DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

[CMS–1830–F]

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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: Final rule.

SUMMARY: This final rule updates and revises the End-Stage Renal Disease (ESRD) Prospective Payment System for calendar year 2026. This rule also includes updates to the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. In addition, this rule updates the requirements for the ESRD Quality Incentive Program and terminates and modifies requirements for the ESRD Treatment Choices Model.

DATES: These regulations are effective on January 1, 2026.

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).

QNETSUPPORT-ESRD@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:

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I. Executive Summary

A. Purpose

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

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

On January 1, 2011, we implemented the 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 includes updates to the ESRD PPS for CY 2026. This rule also modifies the eligibility timeframe for the transitional drug add-on payment adjustment (TDAPA) and establishes 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 rule updates 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 rule removes 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 rule updates the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) clinical measure beginning with PY 2028. This rule also discusses feedback received in response to our requests for 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 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 finalizing our proposals to terminate the ETC Model as of December 31, 2025, and 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

- *Update to the ESRD PPS base rate for CY 2026:* The final CY 2026 ESRD PPS base rate is $281.71, an increase from the CY 2025 ESRD PPS base rate of $273.82. This final amount reflects the application of the wage index budget neutrality adjustment factor (1.00905), the budget neutrality factor for the final non-contiguous areas payment adjustment (NAPA) (0.99860) as discussed in section II.B.8. of this final rule, and a final ESRD Bundled (ESRDB) market basket update of 2.1 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $281.71 (($273.82 × 1.00905 × 0.99860) × 1.021 = $281.71).
- *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 updating the wage index based on this methodology and the latest available data.
- *Annual update to the outlier policy:* We are updating the outlier policy based on the most current data and established methodology. Accordingly, we are updating the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2026 using the latest available CY 2024 claims data. We are updating the ESRD outlier services fixed dollar loss (FDL) amount for pediatric patients using the latest available CY 2024 claims data and updating 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 will decrease from $234.26 to $162.43, and the MAP amount will decrease from $59.60 to $50.19, as compared to CY 2025 values. For adult beneficiaries, the FDL amount will decrease from $45.41 to $14.80, and the MAP amount will decrease from $31.02 to $23.68. 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.
- *Update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2026:* The final CY 2026 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is $10.43. This final offset amount reflects the application of the final ESRDB market basket update of 2.1 percent ($10.22 × 1.021 = $10.43). There are no capital-related assets set to receive the TPNIES in CY 2026 for which this offset will apply.
- *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 final post-TDAPA add-on payment adjustment amount for Korsuva® is $0.1131 per treatment, which will be included in the calculation of the total post-TDAPA add-on payment adjustment for each quarter in CY 2026. The final post-TDAPA add-on payment adjustment amount for DefenCath® is $2.3710 per treatment, which will be included in the calculation for the third and fourth quarters of CY 2026.
- *Update to the timeframe for TDAPA eligibility:* We are modifying 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 revised eligibility timeframe will apply for all new drugs and biological products for which a TDAPA application is submitted on or after January 1, 2028.
- *Non-contiguous areas payment adjustment (NAPA):* We are finalizing a new payment adjustment, the NAPA, 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. This payment adjustment will 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 finalizing our proposal that the NAPA will be budget neutral and will apply a corresponding budget neutrality factor of 0.99860 to the CY 2026 ESRD PPS base rate.

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

- *Update to the dialysis payment rate for individuals with AKI:* We are updating the AKI dialysis payment rate

for CY 2026. The final CY 2026 payment rate is $281.71, which is the same as the final CY 2026 ESRD PPS base rate.

3. ESRD QIP

We are finalizing our proposal 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 finalizing our proposal to update the ICH CAHPS clinical measure. We are reducing the length of the ICH CAHPS Survey by removing 23 questions which we have identified as appropriate for removal. This final rule includes public comments received in response to requests for information that appeared in the CY 2026 ESRD PPS proposed rule. In those requests for information, we solicited public feedback on several topics relevant to the ESRD QIP. We requested information on the current state of health information technology (IT) use in dialysis facilities, including electronic health records (EHRs), 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 also requested 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 finalizing our proposal to terminate the ETC Model and modify the duration during which CMS will 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 discussed our reasons for terminating the model and the changes to the regulation required to implement the termination.

C. Summary of Costs and Transfers

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

TABLE 1—UPDATED ESTIMATED TOTAL COSTS/TRANSFERS

Final changes	Estimated total costs/transfers
Final CY 2026 ESRD PPS updates	The overall economic impact of this final rule is an estimated increase of approximately $180 million in aggregate payments to ESRD facilities in CY 2026. This includes estimated expenditures of approximately $34 million associated with the post-TDAPA add-on payment adjustment.
Final 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 final CY 2026 ESRD PPS base rate, will increase by $1 million.
Finalized 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 finalizing, the overall economic impact of the PY 2027 ESRD QIP will be approximately $146.6 million. We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are finalizing, the overall economic impact of the PY 2028 ESRD QIP will be approximately $145.6 million.
Finalized ETC Model termination	We estimate that, as a result of the termination of the ETC Model, as finalized in this rule, the net Federal impact will be approximately $1 million in savings.

1. Impacts of the Updates to the ESRD PPS

The impact table in section VII.C.5.a. of this final 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 CY 2026 payment changes is projected to be a 2.2 percent increase in Medicare payments. Hospital-based ESRD facilities will have an estimated 1.5 percent increase in Medicare payments compared with freestanding ESRD facilities with an estimated 2.2 percent increase. We estimate that the aggregate Medicare payments under the ESRD PPS will increase by approximately $180 million in CY 2026 compared to CY 2025 as a result of the final payment policies in this rule. Because of the projected 2.2 percent overall payment increase, we estimate there will be an increase in beneficiary coinsurance payments of *2.2* percent in CY 2026, which translates to approximately $40 million. For CY 2026, we estimate total payments associated with the post-TDAPA add-on payment adjustment will be $34 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 final 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 final 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 VII.C.5.b. of this final rule, we estimate that the combined total TDAPA payment amounts for these drugs in CY 2026 will be approximately $500 million, of which, $100 million will be attributed to beneficiary coinsurance amounts.

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

The impact table in section VII.C.5.c. of this final 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 CY 2026 changes is projected to be a 2.0 percent increase in Medicare payments for individuals with AKI. Hospital-based ESRD facilities will have an estimated 1.8 percent increase in Medicare payments compared with freestanding ESRD facilities that will have an estimated 2.0 percent increase. The overall impact reflects the effects of the final Medicare ESRD PPS payment rate update and the final 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 final CY 2026 ESRD PPS base rate, will 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 finalizing in this final rule, the overall economic impact of the PY 2027 ESRD QIP will be approximately $146.6 million. The $146.6 million estimate for PY 2027 includes $125 million in costs associated with the collection of information requirements and approximately $21.6 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 finalizing in this final rule, the overall economic impact of the PY 2028 ESRD QIP will be approximately $145.6 million. The $145.6 million estimate for PY 2028 includes $125 million in costs associated with the collection of information requirements and approximately $20.6 million in payment reductions across all facilities.

4. Impacts of the Termination of the ETC Model

We estimate that, as a result of the termination of the ETC Model, as finalized in this rule, the net Federal impact will be approximately $1 million in savings during the final 18 months of the performance period (January 1, 2026 through June 30, 2027).

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 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

[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 final rule except when referencing specific language in the Act or regulations.

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.[2] 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. Provisions of the Proposed Rule, Public Comments, and Responses to the Comments on the CY 2026 ESRD PPS

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'' (90 FR 29342–29391), referred to as the ''CY 2026 ESRD PPS proposed rule,'' appeared in the July 2, 2025 issue of the **Federal Register**, with a comment period that ended on August 29, 2025. In that proposed rule, we proposed to make a number of annual updates for CY 2026, including routine updates to the ESRD PPS base rate, wage index, outlier policy, TPNIES offset amount, and post-TDAPA add-on payment adjustment amounts. Additionally, we proposed to modify the timeframe for TDAPA eligibility, beginning January 1, 2028, to require a TDAPA application within 3 years of FDA approval, and we proposed a new payment adjustment for ESRD PPS claims from ESRD facilities in certain non-contiguous states and territories. We received approximately 208 public comments on our proposals, including comments from kidney and dialysis organizations, such as large and small dialysis organizations, for-profit and non-profit ESRD facilities, ESRD networks, and dialysis coalitions. We also received comments from patients; healthcare providers for adult and pediatric ESRD beneficiaries; home dialysis services and advocacy organizations; provider advocacy organizations; administrators and insurance groups; a non-profit dialysis association; a professional association; alliances for kidney care and home dialysis interested parties; drug and device manufacturers; health care systems; and the Medicare Payment Advisory Commission (MedPAC). Of these approximately 208 public comments, approximately 108 were unique and approximately 98 were either duplicative submissions or were solely form letters.

We received many comments about ESRD PPS policies for which we did not propose any changes for CY 2026. These comments are briefly summarized in the following paragraphs; however, we are not addressing these comments in this final rule because they are out of scope for the CY 2026 ESRD PPS final rule.

We received approximately 87 timely pieces of correspondence from unique submitters which reflected a form letter advocating for the removal of oral drugs which lower serum phosphate from the ESRD PPS bundled payment. Additionally, we received 41 timely pieces of correspondence from a wide range of commenters that raised concerns about what commenters stated were the negative impacts of the inclusion of oral-only drugs and biological products into the ESRD PPS.

We also received comments that offered suggestions broadly related to improving quality of care for ESRD patients. These included comments proposing the development of a patient bill of rights and responsibilities; comments raising concerns about access to care, particularly in rural areas and in nursing homes; comments raising concerns about patients' current and future access to prescribed medications; and comments that advocated for better

[2] As discussed in section II.B.8 of this final rule, beginning for CY 2026, we are establishing a new facility-level payment adjustment for ESRD facilities in certain non-contiguous areas of the U.S.

patient education about modality choice and vascular access options.

Several comments requested clarification or consideration of changes to existing ESRD PPS policies such as the reporting requirement for ''time on machine''; the ESRD PPS case-mix adjusters; the eligibility criteria for the LVPA; and the scope of items and services that are recognized as renal dialysis services paid under the ESRD PPS. A number of commenters also requested clarification or consideration of changes related to Medicare payment policies outside the ESRD PPS, such as the Kidney Disease Education benefit; palliative care and the hospice benefit; caregiver services in the nursing home setting; payment for ultrafiltration for beneficiaries with congestive heart failure; and policies for telehealth and remote monitoring for home dialysis patients.

Some commenters urged CMS to address their concerns related to Medicare Advantage (MA) plans. These included concerns about network adequacy and payment, particularly in rural areas, as well as recommendations to consider supply chain concerns that affect emergency preparedness. Commenters also encouraged CMS to ensure that MA plans adopt policies similar to the TPNIES and TDAPA, limit MA exclusivity and narrow networks, ensure that MA benchmarks for ESRD reflect any adjustments in FFS ESRD payments, and facilitate home dialysis uptake in beneficiaries with a MA plan.

We received several comments not related to policies we proposed regarding the TDAPA, TPNIES, and the post-TDAPA add-on payment adjustment, which expressed concern that the ESRD PPS does not sufficiently incentivize innovation in dialysis care or pay for innovative technologies. Additionally, commenters requested that we revise cost reports and billing procedures to make TDAPA, TPNIES, and post-TDAPA costs easier to report and payment easier to identify. We also received comments about extending the TDAPA and TPNIES payment periods, expanding the TPNIES for capital related assets beyond home dialysis machines, further clarifying the TPNIES eligibility criteria, and creating a pathway for new clinical laboratory tests related to the treatment of ESRD by establishing a Transitional Laboratory Add-on Payment Adjustment, which the commenters called TLAPA.

We also received several comments regarding the inclusion of oral-only drugs and biological products in the ESRD PPS bundled payment, which was not the subject of a proposal in the CY 2026 ESRD PPS proposed rule. Commenters requested that CMS provide payment for drugs or biological products not consumed by beneficiaries, along with requesting clarification on, or extension of, the increase to the TDAPA amount for phosphate binders of $36.41 for operational costs. Additionally, commenters requested that ESRD facilities provide oral drugs and biological products in specific packaging for nursing homes and include the cost of pharmacist and pharmacist technician salaries in the ESRD PPS bundled payment. Some commenters requested additional monitoring for any adverse effects of including oral-only drugs and biological products in the ESRD PPS bundled payment. We are not providing detailed responses to these comments in this final rule because they are not related to the policy proposals of the CY 2026 ESRD PPS proposed rule. However, we note that we did not propose to change the additional $36.41 increase to the TDAPA amount for phosphate binders, and we are not finalizing any such changes in this rule. As such, the monthly TDAPA amount on any ESRD PPS claim that reports units of phosphate binders in CY 2026 would include the increased $36.41 that we finalized in the CY 2025 ESRD PPS final rule.

As we previously stated, we are not providing detailed responses to these out of scope comments in this CY 2026 ESRD PPS final rule. Nevertheless, we thank the commenters for their input and will consider their recommendations to potentially inform future rulemaking.

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

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. CY 2026 ESRD Market Basket Update

We proposed 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 proposed 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 final rule, we calculated 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) 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 was 2.7 percent. We proposed that if more recent data became available after the publication of the proposed rule and before the publication of this 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. Accordingly, based on IGI's third quarter 2025 forecast of the 2020-based ESRDB market basket, the final CY 2026 ESRDB market basket percentage increase is 2.9 percent.

(2) 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.[3] 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) was 0.8 percentage point. Furthermore, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this 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. Accordingly, based on IGI's third quarter 2025 forecast, the CY 2026 final productivity adjustment is 0.8 percentage point.

(3) CY 2026 ESRDB Market Basket Update

In accordance with section 1881(b)(14)(F)(i) of the Act, we proposed 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 proposed 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 was 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 proposed that if more recent data became available after the publication of the proposed rule and before the publication of this 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 ESRD market basket percentage increase and productivity adjustment in the final rule. Accordingly, the final CY 2026 ESRDB market basket update is calculated using the final CY 2026 ESRDB market basket percentage increase, based on IGI's third quarter 2025 forecast of the 2020-based ESRDB market basket, and the final productivity adjustment, based on IGI's third quarter 2025 forecast. Therefore, the final CY 2026 ESRDB market basket update is equal to 2.1 percent (2.9 percent ESRDB market basket percentage increase reduced by a 0.8 percentage point productivity adjustment).

(4) ESRD Labor-Related Share (LRS)

We define the LRS as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The LRS 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 proposed to continue using a LRS of 55.2 percent, which was finalized in the CY 2023 ESRD PPS final rule (87 FR 67153 through 67154).

(5) Public Comments on the ESRDB Market Basket Percentage Increase, Productivity Adjustment, Annual Update and Labor-Related Share (LRS)

We invited public comment on our proposals related to the ESRDB market basket update and LRS. Several unique commenters including large dialysis organizations (LDOs); small dialysis organizations (SDOs), patient advocacy organizations; nonprofit dialysis associations; two coalitions of dialysis organizations; professional organizations; and MedPAC commented on the proposed update. The following is a summary of the public comments received on these proposals and our responses.

Comment: Several commenters acknowledged the proposed ESRDB market basket update of 1.9 percent; however, most expressed that this update is insufficient to address the current inflationary environment and workforce shortages. A few commenters pointed to their own experience or broader trends in labor costs as an indication that the update is insufficient. Some commenters underscored the importance of accurate payments to providers, ensuring ESRD facilities can hire and retain essential clinical staff, thus mitigating high rates of staff turnover to higher-paying settings. They noted this has direct negative effects on patient experience. Additionally, commenters raised concerns about the impact of this proposal on independent and hospital-based dialysis providers. Several commenters noted that labor, supply, and capital expenses continue to rise, resulting in negative Medicare margins

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

for 2022 and 2023, measured by MedPAC at −1.1 percent and −0.2 percent, respectively.

MedPAC, on the other hand, indicated in its March 2025 report to Congress that for 2026 ESRD PPS payments should be updated according to the amount determined under current law. This recommendation was based on MedPAC's analysis of payment adequacy indicators.

Response: We believe that the CY 2026 ESRDB market basket update accurately estimates the expected input price pressures that ESRD facilities will likely face in 2026.

We acknowledge that labor costs are a significant factor for ESRD facilities' finances (accounting for 46 percent of the 2020-based ESRDB market basket). At the time of the CY 2026 ESRD proposed rule, based on IGI's first quarter 2025 forecast with historical data through the fourth quarter of 2024, the 2020-based ESRDB market basket percentage increase was forecasted to be 2.7 percent for CY 2026. This reflected forecasted compensation price growth of 3.3 percent, which corroborates that labor prices are anticipated to grow at a relatively faster rate than other prices in the ESRDB market basket. As discussed in the CY 2023 ESRD PPS final rule (87 FR 67141), the compensation price measure in the ESRDB market basket reflects the worker skill mix specific to ESRD facilities.

In the CY 2026 ESRD PPS proposed rule, we proposed that if more recent data became available, we would use such data, if appropriate, to derive the final CY 2026 ESRDB market basket update for the final rule. For this final rule, we now have an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the U.S. economy and expected price inflation for CY 2026. Based on IGI's third quarter 2025 forecast with historical data through the second quarter of 2025, we are projecting a CY 2026 ESRDB market basket percentage increase of 2.9 percent (reflecting forecasted compensation price growth of 3.4 percent). Therefore, for CY 2026 a final ESRDB market basket update of 2.1 percent (2.9 percent less 0.8 percentage point for the productivity adjustment) will be applicable, compared to the 1.9 percent ESRDB market basket update that was proposed.

Comment: Several commenters, representing numerous industry interests, stated similar comments to those from recent rulemaking cycles indicating concerns that the ESRDB market basket is ''systemically'' flawed because the market basket fails to accurately capture the changes over time in the prices in the goods and services included in renal dialysis services. Several commenters noted that the ESRDB market basket updates are comparatively lower than those for other Medicare providers and suppliers paid under a PPS. The commenters acknowledged that varying cost structures contribute to this outcome; however, they expressed it is important to highlight these differences because all providers draw from the same labor pools. They stated that lower ESRD PPS updates may impact ESRD facilities' ability to attract caregivers in the current competitive labor market. Additionally, a commenter requested CMS clarify past comments about why we believe different facility types face different cost-pressures as the commenter noted many of the costs, such as labor, were drawn from similar pools.

Commenters raised three main areas of concern with the ESRDB market basket methodology. First, they expressed the capital cost share weight is too high compared to other Medicare market baskets. They also mentioned that capital costs would include costs that are labor-related, yet the price proxy used does not consider labor-related costs. A commenter requested clarification on what capital costs would be considered labor-related.

Second, commenters suggested that the capital building price proxy should match that in the Inpatient Prospective Payment System (IPPS) and Skilled Nursing Facility (SNF) market baskets. The ESRD PPS uses the ''PPI—Industry—Lessors of nonresidential buildings'' price proxy, while the IPPS and SNF PPS use the ''BEA—Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care''. Commenters highlighted the faster growth rate of the latter price proxy and noted that this difference in price trend contributes to the lower overall ESRDB market basket updates generally.

Third, commenters noted that the weight for the proxy ''PPI—Final demand—Finished goods less foods and energy'' in the ESRD PPS is higher than in other Medicare market baskets, with a weight of 11.1 percent compared to 1.2 percent in the IPPS and 0.3 percent in the SNF PPS. They suggested redefining the category in the ESRD PPS to potentially reduce the weight and provide a more accurate update factor.

A commenter requested that CMS implement these changes to the ESRD PPS market basket for CY 2026 to better align it with other Medicare payment systems.

Response: We appreciate the commenters' recommendations regarding areas that could benefit from technical enhancements in the design and methodology of the ESRDB market basket cost weights and price proxies. We did not propose to rebase or revise the ESRDB market basket in the CY 2026 ESRD PPS proposed rule. Additionally, we finalized the 2020-based ESRDB market basket in the CY 2023 ESRD PPS final rule (87 FR 67141). During the CY 2023 rulemaking cycle, the 2020 Medicare cost report data was the most recent fully complete cost data available, reflecting the submitted cost data from ESRD facilities. The ESRDB market basket is created according to section 1881(b)(14)(F)(i) of the Act and must reflect the costs associated with providing ESRD care. The 2020-based ESRDB market basket percent change is calculated based on the weighted price change of individual price proxies and their respective cost weights. The cost weights are primarily derived from the freestanding ESRD Medicare cost reports and represent the relative shares of input costs needed to provide medical services to ESRD beneficiaries. Similarly, other Medicare market baskets, such as the 2022-based SNF market basket and the 2023-based IPPS market basket, reflect the relative share of input costs required to provide skilled nursing and hospital care to Medicare beneficiaries based on data reported in their respective provider Medicare cost reports. The price proxies used in the ESRDB market basket are designed to reflect the specific price pressures faced by ESRD facilities, which can vary from those facing other medical care providers. Although many of the individual costs faced by ESRD facilities are similar to certain individual costs faced by other facility types, the different cost-weights and price proxies result in the different market baskets representing the different cost pressures for each facility type. For instance, the rate of increase in the ESRDB market basket compensation category reflects the price increase for occupations employed by ESRD facilities, which may differ from those in nursing care facilities or hospitals. We recognize that ESRD facilities compete for labor against other facility types and we believe that the ESRDB market basket reflects the realities of the types of labor employed by ESRD facilities.

Regarding the first area of concern raised by the commenters about capital costs, the ESRDB market basket capital cost weight represents 13.8 percent of

total costs as calculated using the ESRD Medicare cost report data. We provided comprehensive details on how these weights were derived in the CY 2023 ESRD PPS final rule (87 FR 67145). Consistent with section 1881(b)(14)(F) of the Act, the ESRDB market basket weight reflects the reported costs of ESRD facilities in relation to total ESRD expenses, and thus it is not relevant how the weight in the ESRDB market basket compares to capital cost category weights in other Medicare market baskets. Additionally, the ESRDB market basket capital-related price proxy captures the anticipated price pressures encountered by freestanding ESRD facilities, often leasing business office space, that would include all factors influencing those costs, including labor costs. We note that rent is an example of a capital cost which we consider labor-related, as labor is a component in the price of rent.

In response to the second area of concern about the ESRD price proxy for fixed capital differing from those used in other Medicare market baskets, they are appropriately different because they reflect the unique capital cost acquisition and financing for each provider type. As described in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154), the ESRDB market basket uses the PPI Industry for Lessors of Nonresidential Buildings (BLS series code #PCU531120531120) to measure the price growth of the Capital-Related Building and Fixtures cost category. This PPI reflects the prices of leases for nonresidential buildings, including professional and office buildings, which we believe is the most technically appropriate price proxy for ESRD fixed capital costs and was finalized in the CY 2015 ESRD PPS proposed rule (79 FR 40223). We will consider alternative price proxies for this and other cost categories during the next rebasing and revising of the ESRDB market basket.

In addressing the third area of concern regarding the ESRDB market basket weight for All Other Goods and Services, as noted in the CY 2023 ESRD PPS final rule (87 FR 67145), the cost weight for All Other Goods and Services was derived by disaggregating the Administrative and General cost weight based on the 2012 Service Annual Survey data, the most recent year of detailed expense data available, which was adjusted to 2020 levels. This data is published by the Census Bureau under North American Industry Classification System (NAICS) Code 621492: Kidney Dialysis Centers. We believe this method is appropriate because it reflects data specific to ESRD facilities, and detailed BEA Benchmark Input-Output data is not available at the six-digit detail level corresponding to NAICS 621492, Kidney Dialysis Centers.

We reiterate, as we have in previous regulatory cycles, that CMS is interested in hearing from commenters and discussing any data or analysis the industry may wish to provide regarding ways to ensure Medicare payments are appropriate and that market basket price proxies and weights are accurate. We welcome any publicly available and representative input cost data that reflects total and category-specific costs for the ESRD industry, or suggestions for revisions to the ESRD cost report that would provide specific detail for any substantial category of expenses that are not separately reported, which commenters can provide through rulemaking or by sending an email to *dnhs@cms.hhs.gov.* We will consider these suggestions for the next rebasing and revising of the ESRDB market basket, noting that any proposal to rebase the ESRDB market basket would occur through notice and comment rulemaking.

Comment: Several commenters expressed their opinion that the LRS of 55.2 percent is insufficient. A commenter highlighted that staffing costs for one of their members constitute approximately 70 percent of operating expenses. The commenters also pointed out that the ESRD LRS is lower compared to other CMS PPS's, such as the LRS for the SNF and Inpatient hospital PPS. Another commenter expressed support for the ESRD LRS of 55.2 percent but noted that, since this figure is based on cost share weights from 2020, it is outdated and should be updated more frequently than merely coinciding with each rebasing to reflect changes in labor-related costs or price pressures between market basket rebasing years. Several commenters expressed a belief that increasing the labor related share would increase the annual market basket increase.

Response: The objective of the LRS is to represent the proportion of the national ESRD PPS base payment rate that is modified by the wage index. CMS adjusts this portion of the base rate to account for geographic variances in area wage levels, utilizing an appropriate wage index which mirrors the relative wage levels and wage-related costs in the geographic location of the ESRD facility.

We define the LRS as those expenses that are labor intensive and vary with, or are influenced by, the local labor market. In the CY 2023 ESRD PPS final rule (87 FR 67153 through 67154) we detailed the use of the 2020-based ESRDB market basket cost weights to determine the LRS for ESRD facilities. Specifically, effective for CY 2023, a LRS of 55.2 percent was based on the sum of the cost weights for: Wages and Salaries, Employee Benefits, Housekeeping, Operations & Maintenance, 87 percent of the weight for Professional Fees, and 46 percent of the weight for Capital-related Building and Fixtures expenses. Nearly all of the cost weights used to determine the LRS were derived from the ESRD Medicare cost reports (CMS Form 265–11, OMB NO. 0938–0236). The LRS used for the ESRD payment system is appropriately different than those estimated for SNF and IPPS PPS because it reflects the cost structure specific to ESRD facilities. Thus, we believe the ESRD LRS of 55.2 percent is appropriate and we are finalizing our proposal to continue to use this LRS for CY 2026 ESRD PPS payments. We note that increasing the LRS would not impact the annual ESRDB market basket increase because, the LRS of 55.2 percent is a percentage of labor-related costs for providing ESRD care which is derived based on the sum of cost weights in the ESRDB market basket. Since the LRS is determined based on the cost share weights, it would not change from year to year until the ESRDB market basket is rebased. Additionally, the LRS does not impact the percentage increase in the ESRDB market basket as that is determined solely based on the ESRDB cost share weights and the weighted growth in the price proxies used in the ESRDB market basket. The LRS is a separate concept that does not impact the ESRDB market basket percentage increase. We will consider the commenters' suggestions related to the LRS, when we next rebase and revise the ESRDB market basket, and any such proposed changes will be made through notice and comment rulemaking.

Comment: One LDO commented that the proposed productivity adjustment of 0.8 percent was significantly larger than in prior years and opined that it exceeded any actual productivity gains experienced by ESRD facilities.

Response: Section 1881(b)(14)(F)(i)(II) of the Act requires the Secretary to reduce the ESRDB market basket increase factor by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which specifies that the productivity adjustment is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary). While we acknowledge that the CY 2026 proposed and final productivity adjustment are greater than recent years, they are

derived from the same methodology as required by the statute, as previously stated. We note that this statutory requirement does not specify that the productivity adjustment reflects the productivity gains experienced by ESRD facilities and is instead based on economy-wide private nonfarm data.

Comment: A commenter noted that across inflation adjusted FFS expenditures, ESRD PPS expenditures have consistently accounted for between 5 and 7.5 percent of total Medicare spending over the past decade and noted that this represented stability for the Medicare Trust Fund. The commenter highlighted that this stability has persisted even as CMS implemented new payment policies such as the TDAPA and TPNIES.

Response: We appreciate the commenters' perspective on the payment stability of the ESRD PPS and agree that the program has been generally stable while providing payment for high quality care for ESRD beneficiaries.

Comment: A few comments addressed the timing of the data upon which the ESRDB market basket and ESRDB market basket update were based. A commenter requested CMS reevaluate the ESRDB market basket methodology and use more recent data. Another commenter expressed a belief that the market basket increase was based on 2020 data and requested CMS use more recent data.

Response: We generally routinely rebase and revise the ESRDB market basket to a base year every 4 to 5 years. We believe that this is reasonable as the cost report data generally does not change much from year-to-year. We note that the 2020 cost report data is used to determine the cost-weights for the 2020-based ESRDB market basket; however the CY 2026 ESRDB market basket percentage increase is based on the expected growth in prices for 2026. The cost weights derived from 2020 ESRD Medicare cost report data are multiplied by the forecasted price growth of each price proxy in the ESRDB market basket to determine the overall ESRDB market basket percentage increase for CY 2026.

Comment: Many commenters report that the ESRDB market basket updates have been under-forecast for four consecutive years from 2021 through 2024. Commenters overwhelmingly requested that CMS utilize its authority to make adjustments to the ESRD PPS and implement a forecast error adjustment policy for the ESRD PPS. While recognizing that updates to the ESRDB market basket are set prospectively, making some degree of forecast error inevitable, commenters asserted that ESRD facilities should not be financially disadvantaged due to Medicare market basket forecasting errors. Many urged CMS to reconsider its decision not to adopt a forecast error policy, arguing that such an adjustment is essential to ensure the funding Congress intended for ESRD facilities.

Furthermore, commenters stated that the forecast errors in the ESRD PPS are disproportionately worse than those in other Medicare payment systems and continued to urge CMS to address what they view as the past underfunding of the payment system. They recommended CMS implement a one-time retrospective adjustment to the base rate in the amount of the current cumulative forecast error, with some suggesting this adjustment cover the entire period since the inception of the ESRD PPS, while others proposed a timeframe from 2019 or 2020 through 2024. Additionally, most commenters stated that they support the implementation of a future forecast error correction policy that would be triggered when the positive or negative error exceeds a 0.5 percentage point threshold, similar to the forecast error adjustment threshold for the SNF PPS.

Some commenters opined on the statutory authority CMS has to establish such an adjustment for the ESRD PPS, and others opined that CMS should implement such an adjustment in this final rule rather than wait for a future year. A few commenters noted that when establishing the forecast error adjustment under the SNF PPS, CMS stated that such an adjustment would not be considered a new source of funding for the payment system. Some commenters opined that such an adjustment would create more predictable payments, in contrast to past CMS statements about predictability under a forecast error adjustment. One LDO characterized forecast errors as being paramount to a rate cut as they impact all future years. One professional association stated that a forecast error adjustment was necessary given consolidation of providers of renal dialysis services.

Response: We acknowledge commenters' opinions about the accuracy of the ESRDB market basket forecasts and their requests for a policy to increase payments based on recent forecast errors.

The ESRDB market basket updates are set prospectively for a future calendar year, which requires that forecasted data be used for part of the period. For example, the CY 2026 market basket update in this final rule incorporates historical data through the second quarter of CY 2025 and forecasted data from the third quarter of CY 2025 through the fourth quarter of CY 2026. Although there is no precedent for adjusting the ESRD payment update to account for market basket forecast error, such an error can be determined by comparing the actual market basket increase for a given year with the forecasted market basket increase. Due to the unpredictability of future price trends, forecast errors can be either positive or negative, as has been observed since the implementation of the ESRD PPS in CY 2011. Historically, these forecast errors have generally been small, with the largest error (in absolute terms) before 2021 being an over-forecast of 0.8 percentage point in 2017. For 2021 through 2024, the ESRDB market basket percentage increase has been under-forecast, and the errors have been larger, mainly due to uncertainties in the overall economy, and specifically in the health sector, resulting from the Public Health Emergency (PHE) for COVID–19 and the unexpectedly rapid acceleration of inflation. The cumulative forecast error since the inception of the ESRD PPS (calendar year 2012 to 2024) is 5.3 percent. The cumulative forecast is calculated as the product of the annual forecast errors and excludes the year 2015, as section 217(b) of PAMA required the CY 2015 ESRD PPS payment update to be 0.0 percent.

Historically, there have been both over and under -forecasts for the ESRDB market basket. However, we acknowledge that recent forecast errors have been larger than prior errors and have been consecutively under-forecast. We did not propose a forecast error policy for CY 2026, and we are not finalizing such a policy in this final rule. We are monitoring the performance of the ESRDB market basket and may propose a policy to address forecast errors in potential future rulemaking, if appropriate. When considering whether such a policy is appropriate, we intend to evaluate all of the information the commenters provided, including the provider consolidation mentioned by the commenter insofar as consolidation could have impacts on access or quality of care.

Comment: A commenter questioned why CMS stated that the cumulative forecast error for the ESRD PPS was at 4.3 percent in the CY 2025 ESRD PPS final rule (89 FR 89096). The commenter provided data from 2019 through 2025 which indicated that the forecast error for the ESRD PPS was ''nearly 8 percent.'' The commented expressed confusion as to the discrepancy between the figure CMS stated in our rule and

the figure they generated from publicly available data.

Response: The CY 2025 ESRD PPS final rule (89 FR 89096) stated that the cumulative forecast error from 2012 through 2023 (the latest historical CY data at the time of rulemaking) was 4.3 percent. We note that the 7.7 percent figure that the commenter provided is generated from data from 2019 through 2025. Historical data is not available for CY 2025. The cumulative forecast error since the inception of the ESRD PPS (calendar year 2012 to 2024) is 5.3 percent which is appropriately calculated as the cumulative product of the forecasted market basket increase (1 plus the percentage increase) divided by the cumulative product of the actual market basket increase (1 plus the percentage increase) less 1.

Comment: Other commenters criticized the methodology of forecasting the ESRDB market basket and requested greater transparency regarding the IGI's methodology. A commenter stated that transparency would better help commenters engage in notice and comment rulemaking. A commenter expressed the belief that, given the accuracy of recent forecasts, it was likely that forecast errors would continue in future years. One LDO opined that the methodology was unable to accurately predict price inflation above 2 percent.

Response: We understand and appreciate calls for greater transparency with the ESRDB market basket forecasts, however, we note that the market basket forecast methodology utilized by IGI is proprietary and we cannot share detailed information. We do not agree with the prediction that forecast errors are likely in future years. In each given year, the ESRDB market basket increase is the most appropriate estimation of the change in prices of the ESRDB market basket based on the latest available data. As we have stated in past rules, the forecast errors during the COVID–19 PHE were nontypical and our preliminary analysis of CY 2025 data indicates the forecast was reasonably accurate for that year. We note that our methodology of forecasting has been able to capture inflation above 2 percent in the past, and was reasonably accurate for the CY 2012, 2013 and 2014 forecasts, the lowest of which was 2.9 percent. The forecast methodology was not able to capture some changes of price that resulted from nontypical inflation during the PHE, and we anticipate the forecast will continue to be accurate during times of more typical inflation.

Comment: Some commenters referenced past statements made by CMS which noted that historically forecast errors had been both positive and negative and have balanced out over time. Commenters opined that with continued errors in forecasts this statement is no longer technically accurate. One LDO stated the belief that it would be unlikely for future over-forecasts to offset past under-forecasts. Another LDO noted that in the majority of years, the ESRDB market basket forecast has been lower than the actual ESRDB market basket update. Additionally, this LDO stated that their preliminary data indicated that 2025 would be the 5th year in a row that the ESRDB market basket increase was under -forecasted.

Response: As of 2020 the cumulative ESRDB market basket forecast errors was negative, indicating forecasted ESRDB market basket increases were greater than actual ESRDB market basket increases. While the forecast errors during the PHE were notably positive, we do not have any reason to believe that this trend will continue. Although the commenter is accurate in noting that most of the ESRDB market basket forecast errors during the life course of the ESRD PPS have been positive, prior to CY 2021 the negative forecast errors did largely offset the positive forecast errors and were generally small (lower than 0.5 percentage point for any given year).

Comment: A professional association further expressed support for a forecast error adjustment by stating that, in contrast to past CMS statements on the matter, although the circumstances of the forecast error differ between the ESRD PPS today and SNF in 2003, the impact on providers is presenting the same.

Response: We recognize that the impact of lower payments on health care providers is generally the same, but we believe the source of the forecast error is important to consider. As we stated earlier in this CY 2026 ESRD PPS final rule and previously noted in the CY 2025 ESRD PPS final rule, the forecast errors in recent years were largely a function of uncertainty in the overall economy and the health sector specifically due to the nature of the COVID–19 PHE and the unforeseen inflationary environment (89 FR 89096). Since these factors tend to apply broadly across payment systems, and since the ESRD PPS has historically been reasonably accurate, we believe the circumstances are notably different from SNF PPS in 2003. While that forecast adjustment was appropriate as SNF was impacted differently from other PPSs, the same is not true for the ESRD PPS presently.

Comment: An LDO noted that the ESRD PPS has a greater cumulative ESRDB market basket forecast error than other Medicare PPSs, despite all Medicare PPSs experiencing similar forecast errors across the PHE.

Response: We recognize that is an accurate statement, however we note that, as discussed previously, we do not make policy determinations for the ESRD PPS based on other payment systems market baskets, performance or forecast accuracy. We intend to continue to monitor the ESRDB market basket forecast and payment rates and would propose changes, if appropriate, through notice and comment rulemaking.

Comment: One LDO opined that CMS has a statutory obligation to annually establish payment rates that reflect increases in dialysis providers' cost of care, and that this obligation has not been met in recent years.

Response: We disagree with the assertion that we have not met our statutory requirement in establishing the annual ESRDB market basket increases. We note that section 1881(b)(14)(F)(i)(I) of the Act requires the update reflect changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services, not the change in costs for ESRD facilities. CMS adjusts the ESRD PPS payment amounts annually by applying the percentage increase in the ESRDB market basket reduced by the productivity adjustment as described in section 1886(b)(3)(B)(xi)(II) of the Act. Updating ESRD PPS payment rates based on changes in costs would involve estimating the change in quantity as well as price, which is not the statutory requirement of the ESRD market basket update. Setting rates prospectively is an intrinsic requirement of a prospective payment system and our established ESRDB market basket update methodology is consistent with the statutory requirement in section 1881(b)(14)(F)(i)(I) of the Act.

Final Rule Action: We did not propose and are not finalizing any changes to the ESRDB market basket methodology for CY 2026. Thus, the final ESRDB market basket update for CY 2026 is 2.1 percent, representing an ESRDB market basket percentage increase of 2.9 percent reduced by a 0.8 percentage point productivity adjustment. Additionally, we did not propose any changes to the LRS and are finalizing the continued use of a LRS of 55.2 percent for CY 2026.

2. 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.[4]

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 LRS of the ESRD PPS base rate. In the CY 2023 ESRD PPS final rule (87 FR 67153), we finalized the use of a LRS 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 the proposed rule, we proposed that the LRS 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 § 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 of the CY 2025 ESRD PPS proposed rule available at *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 noted in the CY 2026 ESRD PPS proposed rule that we were presenting the NEFOM 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. The data in Table 2 is based on data from CY 2023 freestanding ESRD facility cost reports. We note that there are minor differences between the final CY 2026 NEFOM and 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 FINAL RULE NEFOM

ESRD PPS colloquial name	BLS occupation title	Occupation code	ESRD freestanding facilities FTE percentage *
Registered Nurses (RN)	Registered Nurses	29–1141	29.5

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

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

ESRD PPS colloquial name	BLS occupation title	Occupation code	ESRD freestanding facilities FTE percentage *
Licensed Practical Nurses (LPN)	Licensed Practical and Licensed Vocational Nurses	29–2061	3.6
Nurse Aides	Nursing Assistants	31–1131	3.2
Technicians	Health Technologists and Technicians, All Other	29–2099	37.7
Social Workers	Healthcare Social Workers	21–1022	4.8
Dietitians	Dietitians and Nutritionists	29–1031	4.6
Administrative Staff	Medical Secretaries and Administrative Assistants	43–6013	11.2
Management	Medical and Health Services Managers	11–9111	5.4

* Totals may not sum to 100.0 percent due to rounding.

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.[5] 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 stated that 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 did not believe there was sufficient May 2024 OEWS data from which to impute the missing values. To address this missing data, we proposed to instead use the May 2023 BLS OEWS mean 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 proposed to apply in our proposed CY 2026 ESRD PPS wage index were 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. We explained that 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 noted that we could freeze the CY 2023 wage index values for Colorado, which would accomplish a similar purpose, but we believed that our proposed methodology is most consistent with the language at § 413.196(d)(2) as we were using the most current mean hourly wage data from the BLS OEWS for Colorado, which is from the May 2023 OEWS. We stated that should BLS release the May 2024 OEWS estimates for Colorado before the publication of the ESRD PPS final rule, we proposed to use those estimates instead of the adjusted May 2023 OEWS estimates for the final CY 2026 ESRD PPS wage index. We requested comments on this proposed methodology to address the missing Colorado OEWS data. On July 23, 2025, BLS published the OEWS mean hourly wage data for Colorado for the May 2024 release of the OEWS and, consistent with our proposal, we are using the published BLS data for Colorado for May 2024 for the CY 2026 ESRD PPS wage index.

d. CY 2026 ESRD PPS Wage Index

For CY 2026, we proposed 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 proposed 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 final rule are from the April 2025 release of the BLS OEWS, which represents data from six semiannual surveys spanning November 2021 through May 2024.

For CY 2026, we proposed updating the ESRD PPS wage index to use the most recent available BLS OEWS wage data. We proposed that if more recent data became available after the analysis performed for the publication of the proposed rule and before the publication of this 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. For CY 2026, the updated wage data used in the analysis for this final rule are from the April 2025 release of the BLS OEWS, which represents data from six semiannual surveys spanning November 2021 through May 2024.[7]

We received approximately 14 public comments on these proposals including from LDOs, coalitions of kidney organizations, non-profit dialysis organizations, ESRD facilities, a non-profit healthcare organization, and a health insurance organization in Puerto Rico. Multiple commenters discussed the impact of the wage index on payment rates. We interpret these comments to be generally referring to the impact of the wage index on a facility or subset of facilities, as the wage index is implemented budget neutrally and does not have an impact on overall payments under the ESRD

[5] 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.*

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

PPS. The following is a summary of the comments we received and our responses.

Comment: A national kidney non-profit and an LDO expressed support for the current ESRD PPS wage index and stated the belief that it was more appropriate for ESRD facilities than the IPPS wage index which was in use prior to 2025. Several other ESRD facilities, including an LDO, expressed opposition to the methodology and stated that the legacy ESRD PPS wage index was more appropriate

Response: We thank the commenters for expressing their opinion on the current wage index methodology as we continue to evaluate its performance. We agree with the commenters that the current ESRD PPS wage index is the most appropriate wage index for ESRD facilities as it represents cost of labor specific to ESRD facilities, however we acknowledge that some commenters believe the legacy methodology was more appropriate.

Comment: Several commenters stated that 72 percent of wage index areas experienced a decrease in wage index values and asserted that this indicates there is significant variance in the new wage index methodology. Some commenters also noted that the proposed wage index budget neutrality factor for CY 2026 resulted in a nearly 0.9 percent increase to the ESRD PPS base rate and further interpreted that as evidence that the wage index methodology produced lower wage index values. The commenter requested that CMS work with interested parties outside of the rulemaking process to improve the methodology for future years.

Response: We do not believe that our methodology results in significant variance. We believe that the referenced figure of 72 percent of wage index areas is referring to counties presented in the wage index crosswalk in addendum A of the CY 2026 ESRD PPS proposed rule. We are unsure why the commenters chose to analyze the percentage of counties which receive a lower wage index value, even though the wage index is calculated and applied at the CBSA level, but we note that each CBSA contains multiple counties, which means that a decrease in any CBSA's wage index would be replicated across all of its constituent counties. ESRD facilities are not uniformly distributed across counties, and therefore analysis at the county level could overstate or understate the impact of changes in the wage index values for certain CBSAs. In section VII.C of this CY 2026 ESRD PPS final rule, we present a detailed impact analysis based on data from 7,608 ESRD facilities.[8] When analyzed at the facility level, we estimate that 12.6 percent of these ESRD facilities will experience a wage index value change (positive or negative) of less than 0.5 percentage point from CY 2025 to CY 2026, 20.2 percent of these ESRD facilities will experience a wage index increase of 0.5 percentage point or more, and 67.2 percent will experience a wage index decrease of between 0.5 percentage point and 5 percent, which is our threshold for applying the cap on wage index decreases. When evaluated at the facility level, we note that the number of ESRD facilities whose wage index is decreasing is slightly lower than the county-level figure the commenters cited.

Additionally, we note that some of the wage index decreases that we observe for CY 2026 can be attributed to wage index changes that were finalized in CY 2025, but whose impact was mitigated by the 5-percent cap on wage index decreases. As discussed in the CY 2026 ESRD PPS proposed rule (90 FR 29352), the higher-than-average wage index budget neutrality factor proposed for CY 2026 is, in large part, due to the way the ESRD PPS applies the 5 percent cap on wage index decreases and the transition from the legacy wage index methodology to the current ESRD PPS wage index methodology beginning for CY 2025. Specifically, when we implemented the current ESRD PPS wage index methodology, a large number of ESRD facilities experienced a significant change in wage index value, which was expected given that the current methodology is based on different data from the legacy methodology. As we cap the year-over-year reductions in wage index value at 5 percent, but we do not similarly cap the year-over-year increases in wage index values, any large shift in wage index values in a given year will result in a higher-than-typical average ESRD PPS wage index value as the ESRD facilities which would receive a significantly lower wage index value instead receive a higher capped value. Thus, the CY 2025 ESRD PPS wage index had a higher-than-typical average value, which resulted in a lower-than-typical budget neutrality factor for CY 2025. For CY 2026, many ESRD facilities which received a capped value in 2025 are now set to receive a lower value. Thus, the average wage index value for CY 2026 is lower than that of CY 2025, which results in a budget neutrality factor greater than 1, which increases the ESRD PPS base rate. It would not be appropriate to consider relative CY 2026 decreases resulting from the application of the cap in CY 2025, the transition year in which the current wage index methodology was first implemented, as evidence of variability for CY 2026 as the decreases were predominantly due to CY 2025 policies.

We welcome any additional information or suggestions on how best to improve our methodology and ensure ESRD PPS wage index values are appropriately stable and reflective of the labor costs in a given geographic area. We have analyzed the potential factors which have resulted in the changes presented in the CY 2026 wage index and intend to continue to monitor the performance of the methodology. We would propose changes, if warranted, in potential future rulemaking.

Comment: Several commenters requested additional information and transparency on the ESRD PPS wage index methodology.

Response: We are willing to provide additional information on our methodology but are uncertain what exactly commenters are requesting. We note that when we proposed and finalized the ESRD PPS wage index methodology we provided a substantial amount of methodological information in the CY 2025 ESRD PPS proposed rule (89 FR 55760), the CY 2025 ESRD PPS final rule (89 FR 89084), and in Addendum C of the CY 2025 ESRD PPS proposed rule.[9]

Comment: One coalition of dialysis organizations requested CMS publish imputed data points for mean hourly wage data for which BLS did not publish OEWS estimates.

Response: We thank the commenters for this suggestion. We have included a table in Addendum A of this CY 2026 ESRD PPS final rule that includes the mean hourly wage data for all counties and job codes, along with an indicator of whether the wage value is imputed or not.

Comment: Several commenters raised methodological concerns with the ESRD PPS wage index methodology. One professional association noted that BLS data was not stratified by facility type and therefore was not specific to ESRD facilities. One LDO and a coalition of dialysis organizations requested CMS explain why contract labor and overtime-and-benefits were not

[8] Information on the CY 2025 and CY 2026 ESRD facility wage indexes used in this analysis are found in Addendum B of this CY 2026 ESRD PPS final rule.

[9] *https://www.cms.gov/files/document/addendum-c-cms-1805-p-esrd-pps-proposed-wage-index-construction-methodology.pdf.*

included in the methodology. The LDO further noted that overtime and benefits may be impacted by state law and the labor-related share includes overtime and benefits. The LDO also raised concerns regarding the possibility that contract labor could be misattributed to another CBSA, the interaction between existing facility-level payment adjustments and the wage index, and CMS's decision to implement the new methodology budget neutrally for CY 2025.

Response: We recognize the limitations of the data source upon which the ESRD PPS wage index methodology is built. We discussed these limitations in the CY 2025 ESRD PPS proposed rule (89 FR 55769) and, in the CY 2025 ESRD PPS final rule (89 FR 89099, 89116), concluded that, even with these limitations, the methodology represents a significant improvement over the IPPS wage index for use in ESRD facilities. We wish to reiterate that the purpose of the wage index is to estimate the geographic variation in wages, and we believe that this wage index methodology does that appropriately. The issues that the commenters raised regarding contract labor, overtime and benefits would only have a real impact on the resulting wage index should the yearly change in the growth of those wage costs vary significantly from the yearly change in the growth of the mean hourly wage. The commenter raises a valid point about certain laws regarding overtime and benefits, as that could result in geographic variation differing from mean hourly wage, however we do not believe it would be appropriate to base ESRD PPS payment policy directly on state or local legislation. Furthermore, we still believe that the mean hourly wage for ESRD facility-specific occupations would be a better proxy for ESRD facility-specific occupation benefits and overtime, insofar as geographic variation, than the acute hospital wage index. We welcome commenters' suggestions on alternative proxies for mean hourly wage for this labor, and methodological changes that could account for variation in overtime and benefits to be considered in potential future rulemaking.

In the CY 2025 ESRD PPS rulemaking, we did not propose changes to the LVPA or rural adjustment factors as a result of the new ESRD PPS wage index, as we generally do not recalculate established factors when we implement a new policy. For example, when we propose a budget neutral payment adjustment, we do not update the adjustment factor annually according to changes in utilization, nor do we apply a budget neutrality factor to the ESRD PPS base rate in subsequent years.[10] Similarly, we do not believe we are required to reevaluate adjustment factors when we update the ESRD PPS wage index. However, we acknowledge the commenter's point and will continue to evaluate the interaction between the LVPA and the ESRD PPS wage index and propose any potential changes, if appropriate, in future rulemaking. Lastly, we note that we annually apply changes to the wage index in a budget neutral manner and do not believe it would have been appropriate to deviate from this long-established policy for the new ESRD PPS wage index methodology.

Comment: A national forum of ESRD networks commented that if hospital cost reports were not used to calculate the wage index budget neutrality factor, then it would not appropriately reconcile the increased expenses faced by those facilities.

Response: Hospital-based ESRD facilities were included in the impact calculation presented in section VII.C.5. and Appendix B of this final rule. The wage index budget neutrality factor was derived from this analysis, and therefore includes hospital-based ESRD facilities. We believe the commenter may be under the incorrect impression that hospital-based ESRD facilities were excluded from the wage-index budget neutrality analysis. Although hospital-based ESRD facilities are not included in the cost report data for the NEFOM, we note that they are included in the impact analysis for the wage-index budget neutrality factor. The NEFOM is essentially the weights for the mean hourly wage data used when calculating the wage index, and including only freestanding ESRD facilities in the calculation of the NEFOM does not meaningfully disadvantage hospital-based facilities as in any methodology all ESRD facilities' wage index values would be based on a single NEFOM.

Comment: Several commenters specifically discussed the impact of the ESRD PPS wage index methodology on ESRD facilities in certain urban areas, most notably New York. A commenter noted that New York CBSAs experienced a significant decrease in wage index value in the CY 2025 ESRD PPS rule when the current wage index methodology was first implemented and highlighted the fact that many CBSAs in New York were set to see a lower wage index value for CY 2026 based on the proposed wage index.

Response: We appreciate the commenters' concerns regarding the projected decreases in wage index values for certain geographic areas in New York. We acknowledge that several CBSAs in New York are projected to receive lower wage index values for CY 2026; however, the majority of these decreases are relatively modest, with only one CBSA projected to experience a decrease greater than 5 percent. While we recognize that even modest decreases in the wage index may result in meaningful changes in payment amounts, we emphasize that, with the application of the wage index budget neutrality adjustment factor, many geographic areas are expected to experience increases in labor-related payments relative to uncapped CY 2025 wage index values.

We also reiterate that changes to the wage index should not be evaluated in isolation. Because the wage index is a relative measure, decreases in a particular area generally reflect that wages in that area are increasing at a slower rate than the national average, rather than an absolute decline in wage levels.

Comment: A coalition of dialysis organizations opined that the 5 percent cap was not sufficient to mitigate swings in wage index value resulting from the ESRD PPS wage index methodology.

Response: As discussed previously, we do not believe that the ESRD PPS wage index methodology results in unreasonable variance, however some variance is unavoidable. We believe that the 5 percent cap on year over year decreases in wage index value, as codified at § 413.231(c), sufficiently protects ESRD facilities from large, unexpected decreases in wage index value. We are open to suggestions for consideration of alternative policies to ensure the wage index is reasonably predictable while continuing to appropriately reflect relative geographic variation in wages.

Comment: A commenter expressed support for the current 0.6000 wage index floor. The commenter requested CMS perform further analysis on the wage index floor and expressed a belief that such analysis would support an increase to the wage index floor. The commenter specifically suggested that a wage index floor of 0.7000 would be appropriate. This commenter specifically highlighted Puerto Rico and enumerated certain labor costs which they stated contributed to the cost of care in Puerto Rico.

[10] In CY 2011 CMS established the ESRD PPS case-mix adjusters, which were set through regression and budget-neutrality calibration (75 FR 49083). We have not annually updated these factors with each wage index or utilization change. CMS has only revisited them when making a discrete policy proposal such as we did in the CY 2016 ESRD PPS rule (80 FR 68973).

Response: We thank the commenter for the continued support of the wage index floor. We did not propose to change the wage index floor for CY 2026 and are not finalizing any changes in this final rule. We will continue to monitor the appropriateness of the current wage index floor, including the interaction with any labor costs specific to Puerto Rico, and will consider any further changes through notice-and-comment rulemaking in future years.

Comment: We received a few comments in response to our proposal to use adjusted BLS OEWS May 2023 estimates for Colorado should OEWS estimates for the state not be published by the time the final rule was developed. Commenters supported this methodology, however some raised concerns about the situation and what CMS would do if similar issues arose in the future.

Response: Colorado estimates for the May 2024 BLS OEWS were released on July 23, 2025.[11] We acknowledge the concerns of the commenters, but this was a state-specific issue and BLS corrected it expediently. In the future, should there be a regular occurrence of this issue, we would consider potentially addressing it through rulemaking, if necessary.

Comment: A commenter requested CMS publish the uncapped wage index values for CY 2026.

Response: The uncapped wage index values for the proposed and final CY 2026 ESRD PPS wage index are available in Addenda A of the proposed and final rules, respectively. We do not include the uncapped values for ESRD facilities in the facility level impact analysis of Addendum B as we believe that could cause confusion because the uncapped values do not apply for certain ESRD facilities. We note that one can identify the uncapped wage index value for an ESRD facility by looking up the value in Addendum A for the CBSA in which the ESRD facility is located.

Comment: A commenter stated that pediatric hospital-based ESRD facilities faced different wages than other ESRD facilities and indicated that the IPPS wage index would be more appropriate for these ESRD facilities. The commenter requested CMS either implement a blended wage index for pediatric hospital-based facilities or implement an exception process where an ESRD facility could apply to receive the IPPS wage index.

Response: We acknowledge that pediatric hospital-based ESRD facilities likely have different costs, as demonstrated by the analysis which resulted in the Transitional Pediatric ESRD Add-on Payment Adjustment (TPEAPA), a 30 percent increase in the per-treatment payment amount for Pediatric ESRD Patients codified at § 413.235(b)(2). However, higher labor costs do not necessarily mean that an alternative wage index methodology would be appropriate. We believe the TPEAPA appropriately accounts for the differences in wage values faced by pediatric hospital-based ESRD facilities and note that the purpose of the ESRD PPS wage index is to estimate geographic variation in wages faced by ESRD facilities. We continue to believe that the ESRD PPS specific wage index is more appropriate for this purpose for pediatric and hospital-based ESRD facilities as we believe the types of labor utilized by these facilities are likely more similar to other ESRD facilities than acute inpatient hospitals. However, we will take this suggestion into consideration and make any potential changes to the ESRD PPS wage index methodology, if appropriate, in future rulemaking.

Comments: A commenter stated the belief that the ESRD PPS wage index did not reflect true labor costs. The commenter discussed an ESRD facility that had increased labor costs and a decreasing wage index value. Another commenter noted the increase in the costs of nursing labor.

Response: The ESRD PPS wage index is intended to reflect the relative wage costs faced by ESRD facilities. It is not intended to capture overall trends in labor costs. We would expect some ESRD facilities to experience increasing labor costs and decreasing wage index values, as this would likely indicate the ESRD facility is in a geographical location where wages are increasing at a lower rate than the national average.

Final rule action: After consideration of public comments, we are finalizing the use of the CY 2026 ESRD PPS wage index according to our established methodology based on the May 2024 BLS OEWS mean wage data and CY 2023 cost report data. Additionally, we are finalizing the use of the May 2024 BLS OEWS estimates for Colorado, which were not available at the time of proposed rulemaking but were released in July 2025. The final CY 2026 ESRD PPS wage index is set forth in Addendum A and provides a crosswalk between the CY 2025 wage index and the 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. 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 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.[12]
- 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

[11] *https://www.bls.gov/oes/notices/2025/colorado-may-2024-oews-estimates.htm.*

[12] 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.

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.[13] 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 final 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 CY 2023 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-mix adjusted post-TDAPA add-on payment adjustment amount in the calculation of the predicted MAP amounts when applicable (89 FR 89127). 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. CY 2026 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2026, we proposed to update the MAP amounts for adult and pediatric patients using the latest available CY 2024 claims data. We proposed 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). In the proposed rule, we stated that the latest available CY 2024 claims data showed that outlier payments represented approximately 0.8 percent of total Medicare payments. We proposed to update these values with

[13] 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.*

the latest available data, if appropriate, in the final rule.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Several commenters expressed support for the proposed reductions to the FDL and MAP amounts to better target outlier payments at 1.0 percent of total ESRD PPS payments. Some commenters expressed concern about the fact that CY 2024 outlier payments represented less than 1.0 percent of total ESRD PPS payments and urged CMS to continue to monitor this policy.

Response: We appreciate these comments, and we agree with the importance of continued monitoring of the outlier policy. We intend to continue to evaluate the performance of the outlier policy, including the policy and technical changes that were finalized for CY 2025, and may consider additional changes to the outlier policy through future notice and comment rulemaking.

Comment: Several commenters urged CMS to change certain aspects of the ESRD PPS outlier policy. Some commenters stated that a lower target percentage, for example 0.5 percent of total payments, would be more appropriate. These commenters stated that section 1881(b)(14)(D)(ii) of the Act does not require the ESRD PPS outlier percentage to be 1.0 percent. Several commenters also stated that CMS should not include TDAPA and TPNIES payments when calculating total ESRD PPS payments, of which outlier payments are targeted at 1.0 percent.

Response: We appreciate these comments, but we do not agree that either of the suggested revisions to the outlier methodology would be more appropriate than the current outlier policy. As we have previously stated, while we agree that section 1881(b)(14)(D)(ii) of the Act provides the Secretary with discretion to set an appropriate outlier percentage under the ESRD PPS, we continue to believe the 1.0 percent target is more appropriate than a lower outlier percentage. As discussed in the CY 2011 ESRD PPS final rule (75 FR 49134), we established the 1.0 percent outlier percentage because it struck an appropriate balance between our objective of paying an adequate amount for the costliest, most resource-intensive patients while providing an appropriate level of payment for those patients who do not qualify for outlier payments. We continue to believe the 1.0 percent target strikes the appropriate balance, and as we further noted in the CY 2023 ESRD PPS final rule (87 FR 67171), a reduced outlier percentage may not provide the appropriate level of payment for outlier cases and may not protect access for beneficiaries whose care is unusually costly. This is because if we were to decrease the target outlier percentage, we would need to significantly increase the FDL amounts, which would make it more difficult for ESRD facilities to receive outlier payment based on their claims. We did not propose to reduce the outlier percentage for CY 2026, and we are not finalizing any such reduction in this rule.

Likewise, we do not agree with the suggestion to exclude TDAPA and TPNIES payments from total ESRD PPS payments for the purposes of setting the FDL and MAP amounts for CY 2026. We believe that commenters incorrectly assume that excluding TDAPA and TPNIES payments from this calculation would result in an increase to non-outlier payments (that is, total ESRD PPS payments other than those made as part of the outlier adjustment under the ESRD PPS). To the contrary, this change to our calculations would only reduce the total amount of outlier payments, which would be 1.0 percent of a lower total ESRD PPS payment figure, without increasing other (non-outlier) payments under the ESRD PPS, since the base rate would continue to be reduced by 1.0 percent. This change would require us to increase the FDL amounts, which would make it more difficult for ESRD facilities to receive outlier payment based on their claims.

Comment: Several commenters expressed that the proposed updates to the FDL and MAP amounts would not address what commenters stated is an underlying lack of payment adequacy for new drugs that are renal dialysis services. Several commenters advocated for funding mechanisms that would appropriately safeguard patient access to new drugs and biological products after the 2-year TDAPA period expires.

Response: We appreciate the commenters' concerns regarding payment for new renal dialysis drugs and biological products under the ESRD PPS. As the commenters pointed out, and as we have previously stated, the purpose of the ESRD PPS outlier adjustment is not to pay for new drugs and biological products. Rather, the purpose of the ESRD PPS outlier adjustment is to protect access to care for beneficiaries whose care is exceptionally costly. In the CY 2025 ESRD PPS final rule (89 FR 89142), we stated that including new renal dialysis drugs that previously received payment using the TDAPA would help ensure appropriate payment when a patient's treatment is exceptionally expensive due to an ESRD facility furnishing such drugs or biological products to the patient whose treatment requires them.

We note that the post-TDAPA add-on payment adjustment, as discussed in section II.B.6 of this final rule, provides additional payment for certain new renal dialysis drugs and biological products after the end of the 2-year TDAPA period. In the CY 2024 ESRD PPS final rule we stated that one goal of the post-TDAPA add-on payment adjustment is to support continued access to new renal dialysis drugs and biological products and to support ESRD facilities' long-term planning and budgeting for such drugs after the TDAPA period (88 FR 76393). Therefore, we believe that for drugs that are in existing ESRD PPS functional categories, ESRD PPS policy provides appropriate and adequate payment in the short term during the 2-year TDAPA period, in the medium term during the 3 years of payment under the post-TDAPA add-on payment adjustment following the payment of TDAPA, and during the long term when such new renal dialysis drugs and biological products are paid for under the ESRD PPS base rate with no adjustment and are expected to compete with other drugs and biological products in the ESRD PPS. Lastly, we note that ESRD PPS payments are updated annually based on the ESRDB market basket update, to reflect the changes over time of the cost of renal dialysis services and to help ensure that ESRD PPS payments are adequate. The composition of the ESRDB market basket depends on ESRD facilities' spending for drugs and biological products, as well as all other inputs ESRD facilities use in providing renal dialysis services. As we noted in the CY 2024 ESRD PPS final rule (88 FR 76391), CMS generally uses Medicare cost report data that lags by approximately 3 to 4 years prior to the rulemaking year to consider changes to market basket cost categories, cost weights, and price proxies. CMS would be able to analyze Medicare cost report data for CY 2023 and CY 2024 to consider changes to the ESRDB market basket for CY 2027 rulemaking, if appropriate.

Comment: A few commenters stated that by paying only 0.8 percent of total ESRD PPS payments in CY 2024, the ESRD PPS underpaid ESRD facilities by approximately $0.63 per treatment, which the commenters pointed out is greater than the proposed budget neutrality reduction for the proposed NAPA. One of these commenters suggested that the underpayment of

outliers in CY 2026 should be used to pay for the proposed NAPA in CY 2026.

Response: We appreciate the concerns raised by commenters regarding the fact that outlier payments were only 0.8 percent of total ESRD PPS payments in CY 2024, below our 1.0 percent target. We do not agree with the commenter's assertion that that this perceived shortfall could be used to budget-neutralize the proposed NAPA. We do not apply any budget neutrality factor to the ESRD PPS to account for over- or under-payment of outliers each year, relative to the 1.0 percent target established in CY 2011. Rather, we re-calculate the FDL and MAP amounts annually, and we set these values prospectively at a level that we project will be 1.0 percent of total ESRD PPS payments.

As we discuss later in this CY 2026 ESRD PPS final rule, we are finalizing the NAPA as proposed. Although there is no mechanism to apply the methodology that the commenter suggested, we are clarifying in this final rule that the NAPA will be applied to the predicted MAP amounts for facilities located in Alaska, Hawaii, and the US Pacific Territories, in accordance with our longstanding policy of applying patient- and facility-level adjustment factors to the predicted MAP amounts. We note that in the CY 2011 ESRD PPS final rule (75 FR 49085) we established that the calculation of the predicted MAP included the existing facility-level adjustment factors, which were the LVPA and the rural adjustment factor. We note that this has the effect of slightly reducing the outlier thresholds for most ESRD facilities nationwide, which we project will result in slightly higher outlier payments for most facilities in CY 2026.

Comment: A commenter noted that the proposed outlier thresholds were estimated to pay out 1.87 percent of total ESRD PPS payments for CY 2026. The commenter attributed this to the outlier policy's assumptions on utilization being based on 2024 data and interpreted this projected payment as evidence that utilization of outlier eligible services is decreasing over time more than projected for 2024. Another commenter noted the estimated 1.87 percent payments in the proposed rule regulatory impact analysis and raised concerns that given the expansion of the ESRD outlier services list in the CY 2025 ESRD PPS final rule, trends in outlier utilization might be more difficult to predict. Both commenters urged CMS to carefully monitor the performance of the outlier methodology.

Response: We appreciate the comment and acknowledge that our proposed impact results showed that estimated outlier payments would be 1.87 percent of total ESRD PPS payments for CY 2026. The commenter accurately identified that this is an artifact of the payment simulation methodology which creates an apparent discrepancy. We want to further clarify that this apparent discrepancy is due to our methodology, which we finalized in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67177), in which we calculate the adult FDL amount based on a straight-line projection of the FDL amounts which would have achieved the 1 percent target in the most recent 3 years for which we have data. We continue to believe that this methodology of utilizing the trend of retrospectively calculated FDL amounts will allow CMS to more accurately achieve the 1 percent target in future years. However, because our impact methodology relies on simulated CY 2025 and CY 2026 payments using the same set of claims from CY 2024, our estimate of outlier payments for CY 2025 and CY 2026 is based on CY 2024 utilization levels for ESRD outlier services. The commenter accurately notes that because our simulated CY 2026 payments assume that utilization will be the same for 2026 as it was for 2024, it does not capture other historical trends in utilization the same way that our retrospective methodology for projecting the FDL amount does. Accordingly, although our simulated CY 2026 ESRD PPS payments reflect outlier payments that are approximately 1.9 percent of total ESRD PPS payment, we anticipate that the actual utilization of ESRD outlier services in CY 2026 will be such that the final FDL and MAP amounts will result in outlier payments that equal approximately 1.0 percent of total ESRD PPS payments. We agree with the commenters that it is important to monitor the performance of the outlier methodology and will continue to do so and may propose changes to the methodology, if appropriate, in potential future rulemaking.

Final Rule Action: After consideration of public comments, we are finalizing our proposal to update the FDL and MAP amounts for CY 2026 based on the latest available data. The impact of this final 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 final rule for CY 2026. The estimates for the final 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—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 Final 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	$50.64	$24.83
Adjustments:				
Standardization for outlier services	1.0432	0.9768	1.0113	0.9731
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	59.60	31.02	50.19	23.68
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	234.26	45.41	162.43	14.80
Patient-month-facilities qualifying for outlier payment	6.09%	7.05%	7.58%	14.10%

* 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 final FDL amount per treatment amount that determines the CY 2026 outlier threshold amount for adults (column II; $14.80) 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 amount for outlier services from $31.02 to $23.68. For pediatric patients, there is a decrease in the FDL amount from $234.26 to $162.43. There is a corresponding decrease in the adjusted average MAP amount for outlier services among pediatric patients, from $59.60 to $50.19. 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 14.10 percent for adult patients and 7.58 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 CY 2024 claims available for this final rule, outlier payments represented approximately 0.8 percent of total payments, which is slightly below the 1.0 percent target.

4. Impacts to the CY 2026 ESRD PPS Base Rate

a. 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. Annual Payment Rate Update for CY 2026

We proposed an ESRD PPS base rate for CY 2026 of $281.06, which we stated was approximately a 1.9 percent increase from the CY 2025 ESRD PPS base rate of $273.82. As outlined in section II.B.1.b. of the proposed rule, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this 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 invited public comment on our proposed CY 2026 ESRD PPS base rate. The following is a summary of the comments we received and our responses.

Comment: We received numerous comments which discussed payment rates under the ESRD PPS. Commenters generally opined that the payment rate was lower than appropriate due to various reasons. The reasons specific to the annual ESRDB market basket increase are discussed in section II.B.1.b.(5) of this final rule. Commenters that focused on the overall payment rate often indicated a belief that it was inadequate based on MedPAC margins, as reported in MedPAC's March 2025 Report to Congress.[14] Commenters highlighted that this report found that projected CY 2025 Medicare margins for ESRD facilities were 0 and that margins were negative in 2023. A few LDOs stated the belief that MedPAC's margins were overstated because MedPAC did not consider the statutorily required $0.50 ESRD network reduction. One coalition of dialysis providers raised concerns with the use of Medicare marginal profit rather than overall Medicare margins, which CMS has referenced in the past. One LDO noted that many other facility types have positive Medicare margins. A commenter stated that the current payment rate was below the cost of providing renal dialysis services. MedPAC commented that payment rates were adequate based on the analysis in its March 2025 Report to Congress.

Response: We agree with MedPAC that payment rates under the ESRD PPS are adequate. While we view Medicare margins as an important tool in evaluating payment adequacy, we believe other metrics including overall facility margins and marginal profit are also useful tools. We note that the marginal profit analysis by MedPAC indicates that the payment rate is greater than the marginal cost of care, although we appreciate the commenter's concern with the use of marginal profit and will consider it when evaluating MedPAC reports in the future. We note that we do not set payment rates based on Medicare margins or marginal profit but rather based on the statutorily required methodology of basing CY 2011 payments on payments that would have been made in 2011, under the prior payment system, using the lowest per patient utilization from 2007, 2008 or 2009 and then annually increasing that rate by an ESRDB market basket percentage increase reduced by a productivity adjustment as set forth in section 1881(b)(14)(A) and 1881(b)(14)(F) of the Act.

Comment: Several commenters stated various impacts of what they view as lower-than-appropriate payment rates. Two impacts were noted most frequently. First, several ESRD facilities reported difficulty recruiting skilled labor and high turnover, resulting in subsequent quality concerns. Second, several interested parties raised access concerns related to ESRD facility closures. A professional association highlighted nurse burnout and noted several potential areas of improvement that ESRD facilities could implement to reduce turnover at ESRD facilities.

Response: We appreciate these insights into the impact of the ESRD PPS payment rate on ESRD facilities. As we have stated, we believe the payment rate as prescribed by statute is

[14] *https://www.medpac.gov/document/march-2025-report-to-the-congress-medicare-payment-policy/.*

sufficient, however we will continue to monitor these metrics. We appreciate the commenters' suggestions on how ESRD facilities could strengthen their nursing workforce in ESRD facilities. While CMS recognizes the importance of staff retention and maintaining beneficiaries' access to ESRD facilities, we believe the commenters' suggestions are generally outside the scope of the ESRD PPS or Medicare payment policy.

Comment: Some commenters noted that when ESRD patients are unable to access renal dialysis services in an ESRD facility they are likely to go to an emergency department and receive the care at a greater cost to Medicare. Other commenters noted that inpatient stays are often prolonged if a patient is unable to find an outpatient ESRD facility to go to after discharge.

Response: We appreciate commenters raising these concerns and will continue to monitor ESRD beneficiaries' treatments in other sites of service that are not ESRD facilities. We recommend sending any specific issues regarding access to renal dialysis services, such as instances where a beneficiary is unable to locate an outpatient ESRD facility after discharge, to the ESRD PPS payment mailbox: *ESRDPayment@cms.hhs.gov.*

Comment: Some commenters indicated a specific concern for small and independent ESRD facilities. A few commenters cited a MedPAC report that indicated the smallest ESRD facilities had a –19 percent Medicare margin.

Response: We appreciate the commenters' concern. We note that the LVPA provides additional payment to low -volume ESRD facilities, and we finalized changes to the LVPA policy effective CY 2025 which increased the adjustment factor for low-volume facilities furnishing fewer than 3,000 treatments per year, increasing payments for these ESRD facilities. We intend to continue to monitor costs and margins for ESRD facilities, including low volume ESRD facilities, and propose changes to address any discrepancy between the relative payment rate and resource use, if appropriate, through notice and comment rulemaking.

Comment: A commenter stated that supply shortages were increasing costs, resulting in the ESRD PPS payment rate being inadequate.

Response: We would appreciate receiving additional information on the supply shortages the commenter mentions. Such information can be sent to the ESRD PPS payment mailbox: *ESRDPayment@cms.hhs.gov.*

Comment: One LDO stated that insufficient payment rate hampers operational sustainability and highlighted the disproportionate impact on vulnerable populations. Another LDO stated the belief that payment adequacy was more important than predictability, in reference to a request for a forecast error adjustment.

Response: As discussed previously, we believe payment under the ESRD PPS is adequate and appropriate as required by statute. We recognize the commenters' concerns related to sustainability and predictability and acknowledge that lower-than-appropriate payments could cause issues in both respects. As discussed in past rules, we agree that predictability of ESRD PPS payments is important and setting rates prospectively is intrinsic to a prospective payment system. We will consider the commenters' concerns related to sustainability and predictability and would propose any changes, if appropriate, in potential future rulemaking.

Final Rule Action: After consideration of public comments, we are finalizing a CY 2026 ESRD PPS base rate of $281.71. This amount 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 finalizing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the final CY 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 final CY 2026 ESRD PPS wage index and final LRS 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 final CY 2026 wage index budget neutrality adjustment factor is 1.00905. As we are not finalizing any changes to our established ESRD PPS wage index policy, this final 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 LRS. 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 results in a final wage-index budget neutrality factor above 1, meaning the final ESRD PPS base rate increases 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 final 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 did not propose any changes to the TPEAPA amount, it would not be appropriate to apply a budget neutrality factor for the TPEAPA for CY 2026.

NAPA Budget Neutrality Factor: As outlined in section II.B.8. of this final rule, under the authority granted by section 1881(b)(14)(D)(iv) of the Act, we are finalizing a new facility-level payment adjustment for ESRD facilities in Alaska, Hawaii, and certain U.S. Pacific Territories,[15] which we refer to in this final rule as the non-contiguous areas payment adjustment (NAPA). This payment adjustment will apply to ESRD PPS claims for treatments at ESRD facilities in Alaska, Hawaii, Guam, American Samoa, and the Northern Mariana Islands. This payment adjustment is capped at 25 percent and will be applied to the non-LRS of the ESRD PPS base rate, which is 44.8 percent. We are finalizing that this payment adjustment will be budget neutral and will result in a final NAPA budget neutrality factor of 0.99860.

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 outlined in section II.B.1.b.(1). of this final rule, the final CY 2026 ESRDB market basked increase based on the third quarter 2025 CY 2026 projection of the ESRDB market basket is 2.9 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 final rule, the final CY 2026 productivity adjustment is 0.8 percentage point based on the third quarter 2025 forecast (the 10-year moving average of TFP for the period ending CY 2026), thus yielding a final CY 2026 ESRDB market basket update of 2.1 percent for CY 2026. Therefore, the final CY 2026 ESRD PPS base rate is $281.71 (($273.82 × 1.00905 × 0.99860) × 1.021 = $281.71).

5. 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 final 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 the 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 proposed to update the TPNIES offset amount annually according to the methodology described previously.

We proposed 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). We requested public comments on our proposal to update the TPNIES offset amount for capital-related assets for CY 2026.

The following is a summary of the comments we received on this proposal and our responses.

Comment: A commenter stated the belief that the proposed TPNIES offset amount was too low to compensate for TPNIES supplies.

Response: The TPNIES offset amount is not intended to account for the cost of the renal dialysis equipment or supplies. As we explained in the CY 2021 ESRD PPS final rule (85 FR 71423), we apply the TPNIES offset amount so that ESRD facilities using a new and innovative home dialysis machine would receive a per treatment payment to cover some of the cost of the new machine per treatment minus a per treatment payment amount that we estimate to be included in the ESRD PPS base rate for current home dialysis machines that the facilities already own. We note that the actual TPNIES payment for these machines would be based on invoice pricing and reduced by the TPNIES offset amount. For a full description of the methodology for TPNIES for capital related assets please see the CY 2021 ESRD PPS final rule (85 FR 71427).

Final rule action: After consideration of public comment, we are finalizing our proposal to update the CY 2026 TPNIES offset amount. For the CY 2026 final TPNIES offset amount we are using the final ESRDB market basket update factor in section II.B.1.b.(3). of this final rule. Applying the final ESRDB market basket update factor of 1.021 to the CY 2025 TPNIES offset amount results in the final CY 2026 TPNIES offset amount of $10.43 ($10.22 × 1.021 = $10.43).

6. 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 adjustment 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

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

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,[16] 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.[17]

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. Section 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 the proposed rule. As CMS had not received ASP data for quarter 3, 2025, which reflects sales for quarter 1, 2025 for Jesduvroq®, we did not propose to include Jesduvroq® in the calculation of the post-TDAPA add-on payment adjustment for CY 2026 or any future years. Therefore, due to the continued receipt of the latest full calendar quarter of ASP data for the renal dialysis drugs discussed later in this document, there are 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 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.

In the CY 2026 ESRD PPS proposed rule, we presented 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 were unable to present an estimate of the post-TDAPA add-on payment adjustment amount for DefenCath® at that time using a full year of utilization data, however we included a proposed post-TDAPA amount based on the first 6 months of DefenCath® utilization. The proposed post-TDAPA add-on payment adjustment amount for Korsuva® was $0.2633 and the proposed post-TDAPA add-on payment adjustment amount for DefenCath® was $1.4780. Consistent with the methodology finalized in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76389), we proposed to update these calculations with the most recent available utilization and pricing data in the final rule. We invited public comments on our proposed CY 2026 post-TDAPA add-on payment adjustment amounts.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Numerous commenters requested we modify our methodology for calculating the post-TDAPA add-on payment adjustment to be based on per-claim utilization and only apply to claims that include the drug or biological product in question and not be time limited. Commenters generally expressed the opinion that such a payment adjustment would better support innovation within the ESRD PPS. A commenter stated the belief that the current post-TDAPA methodology has harmed patients by failing to provide a sustainable pathway for payment for new drugs and biological products and their suggested methodology would better support innovation.

Response: As we discussed in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76396) we do not agree that a methodology based on per-claim utilization would be appropriate for the post-TDAPA add-on payment adjustment, because it would directly incentivize utilization of a particular drug or biological product, which we noted can result in overutilization. While the TDAPA and post-TDAPA add-on payment adjustments share the goal of supporting access to new renal dialysis drugs or biological products used to treat or manage a condition in an ESRD PPS functional category, the TDAPA's short-term objectives are more consistent with a methodology that is based on per-claim utilization. As we discussed in the CY 2019 and CY 2020 ESRD PPS final rules (83 FR 56935; 84 FR 60654), for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate the new drugs and biological products and make appropriate changes in their businesses to adopt such products. We also explained that the TDAPA provides additional payments for such associated costs and promotes competition among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative. The TDAPA for renal dialysis drugs and biological products in existing ESRD PPS functional categories is inherently transitional in nature and therefore not permanent. We later finalized a post-TDAPA add-on payment adjustment beginning in CY 2024 that that provides a glidepath for inclusion of such new renal dialysis drugs and biological products into the ESRD PPS. In the CY 2024 ESRD PPS proposed rule (88 FR 42460), we stated that a 3-year period for the post-TDAPA add-on payment adjustment would be consistent with the transition period that was finalized at the beginning of the ESRD PPS, when ESRD facilities were transitioned from receiving payments under the composite rate payment system to receiving payments under the ESRD PPS (79 FR 49162).

We believe that the current post-TDAPA add-on payment adjustment methodology provides the most appropriate incentives for ESRD facilities to be efficient with resources, while providing an appropriate level of payment that supports access to new renal dialysis drugs and biological products. We recognize that the policy would not permanently maintain increased payments for new renal dialysis drugs and biological products

[16] CMS Transmittal 13245, dated May 29, 2025, is available at *https://www.cms.gov/files/document/r13245bp.pdf.*

[17] CMS Transmittal 13245, dated May 29, 2025, is available at *https://www.cms.gov/files/document/r13245bp.pdf.*

that receive the TDAPA, and we do not believe that such a permanent increase in payments would be appropriate. We did not propose any changes to the methodology used to calculate the post-TDAPA add-on payment adjustment, the 3-year timeframe of the adjustment or the application of the post-TDAPA add-on payment adjustment to all ESRD PPS claims, for CY 2026, but we will consider the commenters' suggestions for potential future rulemaking.

Comment: We received some comments which specifically discussed the post-TDAPA add-on payment adjustment amount for Korsuva®. These commenters generally said that the per-treatment amount was too low when compared to the ASP of the drug. Some commenters stated that the post-TDAPA add-on payment adjustment actively disincentivizes ESRD facilities from stocking or providing it.

Response: We calculated the proposed post-TDAPA add-on payment adjustment amount for Korsuva® based on our established methodology under § 413.234(g) although, as discussed previously, we recognize that many commenters believe our established methodology does not provide enough payment for drugs and biological products. We strongly disagree with the statement that the post-TDAPA add-on payment adjustment amount for Korsuva® disincentivizes providers from utilizing the drug. As we stated in the CY 2025 ESRD PPS final rule (88 FR 89124), a new renal dialysis drug or biological product must demonstrate to patients and nephrologists that it presents value relative to existing treatment options, and the TDAPA further allows new products to become competitive by providing payment at 100 percent of ASP for the new drug or biological product. We expect that nephrologists and patients would consider all relevant factors and all available treatment options, and make the most appropriate decision for each patient. We do not believe we can infer that utilization of Korsuva® was depressed due to lack of adequate payment during the TDAPA period, because payment under the TDAPA for Korsuva® was based on 100 percent of ASP.

Furthermore, in the CY 2024 ESRD PPS final rule, we stated that one goal of the post-TDAPA add-on payment adjustment is to support continued access to new renal dialysis drugs and biological products and to support ESRD facilities' long-term planning and budgeting for such drugs after the TDAPA period (88 FR 76393). We believe that ESRD PPS policy provides appropriate and adequate payment in the short term during the 2-year TDAPA period, in the medium term during the 3 years of payment under the post-TDAPA add-on payment adjustment following the payment of TDAPA, and during the long term when such new renal dialysis drugs and biological products are paid for under the ESRD PPS base rate with no adjustment and are expected to compete with other drugs and biological products in the ESRD PPS bundled payment.

Comment: A drug manufacturer commented that, based on the preliminary calculation presented in the CY 2026 ESRD PPS proposed rule, they expected that the final post-TDAPA add-on payment adjustment amount for DefenCath® would be too low. They noted that at the time the post-TDAPA add-on payment adjustment would begin being applied for CY 2026 some of the data for the drug would be 2 years old. The manufacturer explained that utilization during that time did not reflect the current utilization of the drug as outside factors resulted in lower utilization of the drug. The manufacturer requested that we include data from quarters 3 and 4, 2025 in the calculation of the post-TDAPA add-on payment adjustment. The commenter stated that basing the post-TDAPA add-on payment amount on the higher 2025 data would provide more appropriate payment for this drug during the two quarters of the post-TDAPA add-on payment adjustment period. The commenter highlighted the policy finalized in the CY 2025 ESRD PPS final rule which allowed for CMS to publish a post-TDAPA add-on payment adjustment amount outside of rulemaking based on the established methodology when a full year of data would not be available at the time of final rulemaking. The commenter urged CMS to not finalize a post-TDAPA add-on payment amount at this time and instead calculate the post-TDAPA add-on payment adjustment for DefenCath® outside of rulemaking. The commenter stated the belief that the resulting add-on payment adjustment amount would be more appropriate.

Response: We appreciate the commenter's concerns regarding the post-TDAPA add-on payment adjustment amount for DefenCath®. As we explained in the CY 2025 ESRD PPS final rule, we determined that it is appropriate to calculate the post-TDAPA add-on payment adjustment amount based on a full year of utilization data. While we recognize that utilization can be influenced by external factors, the examples cited by the commenter primarily reflect health care provider choice in utilization. Although health care provider choice may be affected by a range of considerations, we continue to believe it is appropriate to account for these utilization patterns when calculating the post-TDAPA add-on payment adjustment amount.

We did not propose any changes to our established methodology for the post-TDAPA add-on payment adjustment in the CY 2026 ESRD PPS proposed rule, such as an alternative methodology to establish a post-TDAPA add-on payment adjustment amount outside of rulemaking in cases where there is a full year of utilization data but concerns are raised about that data. Accordingly, we are not finalizing any changes to our post-TDAPA add-on payment adjustment methodology at this time. We note that the period of higher utilization that the commenter discussed will be included when calculating the CY 2027 post-TDAPA add-on payment adjustment amount for DefenCath®, assuming continued receipt of ASP data as required under § 413.234(c)(3).

We will continue to evaluate whether additional flexibilities may be warranted in the post-TDAPA add-on payment adjustment calculation. If we determine that changes are appropriate, we would propose revisions to the methodology through future notice and comment rulemaking. However, we note that we would have significant concerns with adopting the rationale described by the commenter as a basis for excluding or adjusting data, given that many drugs could assert similar claims of lower utilization during the early months of market availability. This type of utilization pattern is expected, as the purpose of the TDAPA for new renal dialysis drugs and biological products in existing ESRD PPS functional categories is to provide additional payment to facilitate incorporation of these products into provider business models. If utilization were immediately at high levels, the TDAPA would not be needed to serve its intended purpose.

Final rule action: After consideration of public comments, we are finalizing the post-TDAPA add-on payment adjustment amounts for each quarter of CY 2026 presented in Table 4 according to our established methodology. The final post-TDAPA add-on payment adjustment amount for Korsuva® is $0.1131 which will be applied to ESRD PPS claims for each quarter of CY 2026. The final post-TDAPA add-on payment adjustment amount for DefenCath® is $2.3710 which will be applied to ESRD PPS claims for the third and fourth quarter of CY 2026. Table 4 shows the final post-TDAPA add-on payment adjustment amounts for each quarter of

CY 2026. We note that there are no drugs or biological products which will be included in the post-TDAPA add-on payment adjustment calculation for any quarter of CY 2026 which lack 12 months of utilization data.

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

Quarter	Add-on amount for Korsuva®	Add-on amount for DefenCath®	Total post-TDAPA add-on payment adjustment amount
Q1 (January–March)	$0.1131	$0	$0.1131
Q2 (April–June)	0.1131	0	0.1131
Q3 (July–September)	0.1131	2.3710	2.4841
Q4 (October–December)	0.1131	2.3710	2.4841

b. Technical Correction to § 413.234(g)(5)

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

We did not receive public comments on this provision, and therefore, we are finalizing the correction as proposed.

7. 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 CY2016 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 the drugs and biological products included in the ESRD PPS bundled payment, as well as those receiving the TDAPA (80 FR 69013 through 69027). As we established in the CY 2011 ESRD PPS final rule, categorizing drugs and biological products based on 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 2 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 fall within an ESRD PPS functional category, we specified that the ESRD PPS base rate would not be modified after the 2-year TDAPA period (83 FR 56943), but, as consistent with the outlier policy at that time, we stated that the drug or biological product would be eligible for outlier payment unless it is a composite rate drug. In this same CY 2019 ESRD PPS final 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), we 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), we 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 focuses 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. 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 3-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 2 to 3 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 proposed 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 also proposed 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 noted 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 proposed a 3-year timeframe for TDAPA eligibility as we believe 3 years strikes a balance between allowing a drug manufacturer's flexibility in the timing of the rollout for their new renal dialysis drug or biological product and ensuring the TDAPA is only available for drugs and biological products that are new to the renal dialysis market. We noted that 3 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 3 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 stated that 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 proposed 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 did not propose 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 noted 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 proposed 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 3 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 proposed 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 proposed this later implementation date as we recognized 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 noted that we had not identified any such drugs or biological products. We stated that, 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 3-year window of FDA approval. We noted that 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 was not our intention with the 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, provided that the 3-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 noted that any drug or biological product which was approved by the FDA more than 3 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 2-year TDAPA period as specified at § 413.234(c)(1) or a full period of at least 2 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 noted 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 either before or after January 1, 2025, would or would not be eligible for the TDAPA under the proposed changes to the TDAPA eligibility criteria. We reiterated in the proposed rule 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 3 years prior to January 1, 2028, submits a TDAPA application prior to January 1, 2028, the TDAPA would still be paid for a full 2-year period as specified at § 413.234(c)(1) or a full period of at least 2 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 solicited comments on all aspects of the 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 solicited comments on the TDAPA eligibility requirements more broadly and welcome any suggestions on how our TDAPA policies could be improved in future rulemaking.

Approximately 13 unique commenters including a provider advocacy organization, a national organization of patients and kidney health care professionals, a network of dialysis organizations and regional offices, drug manufacturers, an advocacy organization, non-profit dialysis organizations, a non-profit kidney organization, a coalition of dialysis organizations, a non-profit kidney care alliance, and LDOs commented on these proposals. The following is a summary of the comments we received and our responses.

Comment: Nearly all commenters supported the proposals pertaining to TDAPA eligibility. Many commenters requested clarification on how the proposed changes would impact drugs or biological products that receive an ESRD or dialysis-related indication after a previous non-ESRD or dialysis-related FDA approval, and if the date of the original FDA approval could disqualify such drugs from receiving the TDAPA under the proposed 3-year eligibility window. Some commenters cited SGLT2 inhibitors as an example that may fall into such category.

Response: We thank commenters for their support of our proposals pertaining to the eligibility criteria for the TDAPA. CMS would like to clarify that our longstanding eligibility criteria for the TDAPA does not exclude NDA Type 10 drugs that receive a new indication (84 FR 60664), and we did not propose any changes to this element of the TDAPA eligibility criteria in the CY 2026 ESRD PPS proposed rule. Specifically, manufacturers of drugs or biological products that receive an ESRD or dialysis-related indication after a previous non-ESRD or dialysis-related FDA marketing approval will, under the proposed eligibility criteria, have 3 years from when the ESRD or dialysis-related indication was granted by FDA to apply for the TDAPA.

We are also clarifying that under our longstanding policy at § 413.234, the TDAPA is paid for 2 years for a new renal dialysis drug or biological product in an existing ESRD PPS functional category. This means that if such a drug or biological product has been paid for using the TDAPA under the ESRD PPS for 2 years, it would not be eligible for any additional TDAPA payment. We note that this policy for TDAPA payment applies to a renal dialysis drug or biological product, not for an indication or a brand name. CMS is also clarifying that if a drug or biological is being paid for or has previously been paid for under the TDAPA under one FDA indication, CMS does not provide for TDAPA eligibility to restart or reapply if the drug or biological product were to obtain a new indication. In other words, a new renal dialysis drug or biological product, whether originally approved for a ESRD or dialysis-related indication or having received an ESRD or dialysis-related indication after a previous non-ESRD or dialysis-related FDA approval, can only qualify for one TDAPA period. Under the final eligibility criteria, effective January 1, 2028, a manufacturer of a drug or biological product that receives FDA marketing approval for treating or managing a condition(s) associated with ESRD would have 3 years from the date of such FDA marketing approval to apply for the TDAPA.

Comment: One interested party commented in support of the proposed changes to the TDAPA eligibility criteria and highlighted some of the potential benefits of the proposed changes regarding increased uptake of home dialysis, particularly in rural areas.

Response: We thank the commenter for their support of the proposed changes to the TDAPA eligibility criteria and for their input on the home dialysis landscape.

Final Rule Action: After consideration of public comments, we are finalizing the 3-year eligibility window for the TDAPA for new renal dialysis drugs and biological products in both existing and new ESRD PPS functional categories, effective January 1, 2028, as proposed. To implement this change, we are finalizing 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) as proposed. We reiterate that we did not propose, nor are we finalizing, to remove the commercial eligibility requirement from the definition of ''new renal dialysis drug or biological product'', as that would have implications for 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 moving the eligibility requirements specific to the TDAPA to new paragraph (c)(5) is to clarify which requirements relate to the TDAPA, and which requirements relate to the definition of ''new renal dialysis drug or biological product.''

8. 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 final 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 LRS 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 final 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 the 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 a few 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,[18] 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.

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, as discussed in the CY 2026 ESRD PPS proposed rule, 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 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 noted that when we refer to ''U.S. Pacific Territories'' in the context of this final 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 [19] and served by the Office of the Insular Affairs,[20] 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. We stated that, 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 finalized in section II.B.8.c of this final rule, 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 this analysis, the non-labor costs associated with furnishing renal dialysis services included the costs associated with capital, administration, drugs,

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

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

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

supplies and laboratory tests from Medicare cost reports.[21] We stated that we recognize that some parts of these cost categories could have overlapped with cost categories included in the LRS; for example, capital costs included both the materials and labor involved in constructing buildings. However, given the limitation of cost report data available for this analysis, we believed 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 encompassed 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 stated that 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 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 showed 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 discussed in the CY 2026 ESRD PPS proposed rule that 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. Non-Contiguous Area Payment Adjustment (NAPA)

As discussed in the CY 2026 ESRD PPS proposed rule (90 FR 29358), 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 did not find substantial overlap between non-contiguous areas and low-

[21] 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.

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 the aforementioned higher non-labor costs.

Under the authority of section 1881(b)(14)(D)(iv) of the Act, we proposed 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 final rule. As proposed, the NAPA would apply only to the non-labor portion of the ESRD PPS base rate, which is 44.8 percent. The magnitude of the proposed NAPA would be dependent on which of the non-contiguous remote areas a given ESRD facility is located in. We also proposed 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 proposed 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 proposed for the NAPA to be applied budget-neutrally, as noted in the prior paragraph. In the CY 2026 ESRD PPS proposed rule, we discussed that 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 estimated to 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 stated that we believed 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 stated that 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 having significantly higher non-labor costs compared to facilities in 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 NAPA, as it is intended to account for non-labor costs, we stated that 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 stated that we believed 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 stated that 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-LRS is slightly smaller than the LRS to which the wage index applies, a NAPA value that equals the payment impact of this wage index value is 1.258682.[22] For simplicity, we rounded 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 estimated the required reduction to the base rate would be notably less at approximately 0.1 percent, or $0.35. In the proposed rule, we stated that we believed 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. In the proposed rule, we stated that we believed 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 noted that the proposed capped NAPA would be more 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

[22] 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.

summarizes the proposed NAPA factors effective for CY 2026. The budget neutrality factor for this proposed NAPA was 0.99859. We indicated that in future years, we intend to review these adjustment factors and consider whether the proposed NAPA (if finalized) remains appropriate when we propose to update the LRS 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 proposed to rename § 413.233 from ''Rural facility adjustment'' to ''Additional facility-level adjustments.'' We also proposed to designate a new paragraph (a) to include the current language of § 413.233. We further proposed 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 proposed to modify § 413.230(a) to include § 413.233 in the list of facility-level adjustments.

We stated that we believe that the proposed new payment adjustment would better align payment with resource use in these non-contiguous remote geographic areas. We requested 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.

Approximately 23 unique commenters including a coalition of dialysis organizations, a non-profit dialysis association, large dialysis organizations (LDOs), a small dialysis organization within a large non-profit health system, a professional association, a non-profit kidney care alliance, a national organization of patients and kidney health care professionals, a non-profit kidney organization, a network of dialysis organizations and regional offices, a provider advocacy organization, a non-profit organization of ESRD networks, a non-profit health insurance organization in Puerto Rico, a non-profit treatment and research center, and MedPAC. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported the proposed NAPA. Many commenters requested that the NAPA be implemented non-budget-neutrally so that establishing the proposed payment adjustment would not require a base rate reduction. Some of these commenters stated that a base rate reduction would penalize patients and providers in areas that were not found to have significantly higher non-labor costs. Other commenters noted that if the proposed NAPA were to be implemented budget-neutrally, the payment adjustment should include the proposed 25 percent cap.

Response: We thank commenters for their support and their input on the budget neutrality of this proposed payment adjustment. In the proposed rule, we stated that we believed the more moderate reduction to the ESRD PPS base rate associated with a capped NAPA would better allow ESRD facilities in contiguous areas to continue to provide high-quality care while better aligning payments to ESRD facilities in certain non-contiguous areas with their relatively higher non-labor costs. We also discussed our belief that implementing the NAPA 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. CMS continues to believe that a NAPA 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 in areas that were not found to have higher non-labor costs. We also note that implementing the NAPA in a non-budget-neutral manner would not be consistent with the longstanding framework within the ESRD PPS to apply case-mix and facility-level payment adjustments that account for renal dialysis goods and services which were originally included in the analysis used for the CY 2011 ESRD PPS final rule in a budget-neutral manner (88 FR 42451). Finally, CMS does not believe that implementing the NAPA will result in harms to patients and ESRD facilities in areas not included under the NAPA because of the $0.40 payment reduction in the base rate, as ESRD facilities located in the contiguous U.S. and the Caribbean territories have relatively lower non-labor costs than ESRD facilities in areas included in the NAPA. CMS's approach is narrowly targeted to reflect observed, cost differentials specific to the non-contiguous states and territories and is informed by our cost analysis that did not identify statistically or operationally meaningful higher non-labor costs in ESRD facilities located in the Caribbean territories of Puerto Rico and the U.S. Virgin Islands. The overall net impact of the base-rate change is small relative to the total allowed payment per dialysis treatment. In addition, the ESRD PPS has existing payment adjustments and program protections, including a wage index floor and the low-volume payment adjustment, which can increase payment to ESRD facilities in Puerto Rico and the U.S. Virgin Islands. Taken together these factors provide financial stability for the ESRD facilities and access to care for the vulnerable Medicare beneficiaries. CMS will continue to monitor patient access indicators and unintended adverse consequences, along with utilization and financial analysis for future use in determining whether we should consider additional policy refinements through rulemaking.

Comment: Some commenters expressed concerns with the potential overlap between ESRD facilities receiving the LVPA and rural facility adjustment and ESRD facilities that would receive the proposed NAPA.

Response: In the CY 2026 ESRD PPS proposed rule (90 FR 29359), we stated that our analysis did not find substantial overlap between non-contiguous areas and low-volume facilities as defined at § 413.232(b). Specifically, there were

only 2 LVPA-eligible ESRD facilities found in non-contiguous areas, which furnish less than 1 percent of renal dialysis treatments in NAPA-eligible areas. Additionally, in the proposed rule CMS discussed that although the rural facility adjustment is likely to account for some of the higher costs for these remote areas, the magnitude of the rural facility adjustment is much smaller than the LVPA and cannot account for all of the higher non-labor costs which the NAPA was proposed to address. Based on our continued evaluation of non-labor costs, CMS continues to believe that the existing facility-level payment adjustments under the ESRD PPS do not currently account for the higher non-labor costs in Alaska, Hawaii, and the U.S. Pacific Territories.

Comment: Some interested parties commented in support of the proposed NAPA, but requested that the payment adjustment be extended to other non-contiguous areas such as Puerto Rico and the U.S. Virgin Islands. Other commenters requested for the proposed NAPA to apply to contiguous areas, including metropolitan regions like New York City, and other high-cost urban regions along the East and West coasts of the contiguous United States. These commenters cited shipping expenses, utility expenses, high costs of living, high costs of administering healthcare services, increasing wage competition, and high occupancy costs such as rental costs and real estate taxes.

Response: As a result of the comments on the CY 2025 ESRD PPS proposed rule, CMS conducted an analysis of non-labor costs in certain remote areas of the United States. 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 beyond the U.S. Pacific Territories. The analysis was prompted by the comments in response to the CY 2025 ESRD PPS proposed rule and was then used to inform the proposal for the NAPA were focused solely on non-labor costs in non-contiguous areas, which is what the payment adjustment is intended to address. We do not believe it is appropriate to apply the NAPA to contiguous metropolitan regions, such as New York City, or other high cost urban areas. The NAPA was developed to address cost differentials specific to non-contiguous states and territories utilizing the data in those state and territory-specific areas. The non-labor cost structures of these non-contiguous areas are not meaningfully reflected in existing contiguous-United States geographic payment mechanisms. Besides departing from the design and scope of the NAPA policy, extension to these contiguous metropolitan regions would risk double-counting costs that are already included by other geographic adjustments. This could lead to duplicative adjustments of costs included in the ESRD PPS bundled payment along with less alignment of resource use with payment. The results of our continual and extensive analysis of non-labor costs do not support expanding the NAPA to non-contiguous areas outside of Alaska, Hawaii, and the U.S. Pacific Territories at this time. As stated in the CY 2026 ESRD PPS proposed rule (90 FR 29360), we intend to review the NAPA adjustment factors and consider whether the proposed NAPA (if finalized) remains appropriate when we propose to update the LRS of the ESRDB market basket. We also stated that, if applicable, CMS would propose any changes to the NAPA methodology or adjustment factors in future notice-and-comment rulemaking.

Comment: Many commenters expressed concerns regarding the methodology that CMS employed in our analysis of non-labor costs in non-contiguous areas. These commenters requested sufficient technical and methodological transparency such that interested parties would have the ability to fully replicate the analytical work conducted by CMS. Specifically, commenters requested that CMS provide a regression output table, standard errors, significance tests, diagnostics such as residual plot or multicollinearity, p-values, t-statistics, confidence intervals, and additional details on how CMS addressed the small sample size when identifying outliers and applying trimming rules for the data provided in Table 6 of the proposed rule. Some commenters also highlighted potential limitations on the cost report data used in our analysis.

Response: We appreciate these detailed evaluations of the potential limitations of our analysis and of the data sources used to inform the proposed methodology for the NAPA. We note that the proposed rule provided a detailed explanation of the methodology and the Medicare Cost Report data used for our analysis. We believe the information provided in the proposed rule was sufficient for most commenters to reproduce and understand our methodology; however, we are providing additional details about the regression analysis for greater clarity in this final rule, as the commenter requested.

The analysis conducted to inform the proposed NAPA was a logarithmic regression which used facility-level average non-labor cost per treatment as the dependent variable. This variable is the sum of the average costs per treatment associated with capital, administration, drugs, supplies and laboratory tests from Medicare cost reports.[23] In the proposed rule, CMS acknowledged that some parts of these cost categories could have overlapped with cost categories included in the LRS; for example, capital costs included both the materials and labor involved in constructing buildings. However, given the limitation of cost report data available for this analysis, we believed including these non-direct labor costs provided a more accurate result.

CMS controlled for various facility-level characteristics in this regression, 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. CMS applied cluster-robust standard errors to account for a provider appearing across multiple years, which appear in parenthesis in Table 8. 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. Our regression included 23,339 observations and resulted in an R-squared value of 0.485. Additional results of our regression can be found in Table 8.

[23] 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.

TABLE 8—TECHNICAL RESULTS OF THE REGRESSION USED TO INFORM THE PROPOSED NAPA

Variables	Results [1]	Cluster-robust standard error
Intercept	*** 13.874	(0.367)
Rural (0/1)	*** −0.133	(0.007)
Alaska (Ref-Lower 48 States)	*** 0.444	(0.074)
Hawaii (Ref-Lower 48 States)	*** 0.187	(0.033)
Guam (Ref-Lower 48 States)	*** 0.270	(0.053)
Northern Mariana Islands (Ref-Lower 48 States).		
American Samoa (Ref-Lower 48 States).		
United States Virgin Islands (Ref-Lower 48 States)	−0.048	(0.031)
Commonwealth of Puerto Rico (Ref-Lower 48 States).		
Ownership—Hospital Based	*** 0.187	(0.023)
Ownership—Independent	*** −0.154	(0.015)
Ownership—Regional Chain	* 0.015	(0.008)
Ownership—Unknown	0.070	(0.081)
Pct Medicare Treatment	*** 0.068	(0.021)
Pct Home Dialysis	*** 0.150	(0.011)
Pediatric Tx >20pct (0/1)	0.063	(0.063)
Avg Case-Mix Multiplier	−0.024	(0.063)
Log(fac Size)	*** −1.667	(0.080)
Log(fac Size)-sq	*** 0.079	(0.004)
Year 2022	*** 0.043	(0.002)
Year 2023	*** 0.055	(0.003)

[1] Presented results are the result of a logarithmic regression and are, therefore, not easily interpretable on their own. To achieve a result with an easily interpretable meaning raise the natural constant ''e'' by the result of a logarithmic regression. This resulting number will be the multiplicative multiplier that represents the amount the predicted nonlabor cost per treatment changes when the corresponding variable is present.

* Significant at the 10 percent level.
** Significant at the 5 percent level.
*** Significant at the 1 percent level.

As we discussed in the CY 2026 ESRD PPS proposed rule (90 FR 29358), CMS 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 to avoid issues with small sample size. 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 both cost per treatment and facility size. These outlier values of non-labor cost per treatment and facility size were 'winsorized' (removed and replaced with a placeholder to maintain error and standard deviations at a comparable rate as if the outliers had not been removed) as opposed to trimmed to preserve the already-limited sample size. We note that despite the small sample size, the results of our analysis were still statistically significant.

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. We note that AKI treatments and their associated costs were excluded from the analysis. CMS has historically emphasized the importance of accurate cost report data for current and potential policies under the ESRD PPS, such as facility-level or case-mix adjustment refinement. In the CY 2025 ESRD PPS proposed rule (89 FR 89101), we strongly urged ESRD facilities to carefully review cost report data to ensure continued accuracy so that future refinements to the ESRD PPS are based on the best data possible.

Comment: MedPAC highlighted some concerns regarding the implementation of a new payment adjustment exclusively for ESRD facilities in non-contiguous areas. The commission cited analyses that have shown a relationship between service volume and per-treatment cost, arguing that such findings demonstrate a need for contiguous, low-volume ESRD facilities to receive additional payment to maintain access to care. MedPAC also raised concerns regarding the sample size used in the regression analysis that informed the proposed NAPA. The commission stated that grouping all of the ESRD facilities in the contiguous U.S. into a single reference group would not account for variation in costs between contiguous ESRD facilities. MedPAC expressed its view that the proposed NAPA would not only wrongfully overlook low-volume, contiguous ESRD facilities, but also negatively impact such facilities through a base rate reduction. The commission reiterated its support for replacing the low-volume payment adjustment (LVPA) and rural facility adjustment with a single payment adjustment for low-volume and isolated (LVI) ESRD facilities, a methodology that MedPAC has strongly advocated for since 2020.

MedPAC also requested that, if CMS were to finalize the proposed NAPA, that the adjustment be based on costs at the facility level rather than the level of a geographical area, noting that the commission's analysis of Addendum B found above-average service volumes in the non-contiguous areas which would be receiving the proposed NAPA, and that the aforementioned relationship between service volume and per-treatment cost is based on the facility level, not the area level. MedPAC also requested that if the NAPA were to be finalized, that the adjustment specifically target low-volume and isolated facilities across the entire United States, not just the non-contiguous areas mentioned in the proposed rule.

Response: CMS thanks MedPAC for its thorough review of the proposed NAPA. As discussed in the CY 2026 ESRD PPS proposed rule, the analysis prompted by the comments in response to the CY 2025 ESRD PPS proposed rule and used to inform the proposal for the NAPA were focused solely on non-labor costs in non-contiguous areas, which is what this payment adjustment is intended to address. The results of our

continual and extensive analysis of non-labor costs do not support expanding the proposed NAPA to non-contiguous areas outside of Alaska, Hawaii, and the U.S. Pacific Territories at this time. We reiterate that the proposed NAPA is not intended to account for general per-treatment cost variations outside of non-labor costs and is not intended to have substantial overlap with or serve the same purpose as the LVPA or rural facility adjustments. In addition, our analysis of non-labor costs across ESRD facilities across the contiguous U.S. did not find relative non-labor costs that were comparable to those incurred by ESRD facilities in the proposed NAPA areas.

Regarding per-treatment costs and geographical isolation, in the CY 2025 ESRD PPS proposed rule (89 FR 89155), CMS explained that the statutory requirements for the LVPA under section 1881(b)(14)(D)(iii) of the Act generally would not allow for CMS to account for geographic isolation outside of the extent to which low-volume facilities face higher costs in furnishing renal dialysis services than other facilities. We also discussed the results of our analysis, and that in general, low-volume ESRD facilities that are rural, isolated, or located in low-demand areas were not found to have higher costs than low-volume ESRD facilities overall.

We acknowledge that variations in per-treatment costs often occur at the facility level, however, we reiterate that the NAPA is not intended to mitigate general per-treatment cost variations, but rather to address the higher non-labor costs in certain non-contiguous areas. We do not believe that implementing the NAPA based on individual facility-level costs would be appropriate given that such an adjustment could provide perverse incentives to report higher non-labor costs, similar to concerns commenters have raised regarding manipulating treatment volume for LVPA eligibility in the past.

Final Rule Action: After considering the comments received on this proposal, we are finalizing the proposed Non-Contiguous Areas Payment Adjustment (NAPA) with a 25 percent cap as proposed. We continue to believe that the capped NAPA strikes an appropriate balance between increasing payments to ESRD facilities in non-contiguous 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. We reiterate that we intend to review the NAPA adjustment factors and consider whether the NAPA remains appropriate when we propose to update the LRS of the ESRDB market basket in future notice-and-comment rulemaking. The final NAPA adjustment factors can be found in Table 9:

TABLE 9—FINAL NAPA FACTORS

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

To implement this new payment adjustment, we are also finalizing our proposals to rename § 413.233 from ''Rural facility adjustment'' to ''Additional facility-level adjustments'', to designate a new paragraph (a) to include the current language of § 413.233, and 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 finalizing our proposal to modify § 413.230(a) to include § 413.233 in the list of facility-level adjustments as proposed.

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 did not include any TPNIES application summaries, CMS analyses, or results in the 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 final rule, we identify any items previously approved for the TPNIES and for which 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.* This Change Request was subsequently rescinded and replaced by Transmittal 13121, dated March 28, 2025, and available at *https://www.cms.gov/files/document/r13121bp.pdf.* This Change Request was subsequently rescinded and replaced by Transmittal 13245, dated May 29, 2025, and available at *https://www.cms.gov/files/document/r13245bp.pdf.*

Table 10 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 10 also identifies the products' HCPCS coding information as well as the payment adjustment effective dates and available end dates.

TABLE 10—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.

We did not receive public comments on the continuing approved TDAPAs for CY 2026.

III. Final 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 reduced by 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. Update of AKI Dialysis Payment

1. 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. Accordingly, we proposed that the CY 2026 AKI dialysis payment rate would be equal to the proposed CY 2026 ESRD PPS base rate of $281.06 ($273.82 × 1.00872 × 0.99859) × 1.019 = $281.06) (90 FR 29352). Additionally, we proposed that if more recent data became available after the publishing of the proposed rule and before the publishing of this final rule, we would use such data, if appropriate, to determine the CY 2026 ESRD PPS base rate.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters encouraged CMS to review the methodology used to calculate the AKI dialysis payment rate and the inclusion of beneficiaries with AKI in the TDAPA.

Response: We appreciate the concerns expressed by the commenters. However, section 1834(r)(1) of the Act provides that the AKI dialysis payment rate amount must be the ESRD PPS base rate for a particular year, as adjusted by any applicable geographic adjustment factor applied under subparagraph (D)(iv)(II) of section 1881(b)(14) of the Act, and may only be adjusted by other adjustment factors under subparagraph (D) on a budget neutral basis.

Additionally, we discussed in the CY 2024 ESRD PPS final rule (89 FR 89172) the rational for not applying the TDAPA to the AKI dialysis payments. The TDAPA policy applies to new renal dialysis drugs and biological products furnished to beneficiaries with ESRD, as provided under § 413.234, and does not extend to beneficiaries with AKI. Recently, in the CY 2025 ESRD PPS final rule (89 FR 89084), we finalized a policy to allow Medicare payment for beneficiaries with AKI to dialyze at home and to permit ESRD facilities to bill Medicare for the home and self-dialysis training add-on payment adjustment for beneficiaries with AKI. We are monitoring and evaluating this policy change. We do not believe it is appropriate to make further AKI payment adjustments without further analysis, but we note we could potentially do so in future years. Additionally, there is a policy to pay separately for all items and services that are not part of the ESRD PPS base rate. We believe it is imperative to wait for substantial data related to the AKI population and its associated utilization, prior to determining the appropriate steps toward further developing the AKI payment rate through rulemaking.

After consideration of public comments, we are finalizing the payment rate for AKI treatment at the ESRD PPS base rate. As discussed in section II.B.4. of this final rule, the final ESRD PPS base rate is $281.71, which reflects the application of the final CY 2026 wage index budget neutrality adjustment factor of 1.00905, the application of the final budget neutrality factor for the non-contiguous areas payment adjustment (NAPA) of 0.99860 discussed in section II.B.8. of this final rule, and the final CY 2026 ESRDB market basket percentage increase of 2.9 percent reduced by the final productivity adjustment of 0.8 percentage point, that is, 2.1 percent. Accordingly, we are finalizing a CY 2026 per treatment payment rate of $281.71 (($273.82 × 1.00905 × 0.99860) × 1.021 = $281.71) for renal dialysis services furnished by ESRD facilities to individuals with AKI.

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 final 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 proposed 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 LRS 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 finalizing a CY 2026 AKI dialysis payment rate of $281.71, adjusted by the ESRD facility's wage index. As discussed in section II.B.2.c. of this final rule, we proposed that if more recent data became available after the publishing of the proposed rule and before the publishing of this final rule, we would use such data, if appropriate, to determine the CY 2026 update the ESRD PPS wage index.

We did not receive public comments on this provision. Accordingly, we are finalizing the AKI geographic adjustment factor using the final CY

2026 ESRD PPS wage index as discussed in section II.B.2. of this final rule.

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 did not propose to reevaluate the budget neutrality factor for CY 2026.

As discussed in the CY 2026 ESRD PPS proposed rule, 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 referred to in the proposed rule as the non-contiguous areas payment adjustment (NAPA), for renal dialysis services furnished to 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. As discussed in the proposed rule, 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 that training adjustment on AKI dialysis payments. We stated that we did not believe it would be appropriate to propose any additional updates to the AKI dialysis payment rate at that time. However, we welcomed comments from interested parties on the potential for other geographic payment adjustments to the AKI dialysis payment rate.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: CMS did not receive any comments regarding either applying the proposed NAPA to Medicare payments for renal dialysis services furnished to beneficiaries with AKI, or the delaying application of the proposed NAPA as we evaluate the effect of the budget neutral application of the training add-on for beneficiaries with AKI.

Several commenters discussed the application of budget neutrality for the training add-on payment adjustment for beneficiaries with AKI. A commenter agreed with the AKI payment amount and the ability of beneficiaries with AKI to dialyze at home. Another commenter while in agreement with the AKI payment amount urged CMS to engage with the Congress to discuss budget neutrality.

Response: We appreciate the comments regarding the application of budget neutrality to the training add-on payment adjustment for beneficiaries with AKI. As we noted in the proposed rule, the add-on payment adjustment for training for home dialysis for beneficiaries with AKI is subject to section 1834(r)(1) of the Act to apply budget neutrality to the add-on adjustment to maintain budget neutrality in total payments under section 1834(r) of the Act. We appreciate the recommendation to notify the Congress of budget neutrality concerns for AKI dialysis payments.

Comment: Several commenters noted that CMS should collect data regarding the care of beneficiaries with AKI and develop methodology for budget neutrality based on actual utilization of the home modality for beneficiaries with AKI.

Response: We appreciate these comments recommending that we collect data pertaining to AKI beneficiary care and the suggestion that we develop a methodology for budget neutrality based on actual utilization of home dialysis for AKI beneficiaries, we agree that additional data would be valuable in assessing the impact of the training add-on payments for AKI. We are evaluating the utilization of home modalities in beneficiaries with AKI and will continue to monitor claims and utilization patterns to evaluate the effect of the training add-on in the AKI population. At this time, we do not have substantial data to support a methodology that would exclude or separately budget for AKI-related training add-on utilization outside of the broader statutory requirement for budget neutrality. We appreciate the input of the commenters, and we may consider refinements as we continue our monitoring and data evaluation. If changes are warranted, any change in methodology that would include additional policy refinements would be made through notice and comment rulemaking.

Comment: A commenter requested that CMS codify the same safety protections for beneficiaries with AKI receiving dialysis at home as those beneficiaries with ESRD.

Response: We appreciate the commenter's concern regarding the safety of beneficiaries with AKI dialyzing in a home setting. We addressed this in the CY 2025 ESRD PPS final rule by noting that the ESRD Facility Conditions for Coverage are sufficiently broad to provide guidance on training, education, and safety standards for AKI patients (89 FR 89171).

Comment: A commenter urged CMS to discuss budget neutrality with the Congress due to the complexity of AKI care including additional laboratory testing.

Response: We appreciate the concerns from commenters regarding the complexity of AKI care; however, any add-on payment adjustment for enhanced monitoring or individual care for beneficiaries with AKI would be subject to the requirement of section 1834(r)(1) of the Act for the add-on adjustment to maintain budget neutrality in total payments under section 1834(r) of the Act. Additionally, we appreciate the recommendation to notify the Congress of budget neutrality concerns for AKI payments.

After consideration of public comments, we are finalizing our proposal to not apply the NAPA to Medicare payments for renal dialysis services furnished to beneficiaries with AKI. Additionally, we did not propose, and are not finalizing, any changes to the current methodology for applying budget neutrality for the training add-on payment adjustment for beneficiaries with AKI using a home dialysis modality.

IV. 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. Updates to Requirements Beginning With the PY 2027 ESRD QIP

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

We refer readers in 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). In the CY 2026 ESRD PPS proposed rule, we proposed to remove the Facility Commitment to Health Equity measure beginning with the PY 2027 ESRD QIP (90 FR 29363). We stated that 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. We noted that, 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. In the proposed rule, we stated that 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 referred readers to our request for comment on ''Request for Information on Measure Concepts under Consideration for Future Years'' in section IV.D.2. of the proposed rule. We describe feedback received in response to that request for comment in section IV.D.2. of this final rule. In the proposed rule, we stated that 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 (90 FR 29363). We noted that 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 stated that 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. We also noted that facilities that have already invested resources to meet this measure's requirements will still find value in the proposal through the reduction in reporting obligations if the measure is eliminated. We stated that 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 noted 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 (90 FR 29363). However, we also noted that if the measure removal is finalized as proposed, 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. We stated in the proposed rule that, 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 invited 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the removal of the Facility Commitment to Health Equity reporting measure, emphasizing concerns about its administrative burden and limited impact on improving patient outcomes. Commenters stated that the burden outweighs the benefits, noting that the measure is more indicative of the socioeconomic vulnerability of the patients than the quality of care a facility provides.

Many commenters supported the removal as part of broader efforts to streamline programs and reduce regulatory burden. A few commenters cited a lack of CBE endorsement, measure testing, and validity in support of removing the measure.

Response: We thank the commenters for their support. We agree that the removal of this measure will reduce the administrative burden on facilities. We note that the Facility Commitment to Health Equity reporting measure went through the rigorous measure development lifecycle outlined at the CMS Measures Management System website,[24] which includes measure testing and reliability analysis. Further, section 1881(h)(2)(B)(ii) of the Act permits the Secretary to specify a measure without endorsement if a feasible and practical measure has not been endorsed by the CBE, provided due consideration is given to measures that have been endorsed or adopted by a consensus organization.

Comment: Several commenters opposed the removal of the Facility Commitment to Health Equity measure, emphasizing its critical role in advancing health equity and addressing disparities in care delivery. Commenters highlighted that the measure provides incentives to prioritize equity work, collect data on social determinants of health, and implement quality improvement initiatives.

A few commenters raised concern that removing the measure would signal a retreat from CMS' stated goals of reducing disparities and improving care for vulnerable populations.

Response: We acknowledge commenters' concerns and agree that holding facilities accountable for high-quality healthcare delivery to all beneficiaries is important and remains a priority for the ESRD QIP. We are continuously evaluating approaches to align ESRD QIP measures with changing national priorities. We remain focused on identifying measures that balance feasibility, provider reporting burden, and impact while continuing to hold facilities accountable for measurable clinical health outcomes and patient safety.

Comment: A few commenters recommended refining the Facility Commitment to Health Equity reporting measure rather than removing it entirely. These commenters suggested modifications to reduce the administrative burden while preserving the measure's intent and improving value. Several commenters proposed adjustments such as stratified sampling or voluntary submission to make the measure more feasible for facilities to implement. Other commenters recommended that, instead of removing the measure, CMS should modify the measure to implement better standardization, technical support in facilities, and equity metrics in performance-based reimbursement.

Response: We thank the commenters for their recommendations and will consider them as we evaluate any potential future measures in this subject. While holding facilities accountable for measurable clinical outcomes and patient safety, we are prioritizing the reduction of provider reporting burden. Facilities are encouraged to continue to engage in activities to close gaps in care and

[24] CMS. Blueprint Measure Lifecycle Overview. Available at *https://mmshub.cms.gov/blueprint-measure-lifecycle-overview.*

collect data that is important to their patient care initiatives and reflect the needs of their patient population.

Final Rule Action: After considering public comments, we are finalizing our proposal to remove the Facility Commitment to Health Equity reporting measure from the ESRD QIP beginning with the PY 2027 ESRD QIP.

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

In the CY 2026 ESRD PPS proposed rule, we proposed 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) (90 FR 29363). For further discussion of our previously established policies regarding measure adoption, retention, and removal, we referred readers to the CY 2024 ESRD PPS final rule (88 FR 76434).

We proposed 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 (90 FR 29363). In the proposed rule, we stated that 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 noted 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 concluded that the costs of the continued use of these measures in the ESRD QIP may outweigh the benefits to providers and patients. We noted that 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. We stated that this will also remove the patient burden associated with repeated Social Drivers of Health screenings across multiple healthcare facilities. We referred readers to our request for comment, ''Request for Information on Measure Concepts under Consideration for Future Years'' in section IV.D.2. of the proposed rule for more information regarding our areas of focus for new measures. We also describe feedback received in response to that request for comment in section IV.D.2. of this final rule. In the proposed rule, we noted that 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. We stated that 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 these measures. With the entire set of measures, we noted that the ESRD QIP continues to incentivize the improvement of dialysis care quality and health outcomes for all patients through measurement and transparency.

In the proposed rule, we stated that 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 (90 FR 29363). In addition, we noted that any measure data received by CMS would not be used for public reporting or payment purposes.

We invited 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.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposals 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, noting that these measures are more indicative of the socioeconomic vulnerability of the patients than the quality of care a facility provides.

A few commenters agreed that the costs associated with the measures outweigh the benefit of their continued use in the program, noting that dialysis facilities do not have resources to address health-related social needs due to resource constraints. A commenter stated that dialysis facilities may already provide referrals to community resources for further support.

Response: We appreciate and thank commenters for their support.

Comment: Several commenters expressed concern about the proposed measure removals. A few commenters raised concerns that patient outcomes are strongly influenced by systemic inequalities related to poverty, race, and access to preventive care. Commenters described how social determinants of health significantly impact health outcomes and the types of care and services patients may require as part of their dialysis treatment plan. These commenters stated that screening for social determinants of health is fundamental to patient-centered care, including clinical outcomes, treatment adherence, and reducing preventable healthcare utilization (for example, hospitalization). Other commenters stated that removing these reporting measures would limit the ability to track such data and address disparities.

Response: We note that removal of these measures from the ESRD QIP does not prevent facilities from measuring and addressing patients' social needs, as clinically appropriate. In addition, these measures are only reported in the aggregate and do not measure the extent to which providers are ultimately connecting patients with resources or services and whether patients are benefiting from these screenings. Therefore, we have determined that these measures are appropriate for removal based on our determination that the cost of including these measures as part of the ESRD QIP measure set outweigh the benefit to providers and patients.

Comment: A few commenters recommended refining the Screening for Social Drivers of Health reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measure rather than removing them entirely. These commenters suggested modifications to reduce the administrative burden while preserving the measures' intent and improving value. Other commenters proposed adjustments such as stratified sampling or voluntary submission to make the measures more feasible for facilities to implement. Some commenters recommended that, instead of removing the measures, CMS should modify the measures to implement better standardization, technical support in facilities, and equity metrics in performance-based reimbursement.

Response: We thank the commenters for their recommendations and will consider them as we evaluate any potential future measures on this subject. While holding facilities accountable for measurable clinical outcomes and patient safety, we are prioritizing the reduction of provider reporting burden. Facilities are encouraged to continue to engage in activities to close gaps in care and collect data that is important to their patient care initiatives and reflect the needs of their patient population.

Comment: A few commenters expressed concern that proposing to remove these measures in the middle of a performance year will create unpredictability for dialysis facilities by setting a precedent for future rulemaking.

Response: We acknowledge commenters' concern regarding the timing around removal of these measures. However, because we have determined that the cost of reporting on these measures outweighs the benefits of retaining them in the program, we are removing these measures at the earliest feasible reporting period so that dialysis facilities will not need to expend additional resources on reporting measures for which we have determined that the costs outweigh the benefits of retaining them in the program. Dialysis facilities that do not report their CY 2025 reporting period data for the Screening for Social Drivers of Health reporting measure, the Screen Positive Rate for Social Drivers of Health reporting measure, and the Facility Commitment to Health Equity measure to CMS will not be considered noncompliant with the measures for purposes of their PY 2027 determination (that is, facilities that do not report CY 2025 reporting period data will not be penalized for CY 2027 payments due to these measures). Any PY 2027 reporting measure data received for the Screening for Social Drivers of Health reporting measure, the Screen Positive Rate for Social Drivers of Health reporting measure, and the Facility Commitment to Health Equity measure by CMS will not be used for PY 2027 public reporting or payment purposes.

Final Rule Action: After considering public comments, we are finalizing 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.

We are also updating the individual measure weights in the Reporting Measure Domain to reflect the finalized removals of 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 beginning with PY 2027, consistent with our policy of weighting each measure in the Reporting Measure Domain equally as reflected in the CY 2023 ESRD PPS final rule (87 FR 67251 through 67253). We are therefore assigning individual measure weights to reflect the updated number of measures in the Reporting Measure Domain so that each measure continues to be weighed equally. We will weigh each measure equally at 3.33 percent to maintain our previously finalized approach of assigning equal weight to each measure in the Reporting Measure Domain. The measures that will be included in each domain, along with the new individual measure weights within the Reporting Measure Domain, beginning with PY 2027, are depicted in Table 11. We will maintain the current weight of the overall Reporting Measure Domain at 10 percent of TPS.

TABLE 11—UPDATED ESRD QIP MEASURE DOMAINS AND WEIGHTS BEGINNING WITH PY 2027

Measures by domain	Measure weight as percent of TPS
Patient and Family Engagement Measure Domain	15.00
ICH CAHPS measure	15.00
Care Coordination Measure Domain	30.00
SHR clinical measure	7.50
SRR clinical measure	7.50
PPPW measure	7.50
Clinical Depression Screening and Follow-Up measure	7.50
Clinical Care Measure Domain	35.00
Kt/V Dialysis Adequacy Measure Topic	11.00
Long-Term Catheter Rate clinical measure	12.00
STrR clinical measure	12.00
Safety Measure Domain	10.00
NHSN BSI clinical measure	10.00
Reporting Measure Domain	10.00
Hypercalcemia reporting measure	3.33
MedRec reporting measure	3.33
COVID–19 HCP Vaccination reporting measure	3.33

Finally, we are also updating the mTPS and payment reduction scale for PY 2027 to reflect the finalized removals of 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 beginning with PY 2027. In the CY 2025 final rule, we stated that for PY 2027, based on the measure set at that time, a facility must meet or exceed an mTPS of 51 to avoid a payment reduction (89 FR 89084). With the removal of 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, which together comprise half of the measures in the Reporting Domain, we are revising the mTPS and associated payment reduction ranges for PY 2027 to reflect only those measures that will be included in the finalized measure set for PY 2027, consistent with the mTPS calculation requirements codified at § 413.178(a)(8) and the payment reduction requirements codified at § 413.177(a). The finalized mTPS and associated payment reduction ranges for PY 2027, using CY 2023 data, will be 56,

and the finalized payment reduction scale is shown in Table 12.

TABLE 12—UPDATED PAYMENT REDUCTION SCALE FOR PY 2027 BASED ON THE MOST RECENTLY AVAILABLE DATA AND FINALIZED MEASURE SET

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

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

1. PY 2028 ESRD QIP Measure Set

In the proposed rule, we proposed to update the ICH CAHPS clinical measure beginning with the PY 2028 measure set. Table 9 of the proposed rule summarized the previously finalized and proposed updated measures that we would include in the PY 2028 ESRD QIP measure set (90 FR 29364). As discussed in IV.C.2. of this final rule, we are finalizing our updates to the PY 2028 ESRD QIP measure set as proposed. We describe the finalized PY 2028 ESRD QIP measure set in Table 13, which includes the previously finalized measures and the measures we are finalizing in this final rule. In the proposed rule, we stated that 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 (90 FR 29364).[25]

TABLE 13—FINALIZED MEASURES FOR THE PY 2028 ESRD QIP MEASURE SET

Consensus-based entity[26] (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 finalizing our proposal to update the ICH CAHPS clinical measure beginning with PY 2028, as discussed in section IV.C.2. of this final rule.

[25] *https://www.cms.gov/medicare/quality/end-stage-renal-disease-esrd-quality-incentive-program/measuring-quality.*

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. In the CY 2026 ESRD PPS proposed rule, we stated that patients with ESRD are a vulnerable population (90 FR 29364). We noted that 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. We also stated that 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.

In the proposed rule, we noted that the ICH CAHPS Survey was developed to capture the experience of in-center hemodialysis patients (90 FR 29364). 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. Survey and Measure Changes

In the CY 2026 ESRD PPS proposed rule, we noted that 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 (90 FR 29364). We noted that 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 noted that 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, in the proposed rule we stated that 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 function of the Quality of Dialysis Center Care and Operations (QDCCO) multi-item measure:
  - ++ How often the dialysis center staff inserted needles with as little pain as possible,
  - ++ How often dialysis center staff talked to patients about what they should eat and drink,
  - ++ How often the dialysis center staff keep health information as private as possible, and
  - ++ How often 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 proposed 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:
  - ++ How often the dialysis center staff asked about how kidney disease affects other parts of patient's lives, and
  - ++ How often 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.[27]

c. Pre-Rulemaking Review Process and Measure Endorsement

In the CY 2026 ESRD PPS proposed rule, we stated that 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 (90 FR 29365). We noted that 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.

In the proposed rule, we stated that 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 (90 FR 29365). We noted that the PRMR Hospital Committee recommended the ICH CAHPS survey changes be implemented.[28] 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.[29] We stated that the E&M process ensures measures submitted for endorsement are evidence-based, scientifically sound, safe and effective. We noted that the current ICH CAHPS Survey measure was endorsed by the CBE in Spring 2019. In the proposed rule, we stated that 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 further stated that we have determined that the updates to the ICH CAHPS clinical measure are

[26] 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.

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

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

[29] Information about the Partnership for Quality Measurement E&M process is available at *https://p4qm.org/EM.* As of August 7, 2025, the ICH CAHPS measures were endorsed with a condition that a robust logic model illustrating the actions accountable entities can take to improve patient experience is included in the next measure evaluation in 2030.

appropriately specified, and therefore the exception in section 1881(h)(2)(B)(ii) of the Act applies. We noted 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, had been submitted to the CBE for endorsement. Following the publication of the CY 2026 ESRD PPS proposed rule, the CBE endorsed the revised ICH CAHPS measure, with a condition that a robust logic model illustrating the actions accountable entities can take to improve patient experience is included in the next measure evaluation in 2030. To ensure that the revised ICH CAHPS Survey is reflected in the updated ICH CAHPS clinical measure beginning with PY 2028, we proposed to implement the revised ICH CAHPS Survey beginning with the CY 2026 Spring survey.

d. Impact to Measure Calculation and Public Reporting

In the proposed rule, we noted that 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 (90 FR 29365). With the proposed implementation of the revised survey, we proposed 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 proposed that all of the measures, including the multi-item and global rating measures, would be weighed equally. We stated that 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.

In the proposed rule, we stated that to determine what impact the changes to the survey measures would have on public reporting, we considered the nature of the changes (90 FR 29365). We noted that psychometric and other analyses were performed on field test data, and no major impact was found. We anticipated 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 proposed 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 stated that we would not miss a refresh for ICH CAHPS data.

e. Survey Administration Changes

We did not propose any survey administration changes with the new survey (90 FR 29365).

f. Case-Mix and Mode Adjustments

In the proposed rule, we noted that prior to public reporting, ICH CAHPS Survey scores are adjusted for the effects of case-mix (patient-mix) (90 FR 29365). 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. We stated that case-mix adjustment is performed within each semiannual survey period after data cleaning. We also noted that 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. We stated that the model used and adjustments are updated semiannually and are available on the ICH CAHPS website at *https://ichcahps.org/Portals/0/PublicReporting/ICHCAHPS_PublicRptCoeffOct2024.pdf.* In the proposed rule, we noted that based on testing the revised survey in a field test, we 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 (90 FR 29366). 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 proposed 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 noted that, in addition to the proposed updates to the ICH CAHPS clinical measure in the proposed rule, we are also exploring additional ways to improve the ICH CAHPS measure. We stated that 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 welcomed public comment on our proposal to update the ICH CAHPS clinical measure for the PY 2028 ESRD QIP and subsequent years.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. While we also received a comment regarding CAHPS surveys other than the ICH CAHPS Survey, that comment is outside the scope of this rule and is not addressed below.

Comment: Several commenters supported the proposed update to remove questions from the ICH CAHPS Survey, noting that it will help to reduce burden and survey fatigue.

Response: We thank the commenters for their support.

Comment: Some commenters supported CMS' work toward modifying the survey to include questions that address the experience of care for patients on home dialysis modalities.

Response: We thank the commenters for their support as we explore the possibility of modifying the survey to include home dialysis questions.

Comment: Some commenters recommended reducing the frequency of survey administration to once annually, while a commenter suggested questions be administered after each dialysis treatment. Another commenter suggested CMS provide survey results in a timely and actionable format with providers and facilities.

Response: We thank the commenters for their suggestions. ICH CAHPS survey results are refreshed every six months on the Care Compare tool on *Medicare.gov*. Less frequent survey administration would delay the delivery of timely and actionable information for dialysis facilities, providers, and patients. Because facilities need 30 completed surveys to have their data reported on Care Compare, administering the survey only once per year would impact the number of facilities publicly reported. We have chosen to focus on reducing the survey length rather than changing the frequency to help increase response rates. The suggestion to administer the survey after each dialysis treatment would significantly increase patient burden since each patient receives dialysis multiple times a week.

Comment: Several commenters supported testing a web with mail follow-up of non-respondents as an alternative mode for survey administration.

Response: We thank the commenters for their support.

Comment: A commenter requested that CMS clarify that research confirms the revised QDCCO measure captures the intended domain of patient experience and that results remain comparable over time.

Response: The revised ICH CAHPS QDCCO measure continues to capture whether patients feel that their dialysis center staff communicated well, kept patients as comfortable and pain-free as possible, behaved in a professional manner, and kept the center clean. The removal of four items did not affect the psychometric functioning, including reliability and validity, of the QDCCO measure. The revised QDCCO measure will establish a new baseline, and results will not be directly comparable to previous QDCCO scores. However, facilities can have their vendors use survey data from prior years to calculate the revised QDCCO score for comparison purposes since CMS is just removing four survey items from the measure.

Comment: A commenter requested that CMS continue to include questions related to nephrology nurses.

Response: The revised ICH CAHPS survey continues to ask questions about dialysis center staff which includes nurses.

Comment: A commenter requested that CMS retain questions related to how often nephrologists provided timely and accurate information to the patient.

Response: Although the questions that comprise the Nephrologist Communication and Caring (NCC) measure as well as the nephrologist rating question were removed from the survey, nephrologists are included in the questions in the Treatment section of the revised survey. Providers and interested parties provided feedback to us that the nephrologist questions should be removed because (1) patients are not always able to differentiate a kidney doctor from other dialysis center staff when answering questions, (2) nephrologists are often separate from the facility and may have patients in multiple facilities, and (3) there is nothing actionable that a facility can do based on the NCC scores or nephrologists' ratings. Based on this feedback, we chose to remove these questions in an effort to shorten the survey.

Comment: A commenter suggested retaining the question which asks how often the dialysis center staff really cared about you as a person.

Response: A Technical Expert Panel that convened in 2023 recommended the removal of this question from the QDCCO multi-item measure. This question shows a strong relationship with two other questions in the QDCCO multi-item measure: how often dialysis center staff show respect for what the patient says and how often the dialysis center staff make the patient as comfortable as possible. Removing the question about how often staff cared about the patient as a person did not negatively affect the psychometric functioning of the overall QDCCO multi-item measure as determined through testing. Given the need to reduce the length of the survey, we chose to remove this item.

Comment: A commenter suggested that facilities be able to use alternative survey vendors and processes for collecting data.

Response: We require standardized data collection to ensure there is comparable data across all facilities.

Comment: A commenter requested that CMS provide technical documentation on the revised case-mix adjustment models and to provide the full revised survey instrument. The commenter also questioned how the revised case-mix adjusters will affect facility-level comparisons.

Response: We have posted the updated ICH CAHPS survey on *https://ICHCAHPS.org.* The case-mix adjustment coefficients are recalculated each time the data are updated on *www.medicare.gov.* Overall, the removal of a few case-mix adjustment factors will have an insignificant impact on the current adjustments since the factors that were removed had little impact on responses.

Comment: A commenter requested the reason behind the different recall periods between the treatment and other sections of the ICH CAHPS survey.

Response: A longer recall period (12 months) is used for the Treatment section because of the nature of the questions. One question, for example, asks how much the patient was involved in choosing the treatment for kidney disease that is right for them. A 3-month recall period would be too short to capture those sorts of decision points and discussions between patients and providers about treatment options.

Final Rule Action: After considering public comments, we are finalizing our proposal to update the ICH CAHPS clinical measure beginning with the PY 2028 ESRD QIP.

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.

In the CY 2026 ESRD PPS proposed rule, we stated that 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 (90 FR 29366). 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 the proposed rule, we estimated the performance standards for the PY 2028 clinical measures in Table 10 using data from CY 2023, which were the most recent data available (90 FR 29366). We are updating these performance standards for all measures, using CY 2024 data, in this final rule, in Table 14.

TABLE 14—UPDATED PERFORMANCE STANDARDS FOR THE 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	96.08%	98.52%	99.73%
Pediatric Hemodialysis (HD) Kt/V	*81.25%	98.29%	*100.00%
Adult Peritoneal Dialysis (PD) Kt/V	87.37%	95.20%	*99.04%
Pediatric Peritoneal Dialysis (PD) Kt/V	*66.49%	83.04%	98.91%
Standardized Readmission Ratio [a]	*34.27	*26.50	*16.18
NHSN BSI	*0.642	*0.215	*0.000
Standardized Hospitalization Ratio [b]	*166.60	*129.14	*87.98
Standardized Transfusion Ratio [b]	*48.29	*26.19	8.07
PPPW	*8.12%	*16.73%	*33.90%
Clinical Depression	89.11%	95.12%	*100.00%
ICH CAHPS: Quality of Dialysis Center Care and Operations**	55.82%	64.90%	76.18%
ICH CAHPS: Providing Information to Patients	71.09%	77.84%	85.11%
ICH CAHPS: Overall Rating of Dialysis Center Staff	52.57%	65.70%	80.74%
ICH CAHPS: Overall Rating of the Dialysis Facility	56.24%	69.41%	83.83%

*Values are the same final performance standards for those measures for PY 2027. In accordance with our longstanding policy, we are using those numerical values for those measures for PY 2028 because they are higher standards than the PY 2028 numerical values for those measures.

**We are finalizing our proposal to update the ICH CAHPS clinical measure beginning with PY 2028, as discussed in section IV.C.2. of this final rule.

[a] Rate calculated as a percentage of hospital discharges

[b] Rate per 100 patient-years

Data sources: VAT measure: 2024 EQRS; SRR, SHR, STrR: 2024 Medicare claims; Kt/V: 2024 EQRS and 2024 Medicare claims; NHSN: 2024 CDC; ICH CAHPS: CMS 2024; PPPW: 2024 EQRS and 2024 Organ Procurement and Transplantation Network (OPTN); Clinical Depression: 2024 EQRS.

In addition, we summarize in Table 15 our requirements for successful reporting on our finalized reporting measures for the PY 2027 and PY 2028 ESRD QIP.

TABLE 15—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 finalizing our proposal to remove the Facility Commitment to Health Equity reporting measure beginning with PY 2027, as discussed in section IV.B.1. of this final rule. We are also finalizing 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 beginning with PY 2027, as discussed in section IV.B.2. of this final rule.

4. Eligibility Requirements for the PY 2028 ESRD QIP

In the proposed rule, we did not propose to update eligibility requirements as part of our proposal to update the ICH CAHPS clinical measure. Our previously finalized minimum eligibility requirements are described in Table 12 of the CY 2026 ESRD PPS proposed rule (90 FR 29367), and provided in Table 16 of this final rule.

TABLE 16—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.

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. In the proposed rule, we stated that for PY 2028, we estimated using available data that a facility must meet or exceed an mTPS of 56 to avoid a payment reduction (90 FR 29368). We noted that the mTPS estimated in the proposed rule was based on data from CY 2023 instead of the PY 2028 baseline period (CY 2024) because CY 2024 data were not yet available. We presented the estimated payment reduction scale in Table 13 of the CY 2026 ESRD PPS proposed rule (90 FR 29368). We are updating and finalizing the mTPS and associated payment reduction ranges for PY 2028, using CY 2024 data, in this CY 2026 ESRD PPS final rule. The mTPS for PY 2028 will be 57, and the finalized payment reduction scale is shown in Table 17.

TABLE 17—UPDATED PAYMENT REDUCTION SCALE FOR PY 2028 BASED ON THE MOST RECENTLY AVAILABLE DATA

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

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

As discussed in the following sections, in the CY 2026 ESRD PPS proposed rule, we requested information on topics to inform future revisions to the ESRD QIP (90 FR 29368 through 29370). First, we requested 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 also requested information regarding potential measurement concepts that could be developed into ESRD QIP measures in the future.

In the CY 2026 ESRD PPS proposed rule, we noted that each of these sections is an RFI only (90 FR 29368). 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.

We stated that respondents are encouraged to provide complete but concise responses (90 FR 29368). 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, we noted we were not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders were 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. We noted that we 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. We stated that 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. Finally, we noted that 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).

In the CY 2026 ESRD PPS proposed rule, we stated that we are considering opportunities to advance FHIR-based reporting of patient assessment data for the submission of ESRD QIP data (90 FR 29368). 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 also noted that 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.

In the proposed rule, we stated that 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 (90 FR 29368).

b. Solicitation for Comment

In the CY 2026 ESRD PPS proposed rule, we sought 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)/Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP/ONC [30])? 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

[30] On July 29, 2024, notice was posted in the **Federal Register** that ONC would be dually titled to the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (89 FR 60903).

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® [31] 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 at *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 invited any feedback, suggestions, best practices, or success stories related to the implementation of these technologies.

We received comments in response to this request for information and have summarized them here.

Comment: Many commenters provided feedback in response to our request for public comment on the current state of health IT use in dialysis facilities.

Several commenters noted that many dialysis facilities, especially small or rural facilities, lack the resources and infrastructure to meet future interoperability mandates. Other commenters recommended that CMS work to provide technical and financial support for EHR modernization, incentivize vendor accountability for delivering certified, interoperable systems, and ensure that any future ESRD QIP interoperability requirements include realistic timelines for adopting updated health IT requirements.

A few commenters emphasized the importance of TEFCA as an on-ramp to help facilitate interoperability, noting the importance of sharing relevant clinical information when dialysis patients are admitted into the emergency department or elsewhere.

Several commenters provided feedback on challenges associated with submitting data to CMS through EQRS, including the burden associated with manually submitting data into the EQRS portal. Commenters stated that the use of FHIR-based standards presents an opportunity to move away from the current monthly batch submission process, allowing facilities to submit their data more promptly and with less manual effort. Commenters also stated that it has the potential to streamline ongoing maintenance in the future, as CMS and data submitters will no longer need to maintain non-industry standard XML specifications for EQRS data. A commenter also highlighted the difficulties associated with acquiring the services of an approved third-party Health Information Exchange (HIE) to submit data. A commenter stated that the use of FHIR-based standards will allow dialysis facilities to submit data directly without acquiring the services of a third-party HIE. Commenters also stated that dialysis facilities may not have sufficient resources to develop and integrate API for data submission and recommended that CMS allow at least 18 to 24 months from the finalization of specifications before APIs are required for compliance.

Another commenter also recommended that CMS engage developers and healthcare providers early in the process of testing initiatives to yield better alignment and more successful implementation. A commenter recommended that CMS: define clear goals and success metrics based upon participants' consensus; provide early access to sandbox environments, sample data, and feedback files; publish draft FHIR implementation guides with sufficient time for input; allow 18 to 24 months for organizations to implement finalized API specifications; and maintain regular feedback loops throughout testing.

Response: We appreciate all of the comments and interest in this topic. While we will not be responding to specific comments submitted in response to this RFI in this final rule, we believe that this input is very valuable to inform the continuing development of our efforts to advance digital quality measurement in the ESRD QIP. We will continue to take all concerns, comments, and suggestions into account for future development and integration of FHIR-based technologies and standardized data for patient assessment instruments.

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

In the CY 2026 ESRD PPS proposed rule, we requested public comment on several measure concepts under consideration for future years (90 FR 29369). First, we sought feedback 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.[32] 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.[33] In the proposed rule, we requested 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

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

[32] 42 U.S.C. 300jj(9).

[33] 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.*

dialysis facilities and both inpatient (including transplant centers) and outpatient facilities and providers.

A second concept about which we sought feedback is for a measure of well-being (90 FR 29369). 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.[34] In the proposed rule, we noted that this comprehensive approach emphasizes person-centered care by promoting the well-being of patients and their care partners. We sought 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 noted that 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. In the proposed rule, we welcomed feedback on the relevant aspects of well-being for the ESRD QIP.

A third concept about which we sought feedback is for measures of nutrition (90 FR 29369 through 29370). In the proposed rule, we noted that 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 assist with dialysis treatment tolerance, improvement in comorbid conditions, and readiness for kidney transplant, if desired. We sought feedback on tools and frameworks that promote healthy eating habits and nutrition for patients requiring dialysis. In the proposed rule, we welcomed feedback on the relevant aspects of nutrition for the ESRD QIP.

A fourth concept about which we sought feedback is for measures of physical activity (90 FR 29370). In the proposed rule, we noted that 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. In the proposed rule, we requested feedback on all relevant aspects of physical activity for the ESRD QIP.

Finally, we sought 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. In the proposed rule, we welcomed feedback on all relevant aspects of CKD prevention and treatment in all settings.

We welcomed public comment on the future measure concepts under consideration for the ESRD QIP described in Table 18.

TABLE 18—FUTURE MEASURE CONCEPTS UNDER CONSIDERATION FOR THE ESRD QIP

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

We received comments in response to this RFI and have summarized them here. While we are not responding to specific comments in this final rule, we intend to use this input to inform our future measure development efforts.

Comment: Several commenters provided feedback in response to our request for public comment on future measure concepts for the ESRD QIP.

Several commenters stated that, while they supported the concept of interoperability, additional resources would be required to meet interoperability standards in dialysis facilities. Another commenter recommended that, to ensure the successful adoption of future measures, future measures should provide technical assistance and funding for facilities with limited resources, align new measures with existing ESRD QIP and interoperability frameworks, and avoid punitive scoring during early implementation. A few commenters stated that the costs and technical burden of FHIR implementation could disproportionately impact independent facilities and smaller/hospital-based organizations, further widening the gap between large dialysis organizations and smaller systems. Other commenters also stated that by enhancing interoperability across healthcare systems, facility can significantly improve the patient experience—especially for individuals with end-stage renal disease (ESRD) who often face a complex and fragmented care journey due to multiple comorbidities.

Several commenters supported the Administration's emphasis on nutrition and environmental influences on healthcare. Commenters agreed that such factors are critically important in the care of people with kidney diseases in the United States, with a commenter noting that nutrition and physical activity are foundational to managing comorbidities and improving dialysis outcomes. A commenter recommended that, in developing future measures aimed at addressing these factors, CMS explore dietary adherence metrics tied to renal nutrition guidelines, access to registered dietitians and nutrition counseling as structural measures, physical activity readiness assessments or engagement tracking via wearable integration or patient self-report. A few commenters agreed that nutrition is a critical aspect of caring for individuals with kidney disease and recommended that CMS consider opportunities to develop an appropriate measure for earlier stages of chronic kidney disease (CKD) where it could be more impactful and support the delayed onset of kidney failure.

Several commenters supported the inclusion of measures that assess well-being, noting that such factors are relevant to health outcomes and quality of life for patients managing chronic conditions like ESRD. A commenter recommended that CMS consider adapting validated tools such as the PROMIS Global Health Scale or WHO–5 Well-Being Index for dialysis populations. This commenter also recommended that measures should be patient-reported, culturally sensitive, and stratified by social risk to ensure they are applied equitably. Another commenter recommended that the ESRD QIP adopt a quality measure of access to palliative care for all beneficiaries over age 75 receiving dialysis, noting the prevalence of many debilitating symptoms among ESRD patients and that palliative care has been proven to significantly increase patient well-being by expertly managing many debilitating symptoms prevalent among ESRD patients, which the commenter further asserts would reduce Medicare spending as a result. A few commenters stated that while well-being is important for all people, including Medicare beneficiaries living with ESRD, attempting to assess their overall health, happiness, and satisfaction in life through a measure in the ESRD QIP

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

would be outside the scope of the program. A commenter recommended expanding the concept of wellness to be more holistic and include not only mental and physical but social, emotional, spiritual, financial, and other quality of life domains.

Response: We appreciate all of the comments and interest in this topic. While we are not responding to specific comments in response to the RFI in this final rule, we believe that this input is very valuable and will continue to take all concerns, comments, and suggestions into account for future development and consideration of future measure concepts for the ESRD QIP.

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.[35] 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. 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. Summary of the Proposed Provisions, Public Comments, and Responses to the Comments on the ETC Model

1. Termination of the ETC Model

In the proposed rule, we proposed 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

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

such testing has begun and before completion of the testing.'' [36]

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 third Annual Evaluation Report (AR3) examined impacts of the ETC Model during calendar years CYs 2021 to 2023, which correspond to the first three model years (MYs) of the model. While AR3 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, AR3 showed no evidence of a change in waitlisting rates in ETC areas relative to comparison areas. Increased rates of home dialysis training were evident in CY 2021 to CY 2023.[37]

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 AR3 evaluation preliminarily showed that net Medicare payments increased by $99 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.[38]

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.[39]

Given these factors, we proposed to terminate the ETC model as of December 31, 2025. Specifically, we proposed 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 sought public comment on our proposal to modify the duration of the ETC Model § 512.320.

Additionally, we proposed 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 PPA7 the last MY and PPA of the ETC Model. Therefore, we also proposed to modify Table 1 to paragraph (c)—ETC Model Schedule of Measurement Years and PPA Periods at § 512.355 to eliminate the entries for MY8 through MY10. We sought 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 MY7, we proposed 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 sought public comment on these proposals.

Also, for the reasons listed previously, we proposed 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 proposed 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 proposed to stop data sharing and the sharing of reports. We sought 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 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. Three 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 was completed and made public in August 2025. This evaluation report covers CYs 2021–2023 and pertains 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 sought public comment on this proposal.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several comments supported the early termination of the ETC Model. Commenters agreed that the lack of substantive evaluation results gave CMS the authority to terminate the model under section 1115A of the Act. A few commenters who supported termination requested that CMS continue its support of the goals of the

[36] 42 U.S.C. 1315a

[37] 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. (2025). *End-stage renal disease treatment choices (ETC) model: Third annual evaluation report* (Contract No. 75FCMC19D0096). The Lewin Group. *https://www.cms.gov/priorities/innovation/data-and-reports/2025/etc-3rd-eval-tech-rpt.*

[38] Ibid.

[39] 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.*

Advancing American Kidney Health initiative, including increasing home dialysis and transplant rates for new ESRD patients. A few commenters included suggestions on future models for CMS consideration to further these goals.

Response: We thank commenters for their support for the termination of the ETC Model. As stated in this final rule, CMS may terminate a model that does not improve quality of care while increasing Medicare spending. As shown in AR1, AR2, and A3, the ETC Model has not increased home dialysis, transplant waitlisting, or living donor transplantation. Further, the AR3 evaluation preliminarily showed that net Medicare payments increased by $99 million over the course of the model. While CMS is encouraged by the national increase in rates of home dialysis, this change could not be attributed to the ETC Model. As such, we agree with commenters and we will finalize the termination of the ETC Model as of December 31, 2025.

Despite the limitations of the ETC Model, CMS remains committed to improving the quality of care delivered to beneficiaries with ESRD. Announced in 2019, Advancing American Kidney Health (AAKH) was signed by President Trump to transform how kidney disease is prevented, diagnosed, and treated within the next decade. One of the goals of AAKH is to ''have 80 percent of new American ESRD patients in 2025 receiving dialysis in the home or receiving a transplant.'' [40] While we have not met this goal, CMS is encouraged by the overall rise in home dialysis rates that has occurred since 2019. CMS remains open to exploring alternative policy options including future models to further utilization of home dialysis where deemed medically appropriate.

After consideration of the public comments, we are finalizing our proposal to terminate the ETC model as of December 31, 2025. Specifically, we are finalizing our proposals 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 are also finalizing as proposed our modifications 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. To align with finalizing our proposal to terminate the ETC Model, we are also finalizing the following to align the regulation text with the new model end date: We are finalizing our proposals to:

- Modify Table 1 to paragraph (c)—ETC Model Schedule of Measurement Years and PPA Periods at § 512.355 to eliminate the entries for MY8 through MY10, 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,
- 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; and,
- 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 will stop data sharing and the sharing of reports.

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.[41] 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.[42]

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 MY7, 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, 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 final rule, changing the payment adjustments would be retroactive. However, initial research by CMS 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 PPA7 was unnecessary.

As part of this alternative that we considered to our proposal, we also recognized 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

[40] U.S. Department of Health and Human Services, Assistant Secretary for Planning and Evaluation. (2019, July 9). Advancing American Kidney Health. *https://aspe.hhs.gov/sites/default/files/private/pdf/262046/AdvancingAmericanKidneyHealth.pdf.*

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

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

would be contrary to the public interest. We stated in the proposed rule that if we received comments providing significant empirical evidence of overwhelming negative effects of the supply shortage on the administration of home dialysis, implementing PPA7 adjustments as currently written may not serve the public interest. We have heard anecdotal evidence that the Baxter supply shortages starting October 1, 2024, 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 were open to seeing data from participants that could adjust our proposal. We stated that 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 were 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 sought public comment on our proposal to make no changes to the schedule and methodologies for the PPA due to Hurricane Helene. We also sought comment on the alternative we considered of making no upward or downward adjustments for MY7 and PPA7 and applying that policy retroactively.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters support CMS' decision to make no changes to the schedule and methodologies for the PPA due to Hurricane Helene.

Response: We thank commenters for their support of not proposing a change to the performance adjustments for the ETC Model in PPA 7.

Comment: A couple commenters expressed concern with the effects of Hurricane Helene and suggested that while data analyses may not show an effect on national rates of PD, there may be regional affects that are unnoticed. Therefore, the commenter suggested that CMS eliminate the performance adjustments in the ETC Model for PPA 7. Another commenter suggested that CMS eliminate performance adjustments on an individual basis. CMS also received comments about the PD supply chain that were out of scope.

Response: While we have considered the potential for regional effects on the rates of PD due to Hurricane Helene, we have seen no data to substantiate this claim. As such, we did not propose adjusting PPA 7.

After consideration of public comments, we will not make any modifications to the proposal to terminate the ETC Model without adjustments to PPA 7.

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 solicited 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 the CY 2026 ESRD PPS proposed rule and in this final rule, we used data from the United States Bureau of Labor Statistics' 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 (90 FR 29372 through 29373). When this analysis was conducted, the most recently available median hourly wage of a Medical Records Specialist was $24.16 per hour.[43] 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 in the CY 2026 ESRD PPS proposed rule. We provide the updated information collection burden to reflect current facility and patient counts, in this 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 final rule, using the most recently available data, we estimate that the aggregate cost of the EQRS data validation for PY 2028 will 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 final rule, we estimate that the aggregate cost of the NHSN data validation for PY 2028 will 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 will 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.

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

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 will 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 will 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 will 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 will be approximately $136.1 million (2,901,090 hours × $46.90).

We are finalizing three measure removals in this final rule that will affect the burden associated with EQRS reporting requirements beginning with PY 2027. We provided 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, in the CY 2026 ESRD PPS proposed rule (90 FR 29373). We are further updating the information collection burden to reflect updated facility and patient counts in this final rule. In the CY 2026 ESRD PPS 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. We are further updating these estimates in this final rule using current 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. There are 121 data elements for 513,475 patients across 7,582 facilities, for a total of 62,130,475 elements across all patients (121 data elements × 513,475 patients). Because we are finalizing the three measure removals as proposed, the total number of data elements will decrease by 7,495,677 data elements based on current patient and facility counts. At 2.5 minutes per element, this will yield approximately 341 hours per facility. Therefore, the updated PY 2027 burden will be 2,588,770 hours (approximately 341 hours × 7,582 facilities), reflecting a burden decrease of 312,320 hours from our previously finalized estimate for PY 2027. Using the Medical Records Specialist wage estimates available at this time, we estimated that the updated PY 2027 total burden cost will be approximately $125 million (2,588,770 hours × $48.32). The updated estimation reduction in burden associated with the removal of the three measures is described in Table 19.

TABLE 19—UPDATED 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
Removal of the Facility Commitment to Health Equity Reporting Measure	−14.10	−$681.51	−$106,937	−$5,167,234.09
Removal of the Social Drivers of Health Reporting Measure	−14.10	−681.51	−106,937	−5,167,234.09
Removal of the Screen Positive for Social Drivers of Health Reporting Measure	−14.10	−681.51	−106,937	−5,167,234.09
	Total Change in Information Collection Burden Hours: –320,813 Total Cost Estimate: Updated Hourly Wage (Varies) × Change in Burden Hours (−320,813) = −$15,501,702			

We provided the burden estimate for PY 2028 in the CY 2026 ESRD PPS proposed rule (90 FR 29374) and are updating the information collection burden to reflect updated facility and patient counts, in this final rule. In the 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. We are further updating these estimates in this final rule, 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. There are 121 data elements for 513,475 patients across 7,582 facilities, for a total of 62,130,475 elements (121 data elements × 513,475 patients). At 2.5 minutes per element, this will yield approximately 341 hours per facility. Therefore, the PY 2028 burden will be 2,588,770 hours (approximately 341 hours × 7,582 facilities). Using the Medical Records Specialist wage estimates available at this time, we estimate that the PY 2028 total burden cost will be approximately $125 million (2,588,770 hours × $48.32).

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 finalizing 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 20. The costs will decrease from $3,628,962 to $2,973,890 which is a savings of $655,072 annually.

TABLE 20—ESTIMATED REDUCTION IN BURDEN ASSOCIATED WITH 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
Finalized updates to ICH CAHPS Survey	−1.4	−$93.58	−9,800	−$655,072

Although we are also finalizing changes to the ICH CAHPS clinical measure in this final rule that will reduce the burden associated with completing the ICH CAHPS survey, we do not anticipate that any of these finalized updates to the ICH CAHPS clinical measure will 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.

VII. 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 finalizes routine updates to the payment rate for renal dialysis services furnished by ESRD facilities and finalizes policy changes to the ESRD PPS for CY 2026, including updates to our ESRD PPS wage index, outlier threshold, TPNIES offset amount, and post-TDAPA add-on payment adjustment amounts to reflect the latest available data for Korsuva® and DefenCath®. We are also finalizing a new payment adjustment to account for higher non-labor costs in certain non-contiguous States and territories and a change to the timeframe for TDAPA eligibility. Failure to publish this final 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 finalizes updates to the payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 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 finalizes updates for the ESRD QIP, which will 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 finalizes our proposal to terminate the ETC Model as of December 31, 2025, due to a lack of statistically significant results. As described in detail in section V.B. of this final 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; section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4); and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select 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 analysis, OMB's Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant pursuant to section 3(f)(1) of Executive Order 12866. Furthermore, in accordance with subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has also determined that this notice meets the criteria set forth in 5 U.S.C. 804(2). Accordingly, we have prepared a Regulatory Impact Analysis that presents, to the best of our ability, the estimated costs and benefits associated with this rulemaking.

1. ESRD PPS

We estimate that the final revisions to the ESRD PPS will result in an increase of approximately $180 million in Medicare payments to ESRD facilities in CY 2026. This includes $10 million associated with the final payment rate updates, the updated post-TDAPA add-on payment adjustment amounts, and the continuation of the approved TDAPA as identified in Table 21. 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 non-contiguous areas payment adjustment (NAPA). In addition, for public awareness, we estimate that the updated CY 2026 post-TDAPA add-on payment adjustments will total approximately $34 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 will total approximately $90 million, an increase from around $30 million in CY 2025.

2. AKI

We estimate that the final updates to the AKI dialysis payment rate will 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 finalizing in this final rule, the updated ESRD QIP will result in $21.6 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 finalizing in this final rule, the updated ESRD QIP will result in $20.6 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, will 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 through June 30, 2027).

5. Summary of Impacts

We estimate that the combined impact of the policies finalized in this rule on payments for CY 2026 is $180 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 $125 million in information collection burden and $21.6 million in estimated payment reductions across all facilities. Additionally, we estimate the impacts of the ESRD QIP for PY 2028 to be $125 million in information collection burden and $20.6 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 final rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this final rule.

1. Benefits

Under the CY 2026 ESRD PPS and AKI dialysis payment, ESRD facilities will continue to receive payment for renal dialysis services furnished to Medicare beneficiaries under a case-mix adjusted PPS. We continue to expect that making prospective 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 dialysis treatments furnished by ESRD facilities by 2.1 percent based on the final CY 2026 ESRDB market basket percentage increase of 2.9 percent reduced by the final CY 2026 productivity adjustment of 0.8 percentage point will improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services. We estimate that overall payments under the ESRD PPS will increase by 2.2 percent as a result of the final policies in this rule.

2. Costs

a. ESRD PPS and AKI

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

b. ESRD QIP

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 policies in this final rule regarding ESRD QIP will create additional cost or burden to ESRD facilities for PY 2027 or PY 2028, we are updating the estimated costs associated with the information collection requirements under the ESRD QIP in this 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 updates to the ESRD PPS and AKI dialysis payment rates will result in a total increase of approximately $180 million in Medicare payments to ESRD facilities in CY 2026, which includes the amount associated with final updates to the outlier threshold amounts, the NAPA, and final 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 $140 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately $40 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary coinsurance payments because of this final rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this

ESRD PPS final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the ESRD PPS final rule, we assume that the total number of unique commenters on this year's ESRD PPS proposed rule, which was 211 for the CY 2026 ESRD PPS proposed rule, is equal to the number of individual reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed this year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on the CY 2026 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 final rule. We used a similar methodology for calculating the regulatory review costs in the CY 2025 ESRD PPS proposed and final rules. We solicited comments on this approach and did not receive any direct responses.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assumed that each reviewer reads approximately 50 percent of this final rule. We sought comments on this assumption, and did not receive any comments.

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 [44] (*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 160 minutes (2.67 hours) for the staff to review half of this final rule, which has a total of approximately 80,000 words. For each entity that reviews the rule, the estimated cost is $353.61 (2.67 hours × $132.44). Therefore, we estimate that the total cost of reviewing this regulation is $7,4611.71 ($353.61 × 211 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 facilities for which we can calculate both current Medicare payments and new Medicare payments.

For this final rule, we use CY 2024 data from the Medicare Part A and Part B Common Working Files as of August 1, 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 final updates to the ESRD PPS base rate are described in section II.B.4. of this final rule. Table 21 shows the impact of the estimated CY 2026 ESRD PPS payments compared to estimated ESRD PPS payments to ESRD facilities in CY 2025.

TABLE 21—IMPACTS OF THE FINAL CHANGES IN MEDICARE PAYMENTS TO ESRD FACILITIES FOR CY 2026

Facility type	Number of facilities	Number of treatments (in millions)	Routine outlier updates (%)	Routine TDAPA and post-TDAPA updates (%)	Routine wage index updates (%)	Budget-neutral non-labor adjustment (%)	Total percent change (%)
	(A)	(B)	(C)	(D)	(E)	(F)	(G)
All Facilities	7,608	25.2	0.0	0.1	0.0	0.0	2.2
Type:							
Freestanding	7,257	24.3	0.0	0.1	0.0	0.0	2.2
Hospital based	351	0.9	−0.6	0.2	−0.2	0.2	1.5
Ownership Type:							
Large dialysis organization	5,854	19.6	0.1	0.3	0.1	0.0	2.4
Regional chain	900	3.1	−0.4	−0.6	−0.2	0.2	1.0
Independent	491	1.5	0.2	0.2	−0.3	−0.1	2.0
Hospital based	351	0.9	−0.6	0.2	−0.2	0.2	1.5
Unknown	12	0.0	0.1	0.2	−1.1	−0.1	1.2
Geographic Location:							
Rural	1,233	3.5	0.0	0.2	−0.1	0.3	2.5
Urban	6,375	21.8	0.0	0.1	0.0	0.0	2.1
Census Region:							
East North Central	1,175	3.3	0.0	0.2	0.7	−0.1	2.9
East South Central	592	1.5	0.2	0.2	1.1	−0.1	3.5
Middle Atlantic	862	3.2	−0.1	0.1	−0.9	−0.1	1.0
Mountain	430	1.5	0.0	0.2	1.2	−0.1	3.3
New England	200	0.9	0.0	0.1	−0.4	−0.1	1.7
Pacific [1]	986	4.7	−0.1	0.0	−0.7	0.5	1.7
Puerto Rico and Virgin Islands	54	0.1	0.0	0.3	0.2	−0.1	2.5
South Atlantic	1,769	5.4	0.0	0.2	0.4	−0.1	2.5
West North Central	474	1.4	0.0	0.2	0.4	−0.1	2.6
West South Central	1,066	3.2	0.0	0.2	−0.3	−0.1	1.8
Facility Size:							

[44] 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.

TABLE 21—IMPACTS OF THE FINAL CHANGES IN MEDICARE PAYMENTS TO ESRD FACILITIES FOR CY 2026—Continued

Facility type	Number of facilities	Number of treatments (in millions)	Routine outlier updates (%)	Routine TDAPA and post-TDAPA updates (%)	Routine wage index updates (%)	Budget-neutral non-labor adjustment (%)	Total percent change (%)
	(A)	(B)	(C)	(D)	(E)	(F)	(G)
Less than 3,000 treatments	602	0.5	−0.1	0.2	0.2	0.0	2.3
3,000 to 3,999 treatments	414	0.6	0.0	0.2	0.2	−0.1	2.4
4,000 to 4,999 treatments	491	0.8	0.0	0.2	0.2	0.0	2.5
5,000 to 9,999 treatments	2,995	7.7	0.0	0.1	0.2	−0.1	2.3
10,000 or more treatments	3,106	15.7	0.0	0.1	−0.1	0.1	2.1
Percentage of Pediatric Patients:							
Less than 2%	7,510	25.0	0.0	0.1	0.0	0.0	2.2
Between 2% and 19%	38	0.1	−0.1	0.3	0.6	0.5	3.3
Between 20% and 49%	8	0.0	−1.5	−0.3	0.4	−0.1	0.3
More than 50%	52	0.0	−1.0	0.2	0.7	−0.1	1.8

[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.

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 finalized in section II.B.3. of this final rule. 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 D and in column G, which shows the distributional impacts of all changes for CY 2026 ESRD PPS payments and are discussed later in this final rule.

Column D represent the changes in simulated payments due to routine changes in TDAPA eligibility for DefenCath®, which will both become outlier eligible and also be included in the post-TDAPA add-on payment adjustment calculation beginning July 1, 2026, at the end of its TDAPA period.

Column E represents the effect of the final 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 will be budget neutral, so the total impact of this final policy change is 0.0 percent. However, we estimate there will be distributional impacts because of this final update. The largest increase will be to ESRD facilities in the Mountain region, which will receive 1.2 percent higher payments because of the updated ESRD PPS wage index. The largest decrease will be for ESRD facilities in the Middle Atlantic region, which will receive 0.9 percent lower payments because of the updated ESRD PPS wage index.

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

Column G reflects the overall impact of the policies discussed in this final rule, including the routine updates to the wage index, outlier thresholds, and post-TDAPA add-on payment adjustment amounts and the newly finalized NAPA described in section II.B.8. of this final rule. This column also reflects the final ESRD PPS payment rate update for CY 2026 of 2.1 percent, which reflects the final ESRDB market basket percentage increase for CY 2026 of 2.9 percent reduced by the final productivity adjustment of 0.8 percentage point. We expect that overall ESRD facilities will experience a 2.2 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 0.3 percent increase to a 3.5 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 G 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 add-on payment adjustment 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 or suppliers (for example, laboratories, and durable medical equipment suppliers.) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2026, we estimate that the ESRD PPS will have zero impact on these other providers.

(3) Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2026 will be approximately $8.2 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 2.2 percent overall increase in the CY 2026 ESRD PPS payment amounts, we estimate that there will be an increase in beneficiary coinsurance payments of 2.2 percent in CY 2026, which translates to approximately $40 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 the CY 2026 ESRD PPS proposed rule (90 FR 29357 through 29360), we proposed 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 final 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. As discussed in section II.B.8. of this final rule, we are finalizing the NAPA as proposed with the 25 percent cap for the reasons discussed in that section.

(b) Change to TDAPA Eligibility Timeframe

We considered alternative timelines for implementing the final regulatory change to the TDAPA eligibility criteria which we proposed 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 believe this would be a reasonable approach, as we did not identify any renal dialysis drugs or biological products that are 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 final rule, we believe that by making this change effective for TDAPA applications received on or after January 1, 2028, we will 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 will 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 will 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 will 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 [45] 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 will continue through June 30, 2026. As stated previously, TDAPA payment generally 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 2026 ESRD PPS proposed rule (90 FR 29379), 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 estimated approximately $40 million in spending of which, 20 percent or approximately $10 million, would have been attributed to beneficiary coinsurance amounts.

We have updated our impact analysis based on the most current 72x claims data from July 2024, when utilization first appeared on the claims, through July 2025. In applying that average to each of the 6 remaining months of the TDAPA payment period in CY 2026, we estimate approximately $50 million in spending of which, 20 percent or approximately $10 million, will be attributed to beneficiary coinsurance amounts in CY 2026.

(2) Vafseo® (Vadadustat)

On November 14, 2024, CMS Transmittal 12962 [46] 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 Transmittal 12999.[47] On May 29, 2025, Transmittal 13245 [48] rescinded and replaced Transmittal 13121 [49] which rescinded and replaced Transmittal 12999. The TDAPA payment period began on January 1, 2025, and will continue through December 31, 2026. As stated previously, TDAPA payment generally 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 2026 ESRD PPS proposed rule (90 FR 29379), 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 estimated approximately $30 million in spending of which, 20 percent or approximately

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

[46] 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.*

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

[48] CMS Transmittal 13245 dated May 29, 2025, available at *https://www.cms.gov/files/document/r13245bp.pdf.*

[49] CMS Transmittal 13241 dated March 28, 2025, available at *https://www.cms.gov/files/document/r13121bp.pdf.*

$10 million, would have been attributed to beneficiary coinsurance amounts.

We have updated our impact analysis based on the most current 72x claims data from January 2025, when utilization first appeared on the claims, through July 2025. In applying that average to each month in 2026, we estimate approximately $40 million in spending of which, 20 percent or approximately $10 million, will be attributed to beneficiary coinsurance amounts in CY 2026.

(3) Phosphate Binders

On November 14, 2024, CMS Transmittal 12962 [50] 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.[51] On May 29, 2025, Transmittal 13245 [52] rescinded and replaced Transmittal 13121 [53] which rescinded and replaced Transmittal 12999. The TDAPA payment period began on January 1, 2025, and will continue through December 31, 2026. Under 42 CFR 413.234(c)(4), for CYs 2025 and 2026, the TDAPA amount for a phosphate binder is based on 100 percent of ASP plus an additional amount derived from 6 percent of per-patient phosphate binder spending based on utilization and cost data.

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 revised this estimate for the CY 2026 ESRD PPS proposed rule based on our analysis of the most current 72x claims data from January 2025, when utilization first appeared on the claims, through March 2025. We explained that 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 estimated 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 solicited comments on this estimate. We received public comments on these estimates, which are discussed in the following paragraphs.

Comment: We received a few comments regarding the budgetary estimates of phosphate binder spending under TDAPA. These commenters expressed concern regarding the decrease in the estimated ESRD PPS spending for phosphate binders in the ESRD PPS bundled payment. Two of these commenters stated that the lower spending estimates for phosphate binders are indicative of depressed utilization of these drugs in the ESRD PPS.

Response: We appreciate these comments regarding the latest phosphate binder utilization estimates. We do not agree with the commenters' suggestion that these lower budgetary estimates reflect depressed utilization of phosphate binders under the ESRD PPS. Rather, we observe that the percentage of patients currently utilizing phosphate binders is comparable to the percentage of ESRD patients utilizing phosphate binders under Part D. In December 2024, approximately 63,000 beneficiaries, or 46.5 percent of ESRD PPS beneficiaries with Part D, were using at least one phosphate binder. By comparison, in June 2025, approximately 72,000 beneficiaries, or 46.6 percent of all ESRD PPS beneficiaries, were using at least one phosphate binder. As we acknowledged in the proposed rule, utilization of phosphate binders was lower in the first quarter of 2025, which could be attributable to ESRD facilities continuing to set up infrastructure to obtain and provide phosphate binders, as well as ESRD patients finishing their phosphate binder prescriptions that were filled in the final quarter of 2024. Additionally, we note we did not apply any methodology to account for confidential rebates and any other discounts provided by pharmaceutical companies to Medicare Part D plans in our calculation of Medicare Part D expenditures for phosphate binders. One study estimates discounts on brand-name drugs increased in Medicare Part D from 25.4% of spending in 2014 to 37.3% in 2018.[54] Accordingly, we based our projections of spending for the remainder of 2025 and 2026 on monthly phosphate binder spending in March, 2025. We believe this assumption was reasonable, since we have continued to observe monthly phosphate binder spending that is more similar to March, 2025 than to spending in earlier months of the year.

Final Rule Action: After considering the comments, we are further revising our estimate of the total CY 2025 ESRD PPS spending for phosphate binders for this CY 2026 ESRD PPS final rule. We are further revising this estimate based on our analysis of the most current 72x claims data from January 2025, when utilization first appeared on the claims, through June 2025. In January, we observed that total spending was approximately $14 million, whereas we observed that total spending was approximately $32 million in February, $36 million in March, $35 million in April, $35 million in May, and $36 million in June. On average, we observed that monthly spending was approximately $35 million between February and June. Projecting forward using the level of utilization and pricing that we observed during this 5-month period in 2025, we estimate approximately $400 million in spending for phosphate binders in CY 2025, of which 20 percent, or approximately $80 million would be attributed to beneficiary coinsurance amounts.

Similarly, using the most current 72x claims data from June 2025 we have estimated CY 2026 spending using the level of utilization and pricing that we observed between February and June 2025. In applying that average to each month in 2026, we estimate approximately $420 million in spending of which 20 percent, or approximately $80 million, will be attributed to beneficiary coinsurance amounts.

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

(1) Effects on ESRD Facilities

To understand the impact of the final 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.

[50] 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.*

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

[52] CMS Transmittal 13245 dated May 29, 2025, available at *https://www.cms.gov/files/document/r13245bp.pdf.*

[53] CMS Transmittal 13241 dated March 28, 2025, available at *https://www.cms.gov/files/document/r13121bp.pdf.*

[54] *JAMA Health Forum.* 2021;2(6):e210626. doi:10.1001/jamahealthforum.2021.0626.

For this final rule, we used CY 2024 data from the Medicare Part A and Part B Common Working Files as of August 1, 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 final rule. Table 22 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. We note that the version of this table which appeared in the CY 2026 ESRD PPS proposed rule as Table 18 (90 FR 29379 and 29380) incorrectly stated that the AKI treatments in column B were in the millions rather than the thousands. This was a typographical error, and we note that the correct labeling of thousands was present in the description of the table and the figures in Addendum B of the proposed rule were accurate.

TABLE 22—IMPACTS OF THE FINAL CHANGES IN MEDICARE PAYMENTS FOR RENAL DIALYSIS SERVICES FURNISHED TO INDIVIDUALS WITH AKI FOR CY 2026

Facility type	Number of facilities (A)	Number of treatments (in thousands) (B)	Routine wage index updates (%) (C)	Budget-neutral non-labor adjustment (%) (D)	Total percent change (%) (E)
All Facilities	5,074	286.2	0.1	−0.1	2.0
Type:					
Freestanding	4,966	281.6	0.1	−0.1	2.0
Hospital based	108	4.6	−0.2	−0.1	1.8
Ownership Type:					
Large dialysis organization	4,195	234.9	0.1	−0.1	2.1
Regional chain	576	30.7	−0.1	−0.1	1.9
Independent	192	15.9	−0.7	−0.1	1.2
Hospital based [1]	108	4.6	−0.2	−0.1	1.8
Unknown	3	0.2	−0.3	−0.1	1.6
Geographic Location:					
Rural	831	45.7	0.0	−0.1	1.9
Urban	4,243	240.5	0.1	−0.1	2.0
Census Region:					
East North Central	831	45.6	0.7	−0.1	2.6
East South Central	378	17.1	0.9	−0.1	2.9
Middle Atlantic	548	33.2	−0.8	−0.1	1.1
Mountain	315	22.4	1.4	−0.1	3.4
New England	148	6.9	−0.4	−0.1	1.5
Pacific [2]	672	51.4	−0.7	−0.1	1.2
Puerto Rico and Virgin Islands	2	0.0	0.9	−0.1	2.9
South Atlantic	1,194	66.3	0.4	−0.1	2.3
West North Central	310	12.7	0.5	−0.1	2.4
West South Central	676	30.6	−0.3	−0.1	1.6
Facility Size:					
Less than 3,000 treatments	183	5.2	0.4	−0.1	2.4
3,000 to 3,999 treatments	229	8.9	0.1	−0.1	2.1
4,000 to 4,999 treatments	293	13.0	0.3	−0.1	2.2
5,000 to 9,999 treatments	2,061	104.7	0.2	−0.1	2.1
10,000 or more treatments	2,308	154.4	0.0	−0.1	1.9
Percentage of Pediatric Patients:					
Less than 2%	5,058	285.5	0.1	−0.1	2.0
Between 2% and 19%	15	0.7	−0.2	−0.1	1.7
Between 20% and 49%	1	0.0	0.3	−0.1	2.3
More than 50%	0	0.0	0.0	0.0	0.0

[1] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[2] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.
[3] Routine updates include updating the base rate (by the market basket, productivity adjustment, and budget neutrality factors).

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

Column E shows the overall impact of all policies discussed in this final rule, including the 2.1 percent increase to the ESRD PPS base rate, which reflects the final ESRDB market basket percentage increase for CY 2026 of 2.9 percent reduced by the final productivity adjustment of 0.8 percentage point. We expect that overall ESRD facilities will experience a 2.0 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 1.1 percent for the Mid-Atlantic region to an increase of 3.4 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 finalizing updates to the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The patient and his or her physician make the decision about where the renal dialysis services are furnished. Therefore, this change will have zero impact on other Medicare providers.

(3) Effects on the Medicare Program

We estimate approximately $80 million will 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 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 NAPA to AKI dialysis payments as discussed in the CY 2026 ESRD PPS proposed rule (90 FR 29362). 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 Total Performance Score (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.

We are updating the estimated impact of the PY 2027 ESRD QIP that we provided in the CY 2026 ESRD PPS proposed rule (90 FR 29381 through 29382) based on the most recently available data. For the PY 2027 ESRD QIP, we estimate that, of the 7,582 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 42.9 percent or 3,256 of the facilities that have sufficient data to calculate a TPS will receive a payment reduction for PY 2027. Among an estimated 3,256 facilities that will receive a payment reduction, approximately 58 percent or 1,883 facilities will receive the smallest payment reduction of 0.5 percent. Based on the policies finalized in this final rule, the total estimated payment reductions for all the 3,256 facilities expected to receive a payment reduction in PY 2027 will be approximately $21,652,956. Facilities that do not receive a TPS do not receive a payment reduction.

Table 23 shows the updated overall estimated distribution of payment reductions resulting from the PY 2027 ESRD QIP.

TABLE 23—UPDATED ESTIMATED DISTRIBUTION OF PY 2027 ESRD QIP PAYMENT REDUCTIONS

Payment reduction	Number of facilities	Percent of facilities *
0.0%	4170	56.2
0.5%	1883	25.4
1.0%	945	12.7
1.5%	312	4.2
2.0%	116	1.6

* 156 facilities not scored due to insufficient data.

To estimate whether a facility will 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 24) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 24.

TABLE 24—DATA USED TO UPDATE THE ESTIMATED 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 2023–Dec 2023	Jan 2024–Dec 2024.
SRR	Jan 2023–Dec 2023	Jan 2024–Dec 2024.

TABLE 24—DATA USED TO UPDATE THE ESTIMATED PY 2027 ESRD QIP PAYMENT REDUCTIONS—Continued

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
SHR	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
PPPW	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
Kt/V Dialysis Adequacy Measure Topic:		
Adult HD Kt/V	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
Pediatric HD Kt/V	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
Adult PD Kt/V	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
Pediatric PD Kt/V	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
VAT:		
% Catheter	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
STrR	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
NHSN BSI	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
Clinical Depression	Jan 2023–Dec 2023	Jan 2024–Dec 2024.

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 final policies outlined in section IV.B. of this final rule. Facility reporting measure scores were estimated using available data from CY 2024. 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 final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2024 and December 2024 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 25 shows the updated 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 25—UPDATED ESTIMATED IMPACT OF ESRD QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2027

	Number of facilities	Number of treatments 2024 (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	7582	24.8	7426	3256	−0.35
Facility Type:					
Freestanding	7237	23.9	7120	3094	−0.34
Hospital-based	345	0.9	306	162	−0.51
Ownership Type:					
Large Dialysis	5839	19.3	5781	2401	−0.30
Regional Chain	894	3.1	870	340	−0.31
Independent	477	1.5	456	346	−0.93
Hospital-based (non-chain)	345	0.9	306	162	−0.51
Unknown	27	0	13	7	−0.50
Facility Size:					
Large Entities	6733	22.4	6651	2741	−0.30
Small Entities [1]	822	2.4	762	508	−0.76
Unknown	27	0	13	7	−0.50
Rural Status:					
Yes	1227	3.4	1196	465	−0.31
No	6355	21.4	6230	2791	−0.36
Census Region:					
Northeast	1060	4	1015	425	−0.35
Midwest	1642	4.7	1601	721	−0.36
South	3419	10	3380	1534	−0.36
West	1397	6	1367	532	−0.30
US Territories [2]	64	0.2	63	44	−0.50
Census Division:					
East North Central	1172	3.3	1145	547	−0.39

TABLE 25—UPDATED ESTIMATED IMPACT OF ESRD QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2027—Continued

	Number of facilities	Number of treatments 2024 (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)
East South Central	591	1.5	586	245	−0.32
Middle Atlantic	860	3.1	822	356	−0.38
Mountain	429	1.4	422	158	−0.29
New England	200	0.9	193	69	−0.25
Pacific	968	4.5	945	374	−0.30
South Atlantic	1765	5.3	1740	805	−0.37
West North Central	470	1.4	456	174	−0.31
West South Central	1063	3.2	1054	484	−0.36
US Territories[2]	54	0.1	53	36	−0.43
Unknown	10	0.1	10	8	−0.85
Facility Size (# of total treatments):					
Less than 4,000 treatments	1190	1.5	1079	403	−0.35
4,000–9,999 treatments	3389	8.4	3355	1313	−0.30
Over 10,000 treatments	3003	14.8	2992	1540	−0.40

[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

We are updating the estimated impact of the PY 2028 ESRD QIP that we provided in the CY 2026 ESRD PPS proposed rule (90 FR 29382 through 29384). For the PY 2028 ESRD QIP, we estimate that, of the 7,582 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 41.7 percent or 3,160 of the facilities that have sufficient data to calculate a TPS will receive a payment reduction for PY 2028. Among an estimated 3,160 facilities that will receive a payment reduction, approximately 59 percent or 1,865 facilities will receive the smallest payment reduction of 0.5 percent. Based on the policies finalized in this final rule, the total estimated payment reductions for all the 3,160 facilities expected to receive a payment reduction in PY 2028 will be approximately $20,624,345. Facilities that do not receive a TPS do not receive a payment reduction.

Table 26 shows the updated overall estimated distribution of payment reductions resulting from the PY 2028 ESRD QIP.

TABLE 26—UPDATED ESTIMATED DISTRIBUTION OF PY 2028 ESRD QIP PAYMENT REDUCTIONS

Payment reduction	Number of facilities	Percent of facilities *
0.0%	4265	57.4
0.5%	1865	25.1
1.0%	902	12.2
1.5%	294	4.0
2.0%	99	1.3

* 157 facilities not scored due to insufficient data.

To estimate whether a facility will 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 27) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 27.

TABLE 27—DATA USED TO UPDATE THE ESTIMATED 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	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
SRR	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
SHR	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
PPPW	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
Kt/V Dialysis Adequacy Measure Topic:		
Adult HD Kt/V	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
Pediatric HD Kt/V	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
Adult PD Kt/V	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
Pediatric PD Kt/V	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
VAT:		

TABLE 27—DATA USED TO UPDATE THE ESTIMATED PY 2028 ESRD QIP PAYMENT REDUCTIONS—Continued

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
% Catheter	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
STrR	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
NHSN BSI	Jan 2023–Dec 2023	Jan 2024–Dec 2024.
Clinical Depression	Jan 2023–Dec 2023	Jan 2024–Dec 2024.

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 finalized policies outlined in section IV.C. of this final rule. Facility reporting measure scores were estimated using available data from CY 2024. 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 final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2024 and December 2024 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 28 shows the updated 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 28—UPDATED 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	7582	24.8	7425	3160	−0.33
Facility Type:					
Freestanding	7237	23.9	7119	3007	−0.33
Hospital-based	345	0.9	306	153	−0.46
Ownership Type:					
Large Dialysis	5839	19.3	5781	2328	−0.29
Regional Chain	894	3.1	870	334	−0.30
Independent	477	1.5	455	338	−0.88
Hospital-based (non-chain)	345	0.9	306	153	−0.46
Unknown	27	0	13	7	−0.50
Facility Size:					
Large Entities	6733	22.4	6651	2662	−0.29
Small Entities [1]	822	2.4	761	491	−0.71
Unknown	27	0	13	7	−0.50
Rural Status:					
(1) Yes	1227	3.4	1195	444	−0.29
(2) No	6355	21.4	6230	2716	−0.34
Census Region:					
Northeast	1060	4	1015	416	−0.34
Midwest	1642	4.7	1601	701	−0.35
South	3419	10	3379	1494	−0.34
West	1397	6	1367	506	−0.28
US Territories[2]	64	0.2	63	43	−0.48
Census Division:					
Unknown	10	0.1	10	8	−0.80
East North Central	1172	3.3	1145	529	−0.37
East South Central	591	1.5	586	237	−0.31
Middle Atlantic	860	3.1	822	349	−0.36
Mountain	429	1.4	422	150	−0.28
New England	200	0.9	193	67	−0.24
Pacific	968	4.5	945	356	−0.28
South Atlantic	1765	5.3	1739	782	−0.35
West North Central	470	1.4	456	172	−0.30

TABLE 28—UPDATED 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)
West South Central	1063	3.2	1054	475	−0.35
US Territories[2]	54	0.1	53	35	−0.42
Facility Size (# of total treatments):					
Less than 4,000 treatments	1190	1.5	1078	389	−0.33
4,000–9,999 treatments	3389	8.4	3355	1298	−0.30
Over 10,000 treatments	3003	14.8	2992	1473	−0.37

[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 will contribute approximately $21,652,956 in Medicare savings. For PY 2028, we estimate that the ESRD QIP will contribute approximately $20,624,345 in Medicare savings. For comparison, Table 29 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2028.

TABLE 29—UPDATED ESTIMATED ESRD QIP AGGREGATE PAYMENT REDUCTIONS FOR PAYMENT YEARS 2018 THROUGH 2028

Payment year	Estimated payment reductions
PY 2028	$20,624,345.
PY 2027	$21,652,956.
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 (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 final rule, we are finalizing updates to the ICH CAHPS clinical measure by removing questions from the ICH CAHPS Survey beginning with PY 2028. We considered not adopting this change. However, we concluded that reducing the length of the ICH CAHPS Survey will 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 30 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 will 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 through June 30, 2027).

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

TABLE 30—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) [55] 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 30 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 30 uses actual HDPA counts and actual PPAs for MYs 1 through 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 will not have resulted in savings to Medicare.

Table 30 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 30, 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 will 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.

[55] 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.* The Lewin Group. *https://www.cms.gov/priorities/innovation/data-and-reports/2024/etc-2nd-eval-rpt.*

(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 final 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 final rule and to the previous citations.

D. Accounting Statement

Consistent with OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf*), we have prepared an accounting statement in Table 31 showing the classification of the impact associated with the provisions of this final rule.

TABLE 31—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS, AND COSTS

Category	Primary estimate
ESRD PPS and AKI (CY 2026)	
Annualized Monetized Transfers	$140 million.
From Whom To Whom	Federal Government To ESRD Providers.
Increased Beneficiary Co-insurance Payments	$40 million.
From Whom To Whom	Beneficiaries To ESRD Providers.
ESRD QIP for PY 2027	
Annualized Monetized Transfers	−$21.6 million.
From Whom To Whom	Federal Government To ESRD Providers.
Annualized Monetized Burden Reduction Costs	−$15.5 million.
ESRD QIP for PY 2028	
Annualized Monetized Transfers	−$20.6 million.
From Whom To Whom	Federal Government To ESRD Providers.
Annualized Monetized Burden Reduction Costs	−$0.7 million.
ETC Model for PYs 2026–2027	
Annual Monetized Transfers	−$1 million.
From Whom To Whom	Federal Government To ESRD Providers.

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.[56] For the purposes of this analysis, we exclude the ESRD facilities that are owned and operated by large dialysis organizations (LDOs) and regional chains, which will 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

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

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 491 ESRD facilities that are independent and 351 ESRD facilities that are hospital-based, as shown in the ownership category in Table 21, 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 780 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 366 nonprofit ESRD facilities that are also considered small businesses, there are 1,256 ESRD facilities that are either small businesses or nonprofit organizations, which is approximately 17 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 21, we estimate that the overall revenue impact of this final rule on all ESRD facilities is a positive increase to Medicare FFS payments by approximately 2.2 percent. For the ESRD PPS updates finalized 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 2.0 percent increase in Medicare FFS payments for CY 2026. Although not displayed in Table 21, we have found that among the 842 ESRD facilities that are small businesses, those furnishing fewer than 3,000 treatments per year are estimated to receive a 1.9 percent increase in Medicare FFS payments, and those furnishing 3,000 or more treatments per year are estimated to receive a 1.8 percent increase in Medicare FFS payments. Additionally, among the 780 nonprofit ESRD facilities, those furnishing fewer than 3,000 treatments per year are estimated to receive a 1.7 percent increase in Medicare FFS payments, and those furnishing 3,000 or more treatments per year are estimated to receive a 1.3 percent increase in Medicare FFS payments.

For AKI dialysis, we are unable to estimate whether patients will 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 final rule. This analysis is based on the assumptions described earlier in this section of this final rule as well as the detailed impact analysis discussed in section VII.C. of this final rule, which includes a discussion of data sources, general assumptions, and alternatives considered.

For the ESRD QIP, we estimate that of the 3,256 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2027 ESRD QIP, 508 are ESRD small entity facilities. We present these findings in Table 23 (''Updated Estimated Distribution of PY 2027 ESRD QIP Payment Reductions'') and Table 25 (''Updated Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2027''). Table 23 shows the overall estimated distribution of payment reductions resulting from the PY 2027 ESRD QIP. Table 25 shows the updated 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 3,160 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2028 ESRD QIP, 491 are ESRD small entity facilities. We present these findings in Table 26 (''Updated Estimated Distribution of PY 2028 ESRD QIP Payment Reductions'') and Table 28 (''Updated Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2028''). Table 26 shows the overall estimated distribution of payment reductions resulting from the PY 2028 ESRD QIP. Table 28 shows the updated 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 terminating the Model effective December 31, 2025.

Therefore, the Secretary has determined that this final 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 final 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this final rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 112 rural hospital-based ESRD facilities, we do not know how many of them are hospital-based with fewer than 100 beds. However, overall, the 112 rural hospital-based ESRD facilities will experience an estimated 2.3 percent increase in payments. Therefore, the Secretary has certified that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates Reform Act (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 final 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 final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of 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 finalized for the ESRD QIP do not create new regulations, nor do the finalized policies create new incremental costs. We estimate that these finalized policies will generate approximately $13.1 million in annualized cost savings relative to PY 2027 based on currently available facility and patient data. Therefore, the updates finalized for the ESRD QIP will be considered an Executive Order 14192 deregulatory action.

I. Congressional Review Act

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

VIII. 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–F, 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.*

IX. Waiver of Delayed Effective Date

In the absence of an appropriation for fiscal year 2026 or a Continuing Resolution, the federal government funding for HHS lapsed on October 1, 2025. During the funding lapse, which lasted from October 1, 2025, through November 12, 2025, only excepted or exempted operations continued, which significantly delayed work on this final rule. CMS identified funding that allowed the agency to restore additional day-to-day operations on a temporary basis beginning on October 27, 2025. However, most of the work on this final rule was not completed in accordance with our usual schedule for final CY payment rules, which aims for an issuance date of November 1 followed by an effective date of January 1 to ensure that the policies are effective at the start of the calendar year to which they apply.

We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued. The 60-day delay in effective date required by the Congressional Review Act, 5 U.S.C. 801(a)(3), can be waived, however, if the agency finds for good cause that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, and the agency incorporates the finding and a brief statement of reasons in the rule issued, 5 U.S.C. 808(2). For the following reasons, we find it would be impracticable and contrary to the public interest to delay the effective date of the ESRD PPS, AKI, ETC Model, and ESRD QIP policies in this final rule. The ESRD PPS is a calendar-year payment system, and we typically issue the final rule by November 1 of each year to ensure that the payment policies for the system are effective on January 1, the first day of the calendar year to which the policies are intended to apply. CMS also updates the AKI dialysis payment rate in the ESRD PPS final rule to ensure that AKI payment policies are effective on January 1, the first day of the calendar year to which the policies are intended to apply. CMS also includes in the ESRD PPS final rule its policies for the ESRD QIP because the performance of a dialysis facility under the ESRD QIP has a direct effect on that facility's payment under the ESRD PPS. In this final rule, we are finalizing policies that impact the PY 2028 ESRD QIP, which corresponds to a facility's ESRD QIP measure set requirements for 2026 beginning with January 1, the first day of the calendar year to which the policies are intended to apply. ETC Model policies are also included in the ESRD PPS final rule as the ETC Model is mandatory and has a direct positive or negative financial impact on participating ESRD facilities. We note that CMS publicly announced its intention to terminate the ETC Model in March of 2025, and we intend to follow to follow through on this commitment.[57] An ESRD facility's ESRD PPS and AKI payments in 2026 will be based, in part, on the policies finalized in this final rule. If the effective date of this final rule is delayed by 60 days, the ESRD PPS, AKI, ETC Model, and ESRD QIP policies adopted in this final rule will not be effective until after January 1, 2026. This would result in ESRD facilities in 2026 receiving payment based on 2025 ESRD PPS and AKI dialysis payment rates, having their payment impacted based on past performance in the ETC Model, and being subject to 2025 QIP reporting requirements. This would be contrary to the public's interest in ensuring that ESRD facilities receive appropriate payments in a timely manner, and that their payments in 2026 properly and completely reflect their performance on quality measures in 2024. Furthermore, such a delay would be impractical as it would require different processing of claims from before and after the delayed effective date, including the use of different systems to process the 2025 payment amounts, 2025 QIP reporting requirements, and the continuation of the ETC model for the portion of 2026 before the delayed effective date. This would require notable additional resource use for ESRD facilities, as well as for CMS and its contractors.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on November 17, 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 amends 42 CFR chapter IV as set forth below:

[57] *https://www.cms.gov/newsroom/fact-sheets/cms-innovation-center-announces-model-portfolio-changes-better-protect-taxpayers-and-help-americans.*

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 addition 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 CERTAIN MODELS

■ 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 revised 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 § 512.370(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.

[FR Doc. 2025–20681 Filed 11–20–25; 4:15 pm]

BILLING CODE 4120–01–P