

Under § 413.231(d), a wage index floor value of 0.6000 is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values, as finalized in the CY 2023 ESRD PPS final rule (87 FR 67161). Currently, all areas with wage index values that fall below the floor are located in Puerto Rico and the U.S. Virgin Islands. However, the wage index floor value is applicable for any area that may fall below the floor. A further description of the history of the wage index floor under the ESRD PPS can be found in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967) and the CY 2023 ESRD PPS final rule (87 FR 67161).

An ESRD facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2023 ESRD PPS final rule (87 FR 67153), we finalized the use of a labor-related share of 55.2 percent. In the CY 2021 ESRD PPS final rule (85 FR 71436), we finalized a temporary policy which applied a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. We finalized that the transition would be phased in over 2 years, such that the reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022. In the CY 2023 ESRD PPS final rule (87 FR 67161), we finalized a permanent policy under § 413.231(c) to apply a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. For CY 2026, as discussed in section II.B.1.b.(4). of this proposed rule, we are proposing that the labor-related share to which the wage index would be applied is 55.2 percent.

In the CY 2011 ESRD PPS final rule (75 FR 49116) and the CY 2011 final rule on Payment Policies Under the Physician Fee Schedule (PFS) and Other Revisions to Part B (75 FR 73486) we established an ESRD PPS wage index methodology to use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the hospital inpatient prospective payment system (IPPS). The ESRD PPS wage index values have historically been calculated without regard to geographic reclassifications authorized for acute care hospitals under sections 1886(d)(8) and (d)(10) of the Act and utilized pre-floor hospital data that are unadjusted for occupational mix. In the CY 2025 ESRD PPS final rule (89 FR 89116) we finalized a new ESRD PPS wage index methodology which uses mean hourly wage data from the Bureau of Labor Statistics (BLS) Occupational Employment Wages & Statistics (OEWS). This wage data is then weighted by a national ESRD facility occupational mix (NEFOM) which is derived from full time equivalent (FTE) data from freestanding ESRD facility cost report data. Treatment data from ESRD facility cost reports is also used to weigh the mean hourly wage data when aggregating the wage data at a CBSA level. As set forth in 42 CFR 413.196(d)(2), we update the ESRD PPS wage index using the most current wage data for occupations related to the furnishing of renal dialysis services from BLS and occupational mix data from the most recent full CY of Medicare cost reports submitted in accordance with § 413.198(b).

For a detailed explanation of the current ESRD PPS wage index methodology, see the discussion in the CY 2025 ESRD PPS final rule (89 FR 89108 through 89117), and for a detailed explanation of the steps we use to calculate the ESRD PPS wage index according to this methodology see Addendum C on the CY 2025 ESRD PPS proposed rule available here: *https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-payment-regulations-and-notices/cms-1805-p*.

b. National ESRD Facility Occupational Mix

Table 2 presents the national ESRD facility occupational mix (NEFOM) alongside the BLS occupation titles and codes for the occupations related to the furnishing of renal dialysis services. We note that we are presenting the NEFOM in this CY 2026 ESRD PPS proposed rule to aid interested parties in their reconstruction of the proposed ESRD PPS wage index, but the actual ESRD PPS wage index uses the total FTEs for each occupation as described in the calculation in Addendum C of the CY 2025 ESRD PPS proposed rule rather than the rounded percentages presented in Table 2. This table is based on data from CY 2023 freestanding ESRD facility cost reports, although we note that the NEFOM has not changed significantly from the NEFOM presented in the CY 2025 ESRD PPS final rule (89 FR 89101).

TABLE 2—CROSSWALK OF BLS OCCUPATION CODES TO ESRD FACILITY COST REPORTS OCCUPATION CLASSIFICATIONS AND THE CY 2026 ESRD PPS PROPOSED RULE NEFOM

ESRD PPS colloquial name	BLS occupation title	Occupation code	ESRD free-standing facilities FTE percentage (rounded)
Registered Nurses (RN)	Registered Nurses	29–1141	30.0
Licensed Practical Nurses (LPN)	Licensed Practical and Licensed Vocational Nurses	29–2061	4.0
Nurse Aides	Nursing Assistants	31–1131	2.4
Technicians	Health Technologists and Technicians, All Other	29–2099	38.1
Social Workers	Healthcare Social Workers	21–1022	4.7
Dietitians	Dietitians and Nutritionists	29–1031	4.5
Administrative Staff	Medical Secretaries and Administrative Assistants	43–6013	10.7
Management	Medical and Health Services Managers	11–9111	5.5

c. Missing May 2024 BLS OEWS Data for Colorado

BLS reported data quality concerns for the May 2024 BLS OEWS estimates for Colorado and did not include any areas of Colorado in this release.[4] Per § 413.196(d)(2) we use the most current BLS wage data for the occupations related to the furnishing of renal dialysis services for our ESRD PPS wage index. In the CY 2025 ESRD PPS final rule, we discussed a methodology for imputing missing data using regression based on the most similar occupation to the occupation for which there was missing data (89 FR 89100). We believe that this methodology is generally most appropriate as it uses current OEWS data to impute the missing estimates; however, that methodology would not be as useful in this situation since the mean hourly wage estimates for all occupations are missing for all 7 CBSAs and one rural area in Colorado. In this instance we do not believe there is sufficient May 2024 OEWS data from which to impute the missing values. To address this missing data, we are proposing to instead use the May 2023 BLS OEWS means hourly wage estimates for the occupations in question and adjust them to be comparable with 2024 wage values by multiplying the wage estimates by an adjustment factor based on the average change in national BLS OEWS wages for each occupation in the NEFOM. The adjustment factors we have applied in our proposed CY 2026 ESRD PPS wage index are the percent change of national average wage for the occupation in question for 2024 compared to the national average wage for that occupation for 2023 from the May 2024 and May 2023 OEWS, respectively. This adjustment is necessary since the wage index is relative and if wages are higher in 2024 relative to 2023, using the unadjusted 2023 values might result in an inappropriately low wage index value for Colorado. Alternatively, we could freeze the CY 2023 wage index values for Colorado, which would accomplish a similar purpose, but we believe that our proposed methodology is most consistent with the language at § 413.196(d)(2) as we are using the most current mean hourly wage data from the BLS OEWS for Colorado, which is from the May 2023 OEWS. Should BLS release the May 2024 OEWS estimates for Colorado before the publication of the ESRD PPS final rule, we propose to use those estimates instead of the adjusted May 2023 OEWS estimates for the final CY 2026 ESRD PPS wage index. We request comments on this proposed methodology to address missing Colorado OEWS data.

d. Proposed CY 2026 ESRD PPS Wage Index

For CY 2026, we are proposing to update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using the ESRD PPS wage index methodology established in the CY 2025 ESRD PPS final rule (89 FR 89098 through 89107) and specified in § 413.196(d)(2). We are proposing to use the most recent available BLS OEWS mean hourly wage data for various occupations related to the furnishing of renal dialysis services weighted by FTE data from CY 2023 freestanding ESRD facility cost reports. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act. For CY 2026, the updated wage data used in the analysis for this proposed rule are from the April 2025 release of the BLS OEWS, which represents data from six semiannual surveys spanning November 2021 through May 2024.[5]

For CY 2026, we propose to update the ESRD PPS wage index to use the most recent available BLS OEWS wage data. We are proposing that if more recent data become available after the analysis performed for the publication of this proposed rule and before the publication of the final rule (for example, an update to the May 2024 BLS OEWS mean hourly wage data or more complete CY 2023 cost report data), we would use such data, if appropriate, to determine the CY 2026 ESRD PPS wage index in the final rule. The proposed CY 2026 ESRD PPS wage index is set forth in Addendum A and provides a crosswalk between the CY 2025 wage index and the proposed CY 2026 wage index. Addendum B provides an ESRD facility level impact analysis. Both Addendum A and Addendum B are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices*.

3. Proposed CY 2026 Update to the Outlier Policy

a. Background

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high-cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care are frailty and obesity. A

[4] All wage data for Colorado is missing in the 2024 OEWS release due to concerns related to the quality of the data. According to BLS, this concern was not with the OEWS survey results, but rather with employment data from the Quarterly Census of Employment and Wages (QCEW). OEWS uses QCEW employment data to adjust estimates to represent all employment that is in scope for the OEWS survey. For more information, see *https://www.bls.gov/oes/notices/2024/colorado-data.htm*.

[5] *https://www.bls.gov/news.release/pdf/ocwage.pdf*.

patient's specific medical condition, such as secondary hyperparathyroidism, may result in higher per treatment costs. The ESRD PPS recognizes that some patients require high-cost care, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237.

Section 413.237(a)(1) enumerates the following items and services that are eligible for outlier payments as ESRD outlier services:

- Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.
- Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.
- Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.
- Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025.
- Renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.[6]
- Renal dialysis drugs and biological products that are Composite Rate Services as defined in § 413.171.

In the CY 2011 ESRD PPS final rule (75 FR 49142), CMS stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the ESRD facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as ESRD outlier services were specified in Transmittal 2134, dated January 14, 2011.[7] We use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests (CRs), when applicable. For example, we use these issuances to identify renal dialysis oral drugs that were or would have been covered under Part D prior to 2011 to provide unit prices for determining the imputed MAP amounts. In addition, we use these issuances to update the list of ESRD outlier services by adding or removing items and services that we determined, based on our monitoring efforts, are either incorrectly included or missing from the list.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its imputed (that is, calculated) MAP amount per treatment for ESRD outlier services exceeds a threshold. In past years, the MAP amount has reflected the average estimated expenditure 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 MAP per treatment plus the fixed dollar loss (FDL) amount. As described in the following paragraphs, the ESRD facility's predicted MAP amount is the national adjusted average ESRD outlier services MAP amount per treatment, further adjusted for case-mix and facility characteristics applicable to the claim. We use the term ''national adjusted average'' in this section of this proposed rule to more clearly distinguish the calculation of the average ESRD outlier services MAP amount per treatment from the calculation of the predicted MAP amount for a claim. The average ESRD outlier services MAP amount per treatment is based on utilization from all ESRD facilities, whereas the calculation of the predicted MAP amount for a claim is based on the individual ESRD facility and patient characteristics of the monthly claim. In accordance with § 413.237(c), ESRD facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and codified in § 413.220(b)(4), using 2007 data, we established the outlier percentage—which is used to reduce the per treatment ESRD PPS base rate to account for the proportion of the estimated total Medicare payments under the ESRD PPS that are outlier payments—at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis used to compute the payment adjustments.

In the CY 2023 ESRD PPS final rule, we finalized an update to the outlier methodology to better target 1.0 percent of total Medicare payments (87 FR 67170 through 67177). We explained that for several years, outlier payments had consistently landed below the target of 1.0 percent of total ESRD PPS payments (87 FR 67169). Commenters raised concerns that the methodology we used to calculate the outlier payment adjustment since CY 2011 results in underpayment to ESRD facilities, as the base rate has been reduced by 1.0 percent since the establishment of the ESRD PPS to balance the outlier payment (85 FR 71409, 71438 through 71439; 84 FR 60705 through 60706; 83 FR 56969). In response to these concerns, beginning with CY 2023, we began calculating the adult FDL amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years. We stated in the CY 2023 ESRD PPS final rule that we would continue to calculate the adult and pediatric MAP amounts for CY2023 and subsequent years following our established methodology. In that same CY 2023 ESRD PPS final rule, we provided a detailed discussion of the methodology we use to calculate the MAP amounts and FDL amounts (87 FR 67167 through 67169).

Lastly, in the CY 2025 ESRD PPS final rule we finalized several methodological and policy changes to the ESRD PPS outlier policy to address concerns that interested parties have raised in recent years. First, we finalized an expansion of the definition of ESRD outlier services in § 413.237(a)(1) to include drugs and biological products that are Composite Rate Services as defined in § 413.171 (89 FR 89126). Second, we finalized a policy to include the case-

[6] Under § 413.237(a)(1)(vi), as of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

[7] Transmittal 2033 issued August 20, 2010, was rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD PPS outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which included one technical correction. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2134CP.pdf.*

mix adjusted post-TDAPA add-on payment adjustment amount in the calculation of the MAP amounts when applicable (89 FR89127). Lastly, we finalized changes to the inflation factors for outlier eligible drugs and biological products, laboratory tests, and supplies. For ESRD outlier drugs and biological products, we use the projected inflation factor for ESRD outlier services that are drugs and biological products derived from the historical trend in average sales price (ASP) prices and utilization for ESRD outlier drugs (89 FR 89127 through 89130). For ESRD outlier laboratory tests and supplies, we use the growth in the producer price index (PPI) Industry for Medical and Diagnostic Laboratories and the PPI Commodity for Surgical and Medical Instruments, respectively (89 FR 89129 through 89130).

b. Proposed CY 2026 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2026, we are proposing to update the MAP amounts for adult and pediatric patients using the latest available CY 2024 claims data. We are proposing to update the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2024 claims data, and to update the ESRD outlier services FDL amount for adult patients using the latest available claims data from CY 2022, CY 2023, and CY 2024, in accordance with the methodology finalized in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67174) and including the changes finalized in the CY 2025 ESRD PPS final rule (89 FR 89108 through 89130). The latest available CY 2024 claims data show that outlier payments represented approximately 0.8 percent of total Medicare payments. We are proposing to update these values with the latest available data, if appropriate, in the final rule.

The impact of this proposed update is shown in Table 3, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2025 with the updated estimates for this proposed rule for CY 2026. The estimates for the proposed CY 2026 MAP amounts, as shown in column II of Table 3, were inflation adjusted to reflect projected 2026 prices for ESRD outlier services.

TABLE 3—PROPOSED OUTLIER POLICY: IMPACT OF UPDATED DATA FOR THE OUTLIER POLICY

	Column I Final outlier policy for CY 2025 (based on 2023 data, price inflated to 2025) *		Column II Proposed outlier policy for CY 2026 (based on 2024 data, price inflated to 2026) **	
	Age <18	Age >=18	Age <18	Age >=18
Average outlier services MAP amount per treatment	$58.30	$32.40	$43.92	$23.11
Adjustments:				
Standardization for outlier services	1.0432	0.9768	1.0244	0.9745
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$59.60	$31.02	$44.09	$22.07
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$234.26	$45.41	$148.38	$12.74
Patient-month-facilities qualifying for outlier payment	6.09%	7.05%	7.05%	14.16%

* Column I was obtained from column II of Table 7 from the CY 2025 ESRD PPS final rule (89 FR 89130).
** The FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2022, 2023, and 2024.

As demonstrated in Table 3, the proposed FDL amount per treatment amount that determines the CY 2026 outlier threshold amount for adults (column II; $12.74) is lower than that used for the CY 2025 outlier policy (column I; $45.41). The lower threshold amount is accompanied by a decrease in the adjusted average MAP for outlier services from $31.02 to $22.07. For pediatric patients, there is a decrease in the FDL amount from $234.26 to $148.38. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from $59.60 to $44.09. We note that the decrease in the projected MAP and FDL amounts for both adult and pediatric patients is due, in part, to the application of the ESRD PPS drug inflation factor following the methodology finalized in the CY 2025 ESRD PPS final rule (89 FR 89127 through 89130), which resulted in a lower inflation factor than would typically occur under the prior methodology. However, as discussed in that rule, we believe this methodology is more appropriate for the ESRD PPS as it more accurately captures trends in the prices and utilization of ESRD PPS outlier services drugs and biological products.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2026 would be 14.16 percent for adult patients and 7.05 percent for pediatric patients, based on the 2024 claims data.

c. Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1.0 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. In the 2023 ESRD PPS final rule, we finalized a change to the outlier methodology to better achieve this 1.0 percent target (87 FR 67170 through 67174). Based on the preliminary CY 2024 claims, outlier payments represented approximately 0.8 percent of total payments, which is slightly below the 1.0 percent target.

4. Proposed Impacts to the CY 2026 ESRD PPS Base Rate

a. Proposed ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), CMS established the methodology for calculating the ESRD PPS per-treatment base rate, that is, the ESRD PPS base rate, and calculating the per-treatment payment amount, which are codified at §§ 413.220 and 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our

regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, training adjustment add-on, the TDAPA, the TPNIES, the post-TDAPA add-on payment adjustment, and the TPEAPA for CYs 2024, 2025 and 2026.

b. Proposed Annual Payment Rate Update for CY 2026

We are proposing an ESRD PPS base rate for CY 2026 of $281.06. This would be approximately a 2.6 percent increase from the CY 2025 ESRD PPS base rate of $273.82. This proposed update reflects several factors, described in more detail as follows:

Wage Index Budget Neutrality Adjustment Factor: We compute a wage index budget neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2026, we are not proposing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the proposed CY 2026 wage index budget neutrality adjustment factor using treatment counts from the 2024 claims and facility-specific CY 2025 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2025. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2026. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the proposed CY 2026 ESRD PPS wage index and proposed labor-related share for CY 2026. The total of these payments becomes the new CY 2026 amount of wage-adjusted expenditures for all ESRD facilities. The wage index budget neutrality factor is calculated as the target amount divided by the new CY 2026 amount. When we multiplied the wage index budget neutrality factor by the applicable CY 2026 estimated payments, aggregate Medicare payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget neutrality adjustment factor ensures that the wage index updates and revisions do not increase or decrease aggregate Medicare payments. The proposed CY 2026 wage index budget neutrality adjustment factor is 1.00872. As we are not proposing any changes to our established ESRD PPS wage index policy, this proposed CY 2026 wage index budget neutrality adjustment factor reflects the impact of all established wage index policies, including the ESRD PPS wage index methodology based on BLS OEWS and freestanding ESRD facility cost report FTE data, the 5 percent cap on year-to-year decreases in wage index values, the 3 -year rural phase-out for ESRD facilities in currently-rural CBSAs that became urban under the new delineations adopted in CY 2025, and the labor-related share. We discussed in the CY 2025 ESRD PPS final rule (89 FR 89131) that the impact of the application of the 5 percent cap on wage index decreases had a sizable impact on the budget neutrality factor for CY 2025 due to the new wage index methodology implemented in that year. That is, because a substantial number of ESRD facilities would have experienced a greater than 5 percent decrease in their wage index value as a result of the new wage index methodology, the budget neutrality adjustment factor needed to offset the effect of limiting those decreases to 5 percent had a larger magnitude impact on the ESRD PPS base rate than we expect it would be in a typical year. However, for CY 2026 the continued application of our established 5 percent cap policy would result in a proposed wage-index budget neutrality factor above 1, meaning the proposed ESRD PPS base rate would increase as a result of its application. This is because the average wage index value is decreasing as, generally, ESRD facilities that received the 5 percent cap in CY 2025 are set to receive a lower wage index for CY 2026. We note that the proposed CY 2026 wage index budget neutrality factor does not include any impacts associated with the TPEAPA, as was the case with the 2024's combined wage index-TPEAPA budget neutrality finalized factor for CY 2024. This is consistent with how we have historically applied budget neutrality for case-mix adjusters, including pediatric case-mix adjusters. We do not routinely apply a budget neutrality factor to account for changes in overall payment associated with changes in patient case-mix in years in which we do not propose any changes to the case-mix adjustment amount. Although the TPEAPA was established under the authority in section 1881(b)(14)(D)(iv) of the Act, which does not require budget neutrality, we stated in the CY 2024 ESRD PPS final rule that we were implementing the TPEAPA in a budget neutral manner because it was similar to the pediatric case-mix adjusters, and it accounts for costs which would have been included in the cost reports used in the analysis conducted when we created the ESRD PPS bundled payment in the CY 2011 ESRD PPS final rule (88 FR 76378). Because the adjustment to maintain budget neutrality associated with the TPEAPA was accounted for in the CY 2024 combined wage index and TPEAPA budget neutrality factor, and we are not proposing any changes to the TPEAPA amount, it would not be appropriate to apply a budget neutrality factor for the TPEAPA for CY 2026.

Proposed NAPA Budget Neutrality Factor: As discussed in section II.B.8. of this proposed rule, under the authority granted by section 1881(b)(14)(D)(iv) of the Act, we are proposing a new facility-level payment adjustment for ESRD facilities in Alaska, Hawaii, and certain U.S. Pacific Territories,[8] which we refer to in this proposed rule as the proposed non-contiguous areas payment adjustment (NAPA). As proposed, this payment adjustment would apply to ESRD PPS claims for treatments at ESRD facilities in Alaska, Hawaii, Guam, American Samoa, and the Northern Mariana Islands. This payment adjustment would be capped at 25 percent and would be applied to the non-labor-related share of the ESRD PPS base rate, which is 44.8 percent. We are proposing that this payment adjustment would be budget neutral and would result in a proposed NAPA budget neutrality factor of 0.99859.

Proposed Market Basket Update: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase. As discussed in section II.B.1.b.(1). of this proposed rule, the latest CY 2026 projection of the ESRDB market basket percentage increase is 2.7 percent. In CY 2026, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As previously discussed in section II.B.1.b.(2). of this proposed rule, the latest CY 2026 projection of the productivity adjustment is 0.8 percentage point, thus yielding a proposed CY 2026 ESRDB market basket update of 1.9 percent for CY 2026. Therefore, the proposed CY 2026 ESRD PPS base rate is $281.06 (($273.82 × 1.00872 × 0.99859) × 1.019 = $281.06). As discussed in section II.B.1.b. of this proposed rule, we are proposing that if more recent data become available after the publication of this proposed rule

[8] See section II.B.8.b of this proposed rule for a discussion of which U.S. Pacific Territories we considered for this proposal.

and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the CY 2026 ESRDB market basket update in the final rule.

We invite public comment on our proposed CY 2026 ESRD PPS base rate.

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

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

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

There are currently no capital-related assets that are home dialysis machines set to receive TPNIES for CY 2026, as the TPNIES payment period for the Tablo® System ended on December 31, 2023, and there are no TPNIES applications for CY 2026. However, as required by § 413.236(f)(3)(v), we are proposing to update the TPNIES offset amount annually according to the methodology described previously.

We are proposing a CY 2026 TPNIES offset amount for capital-related assets that are home dialysis machines of $10.41, based on the proposed CY 2026 ESRDB market basket update of 1.9 percent (proposed 2.7 percent ESRDB market basket percentage increase reduced by the proposed 0.8 percentage point productivity adjustment). Applying the proposed ESRDB market basket update factor of 1.019 to the CY 2025 offset amount results in the proposed CY 2026 offset amount of $10.41 ($10.22 × 1.019 = $10.41). We request public comments on our proposal to update the TPNIES offset for capital-related assets for CY 2026.

6. Proposed Post-TDAPA Add-On Payment Adjustment Updates

In the CY 2024 ESRD PPS final rule we finalized an add-on payment adjustment for certain new renal dialysis drugs and biological products, which would be applied for 3 years after the end of the TDAPA period (88 FR 76388 through 76397). This adjustment, known as the post-TDAPA add-on payment adjustment, is adjusted by the patient-level case-mix adjusters and is applied to every ESRD PPS claim. In that final rule we also clarified that for each year of the post-TDAPA period we would update the post-TDAPA add-on payment adjustment amounts based on utilization and ASP of the drug or biological product. The post-TDAPA add-on payment amounts are calculated based on the methodology codified at § 413.234(g), which is the total drug expenditure divided by the total ESRD PPS treatments multiplied by the case mix standardization for the time period and the 0.65 risk sharing factor, and the ESRDB pharmaceutical price proxy for the payment year (88 FR 76396). In the CY 2025 ESRD PPS final rule (89 FR 89136) we finalized our proposal to publish the post-TDAPA add-on payment adjustment amount after the final rule in certain circumstances to ensure that the post-TDAPA add-on payment adjustment amount can be calculated using 12 months of utilization data.

For CY 2025 there is one drug, Korsuva® (difelikefalin), included in the calculation of the post-TDAPA add-on payment adjustment for each of the four calendar quarters and one drug, Jesduvroq®, included in the calculation for only the fourth calendar quarter. In the CY 2025 ESRD PPS final rule (89 FR 89135), we finalized that the post-TDAPA add-on payment adjustment amount for Korsuva® would be $0.4601 for CY 2025; this figure was updated to $0.4684 in transmittal 13245, which was a correction to CR 13865 after a review found a small error in the calculation of this figure. At the time of rulemaking, we did not have sufficient data to finalize a post-TDAPA add-on payment adjustment amount for Jesduvroq® for CY 2025, so, consistent with our policy finalized in the CY 2025 ESRD PPS final rule (89 FR 89136), we published the final post-TDAPA amount for Jesduvroq® in transmittal 13245.

a. CY 2026 Post-TDAPA Add-On Payment Adjustment Amounts

For CY 2026, we will have three drugs which are in the 3-year period following the end of their TDAPA period and are potentially eligible to be included in the calculation of the post-TDAPA add-on payment adjustment. 42 CFR 413.234(c)(3) states that should CMS not receive the latest full calendar quarter of ASP data for a drug or biological product during the TDAPA or post-TDAPA period, we will not pay any post-TDAPA add-on payment adjustment for such product in any future year. The third quarter of 2025 reflecting quarter 1, 2025 sales would be the latest quarter of ASP data at the time of rulemaking for this proposed rule. As CMS has not received ASP data for quarter 3, 2025, which reflects sales for quarter 1, 2025 for Jesduvroq®, we are not proposing to include Jesduvroq® in the calculation of the post-TDAPA add-on payment adjustment for CY 2026 or any future years. Therefore, conditional upon the continued receipt of the latest full calendar quarter of ASP data for the renal dialysis drugs discussed later in this document, we are anticipating that there would be two drugs included in the calculation of the post-TDAPA add-on payment adjustment for CY 2026.

The post-TDAPA add-on payment adjustment period for one of these drugs, Korsuva®, began on April 1, 2024, so, conditional upon the continued receipt of the latest full calendar quarter of ASP data as described in § 413.234(c)(3), Korsuva® will be included in the calculation for the post-TDAPA add-on payment adjustment for the entirety of CY 2026. The other drug, DefenCath®, began its TDAPA period on July 1, 2024, so it will be included in the post-TDAPA add-on payment adjustment calculation for quarters 3 and 4 of CY 2026, conditional upon the continued receipt of the latest full calendar quarter of ASP data.

For this proposed rule we are presenting the proposed post-TDAPA add-on payment adjustment amounts for Korsuva® based on the most recently available full year of utilization data at this time. We are unable to present an estimate of the post-TDAPA add-on payment adjustment amount for DefenCath® at this time using a full year of utilization data, however we have included a proposed post-TDAPA amount based on the first 6 months of DefenCath® utilization. Consistent with the methodology finalized in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76389), we are proposing to

update these calculations with the most recent available utilization and pricing data in the final rule. Table 4 shows the proposed post-TDAPA add-on payment adjustment amounts for each quarter of CY 2026. The proposed post-TDAPA add-on payment adjustment amount for Korsuva® is $0.2633 and the proposed post-TDAPA add-on payment adjustment amount for DefenCath® is $1.4780. At the time of the development of this proposed rule we do not anticipate that there will be any drugs or biological products which would be included in the post-TDAPA add-on payment adjustment calculation for any quarter of CY 2026 which would lack 12 months of utilization data at the time of final rulemaking.

TABLE 4—PROPOSED POST-TDAPA ADD-ON PAYMENT ADJUSTMENT AMOUNTS FOR CY 2026 BY QUARTER

Quarter	Proposed add-on amount for Korsuva®	Proposed add-on amount for DefenCath® *	Total proposed post-TDAPA add-on payment adjustment amount
Q1 (January–March)	$0.2633	$0	$0.2633
Q2 (April–June)	0.2633	0	0.2633
Q3 (July–September)	0.2633	1.4780	1.7413
Q4 (October–December)	0.2633	1.4780	1.7413

* This figure does not reflect a full year's utilization data; however, we anticipate that by the time of the publication of the final rule we will have a full year's utilization data for DefenCath®.

We note that changes in post-TDAPA add-on payment adjustment amounts from year-to-year, or from the proposed rule to the final rule, are driven by changes in utilization and price for the drug or biological product in question. We invite public comments on our proposed CY 2026 post-TDAPA add-on payment adjustment amounts.

b. Proposed Technical Correction to 42 CFR 413.234(g)(5)

We are proposing to modify the language at § 413.234(g)(5) to fix a typographical error in the spelling of the word ''adjusted''. We welcome public comments on this proposed change or any other areas where the regulatory language should be corrected.

7. Proposed Changes to the TDAPA Eligibility Criteria

a. Background on the TDAPA

Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous (IV) products into the ESRD PPS bundled payment. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process that allowed us to recognize when an oral-only renal dialysis service drug or biological product is no longer oral-only, and a process to include new injectable and IV products into the ESRD PPS bundled payment, and when appropriate, modify the ESRD PPS payment amount.

The processes we finalized in the CY 2016 ESRD PPS final rule are based on whether a drug or biological product fits within one of eleven ESRD PPS functional categories. These ESRD PPS functional categories, which were first established in the CY 2011 ESRD PPS final rule, represent all of the drugs and biological products included in the ESRD PPS bundled payment, as well as those receiving the transitional drug add-on payment adjustment (TDAPA) (80 FR 69013 through 69027). As we established in the CY 2011 ESRD PPS final rule, categorizing drugs and biological products on the basis of drug action allows us to determine which categories (and therefore, the drugs and biological products within the categories) would be considered used for the treatment of ESRD (75 FR 49047). We grouped the injectable and IV drugs and biological products into functional categories based on their action (80 FR 69014). This was done for the purpose of adding new drugs or biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs become commercially available so that beneficiaries have access to them. We finalized the definition of an ESRD PPS functional category in our regulations at § 413.234(a) as a distinct grouping of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

In the CY 2016 ESRD PPS final rule, we established a requirement at § 413.234(b)(2) that, if a new injectable or IV product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or IV product is not considered included in the ESRD PPS bundled payment and the following steps occur. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or IV product is used to treat or manage. Next, the new injectable or IV product is paid for using the transitional drug add-on payment adjustment (TDAPA) described in § 413.234(c). Then, the new injectable or IV product is added to the ESRD PPS bundled payment following payment of the TDAPA.

We finalized in the CY 2016 ESRD PPS final rule that the TDAPA provides additional payment for certain new drugs and biological products. Under § 413.234(c), the TDAPA is based on pricing methodologies under section 1847A of the Act and is paid until sufficient claims data for rate setting analysis for the new injectable or IV product are available, but not for less than two years. During the time a new injectable or IV product is eligible for the TDAPA, it is not eligible as an outlier service. Following payment of the TDAPA, the ESRD PPS base rate would be modified, if appropriate, to account for the new injectable or intravenous product in the ESRD PPS bundled payment.

In the CY 2019 ESRD PPS final rule (83 FR 56927 through 56949), CMS expanded the TDAPA to all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories. For new renal dialysis drugs or biological products that do not fall within an ESRD PPS functional category, we specified that the ESRD PPS base rate would not be modified after the two-year TDAPA period (83 FR 56943), but, as consistent with the existing outlier policy, the drug or biological product would be eligible for outlier payment unless it is a composite rate drug. In this rule, we modified the definition of ''new renal dialysis drug or biological product'' at 413.234(a) to specify that the drug or biological product must be approved by the FDA on or after January 1, 2020. We also changed the basis of payment for

the TDAPA from pricing methodologies under section 1847A of the Act (which includes 106 percent of ASP) to 100 percent of ASP and updated the definitions of ''new renal dialysis drug or biological product'' and ''oral-only drugs'' under § 413.234(a).

In the CY 2020 ESRD PPS final rule (84 FR 60653 through 60681), CMS finalized the exclusion of generic drugs and certain NDA types from TDAPA eligibility to distinguish innovative from non-innovative renal dialysis drugs and biological products. As codified at § 413.234(e)(1) through § 413.234(e)(7), NDA Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the ''parent NDA'' is a Type 3, 5, 7 or 8, are excluded from TDAPA eligibility. Additionally, we finalized a policy to use Wholesale Acquisition Cost (WAC) if ASP data is not available, and if WAC is not available, to then use invoice pricing. We also finalized a policy to no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS does not receive a full calendar quarter of ASP data within 30 days of the last day of the 3rd calendar quarter after we begin applying the TDAPA for that product or if CMS does not receive the latest full calendar quarter of ASP data for the product beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

The CY 2020 ESRD PPS final rule also established the transitional payment for new and innovative equipment and supplies (TPNIES), a non-budget neutral add-on payment adjustment for certain new and innovative equipment and supplies (84 FR 60681 through 60699). TPNIES is codified at § 413.236. When the TPNIES was established, the eligibility criteria at § 413.236(b)(2) defined ''new'' as receiving FDA marketing authorization on or after January 1, 2020. In the CY 2021 ESRD PPS final rule we modified the TPNIES eligibility criteria to reflect the definition of ''new'' to mean within 3 years beginning on the date of FDA marketing authorization (85 FR 71410 through 71414). In the CY 2024 ESRD PPS final rule, we revised § 413.236(b)(2) to further clarify that an equipment or supply for which a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization would be considered new (88 FR 71414 through 76415).

In both the CY 2019 and CY 2020 ESRD PPS final rules (83 FR 56927 through 56949; 84 FR 60653 through 60681), CMS explained that the aim of the TDAPA is to help ESRD facilities incorporate into their business model new drugs and biological products that fall within existing ESRD PPS functional categories by providing additional payments. We further explained that the TDAPA aims to promote competition among the products within the ESRD PPS functional categories and focus Medicare resources on products that are innovative. For new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category, we clarified that the TDAPA could be a pathway toward a potential base rate modification, if appropriate.

b. Proposed Modification to the Eligibility Timeframe for the TDAPA

In the CY 2019 ESRD PPS final rule, we explained that the main goals of the TDAPA are to promote the incorporation of new renal dialysis service drugs and biological products into the ESRD PPS bundled payment and to focus Medicare resources on new and innovative products (84 FR 60653). Under the current regulations, any renal dialysis drug or biological product that receives FDA approval on or after January 1, 2020, would be considered ''new'' under § 413.234(a) and would be eligible for the TDAPA if it meets the other criteria and is not excluded from TDAPA payment under § 413.234(e). When we finalized § 413.234(a) in the CY 2019 ESRD PPS final rule (83 FR 56932), we stated that we believed it was appropriate at that time to consider renal dialysis drugs and biological products to be considered new if they were approved after January 1, 2020. However, because the regulatory definition for ''new renal dialysis drug or biological product'' includes a specific date on which a drug or biological product may start to be considered new but does not specify a date when it is no longer considered new, the current regulatory definition of a new renal dialysis drug or biological product could apply to drugs with FDA approval dates that are increasingly old. For example, for CY 2026 and future years, a renal dialysis drug or biological product approved by FDA in 2020 would be over 5 years old. As the TDAPA currently has no other time-dependent eligibility requirements, that would mean there is the potential for increasingly older drugs to be eligible for and receive the TDAPA. As discussed in the CY 2019 ESRD PPS final rule, CMS grouped drugs and biological products into functional categories based on their action for the purpose of adding new drugs or biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs become commercially available so that beneficiaries have access to them (83 FR 56928). When CMS finalized the expansion of the TDAPA to all new renal dialysis drugs and biological products later in that same rule, one of the main goals was improving beneficiary access to new and innovative products. At the time of the TDAPA expansion, the January 1, 2020, timeframe for the regulatory definition of ''new renal dialysis drug or biological product'' aligned with this goal of TDAPA. However, we do not believe the original intention of this requirement was to ensure that renal dialysis drugs and biological products approved on or after January 1, 2020, would continue to be eligible for the TDAPA in perpetuity after their FDA approval. As noted previously, for the TPNIES, § 413.236(b)(2) provides that an equipment or supply for which a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization is considered new. In the CY 2021 ESRD PPS final rule, when CMS changed the TPNIES eligibility criteria set forth at § 413.236(b)(2), we stated that we did not believe newness should be tied to the effective date of the TPNIES, and that a three-year eligibility window would be consistent with the timeframe for the new-technology add-on payment (NTAP) under the IPPS (85 FR 71411 through 71412). Regarding the NTAP, § 412.87(b)(2) notes that a medical service or technology may be considered new within two to three years after it is released onto the open market. Consistent with the views that CMS expressed regarding the TPNIES eligibility timeframe in the CY 2021 ESRD PPS final rule, we believe that the continued use of the January 1, 2020, date for the TDAPA would allow for some renal dialysis drugs and biological products to potentially qualify for the TDAPA well after they are already established, which would conflict with CMS' original intention for the TDAPA: to provide additional support to ESRD facilities during the uptake period for innovative drugs and biological products and help incorporate them into their business model (84 FR 60663).

We are proposing to modify the language of § 413.234 to reflect that a TDAPA application must be submitted within 3 years of FDA approval for a new renal dialysis drug or biological product to be eligible for the TDAPA. We are also proposing to restructure the

section to consolidate the TDAPA eligibility requirements in a new paragraph (c)(5) in § 413.234, since currently some TDAPA eligibility requirements are included in the definition of ''new renal dialysis drug or biological product'' and the requirement to submit a TDAPA application is not explicitly stated in the regulations. We note that we use the definition of ''new renal dialysis drug or biological product'' for the general drug designation process at § 413.234(b), so we believe it would be more appropriate to move the specific TDAPA eligibility requirements to § 413.234(c). When considering a potential timeframe for TDAPA eligibility, we believe it is important to consider the time and expense it takes for a drug to come to market to ensure that drug manufacturers have enough time to establish infrastructure to adequately produce and distribute the drug. Giving manufacturers sufficient time to plan the rollout of a new renal dialysis drug or biological product would help ensure that it is made available to ESRD facilities, and therefore ESRD patients, during the TDAPA period. We are proposing a 3 -year timeframe for TDAPA eligibility as we believe three years strikes a balance between allowing drug manufacturers flexibility in the timing of the rollout for their new renal dialysis drugs and biological products and ensuring the TDAPA is only available for drugs and biological products that are new to the renal dialysis market. We note that three years is generally consistent with how ''new'' is defined at § 412.87(b)(2) for the NTAP and at § 413.236(b)(2) for the TPNIES, as mentioned previously. Because three years is the timeframe we currently use for assessing whether renal dialysis equipment and supplies are ''new'' for purposes of the TPNIES; this proposed change would also standardize the eligibility timeframe across both the TDAPA and the TPNIES under the ESRD PPS. We believe this proposed change aligns with the TDAPA goals to support innovation by providing additional payment to help ESRD facilities make appropriate changes in their businesses to adopt new drugs and biological products, incorporate these new drugs and biological products into their beneficiaries' care plans, potentially promote competition among drugs and biological products within the ESRD PPS functional categories, and focus Medicare resources on products that are innovative (83 FR 56935; 84 FR 60654 through 60665). To implement this change, we propose the following changes: (1) to add a new paragraph § 413.234(c)(5) which would include the eligibility requirements specific to TDAPA; (2) to revise the definition of ''new renal dialysis drug or biological product'' to remove the eligibility requirements for TDAPA related to having a HCPCS level II application; and (3) to revise the language at § 413.234(b)(1)(ii) and § 413.234(b)(2)(ii) to reference this new paragraph (c)(5). We are not proposing to remove the commercial eligibility requirement from the definition of ''new renal dialysis drug or biological product'' as that would have implications on the ESRD PPS drug designation process and the post-TDAPA add-on payment adjustment, which is not our intention. We note that a drug or biological product must meet the definition of ''new renal dialysis drug or biological product'' to be eligible for the TDAPA, and that the intention of proposing to move the eligibility requirements specific to TDAPA to the new paragraph is to make it clearer which requirements relate to the TDAPA, and which requirements relate to the definition of ''new renal dialysis drug or biological product.''

We propose that this new paragraph, § 413.234(c)(5), would specify the current eligibility criteria and the proposed TDAPA eligibility timeframe for new renal dialysis drugs or biological products that have submitted TDAPA applications either within three years of FDA approval or prior to January 1, 2028. This paragraph would include the requirement that an application be submitted for the TDAPA, which reflects current policy but is not currently specified in the regulation.

We are proposing the 3-year timeframe for TDAPA eligibility would apply for renal dialysis drugs and biological products for which a TDAPA application is submitted on or after January 1, 2028. We are proposing this later implementation date as we recognize that there may be renal dialysis drugs or biological products which were approved by the FDA on or after January 1, 2020, and before January 1, 2023, but for which a TDAPA application has not yet been submitted due to the established eligibility criteria in § 413.234(a), although we note that we have not identified any such drugs or biological products. If we were to finalize this policy effective January 1, 2026, any such renal dialysis drugs and biological products would no longer be eligible for the TDAPA because they would no longer be within the three-year window of FDA approval. Our experience has been that manufacturers generally apply for the TDAPA within the first few months after receiving FDA approval for their products; therefore, we believe that any renal dialysis drugs or biological products approved by the FDA between January 1, 2020, and January 1, 2023, for which a TDAPA application has not yet been submitted would be limited. However, it is not our intention with this proposed policy to prevent existing renal dialysis drugs or biological products which would be eligible for the TDAPA under the current eligibility requirements from receiving the TDAPA. Our proposed changes to § 413.234, specifically our proposed addition of § 413.234(c)(5)(ii), as discussed previously, provides that the three-year window would begin to apply for applications received on or after January 1, 2028. This would provide ample time for any manufacturer of a renal dialysis drug or biological product that received FDA approval between January 1, 2020, and January 1, 2025, to apply for the TDAPA. We note that any drug or biological product which was approved by the FDA more than three years prior to January 1, 2028, should submit their application for the TDAPA prior to January 1, 2028. If this condition and the other requirements are met, such drugs or biological products would still receive a full two-year TDAPA period as specified at § 413.234(c)(1) or a full period of at least two years as specified at § 413.234(c)(2). Renal dialysis drugs and biological products that CMS previously approved for the TDAPA and were paid for using the TDAPA period prior to January 1, 2028, would not be affected by this proposed change. We also note that our proposed change to the TDAPA eligibility timeframe would apply to all new renal dialysis drugs and biological products that are potentially eligible for the TDAPA in the future, including those that fall into existing ESRD PPS functional categories, and those that would fall into new functional categories.

Table 5 presents hypothetical situations in which renal dialysis drugs and biological products that received FDA approval before and after January 1, 2025, would or would not be eligible for the TDAPA under the proposed changes to the TDAPA eligibility criteria. CMS reiterates that renal dialysis drugs and biological products that CMS previously approved for the TDAPA and that were paid for using the TDAPA period prior to January 1, 2028, would not be affected by this proposed change. As noted previously, if a renal dialysis drug or biological product that received FDA approval more than three years prior to January 1, 2028, submits

a TDAPA application prior to January 1, 2028, the TDAPA would still be paid for a full two-year period as specified at § 413.234(c)(1) or a full period of at least two years as specified at § 413.234(c)(2), provided all other applicable requirements in § 413.234 are met.

TABLE 5—HYPOTHETICAL TDAPA-ELIGIBILITY SCENARIOS UNDER THE PROPOSED CHANGES TO THE TDAPA ELIGIBILITY CRITERIA

Hypothetical new renal dialysis drug or biological product FDA approval date	Hypothetical TDAPA application submission date	TDAPA eligibility under the proposed changes
January 10, 2020	December 10, 2027	Eligible.
January 10, 2020	January 2, 2028	Not Eligible.
January 20, 2025	January 19, 2028	Eligible.
January 20, 2025	January 21, 2028	Not Eligible.

We are soliciting comments on all aspects of this proposal, including the proposed 3-year eligibility window, our proposal to apply this change to new renal dialysis drugs and biological products in both existing and new ESRD PPS functional categories, and the proposed CY 2028 implementation date of the policy. Additionally, we are soliciting comments on the TDAPA eligibility requirements more broadly and welcome any suggestions on how our TDAPA policies could be improved in future rulemaking.

8. Proposed Payment Adjustment for ESRD Facilities in Certain Non-Contiguous States and Territories

a. Background

As set forth in § 413.230, the ESRD PPS per treatment payment amount is calculated as the sum of the ESRD PPS base rate, the wage index for the ESRD facility and various patient-level and facility-level payment adjustments, and any applicable outlier payments and add-on payment adjustments which are described previously in this proposed rule. The ESRD PPS wage index is intended to reflect the relative cost of the labor utilized for renal dialysis services in the geographic area in which an ESRD facility is located and is applied to the labor-related share of the ESRD PPS base rate, as defined at § 413.231. In the CY 2025 ESRD PPS final rule, we finalized a new methodology for determining the wage index value for an ESRD facility (89 FR 89116). This methodology uses data from the Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS), weighted according to an occupational mix derived from freestanding ESRD facility cost reports, to better estimate the actual labor costs ESRD facilities incur when furnishing renal dialysis services. A summary of this methodology is available in section II.B.2. of this proposed rule. The ESRD PPS wage index and the other payment adjustments, which include case-mix adjusters, facility level adjustments and add-on payment adjustments, serve to better align relative ESRD PPS payments with relative resource use. These payment adjustments are generally established under section 1881(b)(14)(D) of the Act, which lists several payment adjustments that the Secretary is required or authorized to include in the ESRD PPS.

In the CY 2025 ESRD PPS proposed rule, we discussed the impacts of the proposed new ESRD PPS wage index methodology in more detail (89 FR 55778 through 55780). Specifically, we discussed the regional impact of the then-proposed methodology. We stated that as this methodology better estimates the wage costs for ESRD facilities, and we believed the regional impacts of the new methodology are generally appropriate as they align wage-adjusted payments with relative labor costs. We requested public comment on the regional implications of the proposed policy. As a part of this request for public comment, we highlighted the potential impacts for the U.S. Pacific Territories, which were larger in magnitude compared to most other regions. In response, we received two comments that expressed concerns specifically with the impact of the wage index proposal on the U.S. Pacific Territories, one of which was a letter from interested parties representing Guam, American Samoa, and the Northern Mariana Islands (89 FR 89114). These comments expressed specific concern with the projected payment decrease for these territories associated with the proposed policy and noted that these isolated island territories had higher costs than other regions for certain goods and services.

The letter from the interested parties representing Guam, American Samoa, and the Northern Mariana Islands also built upon concerns raised by multiple commenters, including MedPAC in its June 2020 Report to Congress,[9] reiterating that the current ESRD PPS payment adjustments, including the LVPA, do not accurately target remote or isolated facilities. We note that past commenters have used differing definitions of these terms. The interested parties requested CMS to consider factors that are unique to small island economies such as air freight shipping, greater utility costs, difficulty recruiting and retaining qualified healthcare professionals, and lack of economies of scale when compared to larger ESRD facilities located in the contiguous U.S. Those parties requested that the Secretary establish a new payment adjustment for the U.S. Pacific Territories, outside of the LVPA, to account for the higher cost of providing renal dialysis services in some of the most remote areas of our country. In the CY 2025 ESRD PPS final rule, we responded to these comments by acknowledging that these remote territories may have some higher costs, but noted that most of the goods and services these comments cited were generally not labor-related and therefore, it would be inappropriate to consider them in constructing a wage index value for the region (89 FR 89114 through 89115). While we did make changes to the LVPA in the CY 2025 ESRD PPS final rule, we did not discuss or finalize any change which would address higher costs in remote areas during the CY 2025 rulemaking cycle. As we explained in the CY 2024 ESRD PPS proposed rule (88 FR 42441), our analysis has not found higher costs associated with low-volume facilities in remote areas (including areas in the contiguous U.S.), although we note that the analysis referenced in that rule used a metric for isolation based on distance to the nearest ESRD facility and did not consider remote states or territories separately.

[9] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_reporttocongress_sec.pdf.*

b. Estimating the Extent to Which ESRD Facilities in Non-Contiguous Areas Face Higher Non-Labor Costs Than ESRD Facilities Located in the Contiguous U.S.

As noted in the CY 2025 ESRD PPS final rule, we believe that the new ESRD PPS wage index methodology better estimates the relative labor costs faced by ESRD facilities, and any changes in payment associated with the new wage index methodology were generally appropriate (89 FR 89108 through 89117). However, we recognize the possibility that an ESRD facility could have certain unrecognized costs which are not accounted for by any of the existing payment adjustments under the ESRD PPS. As a result of the comments on the CY 2025 ESRD PPS proposed rule, we have conducted an analysis of non-labor costs in certain remote areas of the United States. We included Alaska, Hawaii, Puerto Rico, and the U.S. Virgin Islands in this analysis in addition to Guam, American Samoa, and the Northern Mariana Islands so that we could evaluate any potential higher non-labor costs in other non-contiguous areas relative to the contiguous U.S. We evaluated all of the non-contiguous areas as the higher non-labor costs mentioned by commenters could have been experienced in other non-contiguous areas outside of just the U.S. Pacific Territories. We note that when we refer to ''U.S. Pacific Territories'' in the context of this proposed rule, we are specifically discussing the three permanently inhabited U.S. Territories in the Pacific region surveyed by the Census Bureau's Island Areas Census [10] and served by the Office of the Insular Affairs,[11] which are Guam, American Samoa and the Northern Mariana Islands. None of the other U.S. Territories located in the Pacific region have Medicare-certified ESRD facilities and, as such, were not considered for the purposes of this analysis. Should an ESRD facility open in another U.S. Pacific Territory we would consider whether it would be appropriate to extend any existing geographic payment adjustments that apply to other U.S. Pacific Territories, such as the payment adjustment proposed in section II.B.7.c of this proposed rule (should that payment adjustment be finalized), to such territory in future rulemaking.

To estimate the extent to which ESRD facilities in certain remote areas face higher costs after accounting for the ESRD PPS wage index, we focused the analysis on the &portion of the costs faced by ESRD facilities that are non-labor related. This analysis used data from freestanding and hospital-based ESRD facility cost reports from cost reporting years beginning between January 1, 2020, and December 31, 2022. For the purpose of this analysis, the non-labor costs associated with furnishing renal dialysis services include the non-salary costs associated with capital, administration, drugs, supplies and laboratory tests from Medicare cost reports.[12] We recognize that some parts of these cost categories could overlap with cost categories included in the labor-related share; for example, capital costs include both the materials and labor involved in constructing buildings. However, given the limitation of cost report data available for this analysis, we believe including these non-direct labor costs provided a more accurate result.

The analysis conducted was a logarithmic regression which used facility-level average non-labor cost per treatment as the dependent variable. As cost report data includes both Medicare and non-Medicare dialysis treatments and costs, this analysis also encompasses all treatments furnished by ESRD facilities. We controlled for various facility-level characteristics including log quadratic facility treatment volume, rurality, wage index value, ownership-type, percent of treatments which are Medicare treatments, percent of treatments which are home dialysis treatments, average case-mix adjustment multiplier for Medicare treatments, an indicator for whether the facility furnished more than 20 percent of its treatments to pediatric patients, and indicators for cost report year. The treatment variables were a variety of indicators for non-contiguous geographic areas including Alaska, Hawaii, Guam, American Samoa, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands. To avoid issues with small sample size, we combined the U.S. Pacific Territories of Guam, American Samoa, and the Northern Mariana Islands in one group and the U.S. Caribbean Territories of Puerto Rico and the U.S. Virgin Islands into another group. We believe that these groupings are reasonable due to the similar nature of the territories within each group in terms of their geographic isolation. To avoid undue influence of very large and small ESRD facilities, we removed data from ESRD facilities in the top and bottom 2.5 percent of cost per treatment and facility size. The regression yielded the relative cost for each state or group of territories when compared to the contiguous United States. The results of the regression are presented in Table 6.

TABLE 6—NON-LABOR COSTS FOR CERTAIN NON-CONTIGUOUS AREAS RELATIVE TO THE CONTIGUOUS U.S.

State or group of territories	Number of ESRD facilities	Regression result	Standard deviation	Relative non-labor cost to contiguous US (%)
Alaska	9	0.490	0.071	56
Hawaii	41	0.205	0.032	21
Guam, Northern Mariana Islands, American Samoa	11	0.294	0.054	31
Puerto Rico, U.S. Virgin Islands	54	* −0.052	0.035	−5

* **Note:** this relative cost factor was found to be statistically non-significant for this group.

The first column in Table 6 lists the states or groups of territories which we analyzed in reference to the contiguous U.S. The second column lists the number of freestanding and hospital-based ESRD facilities in each of those non-contiguous areas. The third and fourth columns show the coefficients of the logarithmic regression and the

[10] *https://www.census.gov/programs-surveys/decennial-census/decade/2020/planning-management/release/2020-island-areas-data-products.html.*

[11] *https://www.doi.gov/oia/islands.*

[12] Cost data from freestanding ESRD facility cost reports (form CMS 265–11) are from Worksheet B, lines 8 through 17.02, columns 3, 4, 7, 8, 9, 11, 12, 13. Cost data from hospital-based ESRD facility cost reports (form CMS 2552–10) are from Worksheet I–2, lines 2 through 11.01, columns 1, 2, 6, 7, 8, & 10, and lines 14 through 16, column 6.

standard deviations of the coefficients, respectively. The final column shows the relative non-labor costs for each non-contiguous area derived from this regression. As this was a logarithmic regression, the natural logarithm used in the regression model is a tool to make the data more amenable to linear analysis. After obtaining the regression coefficients, the exponential function with base *e* (mathematical constant) is used to interpret and predict values on the original scale. This analysis shows that ESRD facilities in Alaska, Hawaii, and the U.S. Pacific Territories each have higher non-labor costs than ESRD facilities in the contiguous U.S. after controlling for the ESRD facility characteristics described previously. ESRD facilities in Puerto Rico and the U.S. Virgin Islands did not demonstrate higher non-labor costs compared to ESRD facilities in the contiguous U.S. Alaska had the highest non-labor costs at 56 percent higher relative to the contiguous U.S., followed by the U.S. Pacific Territories at 31 percent higher, and Hawaii at 21 percent higher. This logarithmic regression analysis had an adjusted R-squared value of 0.473, which indicates that the analyzed variables (including the constants) account for 47.3 percent of the variation in the mean non-labor costs per treatment. The p-values for the regression result for Alaska, Hawaii and the U.S. Pacific Territories were each significant at the one percent level, which means there is a less than one percent chance that the results of the regression were due to random variation. Based on these results, we believe there is reasonable evidence that ESRD facilities in these non-contiguous areas face higher non-labor costs compared to ESRD facilities in the contiguous U.S. after controlling for the ESRD facility characteristics described previously. As noted in the footnote on Table 6, the regression result for the U.S. Caribbean Territories of Puerto Rico and the U.S. Virgin Islands is relatively close to zero and was not significant; so, although it is negative (indicating lower non-labor costs compared to ESRD facilities in the contiguous U.S. after controlling for the ESRD facility characteristics described previously) we cannot be confident that these ESRD facilities have lower average non-labor costs based on this analysis alone.

c. Proposal for a Non-Contiguous Area Payment Adjustment (NAPA)

As discussed previously, we have found that ESRD facilities in certain remote non-contiguous geographic areas have some higher non-labor costs when compared to the contiguous United States. Currently, these higher non-labor costs are generally not accounted for by the ESRD PPS, with some exceptions. The LVPA likely covers some of the non-labor costs associated with being in a non-contiguous area, as some of the additional costs in these areas are likely due to higher costs for certain goods, which, as defined in section 1881(b)(14)(D)(iii) of the Act, the LVPA is intended to help mitigate through additional payment. However, our review has not found substantial overlap between non-contiguous areas and low-volume facilities as defined at § 413.232(b). Additionally, the rural facility adjustment likely accounts for some of the higher costs for these remote areas, although the magnitude of the rural facility adjustment is much smaller than the LVPA, so it cannot account for all of the aforementioned higher non-labor costs.

Under the authority of section 1881(b)(14)(D)(iv) of the Act, we are proposing a new facility-level payment adjustment for ESRD facilities in Alaska, Hawaii, and the U.S. Pacific Territories, which, as described previously, were found to have higher non-labor costs when compared to ESRD facilities in the contiguous U.S. We refer to this proposed payment adjustment as the non-contiguous areas payment adjustment (NAPA) in this CY 2026 ESRD PPS proposed rule. The NAPA would apply only to the non-labor portion of the ESRD PPS base rate, which is 44.8 percent. As proposed, the magnitude of this proposed NAPA would be dependent on which of the non-contiguous remote areas a given ESRD facility is located in. We are also proposing for the NAPA to be applied budget-neutrally, consistent with the longstanding framework within the ESRD PPS to apply any payment adjustment that accounts for costs which were originally included in the analysis used for the CY 2011 ESRD PPS final rule in a budget-neutral manner (88 FR 42451). We are proposing that the NAPA would apply to all ESRD PPS claims for renal dialysis services furnished by ESRD facilities in these non-contiguous areas, including treatments furnished at home and to pediatric ESRD beneficiaries, as we have no evidence to indicate these higher non-labor costs would be unique to adult or in-center ESRD treatments.

When developing the methodology for calculating the proposed NAPA, we considered the results of our analysis as outlined in Table 6. We also considered the potential impact to the proposed ESRD PPS base rate, since we are proposing for this proposed payment adjustment to be applied budget-neutrally, as noted in the prior paragraph. We considered applying the adjustment factors (calculated as 1 + percentages in Table 6) to the non-labor-related portion of the base rate for treatments provided in Alaska, Hawaii, and the U.S. Pacific Territories, which we estimate would require a reduction to the ESRD PPS base rate of approximately 0.2 percent, or $0.47. Given the potential impact to ESRD facilities across the country, we believe it would be appropriate to consider policies that would lessen the potential base rate reduction associated with the proposed NAPA.

We considered policies that have historically been applied in other Medicare payment systems which apply a geographical adjustment for non-labor costs. The IPPS has a Cost-of-Living Adjustment (COLA) for Alaska and Hawaii which is an upwards adjustment factor that applies to the non-labor-related portion of the standardized amount for hospitals and is capped at 25 percent (89 FR 69964, 77 FR 53700 through 53701). We believe that a functionally similar cap would be appropriate for the proposed NAPA for several reasons. First, given the small number of ESRD facilities included in this regression analysis, there is inherent uncertainty in the result of the regression analysis. Additionally, applying a cap to the proposed NAPA would minimize the financial impact to ESRD facilities located in the contiguous U.S. while providing a substantial upward adjustment for ESRD facilities located in Alaska, Hawaii, and the U.S. Pacific Territories, which our analysis demonstrates have significantly higher non-labor costs compared to the contiguous U.S. We examined multiple different data points when determining what level of cap would be the most appropriate for the proposed NAPA, and while there is no one superior methodology from which to derive a cap for the proposed NAPA, as it is intended to account for non-labor costs, we believe it would be appropriate to consider such a payment adjustment in reference to the impact of the ESRD PPS wage index. Specifically, we believe that the impact of the NAPA on non-labor costs should not exceed the impact of the wage index on labor-related costs. Although the wage index and the NAPA account for different types of costs, they both intend to account for the variation in costs based on geographic factors. Additionally, interested parties' concerns about the finalized wage index changes in the CY 2025 ESRD PPS final rule prompted our

analysis of non-labor costs in non-contiguous areas. We believe the former ESRD PPS wage index methodology for the U.S. Pacific Territories was providing additional payment for ESRD facilities in these areas above the amount that is attributable to labor costs in these areas, while the ESRD PPS in general did not account for those areas' relatively higher non-labor costs. Therefore, this higher labor-related payment was potentially compensating for the higher non-labor costs that ESRD facilities in these areas faced. A reasonable upward bound for NAPA would be to align the maximum payment increase under NAPA to be approximately equal to that of the higher wage index values. To avoid undue influence of outliers, we considered a potential NAPA cap based on the 95th percentile of wage index values, which is based on the CY 2026 proposed ESRD PPS wage index is 1.209945. Because the non-labor-related share is slightly smaller than the labor-related share to which the wage index applies, a NAPA value that equals the payment impact of this wage index value is 1.258682.[13] For simplicity, we are rounding this value to 25 percent which is also consistent with the IPPS COLA cap previously discussed.

In comparison to the uncapped NAPA, if we were to apply a 25 percent cap to the NAPA, we estimate the required reduction to the base rate would be notably less at approximately 0.1 percent, or $0.35. We believe this more moderate reduction to the ESRD PPS base rate would better allow ESRD facilities in contiguous areas to continue to provide high-quality care while better aligning payments to ESRD facilities in non-contiguous areas with their relatively higher non-labor costs.

Therefore, under the proposed NAPA, ESRD facilities in these selected geographies would receive up to a 25 percent increase to the non-labor portion of the ESRD PPS bundled payment as determined by the latest available analysis. We believe implementing such a payment adjustment with a 25 percent cap would strike an appropriate balance between increasing payments to areas for which we have evidence of relatively higher non-labor costs and mitigating the impact of this payment adjustment on ESRD facilities located in the contiguous U.S. and the Caribbean territories of Puerto Rico and the U.S. Virgin Islands. In addition, we believe the proposed capped NAPA is appropriate due to the potential for overlap with the other payment adjustments, such as the LVPA, that could account for other costs faced by ESRD facilities in high-cost non-contiguous states and territories. Table 7 summarizes the proposed NAPA factors effective for CY 2026. The budget neutrality factor for this proposed NAPA is 0.99859. We intend to review these adjustment factors and consider whether the proposed NAPA (if finalized) remains appropriate when we propose to update the labor-related share of the ESRDB market basket. If applicable, CMS would propose any changes to the NAPA methodology or adjustment factors in future notice-and-comment rulemaking.

TABLE 7—PROPOSED NAPA FACTORS FOR CY 2026

State or group of territories	Proposed NAPA factor
Alaska	1.25
Hawaii	1.21
Guam, Northern Mariana Islands, American Samoa	1.25

To implement this proposed new payment adjustment, we are proposing to rename 42 CFR 413.233 from ''Rural facility adjustment'' to ''Additional facility-level adjustments.'' We are also proposing to designate a new paragraph (a) to include the current language of § 413.233. We are further proposing to add paragraph (b) to read ''CMS adjusts the non-labor-related portion of the base rate for facilities in Alaska, Hawaii, Guam, American Samoa, and the Northern Mariana Islands''. Lastly, we are proposing to modify § 413.230(a) to include § 413.233 in the list of facility-level adjustments.

We believe that this proposed new payment adjustment would better align payment with resource use in these non-contiguous remote geographic areas. We are requesting comment on this proposal, including the magnitude of the proposed adjustment, implementing the proposed NAPA with a 25 percent cap on the adjustment factors, the budget neutrality of the proposal, the proposed application of NAPA to payments for Pediatric ESRD Patients as defined in § 413.171, the proposed application of NAPA to payment for home dialysis treatments, and the proposed changes to §§ 413.230(a) and 413.233.

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

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we established the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS, under the authority of section 1881(b)(14)(D)(iv) of the Act, to support ESRD facility use and beneficiary access to these new items.

We added § 413.236 to establish the eligibility criteria and payment policies for the TPNIES. Under current § 413.236(b), CMS provides for a TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning a complete application has been submitted to CMS under § 413.236(c) within 3 years of the date of the FDA marketing authorization; (3) is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take effect; (4) has a complete HCPCS Level II code application submitted, in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for non-drug and non-biological items, supplies, and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular CY; (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1); and (6) is not a capital-related asset, except for capital-related assets that are home dialysis machines. For additional background on the TPNIES, we refer readers to the CY 2024 ESRD PPS final rule (88 FR 76410 through 76412).

As indicated in § 413.236(c) CMS includes the summary of each TPNIES application and our analysis of the eligibility criteria for each application in the annual ESRD PPS proposed rule and announces the results in the annual ESRD PPS final rule. Because we did not receive any applications for the TPNIES for CY 2026, we have not included any TPNIES application summaries, CMS analyses, or results in this proposed rule.

D. Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2026

In this section of the proposed rule, we identify any items previously approved for the TPNIES and for which

[13] This is calculated by comparing payment using a wage index value of 1.209945 and a NAPA factor of 1 to payments using a wage index value of 1 and a NAPA factor of x: Base rate*0.552*1.209945 + Base rate*0.448*1 = Base rate*0.552*1 + Base rate*0.448*x. We note that in this formula the base rate is equally applied to every term and cancels out, so the derived x=1.258682 is not dependent on the ESRD PPS base rate value.

payment is continuing for CY 2026. As described in the CY 2025 ESRD PPS final rule, no new items were approved for the TPNIES for CY 2025 (89 FR 89162 through 89163). As such there are no items previously approved for the TPNIES for which payment is continuing in CY 2026.

E. Continuation of Approved Transitional Drug Add-On Payment Adjustments for CY 2026

Under § 413.234(c)(1), a new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the TDAPA for 2 years. In April 2024, CMS approved DefenCath® (taurolidine and heparin sodium) for the TDAPA under the ESRD PPS, effective July 1, 2024. Implementation instructions are specified in CMS Transmittal 12628, dated May 9, 2024, and available at *https://www.cms.gov/files/document/r12628CP.pdf*.

In October 2024, CMS approved Vafseo® (vadadustat) for the TDAPA under the ESRD PPS, effective January 1, 2025. In addition, the following oral-only phosphate binders were also approved for the TDAPA under the ESRD PPS effective January 1, 2025: sevelamer carbonate, sevelamer hydrochloride, sucroferric oxyhydroxide, lanthanum carbonate, ferric citrate, and calcium acetate. These drugs were not considered included in the ESRD PPS bundled payment and were paid separately beginning in CY 2011 (75 FR 49037 through 49053). In the CY 2023 ESRD PPS final rule, we stated that if no other injectable equivalent (or other form of administration) of phosphate binders is approved by the FDA prior to January 1, 2025, we would pay for these drugs using the TDAPA under the ESRD PPS for at least 2 years beginning January 1, 2025 (87 FR 67180).

The implementation instructions for drugs with a TDAPA effective date of January 1, 2025, were specified in CMS Transmittal 12962 dated November 14, 2024, and available at *https://www.cms.gov/files/document/r12962bp.pdf*. This Change Request was subsequently rescinded and replaced by Transmittal 12999, dated December 12, 2024, and available at *https://www.cms.gov/files/document/r12999bp.pdf*.

Table 8 identifies the two new renal dialysis drugs for which the TDAPA payment period as specified in § 413.234(c)(1) would continue in CY 2026: DefenCath® (taurolidine and heparin sodium) and Vafseo® (vadadustat). In addition, while the phosphate binders are not new renal dialysis drugs or biological products as specified in § 413.234(c)(1), the TDAPA payment period for sevelamer carbonate, sevelamer hydrochloride, sucroferric oxyhydroxide, lanthanum carbonate, ferric citrate, and calcium acetate would also continue in CY 2026. As noted previously, we would pay for the oral only phosphate binders using the TDAPA under the ESRD PPS for at least 2 years. Table 8 also identifies the products' HCPCS coding information as well as the payment adjustment effective dates and available end dates.

TABLE 8—CONTINUATION OF APPROVED TRANSITIONAL DRUG ADD-ON PAYMENT ADJUSTMENTS

HCPCS code	Long descriptor	Payment adjustment effective date	Payment adjustment end date
J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis).	7/1/2024	6/30/2026.
J0901	Vadadustat, oral, 1 mg (for ESRD on dialysis)	1/1/2025	12/31/2026.
J0601	Sevelamer carbonate (Renvela or therapeutically equivalent), oral, 20 mg (for ESRD on dialysis).	1/1/2025	1/1/27 or until sufficient claims data for rate setting analysis is available.
J0602	Sevelamer carbonate (Renvela or therapeutically equivalent), oral, powder, 20 mg (for ESRD on dialysis).	1/1/2025	1/1/27 or until sufficient claims data for rate setting analysis is available.
J0603	Sevelamer hydrochloride (Renagel or therapeutically equivalent), oral, 20 mg (for ESRD on dialysis).	1/1/2025	1/1/27 or until sufficient claims data for rate setting analysis is available.
J0605	Sucroferric oxyhydroxide, oral, 5 mg (for ESRD on dialysis)	1/1/2025	1/1/27 or until sufficient claims data for rate setting analysis is available.
J0607	Lanthanum carbonate, oral, 5 mg (for ESRD on dialysis)	1/1/2025	1/1/27 or until sufficient claims data for rate setting analysis is available.
J0608	Lanthanum carbonate, oral, powder, 5 mg, not therapeutically equivalent to J0607 (for ESRD on dialysis).	1/1/2025	1/1/27 or until sufficient claims data for rate setting analysis is available.
J0609	Ferric citrate, oral, 3 mg ferric iron, (for ESRD on dialysis)	1/1/2025	1/1/27 or until sufficient claims data for rate setting analysis is available.
J0615	Calcium acetate, oral, 23 mg (for ESRD on dialysis)	1/1/2025	1/1/27 or until sufficient claims data for rate setting analysis is available.

III. CY 2026 Payment for Renal Dialysis Services Furnished to Individuals With AKI

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a subsection (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies to implement subsection (r) of section 1834 of the Act and the amendments to section 1861(s)(2)(F) of the Act, including the payment rate for AKI dialysis furnished by ESRD facilities (81 FR 77866 through 77872 and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD PPS base rate as set forth in § 413.220, updated by the

ESRDB market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965). In the CY 2025 ESRD PPS final rule we finalized a policy to allow for payment for home dialysis for beneficiaries with AKI. Additionally, we extended the payment adjustment for home and self-dialysis training to AKI dialysis payments in a budget neutral manner and calculated a reduction to the AKI dialysis payment rate which rounded to $0.00 (89 FR 89170).

B. Proposed Update of AKI Dialysis Payment

1. Proposed CY 2026 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including the applicable annual market basket update, geographic wage adjustments, and any other amounts deemed appropriate by the Secretary, for such year. We note that ESRD facilities could bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis. As discussed in section II.B.4. of this proposed rule, the proposed ESRD PPS base rate is $281.06, which reflects the application of the proposed CY 2026 wage index budget neutrality adjustment factor of 1.00872, the application of the proposed budget neutrality factor for the proposed non-contiguous areas payment adjustment(NAPA) of 0.99859 discussed in section II.B.8. of this proposed rule, and the proposed CY 2026 ESRDB market basket percentage increase of 2.7 percent reduced by the proposed productivity adjustment of 0.8 percentage point, that is, 1.9 percent. Accordingly, we are proposing a CY 2026 per treatment payment rate of $281.06 (($273.82 × 1.00872 × 0.99859) × 1.019 = $281.06) for renal dialysis services furnished by ESRD facilities to individuals with AKI. As discussed in section II.B.1. of this proposed rule, we are proposing that if more recent data become available after the publishing of this proposed rule and before the publishing of the final rule, we would use such data, if appropriate, to determine the CY 2026 ESRDB market basket percentage increase and productivity adjustment in the final rule.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and regulations at § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRDB market basket percentage increase and reduced by the productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS. As discussed in section II.B.2.a. of this proposed rule, the ESRD PPS wage index is based on mean hourly wage data from the BLS OEWS weighted by FTE data from freestanding ESRD facility cost reports. We finalized the new methodology for determining the wage index value for an ESRD facility in the CY 2025 ESRD PPS final rule, (89 FR 89116). Accordingly, we applied the same wage index under § 413.231 that is used under the ESRD PPS to the AKI dialysis payment (89 FR 89167). We propose to continue using this same methodology when adjusting AKI dialysis payments to ESRD facilities, consistent with our historical practice of using the ESRD PPS wage index for AKI dialysis payments. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that ESRD facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. We also apply the wage index policies regarding the 0.600 wage index floor (87 FR 67161 through 67166) and the 5 percent cap on wage index decreases (87 FR 67159 through 67161) to AKI dialysis payments to ESRD facilities. ESRD facilities would utilize the same staff to provide renal dialysis services to and educate beneficiaries with AKI as those beneficiaries with ESRD. Therefore, utilizing the same wage index methodology would be appropriate in accordance with § 413.372, which addresses the payment rate for AKI dialysis and refers to § 413.231 for the wage adjustment. As stated previously, we are proposing a CY 2026 AKI dialysis payment rate of $281.06, adjusted by the ESRD facility's wage index. As discussed in section II.B.2.c. of this proposed rule, we are proposing that if more recent data become available after the publishing of this proposed rule and before the publishing of the final rule, we would use such data, if appropriate, to determine the CY 2026 update the ESRD PPS wage index.

3. Other Adjustments to the AKI Dialysis Payment Rate

Section 1834(r)(1) of the Act also provides that the payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act. As discussed in the CY 2025 ESRD PPS final rule, we have extended the home and self-dialysis training add-on payment adjustment under the ESRD PPS to AKI beneficiaries in a budget neutral way (89 FR 89170). We continue to collect data on the uptake of home dialysis treatments for beneficiaries with AKI. We are not proposing to reevaluate the budget neutrality factor for CY 2026.

We considered implementing the proposed new ESRD PPS facility-level payment adjustment for ESRD facilities in Alaska, Hawaii, and the U.S. Pacific Territories, which we refer to in this proposed rule as the non-contiguous areas payment adjustment (NAPA), for beneficiaries with AKI. However, section 1834(r)(1) of the Act indicates that adjustments to AKI dialysis payments, other than the ESRD PPS wage index, must be made budget neutrally across AKI dialysis payments. We made a budget neutral adjustment to the AKI dialysis payment rate to account for the home and self-dialysis training payment adjustment in the CY 2025 ESRD PPS final rule (89 FR 89170). We are in the process of evaluating the effect of training adjustment on AKI dialysis payments. We do not believe it would be appropriate to propose any additional updates to the AKI dialysis payment rate at this time. However, we welcome comments from interested parties on the potential for other geographic payment adjustments to the AKI dialysis payment rate.

IV. Proposed Updates to the End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the ESRD QIP's background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the citations provided at IV.A. of the CY 2024 ESRD PPS final rule (88 FR 76433). We have also codified many of our policies for

the ESRD QIP at 42 CFR 413.177 and 413.178.

B. Proposed Updates to Requirements Beginning With the PY 2027 ESRD QIP

1. Proposed Removal of the Facility Commitment to Health Equity Reporting Measure Beginning With the PY 2027 ESRD QIP

We refer readers to the CY 2024 ESRD PPS final rule where we adopted the Facility Commitment to Health Equity reporting measure into the ESRD QIP (88 FR 76437 through 76446). We propose to remove the Facility Commitment to Health Equity measure beginning with the PY 2027 ESRD QIP. The perceived costs associated with achieving a high score on the measure outweigh the benefit of its continued use in the program. When adopted, we intended the collection of data described in the five domains of this measure to provide individual dialysis facility leadership with meaningful and actionable health data to drive quality improvements to eliminate health disparities. Based on feedback received from dialysis facilities as well as a continued focus on clinical outcome measures, the burden of collecting data for this measure may outweigh the benefits.

One of the goals of the ESRD QIP is to move forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. Removing this measure from the ESRD QIP is one way to accomplish this goal. Our priority is a continued focus on measurable clinical outcomes as well as identifying quality measures on the topics of prevention, nutrition, and well-being. As such, we refer readers to our request for comment on ''Request for Information on Measure Concepts under Consideration for Future Years'' in section IV.D.2. of this proposed rule. With the entire set of measures, the ESRD QIP continues to incentivize the improvement of dialysis care quality and health outcomes for all patients through measurement and transparency. It may be costly for dialysis facilities to continue reporting on the Facility Commitment to Health Equity reporting measure and achieve high performance scores, and removal of this measure would make room both in the program's measure set to enhance the program's focus on other clinical outcomes and for dialysis facility leadership to focus on other priority quality and safety areas. Facilities that have already invested resources to meet this measure's requirements will still find value in this proposal through the reduction in reporting obligations if the measure is eliminated. Facilities would continue to benefit from this reduced administrative burden each year beginning with PY 2027, and the cumulative effect of this benefit over time is likely to outweigh resources expended in response to this measure.

We note that, since facilities have already submitted Facility Commitment to Health Equity reporting measure data for PY 2026, such measure data and scoring information will be available on the CMS Provider Data Catalog (PDC) and will be used for PY 2026 payment determinations. However, any Facility Commitment to Health Equity reporting measure data received by CMS for PY 2027 would not be used for public reporting or payment purposes. If finalized, facilities that do not report to CMS their PY 2027 reporting period data for the Facility Commitment to Health Equity reporting measure would not be penalized for PY 2027 scoring or payment purposes due to this measure.

We invite public comment on our proposal to remove the Facility Commitment to Health Equity reporting measure from the ESRD QIP beginning with the PY 2027 ESRD QIP.

2. Proposed Removal of the Two Social Drivers of Health Reporting Measures Beginning With the PY 2027 ESRD QIP

We propose to remove the two social drivers of health reporting measures from the ESRD QIP beginning with the PY 2027 ESRD QIP: Screening for Social Drivers of Health reporting measure (adopted at 88 FR 76466 through 76476); and Screen Positive Rate for Social Drivers of Health reporting measure (adopted at 88 FR 76476 through 76480). For further discussion of our previously established policies regarding measure adoption, retention, and removal, we refer readers to the CY 2024 ESRD PPS final rule (88 FR 76434).

We propose to remove the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure beginning with the PY 2027 ESRD QIP, under § 413.178(c)(5)(i)(H), Measure Removal Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program. Although understanding the needs of patients receiving dialysis therapy is important, we have heard from some facilities concerned with the resources associated with screening patients via manual processes, manually storing such data, training facility staff, and altering workflows. Further, we note that these measures document an administrative process and report aggregate level results, and do not shed light on the extent to which providers are ultimately connecting patients with resources or services and whether patients are benefiting from these screenings. We have concluded that the costs of the continued use of these measures in the ESRD QIP may outweigh the benefits to providers and patients. Removal of these measures would alleviate the burden on dialysis facilities to manually screen each patient and submit data each reporting cycle, allowing dialysis facilities to focus resources on other clinical outcomes. This will also remove the patient burden associated with repeated Social Drivers of Health screenings across multiple healthcare facilities. We refer readers to our request for comment, ''Request for Information on Measure Concepts under Consideration for Future Years'' in section IV.D.2. of this proposed rule for more information regarding our areas of focus for new measures. Facilities that have already invested resources to meet these measures' requirements will still find value in this proposal through the reduction in reporting obligations if the measures are eliminated. Facilities would continue to benefit from this reduced administrative burden each year beginning with PY 2027, and the cumulative effect of this benefit over time is likely to outweigh resources expended in response to this measure. With the entire set of measures, the ESRD QIP continues to incentivize the improvement of dialysis care quality and health outcomes for all patients through measurement and transparency.

If finalized, facilities that do not report their PY 2027 measure data for the Screening for Social Drivers of Health reporting measure or the Screen Positive Rate for Social Drivers of Health reporting measure would not be penalized for PY 2027 scoring or payment purposes. In addition, any measure data received by CMS would not be used for public reporting or payment purposes.

We invite public comment on our proposal to remove the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure from the ESRD QIP beginning with the PY 2027 ESRD QIP.

C. Proposed Updates to Requirements Beginning With the PY 2028 ESRD QIP

1. PY 2028 ESRD QIP Measure Set

In this proposed rule, we are proposing to update the ICH CAHPS clinical measure beginning with the PY

2028 measure set. Table 9 summarizes the previously finalized and proposed updated measures that we would include in the PY 2028 ESRD QIP measure set. The technical specifications for current measures that would remain in the measure set for PY 2028 can be found in the CMS ESRD Measures Manual for the 2025 Performance Period.[14]

TABLE 9—PREVIOUSLY FINALIZED AND PROPOSED UPDATED MEASURES FOR THE PY 2028 ESRD QIP MEASURE SET

Consensus-based entity[15] (CBE) #	Measure title and description
0258*	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure.
	Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple survey questions.
2496	Standardized Readmission Ratio (SRR), a clinical measure.
	Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
Based on CBE #2979	Standardized Transfusion Ratio (STrR), a clinical measure.
	Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
Based on CBE #0323, # 0321, 2706, and #1423.	(Kt/V) Dialysis Adequacy Measure Topic, a clinical measure topic.
	Four measures of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. The individual Kt/V measures would be adult hemodialysis (HD) Kt/V, adult peritoneal dialysis (PD) Kt/V, pediatric HD Kt/V, and pediatric PD Kt/V.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure.
	Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a reporting measure.
	Percentage of patient-months with total uncorrected serum or plasma calcium lab value reported in EQRS.
1463	Standardized Hospitalization Ratio (SHR), a clinical measure.
	Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on CBE #0418	Clinical Depression Screening and Follow-Up, a clinical measure.
	Facility reports in ESRD Quality Reporting System (EQRS) one of four conditions for each qualifying patient treated during performance period.
Based on CBE #1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure.
	The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure.
	Percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure.
	Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.
3636	COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP), a reporting measure.
	Percentage of HCP who are up to date on their COVID–19 vaccination.

* We are proposing to update the ICH CAHPS clinical measure beginning with PY 2028, as discussed in section IV.C.2. of this proposed rule.
** We are proposing to remove the Facility Commitment to Health Equity reporting measure beginning with PY 2027, as discussed in section IV.B.1. of this proposed rule.
*** We are proposing to remove the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027, as discussed in section IV.B.2. of this proposed rule.

2. Proposal To Update the ICH CAHPS Clinical Measure Beginning With the PY 2028 ESRD QIP

a. Background

Section 1881(h)(2)(A)(ii) of the Act states that the Secretary shall specify, to the extent feasible, measures of patient satisfaction. Patients with ESRD are a vulnerable population. They are reliant on ESRD facilities for life-saving therapy, and they are often reluctant to express concerns about the care they receive from a variety of staff, both professional and non-professional. Patient-centered experience is an important measure of the quality of patient care, and it is a component of the CMS National Quality Strategy, which emphasizes patient-centered care by rating patient experience as a means for empowering patients and improving the quality of their care.

The ICH CAHPS Survey was developed to capture the experience of in-center hemodialysis patients. The ICH CAHPS measure was one of the foundational measures of the ESRD QIP measure set, initially as a reporting measure (76 FR 70269 through 70270) and then as a clinical measure beginning with PY 2018 (79 FR 66198 through 66200).

b. Proposed Survey and Measure Changes

ICH CAHPS Surveys are administered semiannually, and an eligible facility's score on the ICH CAHPS clinical measure is currently based on the three composite or multi-item measures (QDCCO, NCC, and Providing Information to Patients [PIP]) and three global ratings (ratings of nephrologists, dialysis center staff, and dialysis center), all of which are equally weighted. In recent years, commenters have expressed concerns that patients may experience survey fatigue related to both the length of the survey and the frequency of being requested to participate in the survey twice a year. In addition, survey response rates continue to slowly decline, and it is believed that the length of the survey could be a contributing factor.

To address these concerns, we conducted a number of activities related to reducing the length of the current ICH CAHPS Survey. Based on psychometric analyses, discussions with a Technical Expert Panel of ESRD entities, survey experts, and large dialysis organizations, focus groups with dialysis patients, and discussions with the CAHPS Consortium, proposed revisions to the ICH CAHPS Survey used to calculate performance on the ICH CAHPS clinical measure include:

- Removal of four questions, which are unnecessary for the psychometric

[14] *https://www.cms.gov/files/document/esrd-measures-manual-v100.pdf.*

[15] In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

function of the Quality of Dialysis Center Care and Operations (QDCCO) multi-item measure:

++ Whether the dialysis center staff inserted needles with as little pain as possible,

++ whether dialysis center staff talked to patients about what they should eat and drink,

++ whether the dialysis center staff keep health information as private as possible, and

++ whether the patient felt the staff cared about them ''as a person.''

• Removal of all six questions that make up the Nephrologists' Communication and Caring (NCC) multi-item measure.

• Removal of the nephrologist rating question.

Additionally, to reduce the length of the ICH CAHPS Survey, we propose to update the ICH CAHPS Survey to include the following non-measure changes:

• Removal of two core questions not currently used in public reporting measures:

++ Whether the dialysis center staff asked about how kidney disease affects other parts of patient's lives, and

++ whether patients made a complaint to Medicare or their State agencies.

• Removal of nine questions from the About You section and one question from the mail survey proxy series.

• Consolidation of the race and ethnicity questions into one question, as per OMB Statistical Policy Directive No. 15 requirements.[16]

c. Pre-Rulemaking Review Process and Measure Endorsement

As required under section 1890A of the Act, the Secretary must establish and follow a pre-rulemaking review process for selection of quality and efficiency measures, including for the ESRD QIP. The pre-rulemaking review process, which we refer to as Pre-Rulemaking Measure Review (PRMR), includes a review of measures published on the publicly available list of Measures Under Consideration by one of several committees convened by the consensus-based entity (CBE), with whom we contract in accordance with section 1890 of the Act, for the purpose of providing interested parties' input to the Secretary on the selection of quality and efficiency measures under consideration for use in certain Medicare quality programs, including the ESRD QIP.

The revised ICH CAHPS Survey, including the revised QDCCO multi-item measure, was submitted to the 2024 Measures Under Consideration list (MUC2024–060) and underwent evaluation by the PRMR Hospital Committee. The PRMR Hospital Committee recommended the ICH CAHPS survey changes be implemented.[17] The revised ICH CAHPS Survey was submitted to the CBE for endorsement through the Spring 2025 Partnership for Quality Measurement (PQM) Endorsement and Maintenance (E&M) process.[18] The E&M process ensures measures submitted for endorsement are evidence-based, scientifically sound, safe and effective. The current ICH CAHPS Survey measure was endorsed by the CBE in Spring 2019. Although section 1881(h)(2)(B)(i) of the Act generally requires that measures specified by the Secretary for the ESRD QIP be endorsed by the entity with a contract under section 1890(a) of the Act, section 1881(h)(2)(B)(ii) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We have determined that the updates to the ICH CAHPS clinical measure are appropriately specified, and therefore the exception in section 1881(h)(2)(B)(ii) of the Act applies. We note that the ICH CAHPS measure remains an endorsed measure, and the updated ICH CAHPS measure, which only reduces the number of questions in the ICH CAHPS Survey, has been submitted to the CBE for endorsement. To ensure that the revised ICH CAHPS Survey is reflected in the updated ICH CAHPS clinical measure beginning with PY 2028, we are proposing to implement the revised ICH CAHPS Survey beginning with the CY 2026 Spring survey.

d. Impact To Measure Calculation and Public Reporting

ICH CAHPS Survey measure scores are calculated based on two rolling semiannual surveys and are published semiannually for all ICH facilities that meet reporting criteria. With the proposed implementation of the revised survey, we are proposing to calculate the ICH CAHPS clinical measure based on the remaining multi-item measures—the revised QDCCO and PIP—and the remaining global ratings of the dialysis center staff and the dialysis center. In the calculation of the ICH CAHPS clinical measure, we are proposing that all of the measures, including the multi-item and global rating measures, would be weighed equally. The ICH CAHPS clinical measure would continue to be calculated using two rolling semiannual surveys and would be publicly reported for all eligible facilities with 30 or more completed surveys over the reporting period.

To determine what impact the changes to the survey measures would have on public reporting, CMS considered the nature of the changes. Psychometric and other analyses were performed on field test data and no major impact was found. We anticipate that the first Care Compare refresh in which publicly reported scores would be updated to include two semiannual periods using the revised survey would be October 2027 (2026 Spring and 2026 Fall Surveys). Because the April 2027 refresh would include a survey period that used the current survey (2025 Fall) and a survey period that used the revised survey (2026 Spring), we propose to reanalyze the 2025 Fall data without the NCC measure and rating and without the 4 dropped QDCCO measure questions, then combine the reanalyzed data with the 2026 Spring data for public reporting in April 2027. Therefore, we would not miss a refresh for ICH CAHPS data.

e. Survey Administration Changes

No survey administration changes are proposed with the new survey.

f. Case-Mix and Mode Adjustments

Prior to public reporting, ICH CAHPS Survey scores are adjusted for the effects of case-mix (patient-mix). Case-mix refers to characteristics of the patient that are not under control of the facility that may affect reports of in-center dialysis experiences. Case-mix adjustment is performed within each semiannual survey period after data cleaning. The current case-mix adjustment model includes the following variables: overall health, overall mental health, heart disease, deaf or serious difficulty hearing, blind or serious difficulty seeing, difficulty dressing or bathing, age, sex, education, does the patient speak a language other than English at home, whether someone helped complete the survey, and total years on dialysis. The model used and

[16] OMB, The 2024 Statistical Policy Directive No. 15, March 2024. Available at *https://spd15revision.gov/content/spd15revision/en/2024-spd15.html*.

[17] Partnership for Quality Measurement, PRMR 2024 MUC Final Recommendations Spreadsheet. Available at *https://p4qm.org/media/3891*.

[18] Information about the Partnership for Quality Measurement E&M process is available at *https://p4qm.org/EM*.

adjustments are updated semiannually and are available on the ICH CAHPS website at *https://ichcahps.org/Portals/0/PublicReporting/ICHCAHPS_PublicRptCoeffOct2024.pdf*. Based on testing the revised survey in a field test, CMS reviewed the variables included in the case-mix adjustment models currently in use for the ICH CAHPS Survey to determine if any changes needed to be introduced along with the revised survey. Several questions that were included as original case-mix adjusters showed little impact on survey responses, so the questions were removed to shorten the survey instrument. Based on this and the case-mix analysis of the field test data, we propose that the new case-mix adjusters for the revised survey include overall health, overall mental health, age, sex, education, language survey was conducted in, whether someone helped complete the survey, total years on dialysis, and whether diabetes was primary cause of ESRD.

We note that, in addition to the proposed updates to the ICH CAHPS clinical measure in this proposed rule, we are also exploring additional ways to improve the ICH CAHPS measure. We are currently working on developing and testing a web with mail follow-up mode to provide facilities with alternate methods of survey administration, and we are also working on a modified survey to include questions that address the experience of care for patients on home dialysis modalities.

We welcome public comment on our proposal to update the ICH CAHPS clinical measure for the PY 2028 ESRD QIP and subsequent years.

3. Performance Standards for the PY 2028 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as determined appropriate by the Secretary, and must be established prior to the beginning of the performance period for the year involved, as required by sections 1881(h)(4)(B) and (C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (76 FR 70277), as well as § 413.178(a)(1), (3), (7), and (12), for further information related to performance standards.

We continue to believe that our current policy of 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP. Under this policy, we would adopt CY 2026 as the performance period and CY 2024 as the baseline period for the PY 2028 ESRD QIP. In this proposed rule, we are estimating the performance standards for the PY 2028 clinical measures in Table 10 using data from CY 2023, which are the most recent data available. We intend to update these performance standards for all measures, using CY 2024 data, in the CY 2026 ESRD PPS final rule.

TABLE 10—PERFORMANCE STANDARDS FOR THE PREVIOUSLY FINALIZED AND PROPOSED UPDATED ESRD QIP CLINICAL MEASURES FOR PY 2028

Measure	Achievement threshold (15th percentile of national performance)	Median (50th percentile of national performance)	Benchmark (90th percentile of national performance)
Vascular Access Type (VAT):			
Long-Term Catheter Rate	18.35%	11.04%	4.69%
Kt/V Dialysis Adequacy Measure Topic:			
Adult Hemodialysis (HD) Kt/V	95.79%	98.34%	99.68%
Pediatric Hemodialysis (HD) Kt/V	81.25%	92.37%	100.00%
Adult Peritoneal Dialysis (PD) Kt/V	87.34%	94.85%	99.04%
Pediatric Peritoneal Dialysis (PD) Kt/V	66.49%	82.06%	95.18%
Standardized Readmission Ratio [a]	34.27	26.50	16.18
NHSN BSI	0.642	0.215	0
Standardized Hospitalization Ratio [b]	166.60	129.14	87.98
Standardized Transfusion Ratio [b]	48.29	26.19	8.46
PPPW	8.12%	16.73%	33.90%
Clinical Depression	88.21%	94.34%	100.00%
ICH CAHPS: Quality of Dialysis Center Care and Operations *	54.93%	63.89%	75.33%
ICH CAHPS: Providing Information to Patients	70.82%	77.29%	84.95%
ICH CAHPS: Overall Rating of Dialysis Center Staff	51.74%	64.96%	79.23%
ICH CAHPS: Overall Rating of the Dialysis Facility	54.88%	68.62%	83.27%

* We are proposing to update the ICH CAHPS clinical measure beginning with PY 2028, as discussed in section IV.C.2. of this proposed rule.
[a] Rate calculated as a percentage of hospital discharges.
[b] Rate per 100 patient-years.
Data sources: VAT measure: 2023 EQRS; SRR, SHR, STrR: 2023 Medicare claims; Kt/V: 2023 EQRS and 2023 Medicare claims; NHSN: 2023 CDC; ICH CAHPS: CMS 2023; PPPW: 2023 EQRS and 2023 Organ Procurement and Transplantation Network (OPTN); Clinical Depression: 2023 EQRS.

In addition, we summarize in Table 11 our requirements for successful reporting on our previously finalized and proposed updated reporting measures for the PY 2027 and PY 2028 ESRD QIP.

TABLE 11—REQUIREMENTS FOR SUCCESSFUL REPORTING OF ESRD QIP REPORTING MEASURES FOR PY 2027 AND PY 2028

Measure	Reporting frequency	Data elements
MedRec	Monthly	• Date of the medication reconciliation. • Type of eligible professional who completed the medication reconciliation: ○ physician, ○ nurse, ○ advanced registered nurse practitioner (ARNP), ○ physician assistant (PA), ○ pharmacist, or ○ pharmacy technician personnel. • Name of eligible professional.
Hypercalcemia	Monthly	Total uncorrected serum or plasma calcium lab values
COVID–19 Vaccination Coverage Among HCP.	At least one week of data each month, submitted quarterly.	Cumulative number of HCP eligible to work in the facility for at least one day during the reporting period and who are up to date on their COVID–19 vaccination.

*We are proposing to remove the Facility Commitment to Health Equity reporting measure beginning with PY 2027, as discussed in section IV.B.1. of this proposed rule. We are also proposing to remove the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027, as discussed in section IV.B.2. of this proposed rule.

4. Eligibility Requirements for the PY 2028 ESRD QIP

In this proposed rule, we are not proposing to update eligibility requirements as part of our proposal to update the ICH CAHPS clinical measure, as discussed in section IV.C.2. of this proposed rule. Our previously finalized minimum eligibility requirements are described in Table 12.

TABLE 12—PREVIOUSLY FINALIZED ELIGIBILITY REQUIREMENTS FOR SCORING ON ESRD QIP MEASURES BEGINNING WITH PY 2028

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Dialysis Adequacy Measure Topic: Adult HD Kt/V (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Kt/V Dialysis Adequacy Measure Topic: Pediatric HD Kt/V (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Kt/V Dialysis Adequacy Measure Topic: Adult PD Kt/V (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Kt/V Dialysis Adequacy Measure Topic: Pediatric PD Kt/V (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
VAT: Long-term Catheter Rate (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Hypercalcemia (Reporting)	11 qualifying patients.	Before September 1 of the performance period that applies to the program year.	N/A.
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11–25 qualifying patients.
SRR (Clinical)	11 index discharges	N/A	11–41 index discharges.
STrR (Clinical)	10 patient-years at risk	N/A	10–21 patient-years at risk.
SHR (Clinical)	5 patient-years at risk	N/A	5–14 patient-years at risk.
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities would not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period.	Before October 1 prior to the performance period that applies to the program year.	N/A.
Depression Screening and Follow-Up (Clinical).	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	11–25 qualifying patients.
MedRec (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A.
PPPW (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients.
COVID–19 Vaccination Coverage Among HCP (Reporting).	N/A	Before September 1 of the performance period that applies to the program year.	N/A.

*We are proposing to remove the Facility Commitment to Health Equity reporting measure beginning with PY 2027, as discussed in section IV.B.1. of this proposed rule. We are also proposing to remove the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027, as discussed in section IV.B.2. of this proposed rule.

5. Payment Reduction Scale for the PY 2028 ESRD QIP

Under our current policy, a facility does not receive a payment reduction for a payment year in connection with its performance under the ESRD QIP if it achieves a TPS that is at or above the minimum TPS (mTPS) that we establish for the payment year. We have defined the mTPS in our regulations at § 413.178(a)(8).

Under § 413.177(a), we implement the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the mTPS, up to a maximum reduction of 2 percent. For PY 2028, we estimate using available data that a facility must meet or exceed an mTPS of 56 to avoid a payment reduction. The estimated payment reduction scale for PY 2028 based on the most recently available data is described in Table 13. We note that the mTPS estimated in this proposed rule is based on data from CY 2023 instead of the PY 2028 baseline period (CY 2024) because CY 2024 data are not yet available. We will update and finalize the mTPS and associated payment reduction ranges for PY 2028, using CY 2024 data, in the CY 2026 ESRD PPS final rule.

TABLE 13—ESTIMATED PAYMENT REDUCTION SCALE FOR PY 2028 BASED ON THE MOST RECENTLY AVAILABLE DATA

Total performance score	Reduction (%)
100–56	0
55–46	0.5
45–36	1.0
35–26	1.5
25–0	2.0

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

As discussed in the following sections of this proposed rule, we are requesting information on topics to inform future revisions to the ESRD QIP. First, we are requesting information on the current state of health information technology (IT) use in dialysis facilities, including electronic health records, to further ongoing efforts to facilitate successful adoption and integration of Fast Healthcare Interoperability Resources® (FHIR®), FHIR-based technologies and standardized data for patient assessment instruments. We are also requesting information regarding potential measurement concepts that could be developed into ESRD QIP measures in the future.

Note that each of these sections is an RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), these general solicitations are exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

Respondents are encouraged to provide complete but concise responses. These RFIs are issued solely for information and planning purposes; they do not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. These RFIs do not commit the United States Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the United States Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs will be solely at the interested party's expense. Not responding to these RFIs does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor these RFI announcements for additional information pertaining to this request. Note that CMS will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the United States Government to form a binding contract or issue a grant. Information obtained as a result of these RFIs may be used by the United States Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. These RFIs should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become United States Government property and will not be returned. CMS may publicly post the comments received, or a summary thereof.

1. Request for Public Comment on Advancing Digital Quality Measurement in the ESRD QIP

a. Background

We are committed to improving healthcare quality through measurement, transparency, and public reporting of quality data, and to enhancing healthcare data exchange by promoting the adoption of interoperable health information technology (IT) that enables information exchange through the use of FHIR® standards. Proposing to require the use of such technology within the ESRD QIP in the future could potentially enable greater care coordination and information sharing, which is essential for delivering high-quality, efficient care and better outcomes at a lower cost. In the CY 2022 ESRD PPS final rule, we outlined several HHS initiatives aimed at promoting the adoption of interoperable health information technology (IT) and facilitating nationwide health information exchange (86 FR 61941 through 61945). Further, to inform our digital strategy, we sought and received feedback, described in the CY 2022 ESRD PPS final rule, on our intent to explore the use of FHIR-based standards to exchange clinical information through application programming interfaces (APIs), enabling quality data submission to CMS through EQRS, and to work with healthcare standards organizations to ensure their standards support our assessment tools (86 FR 61941 through 61948).

We are considering opportunities to advance FHIR-based reporting of patient assessment data for the submission of ESRD QIP data. Our objective is to explore how dialysis facilities typically integrate health IT with varying complexity into existing systems and how this affects facility workflows. We seek to identify the challenges and/or opportunities that may arise during this integration, and determine the support needed to complete and submit the data in ways that protect and enhance care delivery.

Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

b. Solicitation for Comment

We seek feedback on the current state of health IT use, including EHRs, in ESRD facilities:

- What health IT does your facility use to maintain patient records, and are these health IT certified by the Assistant Secretary for Technology Policy (ASTP) and the Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP)? If your facility uses EHRs that are not certified by ONC, please specify. Does your facility maintain any patient records outside of these electronic systems? If so, is the data organized in a structured format, using codes and recognized standards, that can be exchanged with other systems?
- Does your facility submit patient assessment data to CMS through your current health IT system? If a third-party intermediary is used to report data, what type of intermediary service is used? How does your facility currently exchange health information with other healthcare providers or systems, specifically between facilities and other provider types? What are the challenges?
- Are there any challenges with your current electronic devices that hinder your ability to achieve interoperability, such as collecting, storing, sharing, or submitting data? Please describe any specific issues you encounter. Does limited internet or lack of internet connectivity impact your ability to exchange data with other healthcare providers, including community-based care services, or your ability to submit assessment data to CMS? Please specify.
- What challenges or barriers does your facility encounter when submitting quality data to CMS as part of the ESRD QIP? What opportunities or factors could improve your facility's successful data submission to CMS?
- What types of technical support, guidance, workforce trainings, and/or other resources would be most beneficial for the implementation of FHIR-based technology in your facility for the submission of the data to CMS? How could these resources be designed to minimize complexity and burden on healthcare providers while ensuring the protection of patient care and maintaining staffing capacities during implementation? How could Quality Improvement Organizations (QIOs) or other entities enhance this support?
- How do you anticipate the adoption of FHIR-based standards for reporting patient assessment data could impact provider workflows? What impact, if any, do you anticipate it will have on quality of care?
- Does your facility have any experience using technology that conforms to a version or versions of the United States Core Data for Interoperability (USCDI) standard for data? Is your facility using technology that utilizes APIs based on the FHIR® standard for electronic data exchange? If so, with whom are you exchanging data using the FHIR® standard and for what purpose(s)? Has your facility used a SMART on FHIR® [19] application? If so, was the SMART on FHIR® application integrated with your EHR? Additionally, what benefits or challenges have you experienced with the implementation of FHIR® using APIs or USCDI?
- What might encourage your facility and/or vendors to participate in testing to explore options for transmission of assessments, for example testing the transmission of a FHIR-based assessment to CMS?
- How could the Trusted Exchange Framework and Common Agreement™ (TEFCA™) support CMS quality programs' adoption of FHIR-based assessment submissions consistent with the FHIR® Roadmap (available here *https://rce.sequoiaproject.org/three-year-fhir-roadmap-for-tefca/)*? How might patient assessment data hold secondary uses for treatment or other TEFCA exchange purposes?
- What other information should we consider, that could facilitate successful adoption and integration of FHIR-based technologies and standardized data for patient assessment instruments? We invite any feedback, suggestions, best practices, or success stories related to the implementation of these technologies.

2. Request for Information on Measure Concepts Under Consideration for Future Years

The first concept about which we are seeking feedback is for a measure of interoperability with a focus on systems readiness and capabilities in the dialysis facility setting. The Public Health Service Act defines ''interoperability'' in part, and with respect to health information technology, as health information technology that enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without requiring special efforts by the user.[20] The definition further notes that interoperability of health information technology allows providers and patients to access, exchange, and use electronically accessible health information for authorized use under applicable State or Federal law. To achieve interoperability, a system should adopt and optimize electronic health records (EHRs) and health information exchange services.[21] We request input and comment on approaches to assessing interoperability in the dialysis facility setting, for instance, measures that address or evaluate the level of readiness for interoperable data exchange, or measures that evaluate the ability of data systems to securely share information across the entire spectrum of care with special consideration of exchange of information between dialysis facilities and both inpatient (including transplant centers) and outpatient facilities and providers.

A second concept about which we are seeking feedback is for a measure of well-being. Well-being is a comprehensive approach to disease prevention and health promotion, as it integrates mental, social, and physical health while emphasizing preventative care to proactively address potential health issues.[22] This comprehensive approach emphasizes person-centered care by promoting well-being of patients and their care partners. We are seeking comment on tools and measures that assess for overall health, happiness, and satisfaction in life that could include aspects of emotional well-being, social connections, purpose, and fulfillment. We would like to receive input and comment on the applicability of tools and constructs that assess for the integration of complementary and integrative health, skill building, and self-care. Please provide feedback on the relevant aspects of well-being for the ESRD QIP.

A third concept about which we are seeking feedback is for measures of nutrition. Assessment for nutritional status may include various strategies, guidelines, and practices designed to promote healthy eating habits and ensure individuals receive the necessary nutrients for maintaining health, growth, and overall well-being. Nutrition is a complex concept for patients with ESRD who may also have dietary restrictions, fluid restrictions, and/or frailty; however, adequate nutrition and nutritional support are important for overall health in this population. Maximizing nutrition can

[19] *https://smarthealthit.org/.*

[20] 42 U.S.C. 300jj(9).

[21] The Office of the National Coordinator for Health Information Technology. ''The Path to Interoperability''. September 2013. Available at *https://www.healthit.gov/sites/default/files/factsheets/onc_interoperabilityfactsheet.pdf.*

[22] Well-Being Concepts. CDC Archives. *https://archive.cdc.gov/#/details?url=https://www.cdc.gov/hrqol/wellbeing.htm.*

assist with dialysis treatment tolerance, improvement in comorbid conditions, and readiness for kidney transplant, if desired. We are seeking feedback on tools and frameworks that promote healthy eating habits and nutrition for patients requiring dialysis. Please provide feedback on the relevant aspects of nutrition for the ESRD QIP.

A fourth concept about which we are seeking feedback is for measures of physical activity. Although dialysis therapy presents barriers to physical activity for many patients including physical, structural, psychological, and practical barriers, physical activity and purposeful movement are critical for patients on dialysis. Physical activity can improve physical functioning, sleep, and well-being for patients on dialysis as well as potentially impact comorbid conditions. We are seeking feedback on all relevant aspects of physical activity for the ESRD QIP.

Finally, we are seeking feedback on measures related to chronic kidney disease (CKD) that would encourage early detection, early and appropriate treatment, and delay of progression to ESRD. The prevention or significant delay in the need for dialysis would profoundly impact patients. Please provide feedback on all relevant aspects of CKD prevention and treatment in all settings.

We welcome public comment on the future measure concepts under consideration for the ESRD QIP described in Table 14.

TABLE 14—FUTURE MEASURE CONCEPTS UNDER CONSIDERATION FOR THE ESRD QIP

ESRD QIP quality measure concepts
Interoperability.
Well-being.
Nutrition.
Physical Activity.

While we will not be responding to specific comments in response to this RFI in the CY 2026 ESRD PPS final rule, we intend to use this input to inform our future measure development efforts.

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

A. Background

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of these programs. The purpose of the ETC Model is to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians to encourage greater utilization of home dialysis and kidney transplantation, support ESRD Beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. As described in the Specialty Care Models final rule (85 FR 61114), beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. ESRD Beneficiaries require dialysis or kidney transplantation to survive, and the majority of ESRD Beneficiaries receiving dialysis receive hemodialysis in an ESRD facility. However, as described in the Specialty Care Models final rule, alternative renal replacement modalities to in-center hemodialysis, including home dialysis and kidney transplantation, are associated with improved clinical outcomes, better quality of life, and lower costs than in-center hemodialysis (85 FR 61264).

The ETC Model is a mandatory payment model. ESRD facilities and Managing Clinicians are selected as ETC Participants based on their location in Selected Geographic Areas—a set of 30 percent of Hospital Referral Regions (HRRs) that have been randomly selected to be included in the ETC Model, as well as HRRs with at least 20 percent of ZIP codes™ located in Maryland.[23] CMS excludes all United States Territories from the Selected Geographic Areas.

Under the ETC Model, ETC Participants are subject to two payment adjustments. The first is the Home Dialysis Payment Adjustment (HDPA), which is an upward adjustment on certain payments made to participating ESRD facilities under the ESRD PPS on home dialysis claims, and an upward adjustment to the Monthly Capitation Payment (MCP) paid to participating Managing Clinicians on home dialysis-related claims. The HDPA applies to claims with claim service dates beginning January 1, 2021, and ending December 31, 2023.

The second payment adjustment under the ETC Model is the Performance Payment Adjustment (PPA). For the PPA, we assess ETC Participants' home dialysis rates and transplant rates during a Measurement Year (MY), which includes 12 months of performance data. Each MY has a corresponding PPA Period—a 6-month period that begins 6 months after the conclusion of the MY. We adjust certain payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate, calculated as the sum of the transplant waitlist rate and the living donor transplant rate, during the corresponding MY.

Based on an ETC Participant's achievement in relation to benchmarks based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year, and the ETC Participant's improvement in relation to their own home dialysis rate and transplant rate during the Benchmark Year, we would make an upward or downward adjustment to certain payments to the ETC Participant. The magnitude of the positive and negative PPAs for ETC Participants increases over the course of the Model. These PPAs apply to claims with claim service dates beginning July 1, 2022, and ending June 30, 2027.

CMS has modified the ETC Model several times. In the CY 2022 ESRD PPS final rule, we finalized a number of changes to the ETC Model. We adjusted the calculation of the home dialysis rate (86 FR 61951 through 61955) and the transplant rate (86 FR 61955 through 61959) and updated the methodology for attributing Pre-emptive LDT Beneficiaries (86 FR 61950 through 61951). We changed the achievement benchmarking and scoring methodology (86 FR 61959 through 61968), as well as the improvement benchmarking and scoring methodology (86 FR 61968 through 61971). We specified the method and requirements for sharing performance data with ETC Participants (86 FR 61971 through 61984). We also made a number of updates and clarifications to the kidney disease patient education services waivers and made certain related flexibilities available to ETC Participants (86 FR 61984 through 61994). In the CY 2023 ESRD PPS final rule (87 FR 67136) we finalized further changes to the ETC Model. We updated the PPA achievement scoring methodology beginning in the fifth MY of the ETC Model, which began on January 1, 2023 (87 FR 67277 through 67278). We also clarified requirements for qualified staff to furnish and bill kidney disease patient education services under the ETC Model's Medicare program waivers (87 FR 67278 through 67280) and finalized our intent to publish participant-level model performance information to the public (87 FR 67280). In the CY 2024 ESRD PPS final rule (88 FR 76344) we finalized a policy whereby an ETC Participant may seek administrative review of a targeted review determination provided by CMS.

[23] ZIP code™ is a trademark of the United States Postal Service.

In the CY 2025 ESRD PPS final rule (89 FR 89084) we finalized a modification to the definition of ESRD Beneficiary at 42 CFR 512.310 as that definition is used for the purposes of attributing beneficiaries to the ETC Model.

B. Provisions of the Proposed Rule

1. Termination of the ETC Model

In this proposed rule, we are proposing to terminate the ETC Model as of December 31, 2025. Section 1115A of the Act gives the Secretary the authority to terminate Innovation Center models. Specifically, section 1115A(b)(3)(B) of the Act states that ''The Secretary shall terminate or modify the design and implementation of a model unless the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services, with respect to program spending under the applicable title, certifies), after testing has begun, that the model is expected to—improve the quality of care (as determined by the Administrator of the Centers for Medicare & Medicaid Services) without increasing spending under the applicable title; reduce spending under the applicable title without reducing the quality of care; or improve the quality of care and reduce spending. Such termination may occur at any time after such testing has begun and before completion of the testing.'' [24]

ETC Model performance since 2021 has not been shown to enhance the quality-of-care ETC regions on the key model measures of home dialysis modalities, transplant waitlisting, and living donor transplantation. The second Annual Evaluation Report (AR2) examined impacts of the ETC Model during calendar years CYs 2021 and 2022, which correspond to the first three model years (MYs) of the model. While AR2 showed home dialysis use continued to grow nationally, there was no evidence of faster growth within selected geographic areas relative to the comparison group of geographic areas not selected for the ETC Model. Further, for transplant-related measures, AR2 showed no evidence of a change in waitlisting rates in ETC areas relative to comparison areas. Increased rates of both home dialysis training and transplantation were only evident in CY 2021 and were not sustained in CY 2022.[25]

Also of note is that the ETC Model has not reduced Medicare expenditures throughout the duration of the ETC model and in fact has increased expenditures. The AR2 evaluation preliminarily showed that net Medicare payments increased by $56 million over the course of the model. The model was initially projected to show savings by decreasing payments for participants such that they would likely not be able to hit the required thresholds for performance in the ETC Model. However, due to stronger than expected increases in rates of home dialysis caused by factors other than the model and the effects of the improvement scoring methodology, managing clinicians and ESRD facilities performed better than expected and have received a net increase in payments.[26]

CMS issued an RFI in the CY 2025 ESRD PPS final rule (89 FR 89084) seeking comments about potential future policies that CMS could undertake to increase home dialysis rates and better support beneficiaries. Many of these suggestions that we received from the RFI are actively being tested in the Kidney Care Choices (KCC) Model, such as the Kidney Disease Education (KDE) benefit waiver, home dialysis quality measures focused on retention and optimal starts, efforts to increase transplantation, and a focus on home dialysis primarily through peritoneal dialysis (PD) as the dominant home dialysis modality.

Results of the PY 2022 evaluation for the KCC Model demonstrate promising strides towards the aforementioned shared goals with the ETC model, and more specifically, a statistically significant increase in home dialysis rates for aligned beneficiaries in aggregate. Specifically, KCC participants increased the proportion of patients receiving PD in a given month by 2.3 percentage points. This statistically significant relative increase represents about 26 percent of the pre-KCC mean. Additionally, Comprehensive Kidney Care Contracting (CKCC) model participants increased the proportion of patients receiving PD in a given month by 0.74 percentage points. This statistically significant relative increase represents about 8 percent of the pre-KCC mean.[27]

Given these factors, we are proposing to terminate the ETC model as of December 31, 2025. Specifically, we are proposing to revise the duration of the ETC Model at § 512.320 from claims with claim service dates beginning on or after January 1, 2021, and ending on or before June 30, 2027, to claims with claim service dates beginning on or after January 1, 2021, and ending on or before December 31, 2025. We seek public comment on our proposal to modify the duration of the ETC Model § 512.320.

Additionally, we are proposing to modify our regulation at §§ 512.355(a) through (b) to specify that the final Measurement Year (MY) ends on December 31, 2024, and the final Performance Payment Adjustment (PPA) ends December 31, 2025. This proposal would make MY7 and PPA 7 the last MY and PPA of the ETC Model. Therefore, we also propose to modify Table 1 to paragraph (c)—ETC Model Schedule of Measurement Years and PPA Periods at § 512.355 to eliminate the entries for MY 8 through MY 10. We seek public comment on our proposal to modify our regulation at §§ 512.355(a) through (c) to make MY7 and PPA7 the final MY and PPA of the ETC Model.

In order to align the remaining regulation text with our proposal to terminate the model after MY 7, we propose to modify §§ 512.360(c)(2)(iii), 512.365(b)(1)(ii), 512.365(c)(1)(i)(A), 512.365(c)(1)(ii), 512.365 (c)(2)(i)(A), 512.365 (c)(2)(ii)(A)(*1*) and 512.365 (c)(2)(ii)(A)(2) to remove references to MYs 8 through 10, and change any references to the last MY of the ETC model to reference MY7. We seek public comment on these proposals.

Also, for the reasons listed previously, we propose to modify §§ 512.370(b) introductory text, Table 1 to paragraph (b)(1) of 512.370, 512.370(b)(2), 512.370 (b)(3), 512.370 (c), 512.370(c)(1)(v), and 512.370(d)(2) to remove references to MYs 8 through 10, and change any references to the last MY of the ETC model to reference MY7. Finally, we propose to modify Table 1 to § 512.380—Facility PPA Amounts and Schedule, and Table 2 to § 512.380 to remove references to MYs 8 through 10, and § 512.390(b) to clarify when we propose to stop data sharing and the sharing of reports. We seek public comment on this proposal.

Given this proposed termination, we also plan to stop any data sharing and reports as of November 30, 2025, which would include any information about

[24] 42 U.S.C. 1315a.

[25] Negrusa, B., Wiens, J., Ullman, D., Turenne, M., Mukhopadhyay, P., Young, E., Mandell, R., Stanik, C., Pozniak, A., Goyat, R., Ji, N., Martin, A., Wang, D., Wiseman, J., Tian, S., Milkovich, K., Dahlerus, C., & Hirth, R. (2024). *End-stage renal disease treatment choices (ETC) model: Second annual evaluation report* (Contract No. 75FCMC19D0096). The Lewin Group. *https://www.cms.gov/priorities/innovation/data-and-reports/2024/etc-2nd-eval-rpt/*.

[26] Ibid.

[27] Negrusa, B., Wiens, J., Ullman, D., Dahlerus, C., Hirth, R., Maillet, A., Strubler, D., Pinson, R., Mindock, M., Bacon, K., Kappes, A., Johann, A., Vomacka, B., Schaefer, M.B., Segal, J., Shahinian, V., Li, Y., Shearon, T., Ashby, V., Nahra, T., Gunden, J., Wang, M., Garcia, A., & Yaldo, A. (2024). *Kidney care choices (KCC) model: First annual evaluation report, performance year 2022* (Contract No. 75FCMC19D0096). The Lewin Group. *https://www.cms.gov/kcc-model-eval-ann-rpt-1*.

model performance in MYs 7 through 10. This action accommodates the abbreviated project schedule of our implementation contractor in alignment with the early termination of the model on December 31, 2025. Two evaluation reports have been completed and made public. The First Annual Evaluation Report was published in July 2023 and pertained to the first year of the model (CY 2021), Measurement Years (MYs) 1 and 2. The Second Annual Evaluation Report was published on January 2024 and pertained to CY 2021 and CY 2022, which corresponds to MYs 1–3. The Third Annual Evaluation Report will be completed and is expected to be made public in the second half of 2025. This evaluation report will cover CYs 2021–2023 and pertain to MYs 1–6. We anticipate that there will be a Fourth Annual Evaluation Report expected to be made public after the end of the ETC model. This evaluation report will cover CYs 2021–2025 and pertain to MYs 1–7. We seek public comment on this proposal.

2. Discussion of Hurricane Helene and the ETC Model

Hurricane Helene hit western North Carolina on October 1 and 2, 2024. The hurricane affected a factory operated by Baxter International in Marion, NC that produces approximately 60 percent of the nation's supply of IV fluids and peritoneal dialysis solutions. Baxter stopped providing PD supplies for new starts after October 1, 2024, and it took until February 17, 2025, before all of their manufacturing lines returned to pre-hurricane production levels. Even with that announcement, they stated that ''allocations remain necessary, and we will continue to provide related updates for our customers directly'', suggesting continued disruptions.[28] The final statement released from Baxter on this issue dated May 13, 2025, focused on the complete restoration of inventory levels for IV Solutions only. Interested parties with additional inquiries regarding the production of PD solutions were directed to Vantive.[29]

Given the potential impact of Hurricane Helene on home dialysis, we considered adjusting the schedule and methodologies for the PPA. The impacts of Hurricane Helene could disrupt performance metrics for participants for MY 7, 8, and 9 (CY 2024 Q3 and Q4 through CY 2025 Q1 and Q2) and Benchmark Years (BY) 7, 8, and 9. A decrease in home dialysis for the PD modality in these time periods would begin to affect model performance payment adjustments to claims in July 2025. For the PPA, CMS assesses ETC Participants' home dialysis rate and transplant rate during an MY which includes 12 months of performance data. Some MYs overlap with the previous MY and the subsequent MY for a period of 6 months. Each MY has a corresponding PPA Period—a 6-month period which begins 6 months after the conclusion of the MY. CMS adjusts certain payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate. Based on an ETC Participant's achievement in relation to benchmarks based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year, and the ETC Participant's improvement in relation to its own home dialysis rate and transplant rate during the Benchmark Year, we make an upward or downward adjustment to certain payments to the ETC Participant.

As an alternative considered, we considered proposing that no upward or downward adjustments would be made for MY7 and PPA7 prior to the proposed termination of the model. Due to the timing of the publication of this proposed rule, changing the payment adjustments would be retroactive. However, initial research by the CMS contractor did not show a statistically significant change in home dialysis rates among participants and non participants for ETC Participant performance during October to December of 2024 when compared to January to September 2024. As such, we determined that proposing to eliminate the performance adjustments in the ETC Model for PPA 7 is unnecessary.

As part of this alternative that we considered to our proposal, we also recognize that Section 1871(e) of the Act lays out the principle that substantive changes in regulations shall not be applied retroactively unless the Secretary determines that either such retroactive application is necessary to comply with statutory requirements or failure to apply the change retroactively would be contrary to the public interest. If we receive comments providing significant empirical evidence of overwhelming negative effects of the supply shortage on the administration of home dialysis, implementing PPA 7 adjustments as currently written may not serve the public interest. We have heard anecdotal evidence that the Baxter supply shortages starting October 1 could have reduced home dialysis participation rates, making it difficult for participants to meet their performance benchmarks. This was not reflected in our data analysis, but we are open to seeing data from participants that could adjust our proposal. Without CMS intervention, this could result in negative payment adjustments starting July 1, 2025, which could hurt the ability of managing clinicians and ESRD facilities to continue to serve patients. If payments are cut due to circumstances out of ESRD facilities and Managing Clinician's control, it could hurt beneficiary access or affect the quality of care received by beneficiaries.

We seek public comment on our proposal to make no changes to the schedule and methodologies for the PPA due to Hurricane Helene. We also seek comment on the alternative we considered of making no upward or downward adjustments for MY7 and PPA7 and applying that policy retroactively.

VI. Collection of Information Requirements

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

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

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ESRD QIP—Wage Estimates

We refer readers to the CY 2025 ESRD PPS final rule for information regarding previously used wage estimates and resulting information collection burden calculations (89 FR 89194 through 89195). To derive wage estimates in this proposed rule, we used data from the United States Bureau of Labor Statistics'

[28] Baxter International Inc. (2025, February 17). *Hurricane Helene updates.* Baxter. *https://www.baxter.com/baxter-newsroom/hurricane-helene-updates.*

[29] Baxter International Inc. (2025, May 13). *Hurricane Helene updates.* Baxter. *https://www.baxter.com/baxter-newsroom/hurricane-helene-updates.*

May 2024 National Occupational Employment and Wage Estimates for Medical Records Specialists, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to the ESRD Quality Reporting System (EQRS) (formerly, CROWNWeb) and the Centers for Disease Control and Prevention's (CDC's) NHSN, as well as compiling and submitting patient records for the purpose of data validation. When this analysis was conducted, the most recently available median hourly wage of a Medical Records Specialist was $24.16 per hour.[30] We also calculate fringe benefit and overhead at 100 percent. We adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. Using these assumptions, we estimated an hourly labor cost of $48.32 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP.

We used this wage estimate, along with updated facility and patient counts, to update our estimates for the total information collection burden in the ESRD QIP for PY 2027 and to estimate the total information collection burden in the ESRD QIP for PY 2028. We will update the information collection burden to reflect updated facility and patient counts, in the CY 2026 ESRD PPS final rule.

B. Estimated Burden Associated With the Data Validation Requirements for PY 2028

We refer readers to the CY 2025 ESRD PPS final rule for information regarding the estimated burden associated with data validation requirements for PY 2027 (89 FR 89195).

1. Estimated Burden Associated With EQRS Data Validation Requirements for PY 2028

In this proposed rule, using the most recently available data, we estimate that the aggregate cost of the EQRS data validation for PY 2028 would be approximately $36,240 (750 hours × $48.32), or an annual total of approximately $120.80 ($36,240/300 facilities) per facility in the sample. The burden cost increase associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938–1289).

2. Estimated Burden Associated With NHSN Data Validation Requirements for PY 2028

In this proposed rule, we estimate that the aggregate cost of the NHSN data validation for PY 2028 would be approximately $72,480 (1,500 hours × $48.32), or a total of approximately $241.60 ($72,480/300 facilities) per facility in the sample. While the burden hours estimate would not change, the burden cost updates associated with these requirements will be submitted to OMB as a revision of the information collection request currently approved under OMB control number 0938–1340.

C. Estimated EQRS Reporting Requirements for PY 2027 and PY 2028

To estimate the burden associated with the EQRS reporting requirements (previously known as the CROWNWeb reporting requirements), we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to EQRS for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into EQRS, and the number of facilities submitting data to EQRS. In the CY 2025 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2027 ESRD QIP was approximately $136.1 million for approximately 2,901,090 total burden hours (89 FR 89195). In that final rule, we stated that for PY 2027 there are 136 data elements for 511,957 patients across 7,695 facilities, for a total of 69,626,152 elements across all patients (136 data elements × 511,957 patients). At 2.5 minutes per element, we estimated that this would yield approximately 377 hours per facility. Therefore, we stated that the PY 2027 burden associated with EQRS reporting requirements as finalized in the CY 2025 ESRD PPS final rule would be 2,901,090 hours (approximately 377 hours × 7,695 facilities). Using the May 2023 wage estimate for a Medical Records Specialist, we estimated that the PY 2027 total burden cost would be approximately $136.1 million (2,901,090 hours × $46.90).

We are proposing three measure removals that would affect the burden associated with EQRS reporting requirements beginning with PY 2027. We provide the updated burden estimate for PY 2027 to reflect the impact of these proposals if finalized, as well as to reflect the updated May 2024 wage estimate for a Medical Records Specialist, and provide additional detail in Table 15. We will update the information collection burden to reflect updated facility and patient counts in the CY 2026 ESRD PPS final rule. In this proposed rule, we estimated that the amount of time required to submit measure data to EQRS would be 2.5 minutes per element and did not use a rounded estimate of the time needed to complete data entry for EQRS reporting. There are 121 data elements for 511,957 patients across 7,695 facilities, for a total of 61,946,797 elements across all patients 121 data elements × 511,957 patients). If the three measure removals are finalized as proposed, the total number of data elements would decrease by 7,679,355 data elements based on current patient and facility counts. At 2.5 minutes per element, this would yield approximately 335 hours per facility. Therefore, the updated PY 2027 burden would be 2,581,117 hours (approximately 335 hours × 7,695 facilities), reflecting a burden decrease of 319,973 hours from our previously finalized estimate for PY 2027. Using the Medical Records Specialist wage estimates available at this time, we estimate that the updated PY 2027 total burden cost would be approximately $124.7 million (2,581,117 hours × $48.32).

[30] *https://data.bls.gov/oesprofile/.*

TABLE 15—ESTIMATED REDUCTION IN BURDEN ASSOCIATED WITH REMOVAL OF THREE REPORTING MEASURES BEGINNING WITH THE PY 2027 ESRD QIP

Requirement	Per facility		All facilities	
	Change in annual burden hours	Change in annual cost	Change in annual burden hours	Change in annual cost
Proposal to Remove Facility Commitment to Health Equity Reporting Measure	−13.86	−$669.71	−106,658	−$5,153,714.56
Proposal to Remove Social Drivers of Health Reporting Measure	−13.86	−669.71	−106,658	−5,153,714.56
Proposal to Remove Screen Positive for Social Drivers of Health Reporting Measure	−13.86	−669.71	−106,658	−5,153,714.56
	Total Change in Information Collection Burden Hours: −319,973 Total Cost Estimate: Updated Hourly Wage (Varies) × Change in Burden Hours (−319,973) = −$15,461,095			

We provide the burden estimate for PY 2028 and will update the information collection burden to reflect updated facility and patient counts, in the CY 2026 ESRD PPS final rule. In this proposed rule, we estimated that the amount of time required to submit measure data to EQRS would be 2.5 minutes per element and did not use a rounded estimate of the time needed to complete data entry for EQRS reporting. There are 121 data elements for 511,957 patients across 7,695 facilities, for a total of 61,946,797 elements (121 data elements × 511,957 patients). At 2.5 minutes per element, this would yield approximately 335 hours per facility. Therefore, the PY 2028 burden would be 2,581,117 hours (approximately 335 hours × 7,695 facilities). Using the Medical Records Specialist wage estimates available at this time, we estimate that the PY 2028 total burden cost would be approximately $124.7 million (2,581,117 hours × $48.32).

We intend to re-calculate the burden estimates for PY 2027 and PY 2028, using updated estimates of the total number of ESRD facilities, the total number of patients nationally, as well as a refined estimate of the number of hours needed to complete data entry for EQRS reporting in the CY 2026 ESRD PPS final rule. The information collection request currently approved under the OMB control number 0938–1289 will be revised and submitted to OMB for approval.

D. Estimated ICH CAHPS Reporting Requirements for PY 2028

The information collection request currently approved under OMB control number 0938–0926 for the ICH CAHPS Survey is being revised and submitted to OMB for approval. As we are proposing a reduction of the ICH CAHPS survey from 62 to 39 questions, the survey length is decreasing from 16 to 12 minutes as the time for patients to complete each question ranges from 15 to 18 seconds on average. Although the average number sampled has increased in the information collection request currently approved under OMB control number 0938–0926 being submitted as part of this rule, the hour burden has decreased from 51,300 in the previous projection to 41,500 due to a reduction in the survey length, as described in Table 16. The costs will decrease from $3,628,962 to $2,973,890 which is a savings of $655,072 annually.

TABLE 16—ESTIMATED REDUCTION IN BURDEN ASSOCIATED WITH PROPOSED UPDATES TO ICH CAHPS SURVEY BEGINNING WITH THE PY 2028 ESRD QIP

Requirement	Per dialysis facility		All dialysis facilities	
	Estimated change in annual burden hours	Estimated change in annual cost	Estimated change in annual burden hours	Estimated change in annual cost
Proposed update to ICH CAHPS Survey	−1.4	−$93.58	−9,800	−$655,072

Although we are also proposing changes to the ICH CAHPS clinical measure in this proposed rule that will reduce the burden associated with completing the ICH CAHPS survey, we do not anticipate that any of these proposed updates to the ICH CAHPS clinical measure would affect the facility reporting burden we have estimated for EQRS reporting requirements for PY 2028.

E. ESRD Treatment Choices Model

Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the ETC Model, from the provisions of the PRA. Specifically, this section provides that the provisions of the PRA do not apply to the testing and evaluation of Innovation Center models or to the expansion of such models. If you comment on this information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received by the date and time specified in the **DATES** section of this rule.

VII. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document

VIII. Regulatory Impact Analysis

A. Statement of Need

1. ESRD PPS

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Affordable Care Act (Pub. L. 111–148), established that beginning CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRDB market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule proposes routine updates to the payment rate for renal dialysis services furnished by ESRD facilities and proposed policy changes to the ESRD PPS for CY 2026, including proposed updates to our ESRD PPS wage index, outlier threshold, TPNIES offset, and post-TDAPA add-on payment amounts to reflect the latest available data for Korsuva® and DefenCath®. We are also proposing a new payment adjustment to account for higher non-labor costs in certain non-contiguous States and territories, a proposed change to the timeframe for TDAPA eligibility. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2026 for renal dialysis services furnished to ESRD beneficiaries.

2. AKI

This rule proposes updates to the payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2026 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

3. ESRD QIP

Section 1881(h)(1) of the Act requires CMS to reduce the payments otherwise made to a facility under the ESRD PPS for a year by up to 2 percent if the facility does not satisfy the requirements of the ESRD QIP for that year. This rule proposes updates for the ESRD QIP, which would remove the Facility Commitment to Health Equity reporting measure beginning with PY 2027, remove the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure beginning with PY 2027, as well as update the ICH CAHPS clinical measure by reducing the number of questions on the ICH CAHPS Survey beginning with PY 2028.

4. ETC Model

The ETC Model is a mandatory Medicare payment model tested under the authority of section 1115A of the Act, which authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of such programs.

This rule proposes to terminate the ETC Model due to a lack of statistically significant results. As described in detail in section V.B. of this proposed rule, we believe it is necessary, for the purposes of accuracy, to adopt this change to the ETC Model.

B. Overall Impact Analysis

We have examined the impacts of this rule as required by Executive Order 12866, ''Regulatory Planning and Review''; Executive Order 13132, ''Federalism''; Executive Order 13563, ''Improving Regulation and Regulatory Review''; Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; and distributive impacts). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of Executive Order 12866. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a Regulatory Impact Analysis that presents the costs and benefits of the rulemaking to the best of our ability.

1. ESRD PPS

We estimate that the proposed revisions to the ESRD PPS would result in an increase of approximately $160 million in Medicare payments to ESRD facilities in CY 2026. This includes $160 million associated with the proposed payment rate updates, the updated post-TDAPA add-on payment adjustment amounts, and the continuation of the approved TDAPA as identified in Table 17. In addition, this amount includes, but is not impacted by, any budget neutral proposals for CY 2026 such as the routine updates to the ESRD PPS wage index and the new proposed non-contiguous areas payment adjustment (NAPA). In addition, for public awareness, we estimate that the proposed CY 2026 post-TDAPA add-on payment adjustments would total approximately $27 million, an increase from around $13 million in CY 2025. For CY 2026 we estimate TDAPA payments for drugs and biological products other than phosphate binders would total approximately $70 million, an increase from around $30 million in CY 2025.

2. AKI

We estimate that the proposed updates to the AKI dialysis payment rate would result in an increase of approximately $1 million in Medicare payments to ESRD facilities in CY 2026.

3. ESRD QIP

We estimate that, as a result of our previously finalized policies and the policies we are proposing in this proposed rule, the updated ESRD QIP would result in $22.1 million in estimated payment reductions across all facilities for PY 2027. Additionally, we estimate that, as a result of our previously finalized policies and the policies we are proposing in this proposed rule, the updated ESRD QIP would result in $18.4 million in estimated payment reductions across all facilities for PY 2028.

4. ETC Model

We estimate that terminating the ETC Model on December 31, 2025, would

have a net impact of $1 million in savings to Medicare due to not making performance payment adjustments (PPAs) during PPA8 through PPA10, which correspond with the remaining 18 months of the performance period (January 1, 2026–June 30, 2027).

5. Summary of Impacts

We estimate that the combined impact of the policies proposed in this rule on payments for CY 2026 is $160 million based on the estimates of the updated ESRD PPS and the AKI dialysis payment rates. We estimate the impacts of the ESRD QIP for PY 2027 to be $124.7 million in information collection burden and $22.1 million in estimated payment reductions across all facilities. Additionally, we estimate the impacts of the ESRD QIP for PY 2028 to be $124.7 million in information collection burden and $18.4 million in estimated payment reductions across all facilities.

C. Detailed Economic Analysis

In this section, we discuss the anticipated benefits, costs, and transfers associated with the changes in this proposed rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this proposed rule.

1. Benefits

Under the CY 2026 ESRD PPS and AKI proposed payment, ESRD facilities would continue to receive payment for renal dialysis services furnished to Medicare beneficiaries under a case-mix adjusted PPS. We continue to expect that making prospective Medicare payments to ESRD facilities will enhance the efficiency of the Medicare program. Additionally, we expect that updating the Medicare ESRD PPS base rate and rate for AKI treatments furnished by ESRD facilities by 1.9 percent based on the proposed CY 2026 ESRDB market basket percentage increase of 2.7 percent reduced by the proposed CY 2026 productivity adjustment of 0.8 percentage point would improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services. We estimate that overall payments under the ESRD PPS would increase by 1.9 percent as a result of the proposed policies in this rule.

2. Costs

a. ESRD PPS and AKI

We do not anticipate the provisions of this proposed rule regarding ESRD PPS and AKI rates-setting would create additional cost or burden to ESRD facilities.

b. ESRD QIP

We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for EQRS data validation (previously known as the CROWNWeb validation study) or NHSN data validation. Although we do not anticipate that the proposals regarding ESRD QIP would create additional cost or burden to ESRD facilities for PY 2027 or PY 2028, we intend to update the estimated costs associated with the information collection requirements under the ESRD QIP in the CY 2026 ESRD PPS final rule, with updated estimates of the total number of ESRD facilities, the total number of patients nationally, and a refined estimate of the number of hours needed to complete data entry for EQRS reporting.

3. Transfers

We estimate that the proposed updates to the ESRD PPS and AKI dialysis payment rates would result in a total increase of approximately $160 million in Medicare payments to ESRD facilities in CY 2026, which includes the amount associated with proposed updates to the outlier threshold amounts, the proposed NAPA, and proposed updates to the ESRD wage index. This estimate includes an increase of approximately $1 million in Medicare payments to ESRD facilities in CY 2026 due to the updates to the AKI dialysis payment rate, of which approximately 20 percent is increased beneficiary coinsurance payments. We estimate approximately $130 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately $30 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary coinsurance payments because of this proposed rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this ESRD PPS proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the ESRD PPS proposed rule, we assume that the total number of unique commenters on last year's ESRD PPS proposed rule, which was 191 for the CY 2025 ESRD PPS proposed rule, is equal to the number of individual reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this proposed rule. It is possible that not all commenters reviewed last year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on the CY 2025 ESRD PPS proposed rule. For these reasons we determined that the number of past commenters would be a fair estimate of the number of reviewers of this proposed rule. We used a similar methodology for calculating the regulatory review costs in the CY 2025 ESRD PPS proposed rule. We welcomed any comments on the approach in estimating the number of entities which would review that proposed rule and did not receive any direct responses.

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

Using the BLS OEWS May 2024 National, cross-industry mean hourly wage information for medical and health service managers (SOC 11–9111), we estimate that the cost of reviewing this rule is $132.44 ($66.22 * 2) per hour, including overhead and fringe benefits [31] (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed of 250 words per minute, we estimate that it will take approximately 100 minutes (1.67 hours) for the staff to review half of this proposed rule, which has a total of approximately 50,000 words. For each entity that reviews the rule, the estimated cost is $221.17 (1.67 hours × $132.44). Therefore, we estimate that the total cost of reviewing this regulation is $42,243.47 ($221.17 × 191 commenters).

5. Impact Statement and Table

a. CY 2026 End-Stage Renal Disease Prospective Payment System

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting Medicare payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2025 to estimated payments in CY 2026. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of Medicare payments in CY 2025 and CY 2026 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD

[31] Calculated by multiplying the mean hourly wage for medical and health service managers (SOC 11–9111) by 2 to account for overhead and fringe benefits.

facilities for which we can calculate both current Medicare payments and new Medicare payments.

For this proposed rule, we use CY 2024 data from the Medicare Part A and Part B Common Working Files as of February 14, 2025, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2024 claims to 2025 and 2026 using various updates. The proposed updates to the ESRD PPS base rate are described in section II.B.4. of this proposed rule. Table 17 shows the impact of the estimated CY 2026 ESRD PPS payments compared to estimated ESRD PPS payments to ESRD facilities in CY 2025.

TABLE 17—IMPACTS OF THE PROPOSED CHANGES IN MEDICARE PAYMENTS TO ESRD FACILITIES FOR CY 2026

Facility type	Number of facilities column A	Number of treatments (in millions) column B	Routine outlier update column C (%)	Proposed budget neutral wage index update column D (%)	Proposed budget neutral non-contiguous areas payment adjustment column E (%)	Total percent change (including market basket update) column F
All Facilities	7,582	24.8	0.0	0.0	0.0	1.9
Type:						
Freestanding	7,237	23.9	0.0	0.0	0.0	1.9
Hospital-based	345	0.9	−0.4	−0.2	0.2	1.5
Ownership Type:						
Large dialysis organization	5,839	19.3	0.1	0.1	0.0	2.1
Regional chain	894	3.1	−0.4	−0.2	0.2	0.6
Independent	477	1.5	0.2	−0.3	−0.1	1.7
Hospital-based	345	0.9	−0.4	−0.2	0.2	1.5
Unknown	27	0.0	0.3	−0.6	−0.1	1.6
Geographic Location:						
Rural	1,227	3.4	0.1	−0.1	0.3	2.2
Urban	6,355	21.4	0.0	0.0	0.0	1.8
Census Region:						
East North Central	1,172	3.3	0.0	0.8	−0.1	2.6
East South Central	591	1.5	0.1	1.1	−0.1	3.1
Middle Atlantic	860	3.1	0.0	−0.9	−0.1	0.8
Mountain	429	1.4	0.0	1.0	−0.1	2.9
New England	200	0.9	0.0	−0.4	−0.1	1.4
Pacific[1]	978	4.6	−0.1	−0.7	0.5	1.4
Puerto Rico and Virgin Islands	54	0.1	0.1	0.2	−0.1	2.3
South Atlantic	1,765	5.3	0.0	0.4	−0.1	2.2
West North Central	470	1.4	0.1	0.5	−0.1	2.4
West South Central	1,063	3.2	0.0	−0.3	−0.1	1.5
Facility Size:						
Less than 3,000 treatments	714	0.8	0.0	0.3	0.0	2.2
3,000 to 3,999 treatments	476	0.8	0.0	0.2	−0.1	2.0
4,000 to 4,999 treatments	527	1.0	0.1	0.1	0.0	2.1
5,000 to 9,999 treatments	2,862	7.5	0.0	0.1	−0.1	2.0
10,000 or more treatments	3,003	14.8	0.0	−0.1	0.0	1.8
Percentage of Pediatric Patients:						
Less than 2%	7,488	24.6	0.0	0.0	0.0	1.9
Between 2% and 19%	38	0.1	0.0	0.8	0.5	3.3
Between 20% and 49%	8	0.0	−1.2	0.4	−0.1	0.3
More than 50%	48	0.0	−0.5	0.7	−0.1	2.0

[1] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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

Column C represents the change in payment to each ESRD facility type based on the changes to the outlier FDL and MAP amounts proposed in section II.B.3. We note that this column does not include changes associated with DefenCath® becoming outlier eligible July 1, 2026, at the end of its TDAPA period. These changes are included in column F, which shows the distributional impacts of all changes for CY 2026 ESRD PPS payments and are discussed later in this proposed rule.

Column D represents the effect of the proposed updates to the ESRD PPS wage index for CY 2026, including the continued application of the 5 percent cap on wage index decreases and the continuation of the rural transition policy finalized in the CY 2025 ESRD PPS final rule. This update would be budget neutral, so the total impact of this proposed policy change is 0.0 percent. However, we estimate there would be distributional impacts because of this proposed update. The largest increase would be to ESRD facilities in the East South Central region, which would receive 1.1 percent higher payments because of the updated ESRD PPS wage index. The largest decrease would be for ESRD facilities in the Middle Atlantic region, which would receive 0.9 percent lower payments because of the updated ESRD PPS wage index.

Column E reflects the impact of the proposed NAPA. This proposed adjustment would be applied budget-neutrally, so the total impact is 0.0 percent. However, we estimate there would be distributional impacts because of this proposal. Since all the non-contiguous areas which would receive this payment adjustment are located in the Pacific region, ESRD facilities in the Pacific would receive, on average, 0.5 percent higher payments, and the decrease for other regions due to budget neutrality would be 0.1 percent.

Column F reflects the overall impact of the policies discussed in this proposed rule, including the routine updates to the wage index, outlier thresholds, and post-TDAPA amounts and the newly proposed NAPA described in section II.B.8. of this proposed rule. This column also reflects the proposed ESRD PPS payment rate update for CY 2026 of 1.9 percent, which reflects the proposed ESRDB

market basket percentage increase for CY 2026 of 2.7 percent reduced by the proposed productivity adjustment of 0.8 percentage point. We expect that overall ESRD facilities would experience a 1.9 percent increase in estimated Medicare payments in CY 2026. The categories of types of ESRD facilities in the impact table show impacts ranging from a 3.3 percent increase to a 0.3 percent increase in their CY 2026 estimated Medicare payments. We note that for facility types that have a disproportionately high utilization of DefenCath®, such as regional chains, the overall spending change in column F reflects a notable decrease in CY 2026 payments. This decrease is driven by the change from DefenCath® receiving payment under the TDAPA to inclusion in the post-TDAPA calculation and becoming included in the outlier adjustment in CY 2026.

(2) Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2026, we estimate that the ESRD PPS would have zero impact on these other providers.

(3) Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2026 would be approximately $6.9 billion. This estimate considers a projected decrease in fee-for-service Medicare ESRD beneficiary enrollment of 0.1 percent in CY 2026.

(4) Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 1.9 percent overall increase in the CY 2026 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary coinsurance payments of 1.9 percent in CY 2026, which translates to approximately $30 million.

(5) Alternatives Considered

(a) Non-Contiguous Areas Payment Adjustment

We considered, but did not propose, implementing the NAPA without the 25 percent cap. As discussed in section II.B.8. of this proposed rule, we are proposing this new payment adjustment with a cap of 25 percent on the adjustment factor to mitigate the impact on the ESRD PPS base rate and, therefore, mitigate the impact on payments to ESRD facilities in the contiguous U.S. and in the Caribbean territories of Puerto Rico and the U.S. Virgin Islands. We considered alternative ways to reduce the impact of this proposed payment adjustment on the ESRD PPS base rate, including the exclusion of certain areas from the scope of the adjustment. However, we believe that a cap is the most effective way to provide additional payment to ESRD facilities in these relatively higher non-labor costs, non-contiguous areas without decreasing the ESRD PPS base rate by too large a magnitude.

(b) Change to TDAPA Eligibility Timeframe

We considered alternative timelines for implementing the proposed regulatory change to the TDAPA eligibility criteria which we are proposing in a new paragraph § 413.234(c)(5). One considered alternative was to have the 3-year timeframe for eligibility apply to TDAPA applications received on or after January 1, 2026. We think this would have been a reasonable approach, as we did not identify are any renal dialysis drugs or biological products that would be otherwise eligible for TDAPA but were approved by the FDA between January 1, 2020, and January 1, 2023 (3 years before the effective date of the CY 2026 ESRD PPS final rule). However, as stated in section II.B.7. of this proposed rule, we believe that by making this change effective for TDAPA applications received on or after January 1, 2028, we would allow any drug manufacturers which were operating based on the established TDAPA eligibility requirements sufficient time to prepare for their rollout. Giving manufacturers sufficient time to plan the rollout of a new renal dialysis drug or biological product would help ensure that it is made available to ESRD facilities, and therefore ESRD patients, during the TDAPA period. Since we have not at this time identified any renal dialysis drugs or biological products which were approved by the FDA prior to January 1, 2023, and have not yet applied for TDAPA, we do not believe this later implementation date would lead to any significantly-older drug or biological product applying and receiving the TDAPA.

b. Continuation of Approved Transitional Drug Add-On Payment Adjustments (TDAPA) for New Renal Dialysis Drugs or Biological Products for CY 2026

Eight renal dialysis drugs for which the TDAPA was paid in CY 2025 would continue to be eligible for the TDAPA in CY 2026: DefenCath® (taurolidine and heparin sodium), Vafseo® (vadadustat), and the oral-only phosphate binders sevelamer carbonate, sevelamer hydrochloride, sucroferric oxyhydroxide, lanthanum carbonate, ferric citrate, and calcium acetate. We present our latest estimates in the following paragraphs of TDAPA spending in CY 2026, for public awareness. We are also revising our current estimates of spending for phosphate binders in CY 2025 based on preliminary data from CY 2025 ESRD PPS claims.

(1) DefenCath® (Taurolidine and Heparin Sodium)

On May 9, 2024, CMS Transmittal 12628 [32] implemented the 2-year TDAPA period specified in § 413.234(c)(1) for DefenCath® (taurolidine and heparin sodium). The TDAPA payment period began on July 1, 2024, and would continue through June 30, 2026. As stated previously, TDAPA payment is based on 100 percent of ASP. If ASP is not available, then the TDAPA is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

We based our impact analysis on the average monthly TDAPA payment amount for DefenCath® from the most current 72x claims data from July 2024, when utilization first appeared on the claims, through March 2025. In applying that average to each of the 6 remaining months of the TDAPA payment period in CY 2026, we estimate approximately $40 million in spending of which, 20 percent or approximately $10 million, would be attributed to beneficiary coinsurance amounts.

(2) Vafseo® (Vadadustat)

On November 14, 2024, CMS Transmittal 12962 [33] implemented the 2-year TDAPA period specified in § 413.234(c)(1) for Vafseo® (vadadustat). On December 12, 2024, that transmittal was rescinded and replaced by

[32] CMS Transmittal 12628, dated May 9, 2024, is available at *https://www.cms.gov/files/document/r12628CP.pdf.*

[33] CMS Transmittal 12962, dated November 14, 2024, was available at *https://www.cms.gov/files/document/r12962bp.pdf https://www.cms.gov/files/document/r12628CP.pdf.*

Transmittal 12999.[34] The TDAPA payment period began on January 1, 2025, and will continue through December 31, 2026. As stated previously, TDAPA payment is based on 100 percent of ASP. If ASP is not available, then the TDAPA is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

We based our impact analysis on the average monthly TDAPA payment amount for Vafseo® from the most current 72x claims data from January 2025, when utilization first appeared on the claims, through March 2025. In applying that average to each month in 2026, we estimate approximately $30 million in spending of which, 20 percent or approximately $10 million, would be attributed to beneficiary coinsurance amounts.

(3) Phosphate Binders

On November 14, 2024, CMS Transmittal 12962 [35] implemented the 2-year TDAPA period specified in § 413.234(c)(1) for the following oral-only phosphate binders: sevelamer carbonate, sevelamer hydrochloride, sucroferric oxyhydroxide, lanthanum carbonate, ferric citrate, and calcium acetate. On December 12, 2024, that transmittal was rescinded and replaced by Transmittal 12999.[36] The TDAPA payment period began on January 1, 2025, and will continue through December 31, 2026. As stated previously, TDAPA payment is based on 100 percent of ASP. If ASP is not available, then the TDAPA is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

In the CY 2025 ESRD PPS final rule (89 FR 89197), we estimated that total ESRD PPS spending for phosphate binders would be approximately $870 million in CY 2025. We are revising this estimate for this CY 2026 ESRD PPS proposed rule based our analysis of the most current 72x claims data from January 2025, when utilization first appeared on the claims, through March 2025. In January, we observed that total spending was approximately $14 million, whereas in February and March we observed that total spending was approximately $30 million and $34 million, respectively. Projecting forward using the level of utilization and pricing that we observed in March 2025, we estimate approximately $380 million in spending for phosphate binders in CY 2025, of which 20 percent, or approximately $80 million would be attributed to beneficiary coinsurance amounts. We solicit comments on this estimate.

Similarly, using the most current 72x claims data from March 2025 we have estimated CY 2026 spending using the level of utilization and pricing that we observed in March 2025. In applying that average to each month in 2026, we estimate approximately $410 million in spending of which 20 percent, or approximately $80 million, would be attributed to beneficiary coinsurance amounts.

We intend to further revise the estimates for DefenCath®, Vafseo®, and the phosphate binders for the CY 2026 ESRD PPS final rule based on updated utilization and price information.

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

(1) Effects on ESRD Facilities

To understand the impact of the proposed changes affecting Medicare payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated Medicare payments in CY 2025 to estimated Medicare payments in CY 2026. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the Medicare payment estimates in CY 2025 and CY 2026 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD facilities for which we can calculate both current Medicare payments and new Medicare payments.

For this proposed rule, we used CY 2024 data from the Medicare Part A and Part B Common Working Files as of February 14, 2025, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2024 claims to 2025 and 2026 using various updates. The updates to the AKI dialysis payment amount are described in section III.C. of this proposed rule. Table 18 shows the impact of the estimated CY 2026 Medicare payments for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for renal dialysis services furnished to individuals with AKI in CY 2025.

TABLE 18—IMPACTS OF THE PROPOSED CHANGES IN MEDICARE PAYMENTS FOR RENAL DIALYSIS SERVICES FURNISHED TO INDIVIDUALS WITH AKI FOR CY 2026

Facility type	Number of facilities	Number of treatments (in millions)	Proposed ESRD PPS wage index (%)	Proposed NAPA budget neutrality factor (%)	Total impacts (including market basket update) (%)
	column A	column B	column C	column D	column F
All Facilities	5,022	277.8	0.1	−0.1	1.8
Type:					
Freestanding	4,915	273.5	0.1	−0.1	1.8
Hospital-based	107	4.4	−0.1	−0.1	1.6
Ownership Type:					
Large dialysis organization	4,154	230.0	0.1	−0.1	1.9
Regional chain	568	28.5	0.0	−0.1	1.7
Independent	185	14.7	−0.7	−0.1	1.1
Hospital-based	107	4.4	−0.1	−0.1	1.6
Unknown	8	0.3	0.1	−0.1	1.9
Geographic Location:					
Rural	823	44.6	0.0	−0.1	1.7

[34] CMS Transmittal 12999 dated December 12, 2024, available at *https://www.cms.gov/files/document/r12999bp.pdf.*

[35] CMS Transmittal 12962, dated November 14, 2024, was available at *https://www.cms.gov/files/document/r12962bp.pdf https://www.cms.gov/files/document/r12628CP.pdf.*

[36] CMS Transmittal 12999 dated December 12, 2024, available at *https://www.cms.gov/files/document/r12999bp.pdf.*

TABLE 18—IMPACTS OF THE PROPOSED CHANGES IN MEDICARE PAYMENTS FOR RENAL DIALYSIS SERVICES FURNISHED TO INDIVIDUALS WITH AKI FOR CY 2026—Continued

Facility type	Number of facilities	Number of treatments (in millions)	Proposed ESRD PPS wage index (%)	Proposed NAPA budget neutrality factor (%)	Total impacts (including market basket update) (%)
	column A	column B	column C	column D	column F
Urban	4,199	233.2	0.1	−0.1	1.8
Census Region:					
East North Central	824	44.7	0.7	−0.1	2.4
East South Central	374	16.7	0.9	−0.1	2.7
Middle Atlantic	544	32.3	−0.8	−0.1	0.9
Mountain	313	21.6	1.3	−0.1	3.1
New England	147	6.9	−0.4	−0.1	1.3
Pacific [1]	663	48.9	−0.7	−0.1	1.0
Puerto Rico and Virgin Islands	2	0.0	0.9	−0.1	2.6
South Atlantic	1,181	64.7	0.4	−0.1	2.2
West North Central	308	12.2	0.5	−0.1	2.2
West South Central	666	29.8	−0.3	−0.1	1.4
Facility Size:					
Less than 3,000 treatments	281	10.7	0.3	−0.1	2.1
3,000 to 3,999 treatments	267	11.2	0.2	−0.1	2.0
4,000 to 4,999 treatments	313	14.1	0.1	−0.1	1.8
5,000 to 9,999 treatments	1,960	99.2	0.1	−0.1	1.9
10,000 or more treatments	2,201	142.7	0.0	−0.1	1.8
Percentage of Pediatric Patients:					
Less than 2%	5,007	277.3	0.1	−0.1	1.8
Between 2% and 19%	14	0.5	0.3	−0.1	2.0
Between 20% and 49%	1	0.0	0.3	−0.1	2.1
More than 50%	0	0.0	0.0	0.0	0.0

[1] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

Column A of the impact table indicates the number of ESRD facilities for each impact category, and column B indicates the number of AKI dialysis treatments (in thousands). Column C shows the effect of the proposed CY 2026 wage index described in section II.B.2. of this proposed rule. Column D shows the impact of the proposed NAPA budget neutrality factor, which we are applying to the proposed ESRD PPS base rate. To be clear, we are not proposing the NAPA apply to beneficiaries with AKI, so this column only reflects the impact of the budget neutrality factor associated with that policy.

Column F shows the overall impact of all policies discussed in this proposed rule, including the 1.9 percent increase to the ESRD PPS base rate, which reflects the proposed ESRDB market basket percentage increase for CY 2026 of 2.7 percent reduced by the proposed productivity adjustment of 0.8 percentage point. We expect that overall ESRD facilities will experience a 1.8 percent increase in estimated Medicare payments in CY 2026 for treatment of AKI beneficiaries. The categories of types of ESRD facilities in the impact table show impacts ranging from an increase of 0.9 percent for the Mid-Atlantic region to an increase of 3.1 percent for the Mountain region in CY 2026 estimated Medicare payments for renal dialysis services provided by ESRD facilities to individuals with AKI.

(2) Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are proposing to update the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The patient and his or her physician make the decision about where the renal dialysis services are furnished. Therefore, this change would have zero impact on other Medicare providers.

(3) Effects on the Medicare Program

We estimate approximately $80 million would be paid to ESRD facilities in CY 2026 because of patients with AKI receiving renal dialysis services in an ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

(4) Effects on Medicare Beneficiaries

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

(5) Alternatives Considered

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

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

d. ESRD QIP

(1) Effects of the PY 2027 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to promote improvements in the quality of ESRD dialysis facility services provided to beneficiaries. The general methodology that we use to calculate a facility's TPS is described in our regulations at § 413.178(e).

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2027 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2027, consistent with our regulations at § 413.177.

For the PY 2027 ESRD QIP, we estimate that, of the 7,695 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 41.8 percent or 3,214 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2027. Among an estimated 3,214 facilities that would receive a payment reduction, approximately 60 percent or 1,926 facilities would receive the smallest payment reduction of 0.5 percent. Based on our proposals, the total estimated payment reductions for all the 3,214 facilities expected to receive a payment reduction in PY 2027 would be approximately $22,177,163. Facilities that do not receive a TPS do not receive a payment reduction.

Table 19 shows the updated overall estimated distribution of payment reductions resulting from the PY 2027 ESRD QIP.

TABLE 19—ESTIMATED DISTRIBUTION OF PY 2027 ESRD QIP PAYMENT REDUCTIONS

Payment reduction	Number of facilities	Percent of facilities *
0.0%	4,248	56.9
0.5%	1,926	25.8
1.0%	897	12.0
1.5%	262	3.5
2.0%	129	1.7

* 233 facilities not scored due to insufficient data.

To estimate whether a facility would receive a payment reduction for PY 2027, we scored each facility on achievement and improvement on several clinical measures for which there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 20) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 20.

TABLE 20—DATA USED TO ESTIMATE PY 2027 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
SRR	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
SHR	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
PPPW	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Kt/V Dialysis Adequacy Measure Topic:		
Adult HD Kt/V	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Pediatric HD Kt/V	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Adult PD Kt/V	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Pediatric PD Kt/V	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
VAT:		
% Catheter	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
STrR	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
NHSN BSI	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Clinical Depression	Jan 2022–Dec 2022	Jan 2023–Dec 2023.

For all measures except the SHR clinical measure, the SRR clinical measure, the STrR measure, and the ICH CAHPS measure, measures with less than 11 eligible patients for a facility were not included in that facility's TPS. For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included in the facility's TPS. For the STrR clinical measure, facilities were required to have at least 10 patient-years at risk to be included in the facility's TPS. For the ICH CAHPS measure, facilities were required to have at least 30 survey-eligible patients to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table consistent with the proposed policies outlined in section IV.B. of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2023. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2027 for each facility resulting from this proposed rule, we multiplied the total Medicare payments

to the facility during the 1-year period between January 2023 and December 2023 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 21 shows the estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2027. The table also details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2027 ESRD QIP, the actual impact of the PY 2027 ESRD QIP may vary significantly from the values provided here.

TABLE 21—ESTIMATED IMPACT OF ESRD QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2027

	Number of facilities	Number of treatments 2023 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
All Facilities	7,695	27.0	7,462	3,214	−0.33
Facility Type:					
Freestanding	7,348	26.0	7,135	3,043	−0.32
Hospital-based	347	1.0	327	171	−0.50
Ownership Type:					
Large Dialysis	5,942	21.1	5,792	2,293	−0.27
Regional Chain	908	3.3	881	404	−0.38
Independent	461	1.6	444	341	−0.94
Hospital-based (non-chain)	347	1.0	327	171	−0.50
Unknown	37	0.0	18	5	−0.41
Facility Size:					
Large Entities	6,850	24.4	6,673	2,697	−0.28
Small Entities [1]	808	2.6	771	512	−0.75
Unknown	37	0.0	18	5	−0.41
Rural Status:					
(1) Yes	1,245	3.8	1,209	449	−0.28
(2) No	6,450	23.2	6,253	2,765	−0.34
Census Region:					
Northeast	1,069	4.4	1,033	450	−0.35
Midwest	1,663	5.1	1,620	703	−0.33
South	3,490	11.1	3,374	1,513	−0.35
West	1,408	6.3	1,371	501	−0.27
US Territories [2]	65	0.2	64	47	−0.51
Census Division:					
Unknown	11	0.1	11	9	−0.68
East North Central	1,188	3.6	1,155	531	−0.36
East South Central	602	1.7	582	229	−0.27
Middle Atlantic	870	3.4	836	379	−0.38
Mountain	438	1.5	425	153	−0.26
New England	199	1.0	197	71	−0.26
Pacific	970	4.7	946	348	−0.27
South Atlantic	1,793	5.9	1,737	799	−0.37
West North Central	475	1.5	465	172	−0.28
West South Central	1,095	3.5	1,055	485	−0.35
US Territories [2]	54	0.1	53	38	−0.48
Facility Size (# of total treatments):					
Less than 4,000 treatments	1,207	1.5	1,071	405	−0.37
4,000–9,999 treatments	3,461	9.2	3,377	1,267	−0.28
Over 10,000 treatments	3,027	16.3	3,014	1,542	−0.38

[1] Small Entities include hospital-based and satellite facilities, and non-chain facilities based on EQRS.
[2] Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

(2) Effects of the PY 2028 ESRD QIP on ESRD Facilities

For the PY 2028 ESRD QIP, we estimate that, of the 7,695 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 35.4 percent or 2,725 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2028. Among an estimated 2,725 facilities that would receive a payment reduction, approximately 62 percent or 1,694 facilities would receive the smallest payment reduction of 0.5 percent. Based on our proposals, the total estimated payment reductions for all the 2,725 facilities expected to receive a payment reduction in PY 2028 would be approximately $18,456,799. Facilities that do not receive a TPS do not receive a payment reduction.

Table 22 shows the updated overall estimated distribution of payment reductions resulting from the PY 2028 ESRD QIP.

TABLE 22—ESTIMATED DISTRIBUTION OF PY 2028 ESRD QIP PAYMENT REDUCTIONS

Payment reduction	Number of facilities	Percent of facilities *
0.0%	4,729	63.4
0.5%	1,694	22.7
1.0%	756	10.1
1.5%	185	2.5

TABLE 22—ESTIMATED DISTRIBUTION OF PY 2028 ESRD QIP PAYMENT REDUCTIONS—Continued

Payment reduction	Number of facilities	Percent of facilities *
2.0%	90	1.2

*241 facilities not scored due to insufficient data.

To estimate whether a facility would receive a payment reduction for PY 2028, we scored each facility on achievement and improvement on several clinical measures for which there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 23) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 23.

TABLE 23—DATA USED TO ESTIMATE PY 2028 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Not available	Jan 2023–Dec 2023.
SRR	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
SHR	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
PPPW	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Kt/V Dialysis Adequacy Measure Topic:		
Adult HD Kt/V	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Pediatric HD Kt/V	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Adult PD Kt/V	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Pediatric PD Kt/V	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
VAT:		
% Catheter	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
STrR	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
NHSN BSI	Jan 2022–Dec 2022	Jan 2023–Dec 2023.
Clinical Depression	Jan 2022–Dec 2022	Jan 2023–Dec 2023.

For all measures except the SHR clinical measure, the SRR clinical measure, the STrR measure, and the ICH CAHPS measure, measures with less than 11 eligible patients for a facility were not included in that facility's TPS. For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included in the facility's TPS. For the STrR clinical measure, facilities were required to have at least 10 patient-years at risk to be included in the facility's TPS. For the ICH CAHPS measure, facilities were required to have at least 30 survey-eligible patients to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table consistent with the proposed policies outlined in section IV.C. of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2023. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2028 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2023 and December 2023 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 24 shows the estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2028. The table also details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2028 ESRD QIP, the actual impact of the PY 2028 ESRD QIP may vary significantly from the values provided here.

TABLE 24—ESTIMATED IMPACT OF ESRD QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2028

	Number of facilities	Number of treatments 2023 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
All Facilities	7,695	27.0	7,454	2,725	−0.27
Facility Type:					
Freestanding	7,348	26.0	7,133	2,583	−0.27
Hospital-based	347	1.0	321	142	−0.38
Ownership Type:					
Large Dialysis	5,942	21.1	5,792	1,932	−0.22
Regional Chain	908	3.3	881	337	−0.31
Independent	461	1.6	442	309	−0.80
Hospital-based (non-chain)	347	1.0	321	142	−0.38
Unknown	37	0.0	18	5	−0.38
Facility Size:					

TABLE 24—ESTIMATED IMPACT OF ESRD QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2028—Continued

	Number of facilities	Number of treatments 2023 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
Large Entities	6,850	24.4	6,673	2,269	−0.23
Small Entities [1]	808	2.6	763	451	−0.62
Unknown	37	0.0	18	5	−0.38
Rural Status:					
(1) Yes	1,245	3.8	1,207	362	−0.22
(2) No	6,450	23.2	6,247	2,363	−0.28
Census Region:					
Northeast	1,069	4.4	1,030	385	−0.30
Midwest	1,663	5.1	1,617	586	−0.27
South	3,490	11.1	3,373	1,309	−0.29
West	1,408	6.3	1,370	405	−0.21
U.S. Territories [2]	65	0.2	64	40	−0.41
Census Division:					
Unknown	11	0.1	11	7	−0.54
East North Central	1,188	3.6	1,155	446	−0.29
East South Central	602	1.7	582	177	−0.21
Middle Atlantic	870	3.4	834	327	−0.32
Mountain	438	1.5	425	126	−0.21
New England	199	1.0	196	58	−0.20
Pacific	970	4.7	945	279	−0.21
South Atlantic	1,793	5.9	1,736	706	−0.31
West North Central	475	1.5	462	140	−0.20
West South Central	1,095	3.5	1,055	426	−0.29
US Territories [2]	54	0.1	53	33	−0.38
Facility Size (# of total treatments):					
Less than 4,000 treatments	1,207	1.5	1,063	327	−0.28
4,000–9,999 treatments	3,461	9.2	3,377	1,055	−0.22
Over 10,000 treatments	3,027	16.3	3,014	1,343	−0.32

[1] Small Entities include hospital-based and satellite facilities, and non-chain facilities based on EQRS.
[2] Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

(3) Effects on the Medicare Program

For PY 2027, we estimate that the ESRD QIP would contribute approximately $22,177,163 in Medicare savings. For PY 2028, we estimate that the ESRD QIP would contribute approximately $18,456,799 in Medicare savings. For comparison, Table 25 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2028.

TABLE 25—ESTIMATED ESRD QIP AGGREGATE PAYMENT REDUCTIONS FOR PAYMENT YEARS 2018 THROUGH 2028

Payment year	Estimated payment reductions
PY 2028	$18,456,799.
PY 2027	$22,177,163.
PY 2026	$15,990,524 (88 FR 76500).
PY 2025	$32,457,693 (87 FR 67297).
PY 2024	$17,104,031 (86 FR 62011).
PY 2023	$5,548,653 (87 FR 67297).
PY 2022	$0 [37] (86 FR 62011).
PY 2021	$32,196,724 (83 FR 57062).
PY 2020	$31,581,441 (81 FR 77960).
PY 2019	$15,470,309 (80 FR 69074).
PY 2018	$11,576,214 (79 FR 66257).

(4) Effects on Medicare Beneficiaries

The ESRD QIP is applicable to ESRD facilities. Since the Program's inception, there is evidence of improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. We continue to monitor and evaluate trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more by examining these impacts through the analysis of available data from our existing measures.

(5) Alternatives Considered

In section IV.C.2. of this proposed rule, we are proposing to update the ICH CAHPS clinical measure by removing questions from the ICH CAHPS Survey beginning with PY 2028. We considered not proposing this change. However, we concluded that reducing the length of the ICH CAHPS Survey would help to mitigate ongoing concerns regarding patient burden due to survey fatigue and lead to increased survey response rates, thereby more comprehensively capturing the experience of in-center hemodialysis patients through the ICH CAHPS clinical measure.

e. ETC Model

(1) Overview

The ETC Model is a mandatory payment model designed to test payment adjustments to certain dialysis and dialysis-related payments, as discussed in the Specialty Care Models final rule (85 FR 61114), the CY 2022 ESRD PPS final rule (86 FR 61874), the CY 2023 ESRD PPS final rule (87 FR 67136), and the CY 2024 ESRD PPS final rule (88 FR 76344) for ESRD facilities and for Managing Clinicians for claims

with dates of service from January 1, 2021 to June 30, 2027. The requirements for the ETC Model are set forth in 42 CFR part 512, subpart C. For the results of the detailed economic analysis of the ETC Model and a description of the methodology used to perform the analysis, see the Specialty Care Models final rule (85 FR 61114).

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of the ETC Model relative to baseline expenditures that use actual data for MYs 1–3 and updated methodology. Results were generated from an average of 400 simulations. The datasets and risk-adjustment methodologies for the ETC Model were developed by the CMS Office of the Actuary (OACT).

Table 26 is provided to isolate the total impact of terminating the ETC Model on December 31, 2025 by displaying the projected impact to Medicare for the PYs that will no longer be included in the ETC Model. Negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase in Medicare spending. We estimate that the Medicare program would increase program spending by a net total of $5 million from the PPA between January 1, 2026, and June 30, 2027, less $6 million from training and education expenditures that will not occur due to the model ending. Therefore, the net impact to Medicare spending from terminating the model early is estimated to be $1 million in savings during the final 18 months of the performance period (January 1, 2026–June 30, 2027).

(3) Medicare Estimate—Impact of Model Termination Effective December 31, 2025

TABLE 26—ESTIMATES OF IMPACT ON MEDICARE PROGRAM SPENDING (ROUNDED $M) FOR ENDING THE ESRD TREATMENT CHOICES (ETC) MODEL ON DECEMBER 31, 2025

[Estimates represent the reversal of impacts otherwise projected if the model were to finish originally-specified testing period]

	2026	2027	1.5 Year total *
Net Impact to Medicare Spending	−2	1	−1
Overall PPA Net & HDPA	1	4	5
Clinician PPA Downward Adjustment	4	3	7
Clinician PPA Upward Adjustment	−5	−2	−7
Clinician PPA Net	0	0	0
Clinician HDPA			
Facility Downward Adjustment	46	27	73
Facility Upward Adjustment	−45	−23	−68
Facility PPA Net	1	4	5
Facility HDPA			
Total PPA Downward Adjustment	50	30	80
Total PPA Upward Adjustment	−50	−25	−75
Total PPA Net	1	4	5
Total HDPA			
KDE Benefit Costs	−1	−1	−2
HD Training Costs	−2	−2	−4

* Totals may not sum due to rounding and from beneficiaries that have dialysis treatment spanning multiple years. Negative spending reflects a reduction in Medicare spending. The kidney disease patient education services benefit costs are less than $1M each year but are rounded up to $1M to show what years they apply to.

The ETC Model Second Annual Evaluation Report (2024) [38] examined the impact of the ETC Model through 2022 and found that during the first 2 calendar years of the model, there was no evidence of an impact of the ETC Model on the use of home dialysis modalities, transplant waitlisting, and living donor transplantation, which are the direct targets of the model's payment adjustments. Therefore, the impact of terminating the ETC Model early is simply the negation of the projected performance and other payments for PYs 2026 and 2027 of the model, which are very small on net for that period.

Table 26 uses the assumptions for the performance payment adjustments, kidney disease patient education (KDE) services, and HD training add-ons that were used in the CY 2025 ESRD PPS final rule (89 FR 89209). There is no impact reported for the Home Dialysis Payment Adjustment (HDPA) because the HDPA applied only to claims with claim service dates beginning January 1, 2021 and ending December 31, 2023. In contrast to what was reported in CY 2025 ESRD PPS final rule (89 FR 89209), Table 26 uses actual HDPA counts and actual PPAs for MYs 1–3 (which align with PYs 2022 and 2023). Partial estimates based on actual data were available for PY 2024 and were incorporated into the model for that year. The ETC model's projections were used for PYs 2025–2027. If we had not updated our baseline model projection for actual experience, then the net impact to Medicare spending would not have resulted in savings to Medicare.

Table 26 also includes two updates to the methodology used to generate the estimate. In the CY 2025 ESRD PPS final rule (89 FR 89209) estimates, we interpreted the *percentage* improvement in the ETC participant's MY performance on the home dialysis rate and transplant rate relative to the Benchmark Year rate to be a ''percentage point improvement'' rather than a relative percentage increase. In Table 26, we revised the baseline model's improvement scoring methodology to award improvement points based on relative improvement (this was the original intent of the ETC Model's design). For example, a facility with benchmark home dialysis rate of 5 percent and MY home dialysis rate of 6 percent is now measured to have 20 percent improvement in the home dialysis rate (relative improvement) instead of only 1 percentage point of improvement. No additional changes were made to the improvement thresholds or points awarded used in the improvement scoring methodology. A minor update was also made to the rolling benchmark used in the home dialysis rate calculation to reflect the fact that hospital referral regions not randomized to participate in the ETC

model saw increases in their home dialysis rate during the initial MYs of the model. We modified the rolling benchmark from assuming that hospital referral regions not randomized to participate in the ETC model would have a static home dialysis rate to restricting the geographies included in the model to only be those hospital referral regions that were actually randomized into the model. The values estimated by the model for PYs 2021–2024 were validated against actual reported spending in the HDPA and PPA categories.

(4) Effects on the Home Dialysis Rate, the Transplant Rate, and Kidney Transplantation

The change proposed in this rule is not expected to impact the findings reported for the effects of the ETC Model on the home dialysis rate or the transplant rate described in the Specialty Care Models final rule (85 FR 61355) and the CY 2022 ESRD PPS final rule (86 FR 62017). The ETC Model Second Annual Evaluation Report examined the impact of the model through 2022 and found that during the first 2 calendar years of the model, there was no evidence of an impact of the ETC Model on the use of home dialysis modalities, transplant waitlisting, and living donor transplantation. Therefore, terminating the model early is not expected to have an impact on these trends.

(5) Effects on Kidney Disease Patient Education Services and HD Training Add-Ons

The change in this proposed rule will end the kidney disease patient education services and HD training add-ons described in the Specialty Care Models final rule (85 FR 61355) and the CY 2022 ESRD PPS final rule (86 FR 62017) for the final two PYs of the model.

(6) Effects on Medicare Beneficiaries

The proposal to terminate the model early is not expected to impact the findings reported for the effects of ETC Model on Medicare beneficiaries. Further details on the impact of the ETC Model on ESRD Beneficiaries may be found in the Specialty Care Models final rule (85 FR 61357) and the CY 2022 ESRD PPS final rule (86 FR 61874).

(7) Alternatives Considered

The Specialty Care Models final rule (85 FR 61114), the CY 2022 ESRD PPS final rule (86 FR 61874), the CY 2023 ESRD PPS final rule (87 FR 67136), the CY 2024 ESRD PPS final rule (88 FR 76344), CY 2025 ESRD PPS final rule (89 FR 89084), and the proposed policy herein address a model specific to ESRD. These rules provide descriptions of the requirements that we waive, identify the performance metrics and payment adjustments to be tested, and presents rationales for our changes, and where relevant, alternatives considered. For context related to alternatives previously considered when establishing and modifying the ETC Model we refer readers to section V.B. of this proposed rule and to the previous citations.

D. Accounting Statement

Consistent with OMB Circular A–4 (available at *https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 27 showing the classification of the impact associated with the provisions of this proposed rule.

TABLE 27—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS

Category	Transfers
ESRD PPS and AKI (CY 2026)	
Annualized Monetized Transfers	$130 million.
Bearers of Transfer Gain	Medicare ESRD Facilities.
Increased Beneficiary Co-insurance Payments	$30 million.
Bearers of Transfer Gain	Medicare ESRD Facilities.
ESRD QIP for PY 2027	
Annualized Monetized Transfers	$22.1 million.
Bearers of Transfer Gain	Federal Government.
ESRD QIP for PY 2028	
Annualized Monetized Transfers	$18.4 million.
Bearers of Transfer Gain	Federal Government.
ETC Model for PYs 2026–2027	
Annual Monetized Transfers	$1 million.
Bearers of Transfer Gain	Federal Government.

E. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and States are not included in the definition of a small entity. Therefore, the number of small entities estimated in this RFA analysis includes the number of ESRD facilities that are either considered small businesses or nonprofit organizations.

According to the Small Business Administration's (SBA) size standards, an ESRD facility is classified as a small business if it has average revenues of less than $47 million across the past 5 years.[39] For the purposes of this analysis, we exclude the ESRD facilities that are owned and operated by large dialysis organizations (LDOs) and

[39] *http://www.sba.gov/content/small-business-size-standards.*

regional chains, which would have total revenues of more than $6.5 billion in any year when the total revenues for all locations are combined for each business (LDO or regional chain), and are not, therefore, considered small businesses. Because we lack data on individual ESRD facilities' receipts, we cannot determine the number of small proprietary ESRD facilities or the proportion of ESRD facilities' revenue derived from Medicare FFS payments. Therefore, we assume that all ESRD facilities that are not owned by LDOs or regional chains are considered small businesses. Accordingly, we consider the 477 ESRD facilities that are independent and 345 ESRD facilities that are hospital-based, as shown in the ownership category in Table 17, to be small businesses. These ESRD facilities represent approximately 11 percent of all ESRD facilities in our data set.

Additionally, we identified in our analytic file that there are 775 ESRD facilities that are considered nonprofit organizations, which is approximately 10 percent of all ESRD facilities in our data set. In total, accounting for the 362 nonprofit ESRD facilities that are also considered small businesses, there are 1,235 ESRD facilities that are either small businesses or nonprofit organizations, which is approximately 16 percent of all ESRD facilities in our data set.

As its measure of significant economic impact on a substantial number of small entities, HHS's practice in interpreting the RFA is to consider effects economically ''significant'' on a ''substantial'' number of small entities only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. As shown in Table 17, we estimate that the overall revenue impact of this proposed rule on all ESRD facilities is a positive increase to Medicare FFS payments by approximately 1.9 percent. For the ESRD PPS updates proposed in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of ESRD facility) is estimated to receive a 1.5 percent increase in Medicare FFS payments for CY 2026. An independent facility (as defined by ownership type) is likewise estimated to receive a 1.7 percent increase in Medicare FFS payments for CY 2026. Although not displayed in Table 17, we have found that among the 822 ESRD facilities that are small businesses, those furnishing fewer than 3,000 treatments per year are estimated to receive a 2.0 percent increase in Medicare FFS payments, and those furnishing 3,000 or more treatments per year are estimated to receive a 1.6 percent increase in Medicare FFS payments. Additionally, among the 775 nonprofit ESRD facilities, those furnishing fewer than 3,000 treatments per year are estimated to receive a 1.6 percent increase in Medicare FFS payments, and those furnishing 3,000 or more treatments per year are estimated to receive a 1.1 percent increase in Medicare FFS payments.

For AKI dialysis, we are unable to estimate whether patients would go to certain types of ESRD facilities, however, we have estimated there is a potential for $80 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities that are small businesses or nonprofits.

Based on the estimated Medicare payment impacts described previously, we believe that the change in revenue threshold will be reached by some categories of small entities as a result of the policies in this proposed rule. This analysis is based on the assumptions described earlier in this section of this proposed rule as well as the detailed impact analysis discussed in section VIII.C. of this proposed rule, which includes a discussion of data sources, general assumptions, and alternatives considered.

For the ESRD QIP, we estimate that of the 3,214 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2027 ESRD QIP, 512 are ESRD small entity facilities. We present these findings in Table 19 (''Estimated Distribution of PY 2027 ESRD QIP Payment Reductions'') and Table 21 (''Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2027''). Table 19 shows the overall estimated distribution of payment reductions resulting from the PY 2027 ESRD QIP. Table 21 shows the estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2027, and also details the distribution of ESRD facilities by size, geography, and facility type. We also estimate that of the 2,725 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2028 ESRD QIP, 451 are ESRD small entity facilities. We present these findings in Table 22 (''Estimated Distribution of PY 2028 ESRD QIP Payment Reductions'') and Table 24 (''Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2028''). Table 22 shows the overall estimated distribution of payment reductions resulting from the PY 2028 ESRD QIP. Table 24 shows the estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2028, and also details the distribution of ESRD facilities by size, geography, and facility type.

Regarding the ETC Model, we estimate $1 million in savings to Medicare from proposing to terminate the Model effective December 31, 2025.

Therefore, the Secretary has determined that this proposed rule will have a significant economic impact, reflecting a positive revenue increase, on a substantial number of small entities. This RFA section along with the RIA constitutes our proposed regulatory flexibility analysis.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule would have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 111 rural hospital-based ESRD facilities, we do not know how many of them are hospital-based with fewer than 100 beds. However, overall, the 111 rural hospital-based ESRD facilities would experience an estimated 2.2 percent increase in payments. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately $187 million. We do not interpret Medicare payment rules as being unfunded mandates but simply as conditions for the receipt of payments from the Federal Government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, State, local, or Tribal. Therefore, this proposed rule does not mandate any requirements for State, local, or Tribal governments, or for the private sector.

G. Federalism

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

H. Executive Order 14192, ''Unleashing Prosperity Through Deregulation''

Executive Order 14192, entitled ''Unleashing Prosperity Through Deregulation'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.'' The updates proposed for the ESRD QIP do not create new regulations, nor do the proposals create new incremental costs. We estimate that these proposals, if finalized, would generate approximately $15.4 million in annualized cost savings relative to PY 2027 based on currently available facility and patient data. Therefore, the updates proposed for the ESRD QIP would be considered an Executive Order 14192 deregulatory action if finalized as proposed.

IX. Files Available to the Public

The Addenda for the annual ESRD PPS proposed and final rule will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet and will be posted on CMS's website under the regulation number, CMS–1830–P, at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices*. In addition to the Addenda, limited data set files (LDS) are available for purchase at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile*. Readers who experience any problems accessing the Addenda or LDS files, should contact CMS by sending an email to CMS at the following mailbox: *ESRDPayment@cms.hhs.gov*.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 27, 2025.

List of Subjects

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, Intergovernmental relations, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 2. Section 413.230 is amended by revising paragraph (a) to read as follows:

§ 413.230 Determining the per treatment payment amount.

* * * * *

(a) The per treatment base rate established in § 413.220, adjusted for wages as described in § 413.231, and adjusted for facility-level and patient-level characteristics described in §§ 413.232, 413.233, and 413.235 of this part;

* * * * *

■ 3. Section 413.233 is revised to read as follows:

§ 413.233 Additional facility-level adjustments.

(a) CMS adjusts the base rate for facilities in rural areas, as defined in § 413.231(b)(2).

(b) CMS adjusts the non-labor-related portion of the base rate for facilities in Alaska, Hawaii, Guam, American Samoa, and the Northern Mariana Islands.

■ 4. Section 413.234 is amended—

■ a. In paragraph (a), by revising the definition of ''New renal dialysis drug or biological product'';

■ b. By revising paragraphs (b)(1)(ii) and (b)(2)(ii);

■ c. By adding paragraph (c)(5); and

■ d. By revising paragraph (g)(5).

The revisions and additions read as follows:

§ 413.234 Drug designation process.

(a) * * *

New renal dialysis drug or biological product. An injectable, intravenous, oral or other form or route of administration drug or biological product that is used to treat or manage a condition(s) associated with ESRD. It must be approved by the Food and Drug Administration (FDA) on or after January 1, 2020, under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, be commercially available, and be designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs are excluded until January 1, 2025.

* * * * *

(b) * * *

(1) * * *

(ii) If the new renal dialysis drug or biological product meets the requirements in paragraph (c)(5) of this section and is not excluded under paragraph (e) of this section, the new drug or biological product is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section.

* * * * *

(2) * * *

(ii) If the new renal dialysis drug or biological product meets the requirements in paragraph (c)(5) of this section, the new renal dialysis drug or biological product is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(2) of this section; and

* * * * *

(c) * * *

(5) CMS provides for a transitional drug add-on payment adjustment (as specified in paragraphs (c)(1) and (2) of this section) to an ESRD facility for furnishing a new renal dialysis drug or biological product if the new drug or biological product meets the following requirements:

(i) Has a HCPCS application submitted in accordance with the official Level II HCPCS coding procedures; and

(ii) Has submitted a complete application for the transitional drug add-on payment adjustment to CMS prior to January 1, 2028, or within three years of FDA approval under section 505 of the Federal Food, Drug, and

Cosmetic Act or section 351 of the Public Health Service Act.

* * * * *

(g) * * *

(5) The post-TDAPA add-on payment adjustment that is applied to an ESRD PPS claim is adjusted by any applicable patient-level case-mix adjustments under § 413.235.

* * * * *

PART 512—STANDARD PROVISIONS FOR MANDATORY INNOVATION CENTER MODELS AND SPECIFIC PROVISIONS FOR THE RADIATION ONCOLOGY MODEL AND THE END-STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 5. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315(a), and 1395hh.

■ 6. Section 512.320 is amended by revising to read as follows:

§ 512.320 Duration.

CMS will apply the payment adjustments described in this subpart under the ETC Model to claims with claim service dates beginning on or after January 1, 2021, and ending on or before December 31, 2025.

■ 7. Section 512.355 is amended by revising paragraphs (a) and (b); and table 1 to paragraph (c) to read as follows:

§ 512.355 Schedule of performance assessment and performance payment adjustment.

(a) *Measurement Years.* CMS assesses ETC Participant performance on the home dialysis rate and the transplant rate during each of the MYs. The first MY begins on January 1, 2021, and the final MY ends on December 31, 2024.

(b) *Performance Payment Adjustment Period.* CMS adjusts payments for ETC Participants by the PPA during each of the PPA Periods, each of which corresponds to a MY. The first PPA Period begins on July 1, 2022, and the final PPA Period ends on December 31, 2025.

(c) * * *

TABLE 1 TO PARAGRAPH (c)—ETC MODEL SCHEDULE OF MEASUREMENT YEARS AND PPA PERIODS

Measurement year (MY)	Performance payment adjustment (PPA) period
MY 1—1/1/2021 through 12/31/2021	PPA Period 1—7/1/2022 through 12/31/2022.
MY 2—7/1/2021 through 6/30/2022	PPA Period 2—1/1/2023 through 6/30/2023.
MY 3—1/12022 through 12/31/2022	PPA Period 3—7/1/2023 through 12/31/2023.
MY 4—7/1/2022 through 6/30/2023	PPA Period 4—1/1/2024 through 6/30/2024.
MY 5—1/1/2023 through 12/31/2023	PPA Period 5—7/1/2024 through 12/31/2024.
MY 6—7/1/2023 through 6/30/2024	PPA Period 6—1/1/2025 through 6/30/2025.
MY 7—1/1/2024 through 12/31/2024	PPA Period 7—7/1/2025 through 12/31/2025.

■ 8. Section 512.360 is amended by revising paragraph (c)(2)(iii) introductory text to read as follows:

§ 512.360 Beneficiary population and attribution.

* * * * *

(c) * * *

(2) * * *

(iii) For MY3 through MY7, a Pre-emptive LDT Beneficiary who is not excluded based on the criteria in paragraph (b) of this section is attributed to the Managing Clinician who submitted the most claims for services furnished to the beneficiary in the 365 days preceding the date in which the beneficiary received the transplant.

* * * * *

■ 9. Section 512.365 is amended by revising paragraphs (b)(1)(ii) introductory text, (b)(2)(ii) introductory text, (c)(1)(i)(A) introductory text, (c)(1)(ii)(A), (c)(2)(i)(A), (c)(2)(ii)(A)(*1*) and (*2*) to read as follows:

§ 512.365 Performance assessment.

* * * * *

(b) * * *

(1) * * *

(ii) For MY3 through MY7, the numerator is the total number of home dialysis treatment beneficiary years, plus one half the total number of self dialysis treatment beneficiary years, plus one half the total number of nocturnal in center dialysis beneficiary years for attributed ESRD Beneficiaries during the MY.

* * * * *

(2) * * *

(ii) For MY3 through MY7, the numerator is the total number of home dialysis treatment beneficiary years, plus one half the total number of self dialysis treatment beneficiary years, plus one half the total number of nocturnal in center dialysis beneficiary years for attributed ESRD Beneficiaries during the MY.

* * * * *

(c) * * *

(1) * * *

(i) * * *

(A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY3 through MY7, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY.

* * * * *

(ii) * * *

(A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY3 through MY7, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a diagnosis of vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*1*) of this section. Months in

which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*2*) of this section.

* * * * *

(2) * * *

(i) * * *

(A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY3 through MY7, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a diagnosis of vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(1) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(2) of this section.

* * * * *

(ii) * * *

(A) * * *

(*1*) Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that 1-beneficiary year is comprised of 12-beneficiary months. For MY3 through MY7, months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month, or had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a vital solid organ cancer diagnosis are identified as described in paragraph (c)(1)(i)(A)(*1*) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(*2*) of this section.

(*2*) MY1 and MY2, Pre-emptive LDT beneficiary years included in the denominator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the living donor transplant. For MY3 through MY7, Pre-emptive LDT beneficiary years included in the denominator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the living donor transplant, excluding beneficiaries who had a vital solid organ cancer diagnosis and were receiving treatment with chemotherapy or radiation for vital solid organ cancer during the MY. Months in which an attributed ESRD Beneficiary had a vital solid organ cancer diagnosis are identified as described in paragraph (c)(1)(i)(A)(1) of this section. Months in which an attributed ESRD Beneficiary received treatment with chemotherapy or radiation for vital solid organ cancer are identified as described in paragraph (c)(1)(i)(A)(2) of this section. Pre-emptive LDT Beneficiaries are identified using information about living donor transplants from the SRTR Database and Medicare claims data.

* * * * *

■ 10. Section 512.370 is amended by revising paragraph (b) introductory text, table 1 to paragraph (b)(1), and paragraphs (b)(2) introductory text, (b)(3), (c) introductory text, (c)(1)(v), and (d)(2) to read as follows:

§ 512.370 Benchmarking and scoring.

* * * * *

(b) *Achievement Scoring.* CMS assesses ETC Participant performance at the aggregation group level on the home dialysis rate and transplant rate against achievement benchmarks constructed based on the home dialysis rate and transplant rate among aggregation groups of ESRD facilities and Managing Clinicians located in Comparison Geographic Areas during the Benchmark Year. Achievement benchmarks are calculated as described in paragraph (b)(1) of this section and, for MY3 through MY7, are stratified as described in paragraph (b)(2) of this section. For MY5 through MY7, the ETC Participant's achievement score is subject to the restriction described in paragraph (b)(3) of this section.

(1) * * *

TABLE 1 TO § 512.370(b)(1)—ETC MODEL SCHEDULE OF PPA ACHIEVEMENT BENCHMARKS BY MEASUREMENT YEAR

MY1 and MY2	MY3 and MY4	MY5 and MY6	MY7	Points
90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (90th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	2
75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (75th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.5
50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (50th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1
30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (30th+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	0.5
<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year.	1.1 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.2 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	1.3 * (<30th Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year).	0

(2) *Stratifying achievement benchmarks.* For MY3 through MY7, CMS stratifies achievement benchmarks based on the proportion of beneficiary years attributed to the aggregation group for which attributed beneficiaries are dual eligible or LIS recipients during the MY. An ESRD Beneficiary or Pre-emptive LDT Beneficiary is considered

to be dual eligible or a LIS recipient for a given month if at any point during the month the beneficiary was dual eligible or an LIS recipient based on Medicare administrative data. CMS stratifies the achievement benchmarks into the following two strata:

* * * * *

(3) For MY5 through MY7, CMS will assign an achievement score to an ETC Participant for the home dialysis rate or the transplant rate only if the ETC Participant's aggregation group has a home dialysis rate or a transplant rate greater than zero for the MY.

(c) *Improvement scoring.* CMS assesses ETC Participant improvement on the home dialysis rate and transplant rate against benchmarks constructed based on the ETC Participant's aggregation group's historical performance on the home dialysis rate and transplant rate during the Benchmark Year to calculate the ETC Participant's improvement score, as specified in paragraph (c)(1) of this section. For MY3 through MY7, CMS assesses ETC Participant improvement on the home dialysis rate and transplant rate for ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries, who are dual eligible or LIS recipients to determine whether to add the Health Equity Incentive to the ETC Participant's improvement score, as specified in paragraph (c)(2) of this section.

(1) * * *

(v) For MY3 through MY7, when calculating improvement benchmarks constructed based on the ETC Participant's aggregation group's historical performance on the home dialysis rate and transplant rate during the Benchmark Year, CMS adds one beneficiary month to the numerator of the home dialysis rate and adds one beneficiary month to the numerator of the transplant rate, such that the Benchmark Year rates cannot be equal to zero.

* * * * *

(d) * * *

(2) For MY3 through MY7, CMS calculates the ETC Participant's MPS as the higher of the ETC Participant's achievement score for the home dialysis rate or the sum of the ETC Participant's improvement score for the home dialysis rate calculated as specified in paragraph (c)(1) of this section and, if applicable, the Health Equity Incentive, calculated as described in paragraph (c)(2)(i) of this section, together with the higher of the ETC Participant's achievement score for the transplant rate or the sum of the ETC Participant's improvement score for the transplant rate calculated as specified in paragraph (c)(1) of this section and, if applicable, the Heath Equity Incentive, calculated as described in paragraph (c)(2)(ii) of this section, weighted such that the ETC Participant's score for the home dialysis rate constitutes ⅔ of the MPS and the ETC Participant's score for the transplant rate constitutes ⅓ of the MPS. CMS uses the following formula to calculate the ETC Participant's MPS for MY3 through MY7:

Modality Performance Score = 2 × (*Higher of the home dialysis achievement or* (*home dialysis improvement score* + *Health Equity Bonus* †)) + (*Higher of the transplant achievement or* (*transplant improvement score* + *Health Equity Bonus* †))

† The Health Equity Incentive is applied to the home dialysis improvement score or transplant improvement score only if earned by the ETC Participant.

■ 11. Section 512.380 is amended by revising tables 1 and 2 to § 512.380 to read as follows:

§ 512.380 PPA Amounts and schedules.

* * * * *

TABLE 1 TO § 512.380—FACILITY PPA AMOUNTS AND SCHEDULE

	MPS	Performance payment adjustment period			
		1 and 2 (%)	3 and 4 (%)	5 and 6 (%)	7 (%)
Facility Performance Payment Adjustment	≤6	+4.0	+5.0	+6.0	+7.0
	≤5	+2.0	+2.5	+3.0	+3.5
	≤3.5	0	0	0	0
	≤2	−2.5	−3.0	−3.5	−4.5
	≤.5	−5.0	−6.0	−7.0	−9.0

TABLE 2 TO § 512.380—CLINICIAN PPA AMOUNTS AND SCHEDULE

	MPS	Performance payment adjustment period			
		1 and 2 (%)	3 and 4 (%)	5 and 6 (%)	7 (%)
Clinician Performance Payment Adjustment	≤6	+4.0	+5.0	+6.0	+7.0
	≤5	+2.0	+2.5	+3.0	+3.5
	≤3.5	0	0	0	0
	≤2	−2.5	−3.0	−3.5	−4.0
	≤.5	−5.0	−6.0	−7.0	−8.0

■ 12. Section 512.390 is amended by revising paragraph (b) introductory text to read as follows:

§ 512.390 Notification, data sharing, and targeted review.

* * * * *

(b) Data sharing with ETC Participants. CMS shares certain beneficiary-identifiable data as described in paragraph (b)(1) of this section and certain aggregate data as described in paragraph (b)(2) of this section with ETC Participants regarding their attributed beneficiaries and performance under the ETC Model. Data will not be shared after November 30, 2025.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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