Medicare Program: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model (CMS-1768-F)

On November 7 2022, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* (87 FR 67136) a final rule addressing routine updates to the Medicare End-Stage Renal Disease Prospective Payment System (ESRD PPS), payment updates for renal dialysis services to individuals with acute kidney injury (AKI), updates for the ESRD Quality Incentive Program (QIP) and ESRD Treatment Choices (ETC) Model for calendar year 2023.[1]

Addenda provided by CMS on the ESRD PPS provide wage index files and facility level impact analysis. These are available at https://www.cms.gov/medicaremedicare-fee-service-paymentesrdpaymentend-stage-renal-disease-esrd-payment-regulations-and/cms-1768-f.

TABLE OF CONTENTS

[1] Henceforth in this document, a year is a calendar year unless otherwise specified.

I. Introduction

The final rule would update and revise the ESRD PPS for 2023. This final rule also updates the payment rate for renal dialysis services furnished by ESRD facilities to individuals with acute kidney injury (AKI). CMS rebases and revises the ESRD Bundled (ESRDB) market basket for CY 2023 to a 2020 base year. The 2023 labor-related share is 55.2% based on the 2020-based ESRDB market basket weights. CMS finalizes its proposal to apply a permanent 5-percent cap on any ESRD facility's wage index decrease from its wage index in the prior year. CMS maintains the ESRD PPS outlier policy that targets 1.0 percent of total Medicare ESRD PPS expenditures in outlier payments but makes refinements to its methodology for calculating the fixed-dollar loss (FDL) amount for adult patients. This rule finalizes suppression of seven ESRD QIP measures for payment year (PY) 2023 and updates performance standards for PY 2023. Technical specification changes are announced for PY 2024. Revisions to the program's measure set are finalized for PY 2025 along with reweighting of measures and domains used for determining Total Performance Scores.

CMS estimates that the revisions to the ESRD PPS would increase payments to ESRD facilities by approximately $300 million in 2023. CMS finalizes a 2023 ESRD PPS base rate of $265.57, compared with the final 2022 rate of $257.90.

II. 2023 ESRD PPS

A. Background

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

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

B. Provisions of the ESRD PPS Update

1. 2023 ESRD PPS Update

a. 2023 ESRD Bundled (ESRDB) Market Basket Rebasing and Revision; Market Basket Increase Factor; Productivity Adjustment; and Labor-Related Share

(1) Rebasing and Revising of the ESRDB Market Basket

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRDB input price index. The ESRDB is a fixed weight index that measures the change in price over time of the same mix of goods and services that ESRD facilities use to provide services. CMS rebases and revises the ESRDB market basket every three years and proposed to rebase the ESRDB market basket for 2023 using a 2020 base year—the most recent year for which relatively complete Medicare Cost Report (MCR) data are available. Rebasing means moving the base year for the structure of costs without making any other major changes to the methodology. Revising means changing data sources, cost categories, and/or price proxies used in the input price index.

To rebase the ESRDB, CMS proposed to use 2020 MCRs from independent facilities supplemented with 2012 data from the U.S. Census Bureau's Services Annual Survey (SAS), the most recent year of detailed expense data, inflated to 2020 levels. CMS also proposed to use the May 2020 Occupational Employment Statistics data from the U.S. Department of Labor's Bureau of Labor Statistics (BLS) to estimate the weights for the Wages and Salaries and Employee Benefits occupational blends.

CMS analyzed the cost weights for 2017 through 2020 and found the expenses reported in the MCRs for 2020 were consistent with the prior years. CMS notes that any impacts on utilization due to the COVID PHE were minimal as dialysis is not an optional treatment and continued during the PHE. The 2020 MCRs were for freestanding ESRD facilities whose cost reporting period began on or after October 1, 2019 and before October 1, 2020. CMS proposed to maintain its policy of using data from freestanding ESRD facilities because freestanding facilities account for over 90 percent of the total ESRD facilities in 2020.

Table 1 (reproduced below) presents the 2020-based ESRDB and 2016-based ESRDB market basket major cost weights as derived directly from the MCR data. These figures are the same as those proposed.

Table 1. ESRDB Market Basket
Major Cost Weights: 2016-Based and 2020-Based

Cost Category	2020-based ESRDB Market Basket (%)	2016-based ESRDB Market Basket (%)
Wages and Salaries	34.5	32.6
Employee Benefits	7.7	7.0
Pharmaceuticals	10.1	12.4

Supplies	11.0	10.4
Laboratory Services	1.3	2.2
Housekeeping*	0.5	3.9
Operations & Maintenance	3.7	n/a
Administrative & General	17.5	18.5
Capital-related Building and Fixtures	9.4	9.2
Capital-related Moveable Equipment	4.4	3.8
Note: Totals may not sum to 100.0 percent due to rounding.		
* For the 2016-based ESRDB market basket, this category was referred to as the Housekeeping and Operations cost category. For the proposed 2020-based ESRDB market basket, the Housekeeping and Operations cost category is split into two detailed cost categories: Housekeeping and Operations & Maintenance.		

Table 4 (reproduced below) lists all the cost categories and cost weights in the 2020-based ESRDB compared to the 2016-based ESRDB market basket. These figures are the same as those proposed.

Table 4: ESRDB Market Basket
Detailed Cost Weights: 2016-Based and 2020-Based

2020 Cost Category	2020 Cost Weights (percent)	2016 Cost Weights (percent)
Total	**100.0**	**100.0**
Compensation	**45.9**	**43.6**
Wages and Salaries	36.5	34.5
Employee Benefits	9.5	9.1
Utilities	**1.4**	**2.0**
Electricity	1.2	1.1
Natural Gas	0.1	0.1
Water and Sewerage[1]	n/a	0.8
Medical Supplies & Laboratory Services	**22.4**	**24.9**
Pharmaceuticals	10.1	12.4
Erythropoiesis Simulating Agents (ESA)	6.0	10.0
Other Drugs (except ESAs)	4.1	2.4
Supplies	11.0	10.4
Laboratory Services	1.3	2.2
All Other Goods and Services	**16.6**	**16.4**
Telephone & Internet Services	0.5	0.5
Housekeeping	0.5	3.9
Operations & Maintenance	3.7	n/a
Professional Fees	0.8	0.7
All Other Goods and Services	11.1	11.3
Capital Costs	**13.8**	**13.0**
Capital Related-Building and Fixtures	9.4	9.2

Table 4: ESRDB Market Basket Detailed Cost Weights: 2016-Based and 2020-Based		
2020 Cost Category	**2020 Cost Weights (percent)**	**2016 Cost Weights (percent)**
Capital Related-Machinery	4.4	3.8
[1] Water and Sewerage that was a stand alone cost category in the 2016-based ESRDB market basket * Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and, therefore, the detail may not add to the total due to rounding.		

Comments/Responses: Commenters supported CMS' proposal to rebase and revise the ESRDB market basket. Some commenters indicated that the proposed 2020 cost weights, particularly for labor and related costs, are likely underrepresented as a portion of the market basket. These commenters requested that CMS consider rebasing the ESRDB market basket more frequently than every four years. CMS responded that the 2020 data reflect the latest available data available to estimate the ESRDB market basket cost share weights but will, if technically appropriate, consider rebasing the ESRDB market basket more frequently than usual should the cost weights change significantly.

MedPAC requested that CMS' rebasing of the ESRDB market basket should reflect MedPAC's most recent audit of freestanding ESRD facilities, which found that cost reports have included costs that are not allowable under Medicare. CMS responded that MedPAC found misreporting by some facilities based on 2018 cost report reports. Misreporting of costs would have to be prevalent across a significant percentage of facilities to affect the cost weights. Also, CMS is using 2020 cost reports are used for rebasing the ESDRB cost weights.

Final Rule Action: Finalize as proposed.

To revise the ESRDB, CMS proposed to use the same proxies as those used in the 2016-based ESRDB market basket, except for the price proxy for the Other Drugs (except ESAs) cost category. For the Other Drugs (except ESAs), CMS proposed to use a 50/50 blend of the PPIs for Commodity for Vitamin, Nutrient, and Hematinic Preparations (PPI-VNHP) and Commodity for Pharmaceuticals for human use, prescription (PPI-Pharmaceuticals). CMS continues to believe the PPI-VNHP is an appropriate proxy for the iron supplements, and an analysis of claims data indicates that iron supplement cost account for about half of the All Other ESRD-related Drug costs. CMS proposed the PPI-Pharmaceuticals because it captures the inflationary price pressure for all types of prescription drugs rather than a single therapeutic category of drugs. Public commenters supported this proposal.

Table 7 below shows the price proxies and weights associated with each cost category. This table is unchanged from the proposed rule.

Table 7: Price Proxies and Associated Cost Weights for the 2020-based ESRDB Market Basket		
Cost Category	**Price Proxy**	**2020 Cost Weight**
Total ESRDB Market Basket		100.0%
Compensation		**45.9%**
Wages and Salaries		36.5%
Health-related	ECI for Wages and Salaries for All Civilian Workers in Hospitals.	28.9%
Management	ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial.	3.3%
Administrative	ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support.	1.9%
Services	ECI for Wages and Salaries for Private Industry Workers in Service Occupations.	2.3%
Employee Benefits		**9.5%**
Health-related	ECI for Total Benefits for All Civilian workers in Hospitals.	7.5%
Management	ECI for Total Benefits for Private Industry workers in Management, Business, and Financial.	0.9%
Administrative	ECI for Total Benefits for Private Industry workers in Office and Administrative Support.	0.5%
Services	ECI for Total Benefits for Private Industry workers in Service Occupations.	0.6%
Utilities		**1.4%**
Electricity	PPI Commodity for Commercial Electric Power.	1.2%
Natural Gas	PPI Commodity for Commercial Natural Gas.	0.1%
Medical Materials and Supplies		**22.4%**
Pharmaceuticals		10.1%
ESAs	PPI Commodity for Biological Products, Excluding Diagnostics, for Human Use.	6.0%
Other Drugs	50/50 blend of the PPI Commodity for Vitamin, Nutrient, and Hematinic Preparations, and the PPI Commodity for Pharmaceuticals for human use, prescription	4.1%
Supplies	PPI Commodity for Surgical and Medical Instruments.	11.0%
Laboratory Services	PPI Industry for Medical Laboratories.	1.3%
All Other Goods and Services		**16.6%**
Telephone Service	CPI-U for Telephone Services.	0.5%
Housekeeping	PPI Commodity for Cleaning and Building Maintenance Services.	0.5%
Operations & Maintenance	ECI for Total compensation for All Civilian workers in Installation, maintenance, and repair	3.7%
Professional Fees	ECI for Total Compensation for Private Industry Workers in Professional and Related.	0.8%
All Other Goods and Services	PPI for Final demand - Finished Goods less Foods and Energy.	11.1%
Capital Costs		**13.8%**
Building and Fixtures	PPI Industry for Lessors of Nonresidential Buildings.	9.4%

Table 7: Price Proxies and Associated Cost Weights for the 2020-based ESRDB Market Basket		
Cost Category	**Price Proxy**	**2020 Cost Weight**
Moveable Equipment	PPI Commodity for Electrical Machinery and Equipment.	4.4%
Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and therefore, the detail may not add to the total due to rounding.		

Comments/Responses: Public comments indicated that the ECI for Wages and Salaries for All Civilian Workers in Hospitals is not designed to accurately capture rapid changes in inflation and market dynamics of the type seen as a result of the COVID-19 PHE. Commenters cited a study by Altarum that showed higher growth in healthcare wages and average hourly wages between July 2021 and June 2022 than all private sector jobs as well as fewer available workers pre- and post-pandemic. The commenters argued that ESRD facilities are more vulnerable than other healthcare facilities to these trends as a result of being exclusively dependent on Medicare and the need for specialized staff to work in their facilities.

CMS responded that, in the absence of ESRD-specific data, the highly skilled hospital workforce captured by the ECI for hospital workers (inclusive of therapists, nurses, and other clinicians) is a reasonable proxy for the compensation component of the ESRDB market basket. Additionally, using the relative distribution of workers based on the FTE data reported on the ESRD cost report, the occupational distribution of the compensation costs weights is technically appropriate.

One commenter encouraged CMS to provide more transparency regarding the ESRDB market basket price proxies forecasting models' methodologies and underlying assumptions.
CMS responded that it uses independent forecasts of the price proxies for the CMS market baskets from IHS Global Inc. (IGI), a nationally recognized economic and financial forecasting firm with economic and health sector forecasting model capabilities that extend beyond CMS' expertise. As the forecasting models are proprietary, CMS is not licensed to share information related to the detailed models. More information on the IGI economic forecasts can be found at the following website, https://ihsmarkit.com/products/US-economic-modeling-forecasting-services.html.

Final Rule Action: Finalize as proposed. Rebasing and revising results in a 0.2 percentage point increase to the 2023 ESRDB market.

(2) Labor Related Share for ESRD PPS

The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are influenced by the local labor market. For 2023, CMS proposed a labor-related share of 55.2 percent, compared to the current 52.3 percent based on the 2016-based ESRD market basket (Table 8, reproduced below).

Table 8: Labor-Related Share of Current and Proposed ESRD Bundled Market Basket		
Cost Category	**2020-based ESRDB Market Basket Weights (%)**	**2016-based ESRDB Market Basket Weights (%)**
Wages and Salaries	36.5	34.5

Table 8: Labor-Related Share of Current and Proposed ESRD Bundled Market Basket		
Cost Category	**2020-based ESRDB Market Basket Weights (%)**	**2016-based ESRDB Market Basket Weights (%)**
Employee Benefits	9.5	9.1
Housekeeping*	0.5	3.9
Operations & Maintenance	3.7	n/a
Professional Fees (Labor-Related)	0.7	0.6
Capital Labor-Related	4.3	4.2
Total Labor-Related	**55.2**	**52.3**
*The 2016-based ESRDB labor-related share had a combined category weight for Housekeeping and Operations		

CMS used the same methodology for the 2020-based ESRDB market basket as it used for the 2016-based ESRDB market basket. Public comments supported CMS' proposal that it is finalizing without modification.

(3) 2023 ESRD Market Basket Increase Factor, Adjusted for Productivity

2023 Market Basket Increase Factor. CMS proposed a 2020-based ESRDB market basket of 2.8 percent using the IGI first quarter 2022 forecast with historical data through the fourth quarter of 2021. Using IGI's third quarter 2022 forecast of the 2020-based ESRDB market basket with historical data through the second quarter of 2022, CMS estimates a 2023 market basket of 3.1 percent.

Productivity Adjustment. By law the ESRDB market basket update is reduced by the total factor productivity (TFP) adjustment. The adjustment is equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business TFP. For the proposed rule, this figure was 0.4 percentage points. For the final rule, the figure is 0.1 percentage points based on later information from IGI.

The 2023 ESRD market basket update net of productivity will be 3.0 percent (3.1 percent less 0.1 percentage points).

Comments/Responses: Public comments were in three broad categories:

2023 Market Basket is Too Low. Many commenters expressed their concern that the 2023 ESRD PPS update insufficiently captures the rising costs that ESRD facilities are experiencing for compensation. Commenters indicated that higher compensation costs are the result of significant and lasting effects on staffing and supply costs as a result of the COVID-19 PHE and a demographic shift in labor market conditions that are shrinking the pool of available labor. Many commenters requested that CMS consider using its statutory authority to apply a labor add-on payment adjustment to the ESRD PPS for 2023.

As it has done in other rules in response to comments that the inflation update is too low, CMS cited its statutory obligation to update ESRD rates by the ESRDB market basket net of

productivity. The response indicates that CMS did not propose and is not authorized to apply a labor add-on payment adjustment. CMS believes the 2020-based ESRDB market basket increase adequately reflects the average change in the price of goods and services ESRD facilities purchase to provide renal dialysis services, and is technically appropriate to use as the ESRD PPS payment update factor. The final 2023 ESRDB market basket update reflects the most recent available data regarding both prices and the quantity of labor used to provide renal dialysis services.

Productivity Adjustment. Concerns about the productivity adjustment have also been prevalent in other rules. The general concern is that economy-wide non-farm productivity will be higher than can be achieved by health care facilities—in this case, ESRD facilities. However, public commenters also recognize CMS' statutory limitations and its obligation to offset economy-wide non-farm productivity when calculating the inflation update. Public commenters asked that CMS work with the kidney care community and policymakers to revisit this policy and devise a productivity adjustment that: (1) better reflects factors over which ESRD facilities have control and that affect opportunity for productivity gains, and (2) accounts for the statutory reductions to the ESRD PPS already in place to account for expected gains in efficiency.

CMS' response was similar to those in other rules—reiterating its statutory obligation. CMS will continue to monitor the impact of the ESRD PPS updates, including the effects of the productivity adjustment on ESRD facility margins as well as beneficiary access to care as reported by MedPAC in their annual Report to the Congress.

Forecast Error Adjustment. Forecast error describes the difference between a forecasted market basket and its actual figure based on after-the-fact data. Except for the skilled nursing facility (SNF) update, CMS does not adjust the update for forecast error. For the SNF update, CMS has a threshold for the level of forecast error (0.5 percentage points) before it makes an adjustment to a future update to reconcile past forecast error. Public comments asked CMS to apply a forecast error adjustment to the ESRDB market basket due understatement of the index in 2021 and 2022. Some commenters requested CMS adopt a similar threshold level like it has for the SNF PPS before there is an adjustment for forecast error.

These comments have also been prevalent in other rules and CMS' response has been consistent that forecast error can go in either direction. For example, the 2017 ESRDB forecast error was -0.8 percentage point, while the 2021 ESRDB forecast error was +1.2 percentage point. CMS is concerned about the potential for instability in future rate setting were it to routinely adjust the update for forecast error.

Final Rule Action: CMS is finalizing an ESRD update of 3.0 percent based on the ESRDB market basket of 3.1 percent less TFP of 0.1 percentage point consistent with past practice.

b. 2023 ESRD PPS Wage Indices

Wage Index Data. The ESRD PPS adjusts the labor-related portion (55.2 percent for 2023) of the base rate by a wage index that reflects geographic differences in wage levels using the most

recent hospital wage data collected annually under the inpatient PPS.[2] For 2023, CMS proposed to use updated wage data from hospital cost reporting periods for FY 2019.[3]

For urban areas with no hospital data, CMS computes the average wage index value of all urban areas within the state to serve as a reasonable proxy. For rural areas with no hospital data, CMS computes an average wage index from all contiguous CBSAs. The previously adopted ESRD wage index floor of 0.5000 is applied; wage areas in Puerto Rico are currently the only ones to benefit from the floor.

Comments/Responses: Several commenters indicated the wage index did not appropriately recognize ESRD facility cost to hire and retain staff. CMS responded that this issue is addressed by the ESRDB market basket—not the wage index which is intended to measure the relative difference in wage costs between areas for ESRD facilities.

Other commenters requested two IPPS wage index policies (a lower labor share for hospitals with a wage index below 1.0 and an increase in the wage index for those hospitals with a wage index in the lowest quartile) be adopted under the ESRD PPS. One commenter requested CMS adopt a wage index based on ESRD facility specific data rather than using hospital wage data. CMS responded that these comments are out-of-scope to anything it proposed. However, CMS believes these concerns are addressed by the wage index floor and cap on decreases in the wage index (discussed below) it is adopting for 2023.

Final Rule Action: Finalize without modification.

5 Percent Cap on Wage Index Decreases: In the past, CMS has established transition policies of limited duration to phase in significant changes to labor market areas. It notes, however, that year-to-year fluctuations in an area's wage index can occur due to external factors beyond a provider's control, such as COVID-19 PHE, which are unrelated to changes in labor market areas. It states that predictability in Medicare payments is important to enable providers to budget and plan their operations.

CMS proposed to apply a permanent 5 percent cap on any decrease to a geographic area's wage index from the prior year, regardless of the circumstances causing the decline (e.g., an area's wage index could not be less than 95 percent of its wage index for the prior year). There would be no cap on the reduction for a newly opened or newly certified ESRD facility for its first full or partial calendar year (e.g., there would be no prior year wage index for applying the cap). A newly opened or certified facility would be paid the wage index for the area where it is located.

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[2] Under the statute, CMS provides many adjustments to the hospital wage index (geographic reclassification, rural floor, a lower labor share for hospitals with a wage index below 1.0 among others). None of these adjustments are used for the ESRD wage index.

[3]Addendum A provides a crosswalk between the 2022 wage index and the proposed 2023 wage index and Addendum B provides an ESRD facility level impact analysis. These are available at https://www.cms.gov/medicaremedicare-fee-service-paymentesrdpaymentend-stage-renal-disease-esrd-payment-regulations-and/cms-1768-f.

Comments/Responses: Commenters, including MedPAC, supported the 5 percent cap on decreases to the wage index. MedPAC indicated the 5 percent cap should also apply to wage index increases. Other commenters raised concerns about budget neutral application of the wage index. CMS indicated it will take these comments into account to inform future rulemaking. In response to MedPAC, CMS indicated that a limit on decreases was proposed to enable ESRD facilities to more effectively budget and plan their operations. A limit on increases would not be needed for this purpose.

Several commenters asked CMS to implement the proposed 5 percent cap retroactively to protect facilities that experienced substantial reductions to their wage index due to the adoption of the new CBSA delineations in 2021. CMS did limit that reduction in 2021 to 5 percent but allowed the remainder of the reduction to occur in 2022 irrespective of whether it was more than 5 percent. In response to the comment, CMS indicated it did not make any proposal to address that issue and it believes that its new cap policy should apply prospectively beginning with 2023.

Final Rule Action: CMS is finalizing its policy as proposed and will make the 5 percent cap on reductions to ESRD wage indexes budget neutral.

Wage Index Floor: Under the ESRD PPS, a wage index floor value is applied as a substitute wage index for areas with very low wage index values. The wage index floor of 0.5000 has been in effect since January 1, 2019. For 2023 and subsequent years, CMS proposed to increase the wage index floor to 0.6000.

Currently, only rural Puerto Rico and 8 urban areas in Puerto Rico receive the wage index floor of 0.5000. The next lowest wage index is the Virgin Islands with a value of 0.6004. For 2023, Puerto Rico would have the only areas subject to the wage index floor of 0.6000.

Comments/Responses: MedPAC opposed the proposed wage index floor increase, recommending that CMS establish an ESRD-specific wage index rather than one based on hospital data. Several commenters agreed with MedPAC's recommendation. Although an ESRD facility wage index that more specifically targets the labor mix applicable to ESRD facilities could potentially identify more granular cost differences between labor market areas, some commenters expressed concern that it could increase the reporting burden on ESRD facilities. CMS responded it used wage data from BLS and FTEs by occupation reported on the cost reports for independent ESRD facilities to support the proposed increase in the wage index floor to 0.6. It continues to believe these data support the wage index floor it proposed.

While most commenters supported finalizing the wage index floor policy as proposed, these same commenters also stated that CMS should consider future refinements to the wage index floor policy based on later data that reflects the worsening economic situation in Puerto Rico since 2013 through 2015—the cost report data years CMS used for its analysis. CMS responded that it used 2013 to 2015 to determine if the wage index floor could be appropriately set at a higher value, not to determine the exact value for a new wage index floor. The proposed increase in the wage index floor was intended to balance between providing additional payments to areas that fall below the wage index floor while minimizing the impact on average payment rates for all ESRD facilities.

Other public comments expressed concerns about issues specific to Puerto Rico to justify a higher floor: economic conditions that have led health care professionals to relocate from Puerto Rico to the U.S. mainland; requirements to only employ Registered Nurses (RNs) rather than technicians for medical care; requirements that RNs and other ESRD facility staff in Puerto Rico must be bilingual; and the higher incidence of disease burden in Puerto Rico than elsewhere. CMS believes higher wage costs associated with these variables would be captured in the information that is used to develop the wage index. With respect to disease burden, CMS does not believe the wage index is the appropriate policy lever to address that issue.

Final Rule Action: CMS is finalizing its proposal to increase the wage index floor from 0.5 to 0.6 without modification.

c. 2023 Update to the Outlier Policy

An ESRD facility is eligible for outlier payments if its actual or imputed Medicare Allowable Payment (MAP) per treatment for ESRD outlier services exceeds a threshold, which is equal to the facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus a fixed-dollar loss amount (FDL). CMS updates the national adjusted average MAP amounts and FDL amounts each year using the latest available data. The final rule discusses CMS' longstanding methodology for calculating the national average MAP amount and establishing the FDL amount at a level that results in projected outlier payments that equal 1.0 percent of total payments under the ESRD PPS.

CMS notes that for several years, outlier payments have consistently been below the target 1.0 percent of total ESRD PPS payments. Commenters, including MedPAC, have raised concerns about the methodology CMS uses to set the FDL. In the 2022 ESRD proposed rule,[4] CMS stated it was considering potential revisions to the calculation of the outlier thresholds and published an RFI to solicit comments on potential approaches. Commenters focused on three main suggestions: (1) reducing the target percentage to 0.5 or 0.6 percent, which commenters argued would more closely align with the historical percentage paid under the ESRD PPS; (2) re-allocating money from the ESRD PPS that is not paid for outliers—either by allowing unspent funds to apply to a subsequent year's withhold amount or establishing a payment mechanism to support ESRD facilities' activities aimed at reducing health disparities; and (3) changing the methodology used to calculate the FDL and MAP amounts to better account for historical trends in utilization but also changes in prices and utilization of new and innovative products.[5]

CMS is concerned that reducing the outlier percentage from 1.0 percent to 0.5 or 0.6 percent would not directly address the root cause of outlier payments totaling less than 1 percent of overall ESRD PPS payments in prior years. Reducing the outlier percentage may not protect access for beneficiaries whose care is unusually costly. Reallocating money from the ESRD PPS that is not paid for outliers would present operational challenges because of the lags in the claims process and refiling of claims, which often occur over different calendar years.

[4] 86 FR 36041-36042

[5] A detailed comment summary is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.

For 2023 and subsequent years, CMS proposed to continue to calculate the adult and pediatric MAP amounts following its established methodology but to prospectively calculate the adult FDL amounts based on their historical trends that would have achieved the 1.0 percent outlier target in the 3 most recent available data years. CMS also proposed to adjust the calculation of the historical FDL trend for years that immediately follow the end of a period during which CMS has paid for a product using the TDAPA or TPNIES payment adjustments under the ESRD PPS. CMS did not propose to apply this method to the calculation of the pediatric FDL amounts because that population is too small to reliably use this method.

The proposed rule discussed the detailed steps for prospectively calculating the adult FDL. For 2023, CMS proposed that the outlier services MAP amounts and pediatric FDL amounts would be derived from claims data from 2021. CMS proposed that the adult FDL amounts for 2023 would be derived from the projected FDL trend calculated according to the proposed methodology. Based on the latest available data, the proposed FDL amount for pediatric beneficiaries would decrease from $26.02 to $21.51, and the MAP amount would decrease from $27.15 to $25.62 as compared to 2022 values. For adult beneficiaries, the proposed FDL amount would decrease from $75.39 to $40.75, and the MAP amount would decrease from $42.75 to $36.85. (Lowering the threshold means that it will be easier for a case to qualify for outliers making it more likely that CMS will achieve its goal of 1 percent of payments being made as outliers.)

CMS believes the proposed updates to the methodology for calculating the adult FDL amount will more effectively target 1.0 percent of total ESRD PPS payments. CMS estimates that the percentage of patient months qualifying for outlier payments in 2023 will be 11.54 percent for adult patients and 13.58 percent for pediatric patients.

Comments/Responses: Several commenters made comments that CMS previously rejected (reduce the outlier percentage and reallocate money from the ESRD PPS that is not paid for outliers to future year ESRD payments). There were comments requesting that CMS analyze the cost of providing care in pediatric facilities and develop a pediatric-specific ESRD PPS base rate to appropriately compensate these specialized facilities for their work. CMS noted its past solicitation of comments on ESRD payment for pediatric patients and will take those comments into consideration to potentially inform future rulemaking.

Other commenters expressed support for the revised outlier methodology for adult patients. MedPAC supported CMS' proposal but did suggest some technical refinements for how to account for drug price inflation based on ASP values rather than the ESRDB market basket pharmaceutical price proxies that are currently used. CMS will take this suggestion into account in future rulemaking.

Some commenters expressed concerns about using TDAPA and TPNIES expenditures in the calculation of the FDL and MAP amounts, claiming that inclusion of these expenditures will increase the dollars withheld from the ESRD PPS base rate and result in the outlier pool paying less than the 1 percent target. CMS responded that it did not propose to include any TDAPA or TPNIES expenditures in estimates of ESRD outlier payments for setting the FDL and MAP amounts for any services that would not be eligible ESRD outlier services in the target year.

Further, CMS proposed to account for the introduction of such newly eligible ESRD outlier services by calculating a retrospective trend line based on prior years' TDAPA or TPNIES utilization. Because these expenditures will be added to the retrospective FDLs to calculate the adjusted retrospective FDLs under the proposed methodology, the inclusion of TDAPA or TPNIES utilization will always reduce the slope of the trend line of the adjusted retrospective FDL.

Final Rule Action: CMS is finalizing its proposed outlier methodology without modification. Figure 1 of the final rule presents how the FDL amounts would have changed in prior years using this methodology. Table 11 shows the impact between 2022 and 2023 of CMS' revised outlier payment methodology:

TABLE 11: Outlier Policy: Impact of Using Updated Data for the Outlier Policy

	Column I Final outlier policy for 2022 (based on 2020 data, price inflated to 2022)*		**Column II Final outlier policy for 2023 (based on 2021 data, price inflated to 2023)****	
	Age < 18	**Age >= 18**	**Age < 18**	**Age >= 18**
Average outlier services MAP amount per treatment	$ 25.91	$ 44.49	$24.13	$41.36
Adjustments				
Standardization for outlier services	1.0693	0.9805	1.0819	0.9774
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$27.15	$42.75	$25.59	$39.62
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$26.02	$75.39	$23.29	$73.19
Patient-month-facilities qualifying for outlier payment	12.89%	7.08%	12.90%	5.90%

*Column I was obtained from Column II of Table 1 from the CY 2022 ESRD PPS final rule (86 FR 61883).
**The FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2019, 2020, and 2021.

d. Impacts to the 2023 ESRD Base Rate

CMS is adopting a 2023 ESRD PPS base rate of $265.57, compared with the final 2022 rate of $257.90. As shown in the table below, this increase is the result of: Application of the wage index budget neutrality adjustment of 0.999730 and the update factor of 3.0 percent. The update factor reflects an estimated increase of 3.1 percent in the ESRDB and an estimated productivity adjustment of -0.1 percent.

2023 ESRD PPS Base Rate	
Base Rate Update Components	**Amount**
Final 2022 ESRD PPS Base Rate	**$257.90**
Wage index budget neutrality adjustment	0.999730
Market basket increase	+3.1%
Productivity adjustment	-0.1%
Subtotal: update factor	+3.0%
2023 ESRD PPS Base Rate	**$265.57**

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

In the 2021 ESRD final rule[6], CMS expanded eligibility for transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) to capital-related assets that are home dialysis machines used by a single patient. The methodology used by the Medicare Administrative Contractors (MACs) to establish the TPNIES payment for these items accounts for the cost of the home dialysis machine that is already in the ESRD PPS base rate ("TPNIES offset amount"). 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 years.

The methodology for calculating the TPNIES offset amount is annually updated by the ESRD bundled market basket percentage increase factor (3.1 percent) minus the productivity adjustment factor (0.1 percentage points).[7] The 2022 TPNIES offset amount is $9.50. The 2023 TPNIES offset amount for capital-related assets that are home dialysis machines is $9.79 ($9.50 x 1.030 =$9.50). CMS updates this amount using the most recent data available in the final rule.

CMS clarifies in response to a comment about how the TPNIES offset amount is included in the calculation of payments under the ESRD PPS. It states that under the policy at §413.236(f)(iii) that was established in the CY 2020 ESRD PPS final rule, the annually adjusted offset amount is subtracted from the MAC-determined price to account for the cost of home dialysis machine that is already in the ESRD PPS base rate.

f. Revision to the Oral-only Drug Definition and Clarification Regarding the ESRD PPS Functional Category Descriptions

(1) Background

Section 1881(b)(14)(B) (iii) of the Act states that renal dialysis services include other drugs and biologicals[8] that are furnished to individuals for treatment of ESRD and for which payment was made separately under this title, and any oral equivalent form of such drug or biological. Although CMS included oral-only renal dialysis service drugs and biologicals in the definition of

[6] 85 FR 71427

[7] §413.236(f)(3)

[8] To be consistent with FDA nomenclature, in the 2019 ESRD PPS final rule (83 FR 56922), CMS began using the term "biological products" instead of "biologicals". CMS uses the term "biological products" except when referencing specific language in the Act or regulations.

renal dialysis services in the 2011 ESRD final rule, it also finalized to delay payment under the ESRD PPS until January 1, 2014.[9] CMS identified phosphate binders and calcimimetics as oral-only drugs in the ESRD PPS functional category for bone and mineral metabolism. However, inclusion of any oral only renal dialysis service drugs and biologicals in the ESRD PPS (including any applicable outlier payments) has been delayed until January 1, 2025 by statute.

In the proposed rule, CMS discusses the legislation that has delayed payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS. CMS implemented the last legislated delay in the 2016 ESRD PPS final rule by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS at §413.174(f)(6) from January 1, 2024 to January 1, 2025. CMS also changed the date for outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2024 to January 1, 2025 (§413.237(a)(1)(v)). An oral-only drug is a drug or biological with no injectable equivalent or other form of administration other than orally. CMS stated it would use rulemaking to include the oral and any non-oral version of the drug in the ESRD PPS bundled payment when the drug or biological was no longer considered an oral-only drug. CMS noted it would pay for the existing oral only drugs using the transitional drug add-on payment adjustment (TDAPA) for 3 years and then through a distinct ESRD functional category where the end action effect (as described below) is the treatment or management of a condition or conditions associated with ESRD (including for oral only drugs when paid under the ESRD PPS).

In 2017, FDA approved an injectable calcimimetic. CMS paid for calcimimetics using the TDAPA under the ESRD PPS for 3 years (2018-2020) and as of January 1, 2021, included it the ESRD PPS base rate. Phosphate binders are still considered oral-only drugs and under current law will be paid under Medicare Part D until January 1, 2025, as long as they remain oral-only drugs. Beginning January 1, 2025 payment will be incorporated into the ESRD PPS, and separate payment will no longer be provided. CMS notes that if an injectable equivalent or other form of administration of phosphate binders were approved by FDA prior to January 1, 2025, CMS would pay for the oral and any non-oral version of the drug using the TDAPA for at least 2 years. If no other form of administration of phosphate binders is approved by the FDA prior to January 1, 2025, CMS would pay for the oral version of the drug using the TDAPA for at least 2 years beginning January 1, 2025 before undertaking rulemaking to modify the ESRD PPS base rate to account for the cost of the drug is the ESRD PPS bundled payment.

(2) CMS Observations Regarding Decrease in Drug Utilization and Medicare Expenditures when Drugs are Included in the ESRD PPS

In the proposed rule, CMS summarized the trends in drug utilization and Medicare expenditures for renal dialysis drugs and biological products. CMS observed two distinct patterns during the transition of payment for calcimimetics from Part D to Part B. First, beginning in 2018, when calcimimetics were paid using the TDAPA, there was a significant increase in the utilization of calcimimetics across all patient populations and as utilization increased, cost decreased. Second, after incorporation of calcimimetics into the ESRD PPS bundled payment, CMS noted a decrease in overall utilization of calcimimetic drugs. with a pronounced decrease in the most expensive injectable calcimimetic. CMS noted that it has not observed any sustained increase in adverse

[9] 75 FR 49038-49053

outcomes related to incorporation of renal dialysis drugs or biological products, including adverse outcomes related to changes in utilization of different forms of calcimimetics. CMS concluded this information supports its longstanding view that oral-only renal dialysis service drugs and biological products are an essential part of the ESRD PPS bundled payment.

(3) CMS Observations on Part D Spending for Dialysis Drugs
In the proposed rule, CMS summarized studies examining trends in Medicare spending for calcimimetics and phosphate binders. In 2018, Medicare Part D spending for phosphate binders accounted for 40 percent of all Medicare Part D spending for dialysis beneficiaries.[10] MedPAC's March 2022 Report to Congress noted that the future incorporation of phosphate binders into the ESRD PPS bundled payment is expected to provide better drug management for ESRD beneficiaries, improve access to these medications, and improve provider efficiency.[11] MedPAC stated this is important because some beneficiaries lack Part D coverage or have coverage less generous than the standard Part D benefit.

(4) The Oral-Only Drug Definition and "Functional" Equivalence under the ESRD PPS
For the oral-only drug policy, CMS does not rely on the FDA's regulatory definitions of drug equivalences that include pharmaceutical equivalent, bioequivalents, and therapeutic equivalents. CMS considers "functional" equivalence, which is not described in FDA's regulations, when evaluating whether there is a form of administration other than oral to determine if a drug or biological product is an oral-only drug. [12]A drug or biological product is functionally equivalent if it has the same end action effect as another renal dialysis drug or biological product.

(5) Revision to the Definition of Oral-Only Drug
CMS finalizes its proposal to include the word “functional” in the definition of oral-only drug. The finalized definition states that an oral-only drug is a drug or biological product with no injectable functional equivalent or other form of administration other than an oral form (§413.234(a)). To apply this change effective January 1, 2025, as proposed, CMS finalizes a technical change at §413.234(a) to indicate this definition becomes effective January 1, 2025.

CMS notes this language is consistent with the policy previously established for phosphate binders and calcimimetics. In addition, CMS believes this proposed modification will help ensure it does not perpetuate any further delays in incorporating drugs and biological products that are renal dialysis services into the ESRD PPS bundled payment as soon as possible under current law. This change will also limit the scope of any new drugs or biological products that could be considered oral-only drugs and facilitate incorporation of these renal dialysis services into the ESRD PPS.

As discussed above, the incorporation of Part D drugs into the ESRD PPS has expanded access to drugs for beneficiaries lacking Part D coverage. Specifically, CMS notes that a significant increase in calcimimetics among the African-American/Black minority population when CMS

[10] MedPAC's March 2021 Report to Congress: Medicare Payment Policy available at https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy.
[11] https://www.medpac.gov/document/march-2022-report-to-the-congress-medicare-payment-policy.
[12] CMS notes that neither ATRA, PAMA, nor ABLE included a definition of "equivalent" for purposes of the oral-only drug determination.

began paying for these drugs using the TDAPA. Thus, CMS believes the proposed modification would facilitate the inclusion of oral renal dialysis drugs into the ESRD PPS bundled payment and support health equity for beneficiaries who lack Part D coverage or have less generous than the Part D standard benefit.

Commenters generally expressed support for the proposed change to the definition of oral-only drugs. MedPAC commented that this proposal would help maintain the integrity of the ESRD PPS bundled payment. A drug manufacturer and a non-profit kidney organization expressed concerns and recommended that within the determination of functional equivalence, CMS should consider drug comparisons at the drug class or subgroup level and not the functional category level. Some commenters suggested that functional equivalence for an oral-only drug should be evaluated on mechanism of action and not end action effect. In response, CMS reiterates its long standing policy that the ESRD PPS functional categories are not based on the mechanism of action, but rather their end action effect (80 FR 69015-69017). CMS also believes that the functional category framework helps ensure that the ESRD PPS appropriately supports the unique needs of each ESRD patient.

In response to commenters requesting information about the process CMS uses to determine functional equivalence, CMS notes the drug designation process is discussed in the Medicare Benefit Policy Manual, Pub. 100-2, Chapter 11, Section 20.3.1. As an overview, CMS reviews the data and information in the new product's FDA approved physician labeling, reviews the new product's information presented for obtaining a HCPCS codes, and conducts an internal review. CMS disagrees with comments that CMS should rely on the expertise and role of FDA to make the functional equivalence determinations. CMS states it is CMS' role, not the FDA, to make determinations about the ESRD PPS payment policy.

(6) Revisions to Clarify the ESRD PPS Functional Category Descriptions
In the 2011 ESRD final rule,[13] CMS established three categories of drugs and biological products: drugs and biologicals that are not considered for the treatment of ESRD; drugs and biologicals that are always considered for the treatment of ESRD; and drugs and biologicals that may be used for the treatment of ESRD but are also commonly used to treat other conditions. The categories of drugs and biologicals that were always considered used for the treatment of ESRD were identified as access management, anemia management, anti-infective; bone and mineral metabolism, and cellular management. In the 2015 ESRD final rule, CMS removed anti-infective from this list of categories of drugs and biologicals included in the ESRD PPS base rate.

In the 2016 ESRD final rule,[14] CMS established a TDAPA policy that is based on a determination of whether or not a drug fits into an existing ESRD PPS functional category. In response to comments, CMS listed each ESRD PPS functional category and provided examples of drugs in certain categories. In the 2019 ESRD PPS final rule,[15] CMS emphasized that the functional categories are deliberately broad.

[13] 75 FR 49044 - 49053
[14] 80 FR 69023 - 69024
[15] 83 FR 56941

CMS finalizes its proposal to make the following clarifications to the existing ESRD PPS functional categories:

- Indicate that certain functional categories may include, but are not limited to, drugs that have multiple clinical indications. For example, drugs and biological products in the anxiolytic functional category could have multiple clinical indications.
- Add the term "biological products" to the descriptions of several ESRD PPS functional categories, which currently refer only to "drugs"
- Update the examples provided in some category descriptions to describe the end-action effect of drugs or biological products included in that functional categories.

The final clarifications to the descriptions of the ESRD PPS functional categories are shown in italics in Table 13 (reproduced below). CMS believes these changes will ensure the descriptions of the functional categories are clearer to potential TDAPA applicants and the public.

Table 13: Final ESRD PPS Functional Category Descriptions

Functional Category	*Description and Examples*
Access Management	Drugs/*biological products* used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management	Drugs/*biological products* used to stimulate red blood cell production and/or treat or prevent anemia. *Examples of drugs/biological products in this category include ESAs and iron.*
Bone and Mineral Metabolism	Drugs/*biological products* used to prevent/treat bone disease secondary to dialysis. *Examples of drugs/biological products in t*his category include phosphate binders and calcimimetics.
Cellular Management	Drugs/*biological products* used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.
Antiemetic	*Drugs/biological products* used to prevent or treat nausea and vomiting secondary to dialysis. Excludes antiemetics used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	*Drugs/biological products u*sed to treat infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs/*biological products* in this *category are included for their action to* treat itching *secondary* to dialysis *but may have* multiple clinical indications.
Anxiolytic	Drugs/*biological products* in this *category* are included for the treatment of restless leg syndrome *secondary* to dialysis *but may* have multiple *clinical indications*.
Excess Fluid Management	Drugs/*biological products/*fluids used to treat fluid excess *or fluid* overload.
Fluid and Electrolyte Management Including Volume Expanders	Intravenous drugs/*biological products/*fluids used to treat fluid and electrolyte needs.

Table 13: Final ESRD PPS Functional Category Descriptions	
Pain Management	Drugs/*biological products* used to treat graft site pain and to treat pain medication overdose.

CMS summarizes comments from four organizations: MedPAC, a physician's professional association, a drug manufacturer, and a coalition of dialysis organizations. MedPAC supported the proposed revisions; two commenters suggested CMS should not proceed with its proposal. In response, CMS reiterates that the intent of the ESRD functional category framework is to broadly describe the renal dialysis drugs and biological products that are currently available and to facilitate adding new drugs. In response from concerns that the phase "secondary to dialysis" is not appropriate for the antipruritic and bone mineral metabolism functional categories, CMS notes it has previously used "secondary to dialysis" and it believes the provision of renal dialysis services is central to the ESRD PPS, and that all renal dialysis service drugs and biological products are "secondary to dialysis".

In response to a comment, CMS affirms that the antipruritic KORSUVA qualifies for the TDAPA and will receive the TDAPA from April 1. 2022 until March 31, 2024 (CR 12583).

C. Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for 2023 Payment

1. TPNIES Eligibility Criteria

In the 2020 ESRD PPS final rule,[16] CMS established transitional add-on payment for TPNIES under the ESRD PPS. In the 2021 ESRD PPS final rule,[17] CMS made several changes to the TPNIES eligibility criteria and expanded the TPNIES policy to include certain capital-related assets[18] that are dialysis machines that are used in the home for a single patient. To be eligible for the TPNIES adjustment, the renal dialysis equipment or supply item must meet all the following requirements:

1. Has been designated by CMS as a renal dialysis service under §413.171;
2. Is new, meaning it is within 3 years of the date of the FDA marketing authorization;
3. Is commercially available by January 1 of the year in which the payment adjustment would take effect;
4. Has a Healthcare Common Procedure Coding System (HCPCS) Level II code application submitted in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the year;
5. Is innovative, meaning it meets the substantial clinical improvement criteria specified in §412.87(b)(1) (criteria used by CMS for the IPPS New Technology Add-on Payment); and

[16] 84 FR 60681 - 60698
[17] 85 FR 71410 - 71464
[18] Capital-related assets are defined in the Provider Reimbursement Manual (chapter 1, section 104.1) as assets that a provider has an economic interest in through ownership (regardless of the manner in which they were acquired).

6. Is not a capital-related asset, except for capital-related assets that are home dialysis machines.

A determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis of treatment of Medicare beneficiaries means one of the following:

- The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatment; or
- The new renal dialysis equipment or supply offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must be evidence that use of the renal dialysis service to make a diagnosis affects the management of the patient; or
- The use of the new dialysis equipment or supply significantly improves clinical outcomes relative to renal dialysis services previously available as demonstrated by one or more of the following:
    - A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication;
    - A decreased rate of at least one subsequent diagnostic or therapeutic intervention;
    - A decreased number of future hospitalizations or physician visits;
    - A more rapid beneficial resolution of the disease process including, but not limited to, a reduced length of stay or recovery time;
    - An improvement in one or more activities of daily living;
    - An improved quality of life; or
    - A demonstrated greater medication adherence or compliance; or
- The totality of the circumstances otherwise demonstrates that the new renal dialysis equipment or supply substantially improves, relative to renal dialysis serves previously available, the diagnosis or treatment of Medicare beneficiaries.

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

CMS has also established a process for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. CMS will only consider a complete application received by February 1 prior to the particular year. FDA marketing authorization must occur by September 1 prior to the particular year.

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

2. Applications for the TPNIES

For 2023, CMS does not approve the three applications received for TPNIES:

- CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System)
- SunWrap™ System, and
- THERANOVA 400 Dialyzer / THERANOVA 500 Dialyzer (THERANOVA).

The summary below provides a high-level discussion of each application. Readers are advised to review the proposed rule for more detailed information.

a. CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System)

CloudCath submitted an application for the CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System) for CY 2023.[19] According to the applicant, the technology is a tabletop passive drainage system that detects and monitors solid particles in dialysate effluent during peritoneal dialysis (PD) treatment. Solid particles may indicate that the patient has peritonitis. The CloudCath System consists of three components: a drain set, optical sensor, and patient monitoring software. The CloudCath System is compatible with several PD cyclers and when attached to a compatible cycler, the dialysate effluent runs through the drain set and the CloudCath optical sensor.

The applicant claimed that the risk of PD-related peritonitis and the challenges for detected PD-related peritonitis are the main reasons that only approximately 12 percent of eligible patients are on PD therapy. The applicant discussed guidelines by the International Society for Peritoneal Dialysis (ISPD) which recommend that PD patients presenting with cloudy effluent be presumed to have peritonitis and receive appropriate treatment until the diagnosis can be confirmed or excluded. The guidelines recommend that patients self-monitor for symptoms of peritonitis, cloudy dialysate and /or abdominal pain.

The applicant asserted that under the current standard of care, patients face challenges in detecting peritonitis due to difficulty in closely examining their own dialysate effluent during PD treatments. The applicant stated the Cloud Cath System addresses these challenges by detecting changes in dialysate effluent at much lower levels of particle concentrations that the amount needed for visual detection by patients and notifies the patient and provider when the effluent turbidity exceeds the notification threshold. The software also allows for data trending and remote monitoring by a provider.

Renal Dialysis Service Criterion (§ 413.236(b)(1))
CMS considers monitoring for peritonitis a service that is essential for dialysis and meets the renal dialysis service criterion.

[19] The applicant submitted a 2022 TPNIES application for the CloudCath System (85 FR 36343 - 36347) and withdrew the application because it did not receive FDA marketing authorization by July 6, 2021 (the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services).

Newness Criterion (§ 413.236(b)(2))
The applicant stated that the CloudCath System received FDA marketing on February 9, 2022. CMS concludes the system meets the newness criterion.

Commercial Availability Criterion (§ 413.236(b)(3)
The applicant expected the CloudCath System would be commercially available immediately after receiving FDA marketing authorization. Based on additional information provided by the applicant, CMS concludes the system meets the commercial availability criterion.

HCPCS Level II Application Criterion (§ 413.236(b)(2))
The applicant stated it intends to submit a HCPCS Level II code application by the July 5, 2022 deadline. CMS received the application and concludes the system meets this criterion.

Innovation Criterion (§ § 413.236(b)(5) and 412.87(b)(1))
The applicant asserted that the CloudCath System offers significantly improved clinical improvement over existing technologies by monitoring changes in PD effluent turbidity through continuous remote monitoring in patients earlier than the current standard of care. The applicant claims that the use of the CloudCath System changes the management of peritonitis by enabling clinicians to both diagnose peritonitis and initiate antibiotic treatment earlier. The applicant also asserted that the CloudCath System reassures patients that if peritonitis occurs it will be detected early and provides patients confidence to remain on home-PD, which will ultimately improve their quality of life.

CMS summarizes this information provided in the application. In the proposed rule, CMS noted that because the applicant claims to offer the ability to diagnosis a medical condition, PD-related peritonitis, earlier in a patient population than allowed by currently available methods, the applicant must include evidence that the diagnosis affects the management of the patient.

CMS was concerned that the studies submitted do not provide sufficient information for it to determine whether the technology represents an advance that substantially improves the treatment of Medicare beneficiaries compared to available renal dialysis services. CMS noted that the studies are "proof of concept" as they only provide evidence that the CloudCath System's detection of solid particles in dialysate effluent may indicate PD-related peritonitis and may do so earlier that patient observation and a cell count test. The studies, however, did not provide evidence how the observations from the CloudCath System affect the management of the patient. CMS was concerned that it will not be able to make a determination on whether early detection of PD-related peritonitis by the CloudCath System meets the substantial clinical improvement criterion.

CMS also stated healthcare providers may decide to wait for confirmation of peritonitis by patient symptoms, cell count, or positive culture consistent with recommendations in the ISPD guidelines. CMS noted that no evidence was submitted to demonstrate that the CloudCath System would affect medical management of the patient by replacing one of the ISPD guidelines for diagnosis. In addition, CMS was concerned that beginning treatment for presumed PD-related peritonitis in patient with ESRD prior to the occurrence of any of the ISPD guidelines would be harmful to patients and that the potential for false positive results may lead to treatment in a

vulnerable group of beneficiaries. CMS was also concerned there is insufficient evidence presented to demonstrate that the CloudCath System improves patients' quality of life (QoL).

CMS received many comments from the applicant, patients, clinicians, ESRD facilities and professional organizations; some commenters supported the device and other commenters raised concerns about the substantial clinical improvement claims. The applicant also provided additional information which CMS summarizes in the final rule.

CMS still concludes there is no evidence that using the CloudCath System affects the management of patients in a way that improves the diagnosis and treatment of peritonitis and reiterates its concerns discussed in the proposed rule. CMS determines that the CloudCath System does not meet the innovation criteria.

Capital Related Assets Criterion (§ 413.236(b)(6))
CMS determines the CloudCath System does not meet the definition of a capital related asset because the device is not subject to depreciation nor is it used by a provider as part of a regular lease agreement.

Final Decision: For 2023, CMS determines the evidence and public comments are not sufficient to determine that the CloudCath System meets all the eligibility criteria to qualify for the TPNIES. CMS notes that based on the FDA marketing authorization date of February 9, 2022, the applicant is eligible to apply for the TPNIES for 2024, 2025, or 2026.

b. SunWrap™ System

Sun Scientific, Inc. submitted an application for the SunWrap System. According to the applicant, the technology is comprised of a compression sleeve with a transparent air bladder and hand pump designed to provide static pneumatic compression to the forearm and/or upper arm following dialysis needle removal from the arteriovenous (AV) fistula access.
After removal of a dialysis needle from arteriovenous (AV) fistula access and gauze is placed over the access site, the technology provides a sufficient source of pressure to compress the arteriovenous (AV) intervention puncture site with adjustable compression at 20-30 mmHg and 30-40 mmHg. The applicant provided a SunWrap System brochure noting that the product is indicated for post-HD treatment needle puncture management for hemostasis of needle site and is contraindicated for use directly on an open wound.

The applicant stated that the SunWrap System replaces the current method of compression for bleeding control, which relies on manual pressure to the puncture site for up to 15 minutes following removal of the dialysis needle. The applicant stated that inadequate or incorrect application of compression can result in discomfort, excessive bleeding, hematoma, fistula damage, and potentially even death.

Renal Dialysis Service Criterion (§ 413.236(b)(1))
CMS considers compression to the HD access site following dialysis needle removal a service that is essential for dialysis and meets the renal dialysis service criterion.

Newness Criterion (§ 413.236(b)(2))
The applicant did not submit an FDA marketing authorization date but indicated that the SunWrap System is considered FDA Class I Exempt. CMS noted that Class I exempt status is determined by FDA and that the FDA website lists devices exempt from the premarket notification (510(k)) requirements. The applicant submitted additional information pertaining to registration and product classification: (1) a document labeled Class I Exempt Documentation and (2) listing, registration, and Firm Establishment Identifier (FEI) numbers for SunWrap. The applicant also submitted a product brochure. CMS also identified additional information on the FDA website about SunWrap devices.

CMS was concerned that the SunWrap System might not meet the newness criterion. First, the product brochure listed seven products and it was not clear to CMS which products are the subject of the TPNIES application and which products are registered on the FDA website. CMS was also concerned that the applicant did not clearly indicate the date of Class I Exempt status and it was unclear if that date is within the three-year newness period.

CMS noted that manufacturers of devices within the Class I Exempt category are not required to submit to FDA a premarket notification and obtain FDA clearance before marketing in the U.S. The manufacturer is required to register its establishment and list its devices with FDA.[20] CMS stated that exempt devices still must comply with regulatory controls to provide a reasonable assurance of safety and effectiveness for such devices.

One commenter agreed with CMS regarding the lack of clarity about which product is the subject of the TPNIES application. The applicant did not provide any additional information and without any evidence that the technology is within the 3 years beginning date of the FDA marketing authorization, the SunWrap System does not meet the newness criterion.

Commercial Availability Criterion (§ 413.236(b)(3)
The applicant stated that the SunWrap System is commercially available. CMS did not receive any additional information and it still questions which of the seven products of the application meet the commercial availability criterion.

HCPCS Level II Application Criterion (§ 413.236(b)(2))
The applicant stated it submitted a HCPCS Level II code application on January 31, 2022. CMS received the application and concludes the system meets this criterion.

Innovation Criterion (§ § 413.236(b)(5) and 412.87(b)(1))
The applicant discussed six substantial clinical improvement claims: (1) a reduction in at least one clinically significant adverse events; (2) a decreased rate of at least one subsequent diagnostic or therapeutic intervention; (3) a decreased number of future hospitalizations or physician visits; (4) a more rapid beneficial resolution of the disease process treatment; (5) an improvement in one or more activities of daily living; and (6) an improved quality of life. The applicant provided a summary of a non-published, single pilot study at two vascular access laboratory sites.

[20] Learn if a Medical Device Has Been Cleared by FDA for Marketing. Available at: https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing.

CMS summarized this information in the proposed rule. CMS noted that it is not clear how the evidence submitted supports the applicant's substantial clinical improvement claims and stated it would be helpful if the applicant directly linked each claim to the relevant supporting information. CMS also requested additional information about the single pilot study including the study type, patient demographics and endpoints. CMS requested any additional information demonstrating that the SunWrap System represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

CMS received several comments about the substantial clinical improvement claims; one commenter supported the claims and the remaining commenters expressed concerns in support of CMS' concerns. The applicant did not provide any additional information.

CMS concludes there is no evidence that the SunWrap System does not meet the innovation criteria.

Capital Related Assets Criterion (§ 413.236(b)(6))
The applicant did not address this criterion in the proposed rule and did not provide any comment on this criterion. CMS concludes that the SunWrap System does not meet the definition of a capital related asset because the device is not subject to depreciation nor is it used by a provider as part of a regular lease agreement.

Final Decision: For 2023, CMS determines the evidence and public comments are not sufficient to determine that the SunWrap System meets all the eligibility criteria to qualify for the TPNIES.

c. THERANOVA 400 Dialyzer / THERANOVA 500 Dialyzer (THERANOVA)

Baxter Healthcare Corporation submitted an application for the THERANOVA 400 Dialyzer and the THERANOVA 500 Dialyzer.[21] The 400 and 500 denote differences in surface area; the application collectively refers to the products as "THERANOVA".

According to the applicant, THERANOVA is a new class of single-use dialyzers intended to treat renal failure by hemodialysis (HD). The dialyzer consists of an innovative three-layer membrane structure that offers a higher permeability than high-flux dialyzers, with improved removal of certain harmful proteins known as large middle molecules (LMMs) while selectively maintaining essential proteins such as albumin. THERANOVA is used with standard HD machine. The applicant stated that THERANOVA is intended to treat kidney failure by expanded hemodialysis (HDx).

Renal Dialysis Service Criterion (§ 413.236(b)(1))
CMS considers a dialyzer a supply essential for the delivery of maintenance dialysis and demines THERANOVA meets the renal dialysis service criterion.

[21] A TPNIES application was submitted for 2021 and discussed in the 2021 ESRD proposed rule (85 FR 42167 – 42177) and the 2021 ESRD final rule (85 FR 71444 – 71457). CMS did not find the submitted evidence and public comments sufficient in meeting the substantial clinical improvement criterion and the TPNIES was not approved.

Newness Criterion (§ 413.236(b)(2))
The applicant stated that the THERANOVA received FDA marketing authorization for home use on August 28, 2020. CMS concludes THERANOVA meets the newness criterion.

Commercial Availability Criterion (§ 413.236(b)(3)
The applicant stated that THERANOVA is commercially available in the U.S.

HCPCS Level II Application Criterion (§ 413.236(b)(2))
The applicant stated it intends to submit a HCPCS Level II code application by the July 5, 2022 deadline. CMS received the application and concludes the system meets this criterion.

Innovation Criteria (§ § 413.236(b)(5) and 412.87(b)(1))
The applicant discussed five substantial clinical improvement claims: (1) decrease in the number of future hospitalization by up to 45 percent; (2) improved recovery time by up to 2 hours; (3)improved QoL as indicated by pruritis, improvements in two Kidney Disease Quality of Life (KDQol) survey domains, and improved London Evaluation of Illness (LEVIL) scores; (4) reduced restless leg syndrome by 10 percent or more; and (5 reduced rate of subsequent therapeutic interventions such as reduced need for erythropoietin stimulating agents (ESAs), iron, and insulin. The applicant supported these claims with seven published papers, one paper accepted for publication, and one poster. CMS noted that several of the studies were secondary analyses of the same trial data.

The applicant also addressed comments related to its 2021 TPNIES application. The applicant noted that physicians who use THERANOVA continue to support the application. The applicant asserted that all substantial clinical improvements are now supported by at least one study that has been peer reviewed and either published, accepted for publication, or is being prepared for publication. The applicant also believed the findings are applicable and generalizable to the U.S. Medicare population and this finding is bolstered by additional U.S. specific information and findings. The applicant asserted that with the updated and additional information provided, the application has addressed concerns previously identified.

CMS summarized this information in the proposed rule. CMS discussed concerns about the design of the studies including the open-label and observational design of most of the studies which may potentially bias results. CMS also noted that many of the studies are single-arm studies that do not employ a control group which may impact the ability to determine if observed improvements in clinical outcomes are due to the use of THERNOVA or associated with previously available dialysis membranes.

CMS received many comments about the substantial clinical improvement claims; some clinicians and patients supported the claims while some clinicians and dialyzer companies expressed concerns in support of CMS' concerns. The applicant provided information addressing CMS' concerns; this information is summarized in the final rule.

After reviewing the application, the additional information submitted by the applicant, and comments, CMS determines that the THERANOVA has not shown that it represents an advance

that substantially improves, relative to renal dialysis services previously available, the treatment of Medicare beneficiaries. CMS concludes THERANOVA does not meet the innovation criteria.

Capital Related Assets Criterion (§ 413.236(b)(6))
The applicant stated that the THERANOVA System does not meet the definition of a capital related asset because the device is not subject to depreciation nor is it used by a provider as part of a regular lease agreement. CMS agrees.

Final Decision: For 2023, CMS determines the evidence and public comments are not sufficient to determine THERANOVA S meets all the eligibility criteria to qualify for the TPNIES. CMS notes that based on the FDA marketing authorization date of August 28, 2020, the applicant is eligible to apply for the TPNIES for 2024.

D. Continuation of Approved TPNIES for 2023

The Tablo hemodialysis system was approved for TPNIES for 2022 and CMS will continue the TPNIES for 2023.

Table 14: Continuation of Approved TPNIES			
HCPCS Code	Long Descriptor	Effective Date	End Date
E1629	Tablo hemodialysis system for the billable dialysis service	1/1/2022	12/31/2023

E. Continuation of Approved TDAPA for 2023

In December 2021, CMS approved Korsuva™ (difelikafalin) for the TDAPA, effective April 1, 2022. Korsuva is an antipruritic drug approved by the FDA for a single indication, chronic kidney disease associated pruritus. CMS finalizes the TPNIES will end March 31, 2014.

Table 15: Continuation of Approved TPNIES			
HCPCS Code	Long Descriptor	Effective Date	End Date
J0879	Injection, difelikefalin, 0.1 microgram (for ESRD on dialysis)	4/1/2022	3/31//2024

F. Summary of Request for Information About Addressing Issues of Payment for New Renal Dialysis Drugs and Biological Products After TDAPA Period Ends

1. Background

Section 217(c) of PAMA required the Secretary to establish a process for including new injectable and intravenous products into the ESRD PPS bundled payment as part of the 2016 ESRD rulemaking. For the complete history of TDAPA policy, CMS refers the reader to the 2016 ESRD PPS final rule (80 FR 60023 – 69024), 2019 ESRD PPS final rule (83 FR 56932 – 56948), and 2020 ESRD final rule (84 FR 60653 – 60681).

Under current TDAPA policy at §413.234(c), a new renal dialysis drug or biological product that is within an existing ESRD PPS functional category[22] is considered included in the ESRD PPS base rate and is paid the TDAPA for 2 years. After the TDAPA period, the base rate will not be modified. If the new drug or biological product is not within an existing functional category, it is not considered included in the base rate and it will be paid the TDAPA until sufficient claims data for rate setting analysis is available, but not less than 2 years. After the TDAPA period, the ESRD PPS based rate will be modified, if appropriate, to account for the new renal dialysis drug or biological product in the ESRD PPS bundled payment.

CMS notes that dialysis associations and pharmaceutical representative have expressed concerns that after the TDAPA period ends it is a challenge for ESRD facilities to sustain the expense of these drugs and biological products without additional payment. As discussed in the proposed rule, CMS' analysis of renal dialysis drugs and biologicals paid for under the ESRD PPS has found that costs and utilization to have decreased over time relative to market basket growth for some high volume formerly separately billable renal dialysis drugs. CMS stated it believed that any potential methodology for an add-on payment adjustment in these circumstances should adapt to changes in price and utilization over time.

2. Suggestions for Possible Methodologies for an Add-on Payment Adjustment for Certain Renal Dialysis Drugs and Biological Products Within an Existing Functional Category

Section 1881(b)(14)(D)(iv) of the Act provides that the ESRD may include other payment adjustments as the Secretary determines appropriate, such as a payment adjustment – (1) for pediatric providers of services and renal dialysis facilities; (II) by a geographic index, as the Secretary determines to be appropriate; and (III) for providers of services or renal dialysis facilities located in rural areas.

In response to patient access concerns, CMS is considering whether it would be appropriate to establish an add-on payment adjustment for certain renal dialysis drugs and biological products after their TDAPA period ends. Any add-on payment adjustment would be subject to the Medicare Part B beneficiary co-insurance.

In the proposed rule, CMS discussed four methods to develop an add-on payment adjustment for these products. These methods differ in terms of which formerly separately billable renal dialysis drugs and biological products would be considered for a potential add-on payment adjustment. CMS noted that under all the options, CMS would apply a reconciliation methodology only when an add-on payment adjustment would align resource use with payment for a renal dialysis drug or biological product in an existing ESRD PPS functional category.

(1) Reconcile the average expenditure per treatment for the renal dialysis drug or biological product that was paid by the TDAPA with any reduction in the expenditure per treatment across all other formerly separately billable renal dialysis drugs and biological products.

[22] CMS defines an ESRD functional category in §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 (80 FR 69077).

- For example, if the reduction in the cost of all formerly separately billable renal dialysis drugs and biological products per treatment excluding the TDAPA is $5 and the cost of the product paid for under the TDAPA is $10, the add-on payment adjustment would be $5 ($10 - $5).
- The reductions in formerly separately billable renal dialysis drug and products expenditures per treatment would be calculated by using the difference between these expenditures in the most recent year with claims data available and these expenditures in the current base year for the ESRD market basket, proposed to be 2020 in this rule.
    - For example, for calculating the add-on payment adjustment for 2023, the reduction in formerly separately billable renal dialysis drugs and biological product expenditures would be the difference between these expenditures in 2021 (the year with the most recent claims data) and those in 2020.

(2) Reconcile the average expenditure per treatment for the renal dialysis drug or biological product that was paid by the TDAPA with any reduction in expenditures for other formerly separately billable renal dialysis drugs or biological products, where the reduction can be empirically attributed to the product that was paid using the TDAPA.

- For example, if the utilization of the drug or biological product paid for using the TDAPA was statistically associated with reduction in expenditures of one drug in a functional category amount to $1 per treatment, and the cost per treatment of the product that was paid using the TPADA is $10, the add-on payment adjustment would be $9 ($10 - $1.

(3) Reconcile the average expenditure per treatment for the renal dialysis drug or biological product that was paid by the TDAPA with any reduction in expenditures for other formerly separately billable renal dialysis drugs or biological products that fall into one or more functional categories, where such expenditure reduction is data-driven based on end action effect, to be attributable to the renal dialysis drug or biological product that was paid for using the TDAPA.

- For example, if the cost per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA is $10 and the reduction in the expenditure for other clinically related formerly separately billable renal dialysis drug is $0.50 per treatment, the add-on payment adjustment wound be $9.50 ($10 - $0.50).

(4) Only use the average expenditure per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA.

- For example, if the per treatment cost of the renal dialysis drug or biological product paid for using the TDAPA is $10, this would be the amount of the add-on payment adjustment.

In the proposed rule, CMS sought feedback on options regarding the add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends needed. CMS also requested information about what the

appropriate criteria should be for determining whether renal dialysis drugs or biological products should receive an adjustment and how should it be calculated.

4. Summary of Comments Received

CMS provides a high-level description of the 27 comments it received. CMS will provide more detailed information about these comments in a future posting on the CMS website located at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational-Resources.

Need for Establishing an Add-On Payment Adjustment. Most commenters supported the establishment of an add-on payment adjustment after the TDAPA period ends to support the adoption of new renal dialysis drugs and biological products. MedPAC opposed this type of add-on payment adjustment because it would undermine competition with existing drugs in the ESRD PPS bundled payment and encourage higher launch prices.

Criteria for Receiving Add-On Payment Adjustment. Most commenters supported allowing all new renal dialysis drugs and biological products to be eligible to receive an add-on payment adjustment after the TDAPA period ends. MedPAC recommended that CMS limit the add-on payment to new renal dialysis drugs and biological products that show a substantial clinical improvement compared with existing products in the ESRD PPS bundled payments.

Calculating an Add-On Payment Adjustment. Several commenters supported reconciling the expenditure of the new drug or biological product with any reduction in expenditures for other formerly separately billable renal dialysis drugs that are clinically or statistically related to the introduction of the new renal dialysis drug in the bundle. Several commenters believed that the FDA-approved label for primary indication should be used to determine clinical association instead of end-action effect. MedPAC opposed calculating any add-on payment adjustment, but noted that if an add-on payment adjustment were applied, the approach used with TPNIES would be appropriate.

Public Comments on TDAPA and TPNIES. Commenters urged CMS to allow TDAPA and TPNIES for at least three years to allow for two full years of data collection and then increase the base rate to reflect the value of any improved outcomes after the period ends. A commenter suggested that the TDAPA payment amount should be restored to the original ASP + 6 percent amount. Commenters also suggested creation of pathways for incorporation of new clinical diagnostic lab tests related to the treatment of ESRD. CMS notes that these topics were not included in any proposals and believes they are out of scope for this rulemaking. CMS will consider these comments for potential future refinements.

G. RFI on Health Equity with a Focus on the Pediatric Payment

1. Background

CMS reiterates its commitment to achieve health equity for all Medicare beneficiaries and discusses its related activities, including the development of the CMS Framework for Health

Equity.[23] CMS defines health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.[24]

As part of potential refinement of the ESRD PPS, CMS has convened four contractor-led TEPs. CMS presents information presented at the December 2021 Technical Expert Panel (TEP) which identified subpopulations for which health disparities may exist among the ESRD population. Based on enrollment numbers in January 2020, CMS' ESRD data contractor provided the following information.

- Sex – The ESRD PPS population was 58.7 percent male compared to 46.9 percent male in the non-ESRD Medicare population.
- Age – Approximately 40 percent of the ESRD PPS beneficiary population were younger than 60 compared to 10 percent in the non-ESRD Medicare population.
- Original Reason for Medicare Entitlement – Forty-seven percent of the ESRD population was originally eligible for Medicare due to disability (with or without ESRD) compared to 21 percent for the non-ESRD Medicare population.
- Race and Ethnicity – Members of racial or ethnic minority groups comprised a larger proportion of the ESRD Medicare population compared to the non-ESRD Medicare population. Black/African-Americans comprised 34.5 percent of the ESRD population, compared to 8.9 percent of the non-ESRD Medicare population.
- Urban and Rural Residency – Approximately 84 percent of ESRD beneficiaries live in urban areas and approximately 79.6 percent of the non-ESRD Medicare populations lived in urban areas.
- Socioeconomic status proxy – Among the ESRD Medicare population, 42.5 percent were dually eligible as compared to 15.4 percent of the non-ESRD Medicare population. ESRD Medicare beneficiaries were more likely enrolled in Medicare Part D, 73 percent as compared to 61 percent of non-ESRD Medicare beneficiaries.
- ADI[25] – ESRD Medicare beneficiaries were more likely to be living in socioeconomically disadvantaged neighborhoods compared to non-ESRD Medicare beneficiaries.

2. TEP Focused on Health Disparities Represented in the ESRD PPS

The December 2021 TEP was also designed to obtain input on health disparities among patients who are historically medically underserved and are represented in the ESRD PPS patient populations. The TEP Summary Report includes a discussion of various topics, including the types of direct patient care labor used in renal dialysis care, the case-mix payment adjustment

[23] https://ww.cms.gov.sites/default/files/2022-04/CMS%20Framework%20forHealth%20Equity_2022%2004%2006.pdf
[24] https://www.cms.gov/pillar/health-equity
[25] ADI is a measure constructed by HRSA and has been validated, refined and adapted by researchers at the University of Wisconsin, Madison to rank neighborhoods by socioeconomic disadvantage. https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-

model, subpopulations at risk of health disparities and for whom data are not currently available, and the special cases of pediatric patients receiving renal dialysis services.[26]

3. Summary of RFI on Advancing Health Equity Under the ESRD PPS

CMS sought feedback on a wide range of payment policy issues that could be refined under the impact ESRD PPS. CMS received comments on these issues from approximately 13 commenters. A short synopsis is provided; CMS will provide a more detailed summary of the comments it received on its website at https://www.cms.gov/MEdicare/Medicare-Fee -for-ServicePayment/ESRDpayment/Educationsl-Resources.html. CMS will take this information into consideration during future rulemaking.

Refinements to Mitigate Health Disparities. Commenters offered a number of suggestions, including add-on payment and other adjustments to the facility payor mix to provide for social work staffing and complex care coordination and using an add-on percentages for higher percentages of dual eligible home dialysis patients and patients with housing or food insecurities. A few commenters supported adoption of a payment model similar to the ETC Model.

Comorbidities. Several commenters thought the current comorbidity case mix adjusters are methodologically unsound and should be eliminated. Two commenters referenced research by MedPAC and The Moran Company as resources to inform CMS policy on comorbidities and claims adjustment.

Subpopulation. Several commenters supported the inclusion of social determinants of health measures identified by CMS in the proposed rule: food insecurity, housing instability, transportation problems, utility health needs, interpersonal safety, mental health needs, and non-English speaking. Other commenters spoke to the lack of caregiver support as factors contributing to health disparities. One commenter suggested that CMS develop and use Z codes to track SDOH and suggested until these were available, CMS could use dual eligible status or Area Deprivation Index and Social Vulnerability Index at the 9-digit Zip code level.

Demographic Information and Social Determinants of Health. Commenters were supportive of collecting SDOH but were concerned about the associated increased administrative burden. Commenters suggested several ways to collect this information including the use of Z codes.

Revisions to Case-mix Categories in the ESRD PPS. Commenters suggested several recommendations for revisions including a payment adjustment for facilities treating a large proportion of patients with SDOH that would be similar to the Disproportionate Share Hospital (DSH) payments. Another commenter suggested using the complication/comorbidity (CC) or a major complication/comorbidity (MCC) approach as used in the IPPS.

Renal Dialysis Technologies, Treatments, and Clinical Tools. CMS received several recommendations including CMS should work with the HHS Office for Civil Rights to address health literacy issues and improve education materials. Another commenter suggested CMS incorporate peer mentors and navigators is assist in education of ESRD patients.

[26] https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-

4. Health Disparities Faced by Pediatric Patients Receiving Renal Dialysis Services within the ESRD PPS

a. Background

In 2019, the Medicare dialysis pediatric population was approximately 14 percent of the total population and only 1.4 percent of ESRD facilities were pediatric facilities (a pediatric facility is defined as a providing at least 100 pediatric dialysis treatments). Pediatric facilities also have higher direct patient care labor expenditures than adult facilities.

The December 2020 TEP discussed the pediatric dialysis payment adjustment[27] and the 2022 ESRD PPS proposed rule.[28] Topics discussed included the types of time and specialized staffing needed for pediatric patients, the true costs of pediatric dialysis costs, and the common comorbidities seen in the pediatric population.

b. Summary of Comments

CMS sought feedback how to improve CMS' ability to detect and reduce health disparities for pediatric patients receiving renal dialysis services. CMS received comments on these issues from 10 commenters. A short synopsis is provided; CMS will provide a more detailed summary of the comments it received on its website at https://www.cms.gov/MEdicare/Medicare-Fee -for-ServicePayment/ESRDpayment/Educationsl-Resources.html. CMS will take this information into consideration during future rulemaking.

All commenters agreed that health disparities faced by pediatric patients receiving dialysis are different than adults. Commenters discussed the economic determinants of health and SDOH, especially adequate housing, nutrition, and transportation. Commenters also expressed concerns about the lack of information about the true costs of pediatric dialysis treatment and suggested a pediatric patient level case-mix adjuster.

III. 2023 Payment for Renal Dialysis for Acute Kidney Injury (AKI)

An individual with AKI has acute loss of renal function but does not require renal dialysis services for permanent kidney failure. Since 2017, CMS has paid ESRD facilities to treat patients with AKI the ESRD PPS base rate updated by the ESRDB minus a productivity factor, and adjusted for wages and any other amount deemed appropriate by the Secretary. CMS proposed this same policy for 2023. Therefore, the AKI dialysis payment rate for 2023 will equal $265.57, adjusted by the facility's wage index including application of the wage index floor increase (discussed above in section II.B) and the permanent 5 percent cap on wage index decreases.

Comments/Responses: There were a variety of comments requesting that CMS provide payment for AKI treatment to patients doing home dialysis. CMS indicated that these comments were out-of-scope to anything it proposed. It added that this population requires close medical supervision

[27] https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf
[28] 86 FR 36398; 36402 - 36404

by qualified staff during their dialysis treatment, implying that it does not believe there should be payment for AKI when patients are doing home dialysis.

Other commenters asked that CMS share information about any specific data elements and monitoring plans, as well as the data it is collecting and analyzing while monitoring the AKI benefit. CMS responded that this comment was also out-of-scope but that it has been monitoring the trends of AKI beneficiaries in ESRD facilities and acute inpatient hemodialysis. The results of the data analysis will be shared in the future in public use files on the ESRD PPS website.

In the regulatory impact analysis section of the final rule, CMS estimates that approximately $80 million would be paid to ESRD facilities in 2023. Table 32 of the final rule shows an overall impact of the changes to be a 2.9 percent increase in payment for renal dialysis services furnished to individuals with AKI. Hospital-based ESRD facilities have an estimated 2.8 percent increase in payments compared with freestanding ESRD facilities with an estimated 2.9 percent increase.

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

Invoking the measure suppression policy adopted during CY 2022 ESRD PPS rulemaking, CMS finalizes as proposed to suppress multiple measures for payment year (PY) 2023 due to COVID-19 PHE impacts. Measure suppression necessitates recalculation of the previously finalized minimum Total Performance Score (mTPS) for PY 2023 from 57 to 83. CMS intends to resume using data from all of the program's measures for the purposes of scoring and payment adjustments beginning with PY 2024. CMS affirms technical specifications updates as announced for 2 measures to begin with PY 2024. For PY 2025, CMS finalizes several changes to the program's measure set: adding 1 measure, revising 2, creating a new domain, and reweighting the 4 existing measure domains. No new requirements are being proposed for PY 2026. Additionally, CMS reviews feedback received in response to several requests for information (RFI) related to potential new home dialysis measures, screening for health-related social needs, and advancing health equity within the ESRD QIP.

CMS estimates that the reporting burden associated with the ESRD QIP for PY 2023 and PY 2024 will total $208 million, unchanged from prior estimates. CMS believes that measure suppression as proposed for PY 2023 would not materially change the estimated burden. Prior burden estimates for PY 2025 and 2026 are updated from $215 million to $220 million due to changes in facility numbers and patients, wage changes, and estimated labor time required. Several changes are made to previous ESRD QIP regulatory impact estimates as discussed in section VII of the rule and of this summary.

A. Background

The ESRD QIP is authorized by section 1881(h) of the Act. For CY 2022, facilities are assessed on a quality measure set that includes nine scored, "clinical" measures (e.g., hypercalcemia) and five "reporting" measures that are not scored (e.g., medication reconciliation). A payment reduction of up to 2 percent is applied to facilities that fail to submit data satisfactorily or achieve the applicable minimum TPS. Facility performance results are displayed publicly via the *Care*

Compare tool.[29] Payment years coincide with calendar years for the ESRD QIP and there is a 2-year lag between performance years and associated payment years. The baseline year is the calendar year 2 years prior to the performance year for achievement threshold, benchmark and mTPS calculations. The baseline year for the improvement threshold is the calendar year 1 year prior to the performance year.

More information about the ESRD QIP is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP and https://qualitynet.cms.gov/esrd/esrdqip.

B. Measure Suppression for PY 2023

1. General Considerations

No changes were proposed to the measure suppression policy itself. CMS specifically finalizes the suppression of 6 clinical measures as proposed and adds suppression of a seventh (Standardized Fistula Rate) for PY 2023 after determining that these measures, and Total Performance Scores calculated with them, had been significantly affected by the COVID-19 PHE. Suppression determinations were made based on measure-specific internal data analyses and guided by the 4 measure suppression factors adopted during CY 2022 ESRD PPS rulemaking (e.g., significant deviation in a measure's national performance compared to recent years; 87 FR 67224). Rationales are provided separately for each measure as discussed subsequently in the rule and this summary. CMS will provide to facilities confidential reports of their performance rates for all measures to support their performance improvement initiatives, as well as report performance data publicly with caveats noted about inclusion of suppressed measure data.

CMS received comments about application of the ESRD QIP's measure suppression policy for PY 2023. Many supported suppression of the 6 clinical measures as proposed. Some recommended suppression of all of the ESRD QIP's measure set for PY 2023 due to current economic conditions, workforce shortages, and continued COVID-19 PHE impacts. For similar reasons and citing one or more measure suppression factor, others requested suppression of specific individual measures: CDC National Health Safety Network (NHSN) Bloodstream Infection (BSI), Ultrafiltration Rate, and Hypercalcemia.

Many commenters recommended that CMS suspend scoring and payment penalties for PY 2023 as was done through the special ESRD QIP payment policy for PY 2022 (see §413.178(h) for details) due to ongoing PHE-related challenges. They also noted that scoring and penalty assessment have been suspended for 2023 for the Hospital Value-Based Purchasing Program (HVBP).

CMS notes having updated its internal analyses of ESRD QIP measure performance and potential measure suppression since the proposed rule was published as a result of which the Standardized Fistula Rate will also be suppressed for PY 2023 (discussed later in the rule and

[29] Accessible at https://www.medicare.gov/care-compare/?providerType=DialysisFacility&redirect=true.

this summary). CMS states that its analyses of the remaining, non-suppressed measures do not warrant their suppression.

CMS disagrees that scoring and penalty suspension is appropriate for PY 2023. CMS describes differences from PY 2022 when suspension was adopted, including that the 2023 performance period is not truncated and operational issues with the ESRD Quality Reporting System (EQRS) have been resolved.[30] CMS states that fewer measures and domains of the ESRD QIP are being affected by its suppression plan compared to the HVBP program.

2. Standardized Hospitalization Ratio (SHR) Clinical Measure

After receiving supportive comments, CMS finalizes suppression of the SHR clinical measure for PY 2023 as proposed, citing diminished measure reliability and significant deviation form historical measure performance (Measure Suppression Factor 1).

This measure assesses hospital admissions for patients treated by each facility as a risk-adjusted, observed/expected ratio and it was suppressed for PY 2022. CMS adds that its updated analysis of this measure's performance showed disproportionate spikes in ESRD patient hospitalizations and mortality related to the Delta and Omicron variants of the SARS-CoV-2 virus.

3. Standardized Readmission Ratio (SRR) Clinical Measure

After receiving supportive comments, CMS finalizes suppression of the SRR clinical measure for PY 2023 as proposed, citing changed patterns of index hospitalization and mortality that produced downstream effects on readmissions leading to diminished measure reliability and significant deviation from historical measure performance (Measure Suppression Factor 1).

This measure assesses hospital readmission events for patients treated by each facility as a risk-adjusted, observed/expected ratio and it was suppressed for PY 2022. CMS adds that its updated analysis showed continued aberrant hospitalization and mortality patterns and subsequent impacts on readmissions throughout the 2021 performance period applicable to this measure.

4. Long-Term Catheter Rate and Standardized Fistula Rate Clinical Measures

CMS finalizes with modification its proposal for suppression of the Long-Term Catheter Rate clinical measure for PY 2023, citing spikes in catheter insertion rates that have led to significant deviation from historical performance (Measure Suppression Factor 1). CMS modifies its proposal by adding suppression of the Standardized Fistula Rate clinical measure for PY 2023 due to reduced volumes of procedures to establish and maintain fistulas for hemodialysis access that in turn have resulted in aberrant fistula rate measure performance (Measure Suppression Factor 1).

Commenters supported the initial proposal for catheter rate measure suppression for PY 2023 and suggested that the fistula rate measure also be suppressed since the measures represent two

[30] Data submission from facilities to CMS transitioned from the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) system to a new ESRD Quality Reporting System (EQRS) in November 2020.

facets of the same measure topic—hemodialysis vascular access. In general, arteriovenous fistulas are strongly preferred over vascular catheters for chronic hemodialysis access.

The catheter rate measure but not the fistula rate measure was suppressed for PY 2022. CMS agrees with commenters about Standardized Fistula Rate clinical measure suppression for PY 2023 based on its updated analysis of vascular access procedure patterns. The significant pattern changes are shown in Tables 17-19 of the rule (section IV.B.2.d.), from which CMS concludes that Measure Suppression Factor 1 is applicable to the fistula rate measure.

5. Consumer Assessment of Healthcare Providers and Systems In Center Hemodialysis Survey (ICH CAHPS)

CMS finalizes as proposed to suppress results of the ICH CAHPS experience-of-care survey for PY 2023, citing significant deviations in top box survey item performance and dialysis facility staffing shortages that impact beneficiary satisfaction with their care (Measure Suppression Factors 1 and 4).

Most commenters supported measure suppression though a few voiced concern about whether Factor 4 was in fact applicable.

CMS states that declining numbers of completed ICH CAHPS surveys continue to be associated with measure performance deviations (Factor 1). CMS also notes PHE-related healthcare worker staffing shortages may disproportionately affect the subspecialized workforce required in dialysis facilities and skew responses to survey items that specifically ask about facility staff performance (Factor 4).

6. Percentage of Prevalent Patients Waitlisted (PPPW) Clinical Measure

CMS finalizes as proposed suppressing the PPPW clinical measure for PY 2023, citing the continuing declines in measure performance throughout 2021 resulting in national performance measure deviation and rapid changes in patterns of referral for transplant waitlisting and transplant procedures (Measure Suppression Factors 1 and 4).

Commenters supported PPPW clinical measure suppression for PY 2023. It was not suppressed for PY 2022 as initial measure declines had appeared to stabilize before emergence of the Delta and Omicron SARS-CoV-2 virus variants. CMS' analysis of the most recently available data confirms that measure performance continues to decline.

7. Kt/V Dialysis Adequacy (Comprehensive) Clinical Measure

CMS finalizes as proposed the suppression of the Kt/V dialysis adequacy clinical measure for PY 2023, citing significant deviations from prior national performance (Measure Suppression Factor 1).[31]

[31] K is dialyzer clearance, t is dialysis time, and V is total body water volume. Dialysis adequacy as delivered during actual treatments is compared to pre-treatment specified thresholds.

Commenters supported Kt/V dialysis adequacy clinical measure suppression for PY 2023, stating that dialysis adequacy has been negatively impacted by the COVID-19 PHE.

CMS observes that patients have experienced delays of their dialysis treatments while infected with COVID-19 and because of logistical challenges in reaching care reliably (e.g., limited transportation options). Delays have led to patients presenting for dialysis in poorer condition and needing more aggressive dialysis prescriptions (higher Kt/V thresholds). Early in 2021, Kt/V rates fell then appeared to stabilize, so the measure was not suppressed for PY 2022. More recent data show resumption of dialysis adequacy declines with emergence of the Delta and Omicron SARS-CoV-2 virus variants. Further, falling dialysis adequacy has been exacerbated by declines in standard fistula rates, as dialysis via fistula achieves higher Kt/V rates than via catheters.

8. Measures Not Being Suppressed for PY 2023

As discussed in section IV.B.2.a. of the rule, CMS data analyses at this time do not support suppression during PY 2023 for the ESRD QIP measures listed below.

- *Clinical Measures* (facility is scored on achievement and improvement)
    - Hypercalcemia
    - CDC National Health Safety Network Bloodstream Infection
- *Reporting Measures* (facility is awarded points for successfully reporting data)
    - Ultrafiltration Rate
    - Clinical Depression Screening and Follow-up
    - CDC National Health Safety Network Dialysis Event
    - Standardized Transfusion Ratio (STrR)
    - Medication Reconciliation

C. Performance Standards, Total Performance Scoring, and Payment Reductions for PY 2023

1. Performance Standards (§413.178(d)(2))

CMS finalizes as proposed using CY 2019 data to calculate all PY 2023 measure performance standards (achievement threshold, benchmark, improvement threshold) and the mTPS. Conforming changes are made such that for PY 2025, the baseline period is CY 2021 for purposes of calculating the achievement threshold, benchmark and minimum total performance score, and calendar year 2022 for purposes of calculating the improvement threshold. The performance period for PY 2025 is CY 2023. Beginning with PY 2026, the performance period and corresponding baseline periods are each advanced 1 year for each successive payment year.

Most commenters supported using CY 2019 as the baseline period for PY 2023 standard setting. Several expressed reservations about setting standards using pre-pandemic data for a payment year during which pandemic effects are likely to persist.

Under current ESRD QIP policy, CY 2020 would be the baseline period and CY 2021 would be the performance period for PY 2023. CMS notes, however, that 2020 data are incomplete due to (1) purposeful exclusion of CY 2020 Q1 and Q2 data from all CMS quality program scoring,[32] and (2) operational issues encountered during the transition from the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) to a new ESRD Quality Reporting System (EQRS) in November 2020. CY 2019 thus represents the most recent year for which a full year of data is available for use as a baseline in performance standards calculations.

CMS acknowledges the inherent tension created when performance-contingent payment adjustments will be made based on a mix of pre- and post-pandemic performance data. However, CMS states that the ESRD QIP measure suppression policy and its data-driven, measure-specific application to scoring the program's measures (and the downstream mTPS calculation) will largely mitigate performance impacts of the COVID-19 PHE for PY 2023. CMS regards its baseline year policy modification for PY 2023 as an appropriate and temporary response to an unprecedented PHE.[33] CMS notes that ESRD QIP standard setting policy also provides for baseline year substitution options to ensure that performance standards for a measure for a year cannot be lower than those for the preceding year for that measure.

2. Total Performance Scoring

CMS finalizes with modifications special scoring policies at new §413.178(i) *Special rules for payment year 2023* to accommodate suppression of 6 ESRD QIP clinical measures as originally proposed and modified to include the addition of the Standardized Fistula Rate, for a total of 7 suppressed measures.[34] In accordance with the special rules:

- The agency will calculate facility-level performance rates for the 7 suppressed measures as usual but will not score the measures or include them in TPS calculations for any facility.
- For the 7 non-suppressed measures, facility-level rates will be calculated as usual and the measures will be scored according to the PY 2023 performance standards.
- The mTPS for PY 2023 will be defined as the TPS of a facility performing at the 50th percentile nationwide during the calendar year 2019 baseline period on the 2 non-suppressed clinical measures and at the median of national ESRD facility performance on the 5 non-suppressed reporting measures.

Comments on the special rules for PY 2023 and CMS responses are described above in section IV.B.1. of this summary and IV.B.2.a. of the rule.

[32] The data exclusion memorandum is available at https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf

[33] A policy modification to use CY 2019 data as the baseline for PY 2024 standard setting was already finalized during CY 2022 ESRD PPS rulemaking (86 FR 61922 through 61923) based on considerations similar to those described above for PY 2023.

[34] Suppressed and non-suppressed measures are catalogued above in summary section IV.B.

3. Estimated Payment Reductions

Prior to measure suppression, mTPS for PY 2023 had been estimated at 57 points during CY 2021 rulemaking. Finalized measure suppression and the special scoring rules for PY 2023 produce a "recalculated" mTPS for PY 2023 of 83 points, up from 80 points as estimated in the CY 2023 proposed rule because suppression of the Standardized Fistula Rate has been added. No changes are being made to the established ESRD QIP payment policy at §413.177(a) that provides for a 0.5 percent payment reduction for every 10 points that a facility's TPS is less than mTPS, up to a maximum reduction of 2 percent. Applying the policy produces the finalized reductions for PY 2023 shown below, reproduced from Table 16 of the rule.

TABLE 16: Finalized Payment Reduction Scale for PY 2023	
Total Performance Score	**Payment Reduction**
100 – 83	0.0%
82-73	0.5%
72-63	1.0%
62-53	1.5%
52-0	2.0%

Some commenters objected to scoring facilities based only on non-suppressed measures because it does not meaningfully represent facility quality performances due to mTPS skewing. They observed that the recalculated mTPS is much higher than that of 57 points as projected for PY 2023 during CY 2021 rulemaking, reflecting changes in scored measure weights that are an unintended consequence of measure suppression.

CMS acknowledges the concerns raised but asserts that scoring based only on the non-suppressed measures for PY 2023 is appropriate based on the most recent data analyses showing COVID-19 PHE impacts on some but not all ESRD QIP measures. Despite the higher than previously calculated mTPS, CMS estimates that the number of facilities receiving payment reductions for PY 2023 will be approximately 10.5 percent compared to an estimated 24.2 percent when mTPS of 57 points was projected during CY 2021 rulemaking.

D. Measure Specification Technical Updates

1. Updates Beginning with PY 2024

In the proposed rule CMS invited comments on technical updates to the measure specifications for the standardized hospitalization (SHR) and standardized readmission (SRR) measures. As announced, results for these measures are currently expressed as risk-adjusted ratios but instead will be scored and reported as risk-standardized rates beginning with PY 2024. CMS has modeled scoring for the updated measures and found the revised specifications to be technical changes that do not substantively change the measures themselves. CMS invokes its previously established subregulatory process for announcing nonsubstantive changes (i.e., notice-and-comment rulemaking is not required). Revised PY 2024 performance standards for the updated measures (expressed as rates) are provided in Table 20 of the rule.

Supportive comments were received. A few suggestions were made to modify the methodology for converting the measure ratios to measure rates. CMS responds that the methodology being adopted for this purpose is the same as that used in the Star Rating calculation under the Dialysis Facility Compare program.[35]

2. Updates Beginning with PY 2025

a. Standardized Transfusion Ratio (STrR) Measure

In the proposed rule CMS invited comments on technical updates to the measure specifications for the standardized transfusion ratio (STrR) measure. As announced, STrR results, currently expressed as risk-adjusted ratios, instead will be scored and reported as a risk-standardized rates beginning with PY 2024. CMS has modeled scoring for the updated measure and found the revised specifications to be technical changes that do not substantively change the measures themselves. CMS invokes its previously established subregulatory process for announcing nonsubstantive changes (i.e., notice-and-comment rulemaking is not required). Substantive changes to the STrR measure also were proposed and are discussed in section IV.E.1.b. in the rule and later in this summary.

A commenter asked for additional information about the STrR measure methodology. CMS responds that the STrR compares observed to expected transfusion ratios that will now be converted to rates and will thereby align the STrR measure's specifications with those for the updated SHR and SRR measures. Full measure specification details will be available in an updated version of the ESRD QIP Measures Manual.[36]

b. Covariate Adjustment for Patient History of COVID-19

In the proposed rule CMS announced addition of a covariate adjustment for patient history of COVID-19 in the preceding 12 months as a nonsubstantive update to the technical specifications of the SHR and SRR measures beginning with PY 2025. This change follows the ESRD QIP policy for announcement of technical updates through a subregulatory rather than formal rulemaking process. Changes will be applied to these 2 measures in their updated rate format as their transitions from ratios to rates will have been implemented starting with PY 2024. CMS states that the covariate adjustment will account for lasting effects of COVID-19 illness on some ESRD beneficiaries (so-called "long haulers"). Persistent COVID-19 effects (e.g., palpitations, post-viral syndrome) could trigger admission and readmission, thereby worsening facility performances on the SHR and SRR measures.

CMS received comments supportive of the announced technical changes to add the covariate COVID-19 adjustment to the SHR and SRR measures. Implementation prior to PY 2025 was encouraged and more detailed measure methodology information requested.

[35] Information about the Dialysis Facility Compare Star Ratings System is available at https://data.cms.gov/provider-data/topics/dialysis-facilities/dialysis-facilities-quality-of-patient-care-rating.
[36] The Manual can be downloaded through the ESRD QIP website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/06_MeasuringQuality.

CMS responds that PY 2025 represents the earliest possible implementation timeframe for adding the covariate adjustment due to measure data collection timelines. Full SHR and SRR measure information will be available in an updated version of the ESRD QIP Measures Manual after publication of the CY 2023 ESRD PPS final rule.

CMS notes that adding a similar covariate adjustment to the STrR measure is under consideration once that measure is converted from reporting to clinical status (finalized later in the rule and this summary). Covariate addition to the STrR measure would be announced through the usual subregulatory process for communicating technical specification updates.

E. Revisions to the ESRD QIP Measure Set and Measure Weights Beginning with PY 2025

1. Measure Addition: COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)

CMS finalizes as proposed to add the *COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)* measure to the ESRD QIP measure set beginning with PY 2025. The measure tracks the percentage of healthcare personnel (HCP) who receive a complete COVID-19 vaccination course as defined in the FDA authorizations and approvals for the various vaccines.

Some commenters were supportive. Others voiced concern about measure reporting burden and overlap with other ongoing mandatory reporting programs (e.g., state-level public health agencies). Several asked to exclude vaccination tracking of contract employees and those with religious objections. Recommendations were made to delay measure adoption pending NQF endorsement and development of a data validation process.

CMS views the reporting burden as minimal since dialysis facilities already report other required measures using the CDC National Health Safety Network (NHSN). CMS states that any reporting burden is outweighed by the benefit of encouraging facilities to support vaccination of their personnel as part of protecting ESRD patients from COVID-19 disease, as their COVID-related mortality and morbidity have been disproportionately greater than for the general population. Tracking vaccination of contract workers is necessary for a complete picture of a facility's personnel vaccination success. Personnel with medical contraindications to vaccination are excluded by the measure's specifications and those with religious objections are reported in the category of declined vaccination.

This measure is already required for reporting in multiple other CMS quality programs including inpatient and post-acute care facilities, and it obtained NQF endorsement in July 2022. Measure specifications are available for download at https://www.cdc.gov/nhsn/nqf/index.html.

2. Status Change for the Standardized Transfusion Ratio (STrR) Measure

CMS finalizes as proposed to convert the StrR measure from reporting to clinical (i.e., scored) measure status beginning with PY 2025. Also starting with PY 2025, in this rule CMS has announced a technical specification update such that the measure result will be presented as a rate rather than a ratio.

This measure tracks inpatient transfusion events at the dialysis facility level and satisfies the statutory requirement for inclusion of an anemia management measure in the ESRD QIP measure set.[37] The measure's status has fluctuated between clinical and reporting over the time since its adoption into the ESRD QIP beginning with PY 2018.

Commenters raising concerns outnumbered those indicating support for the status change. The former group described difficulties in obtaining transfusion event information from hospitals, the site at which many of the transfusions are administered. Others cited concerns about accuracy of hospital coding of transfusions administered to ESRD patient treatment for anemia. Replacement of the STrR measure by a hemoglobin threshold measure (e.g., Hb < 10 g/dL) was suggested.

CMS responds with a detailed account of the measure's history in the ESRD QIP measure set (see section IV.E.1.b. of the rule). The measure's specifications have been revised to reflect proper hospital ICD-10-CM and to increase capture of transfusion events. After the most recent revisions, the NQF reviewed the measure in November 2020 and renewed its endorsement. CMS rejects adopting a hemoglobin threshold measure at this time as studies of anemia management in dialysis patients have shown large outcome variations. CMS also observes that cooperation between hospitals and dialysis facilities about shared patients should be expected.

3. Status Change for the Hypercalcemia Measure

CMS finalizes as proposed to change the status of the Hypercalcemia measure from clinical to reporting beginning with PY 2025. Reporting will use the formula below and the measure will be placed in the new ESRD QIP "Reporting" domain (finalized later in the rule and described further below in this summary). The measure will still satisfy the statutory requirement for inclusion of a metric of bone mineral metabolism in the ESRD QIP measure set.[38]

$$\left(\frac{\text{number of patient - months successfully reporting data}}{\text{number of eligible patient - months}} \times 12\right) - 2$$

Some commenters supported the status change while a few recommended that the measure instead be removed entirely from the ESRD QIP measure set starting with PY 2025. Most agree that the measure is topped out (i.e., no longer detects meaningful performance differences), prompting it to be moved to Reserve status by the NQF. Support was expressed for Serum Phosphorus as a replacement measure.

CMS acknowledges that the Hypercalcemia measure is very close to meeting the agency's criteria for being considered topped out. Retaining the measure but in a reporting status meets the statutory requirement for a bone mineral metabolism measure while allowing CMS time to identify a suitable replacement measure. CMS states that Serum Phosphorus is being considered.

4. ESRD QIP Summary Measure Table

CMS lists the PY 2025 ESRD QIP measures in Table 22 of the rule. This measure set retains all 14 measures from PY 2024 and reflects addition of the COVID-19 HCP Vaccination measure.

[37] The requirement is found under section 1881(h)(2)(A)(iv)(I) of the Social Security Act.
[38] The requirement is found under section 1881(h)(2)(A)(iv)(II) of the Social Security Act.

CMS further notes that the PY 2025 measure set captures technical updates to the SHR, SRR, and STrR measures as announced in this rule along with the finalized status changes for the STrR and Hypercalcemia measures. The table below includes all measures from Table 22 and lists prior-year measure sets for reference.

Table: ESRD QIP Measure Sets by Payment Year and Measure Status 2021-2025*
Measure Status: C = Clinical Measure R = Reporting Measure

NQF #	Measure Short Descriptor	2021	2022-2024	2025
0258	In-Center Hemodialysis CAHPS measure	C	C	C
2496	Risk-Standardized Readmission Ratio/Rate (RSRR)[a]	C	C	C
2979**	Standardized Transfusion Ratio/Rate (STrR)[a]	C	R	C
	Kt/V Dialysis Adequacy (Comprehensive)	C	C	C
2977	Vascular Access: Standardized AV Fistula Rate	C	C	C
2978	Vascular Access: Long-term Catheter Rate	C	C	C
1454	Hypercalcemia	C	C	R
1463	Risk-Standardized Hospitalization Ratio/Rate (RSHR)[a]	C	C	C
0148**	Clinical Depression Screening and Follow-up	R	R	R
	Ultrafiltration Rate	R	R	R
1460**	NHSN Bloodstream Infection (BSI)	C	C	C
	NHSN Dialysis Event	R	R	R
	Percentage of Prevalent Patients Waitlisted (PPPW)		C	C
2988	Medication Reconciliation (MedRec)		R	R
	COVID-19 HCP Vaccination			R

* Created by HPA from Table 22 in the final rule with material added for prior years from final rule tables for those years.
** QIP measure is based on this NQF-endorsed measure.
[a] Standardized Readmission *Ratio* becomes the Risk-Standardized Hospital Readmission *Rate* in 2025. Standardized Hospitalization *Ratio* becomes the Risk-Standardized Hospitalization *Rate* in 2025. Standardized Transfusion *Ratio* becomes the Standardized Transfusion *Rate* in 2025.

5. Measure Weights and Domains for Use in Total Performance Scoring Starting with PY 2025

Starting with PY 2025, CMS finalizes as proposed to add a new Reporting Measure Domain to the 4 existing domains: Patient and Family Engagement, Clinical Care, Care Coordination, and Safety. All ESRD QIP reporting measures will be moved to the new domain based on their status as finalized for PY 2025. To accommodate the new domain and its measures, CMS finalizes as proposed revised domain weights and individual measure weights for use in TPS scoring of facilities beginning with PY 2025.

Most commenters were supportive while a few expressed concerns. The latter group variously suggested reducing the overall number of measures, increasing the weight of the new Reporting domain, equally weighting all domains, reducing weights for the STrR and CAHPS survey measures, and increasing the PPPW measure weight. Also recommended was changing the relative weights of the Long-Term Catheter and Standardized Fistula rates to favor fistulas over catheters for chronic dialysis access.

CMS believes that the proposed weight changes, taken together, better incentivize performance improvement by increasing emphasis during TPS scoring on measures with greater room for improvement, particularly those focusing on patient outcomes. The agency also believes that the changes are responsive to concerns voiced by stakeholders about disproportionately high impacts of a few measures on facility scores. Tables 23 and 24 in the rule show the current and proposed measure domains and weights, respectively. The tables below show the same information rearranged as line-item comparisons.

Table: Measures and Measure Weights for PY 2024 and PY 2025 (Measures with Weight Changes Shown in **Bold Font**)		
Measure Short Descriptor	**PY 2024 Weight**	**PY 2025 Weight**
Kt/V Dialysis Adequacy (Comprehensive)	9.00	11.00
Standardized Transfusion Ratio (STrR)	10.00	12.00
Vascular Access Type Measure Topic*	12.00	12.00
Hypercalcemia	3.00	1.67
In-Center Hemodialysis CAHPS	15.00	15.00
Ultrafiltration Rate reporting measure	6.00	1.67
Standardized Readmission Ratio (SRR)	12.00	12.00
Standardized Hospitalization Ratio (SHR)	12.00	12.00
Percentage of Prevalent Patients Waitlisted (PPPW)	4.00	6.00
NHSN Bloodstream Infection (BSI)	8.00	10.00
Medication Reconciliation (MedRec) reporting measure	4.00	1.67
Clinical Depression Screening and Follow-up reporting measure	2.00	1.67
NHSN Dialysis Event reporting measure	3.00	1.67
COVID-19 HCP Vaccination**	N/A	1.67
* Vascular Access Type Measure Topic combines the Long-term Catheter Rate and the Standardized AV Fistula Rate ** This measure will be added starting in PY 2025 if finalized		

Table: Domains and Domain Weights for PY 2024 and PY 2025		
Domains: Patient and Family Engagement (PFE), Care Coordination (CC), Clinical Care (Clin), Safety (S), Reporting (R) (Measures with Domain Changes Shown in **Bold Font**)		
Measure Short Descriptor	**PY 2024 Domain**	**PY 2025 Domain**
Kt/V Dialysis Adequacy (Comprehensive)	Clin	Clin
Standardized Transfusion Ratio/Rate (STrR)	Clin	Clin
Vascular Access Type Measure Topic*	Clin	Clin
Hypercalcemia	**Clin**	**R**
In-Center Hemodialysis CAHPS	PFE	PFE
Ultrafiltration Rate	**Clin**	**R**
Standardized Readmission Ratio/Rate (SRR)	CC	CC
Standardized Hospitalization Ratio/Rate (SHR)	CC	CC
Percentage of Prevalent Patients Waitlisted (PPPW)	CC	CC
NHSN Bloodstream Infection (BSI)	S	S

Table: Domains and Domain Weights for PY 2024 and PY 2025		
Domains: Patient and Family Engagement (PFE), Care Coordination (CC), Clinical Care (Clin), Safety (S), Reporting (R) (Measures with Domain Changes Shown in **Bold Font**)		
Measure Short Descriptor	**PY 2024 Domain**	**PY 2025 Domain**
Medication Reconciliation (MedRec)	**S**	**R**
Clinical Depression Screening and Follow-up	**CC**	**R**
NHSN Dialysis Event	**S**	**R**
COVID-19 HCP Vaccination**	(N/A)	R
* Vascular Access Type Measure Topic combines the Long-term Catheter Rate and the Standardized AV Fistula Rate ** This measure will be added starting in PY 2025 if finalized		

F. Future Performance Standards and Payment Adjustments

1. PY 2024

PY 2024 performance standards are based on 2019 data and were published as Table 3 in the CY 2022 ESRD PPS final rule (86 FR 61924). CMS chose to use 2019 rather than 2020 data due to impacts of the COVID-19 PHE; 2019 is the most recent full year of data available for baseline standard setting. The finalized payment reduction scale for PY 2024 appeared as Table 6 in the CY 2022 final rule (86 FR 61927), reproduced below. The mTPS for the year was finalized at 57 points.

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

2. PY 2025

Performance standards for the PY 2025 non-suppressed measures are updated from those published in the CY 2023 proposed rule and are shown in Table 25 of the final rule. Table 25 also shows the PY 2025 standards for the suppressed measures that utilize CY 2019 as their baseline year. Requirements for successful reporting (i.e., frequency and data elements) of the ESRD QIP reporting measures for PY 2025 are shown in Table 26 of the rule. Table 27 of the rule lists the eligibility (minimum data requirements) for the ESRD QIP clinical (i.e., scored) measures along with any applicable small-facility adjusters; these are unchanged from those for PY 2024.

CMS provides the finalized payment reduction scale for PY 2025 based on the most recently available data as Table 29 in the rule, reproduced below. The finalized mTPS for PY 2025 is 55 points, unchanged from the estimate provided in the proposed rule. A facility will have to meet or exceed a total performance score of 55 to avoid a payment reduction.

TABLE 29 – Finalized Payment Reduction Scale for PY 2025 Based on the Most Recently Available Data	
Total Performance Score	**Reduction**
100 – 55	0.0%
54-45	0.5%
44-35	1.0%
34-25	1.5%
24-0	2.0%

3. PY 2026

a. Measure Set, Measurement Periods, and Performance Standards

Per policy, the finalized PY 2025 ESRD QIP measure set will be used for PY 2026. The baseline period will be CY 2022 and the performance period will be CY 2024 for PY 2026. At this time CMS is not proposing any changes to the measure set or to the measurement periods to begin in PY 2026.

CMS provides estimated performance standards for the PY 2026 ESRD QIP clinical measures in Table 30 of the rule; the estimated standards use the most recently available data, CY 2021. The standards will be updated during CY 2024 rulemaking using data from the applicable baseline year, CY 2022.

Performance standards will continue unchanged for PY 2026 for 4 measures (Medication Reconciliation, Ultrafiltration Rate, Clinical Depression Screening and Follow-up, and NHSN Dialysis Event), and standards will be added for the COVID-19 HCP Vaccination and Hypercalcemia measures.

b. Scoring Facility Performance

Measure weights and domain weights for scoring and mTPS calculations for PY 2026 will be the same as those for PY 2025, shown in Table 24 of the rule (and in the unnumbered tables above in section IV.E.5. of this summary). Impact estimates will be updated when baseline year data become available.

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

1. RFI: Quality Indicators for Home Dialysis Patients

In the ESRD PPS CY 2023 proposed rule, CMS requested information regarding strategies to monitor and assess the quality of care delivered to patients who dialyze in their homes with

particular emphasis on measures not currently part of the ESRD QIP measure set. CMS notes that facilities supporting home dialysis patients often fail to satisfy data minimum thresholds for several ESRD QIP measures (e.g., ICH-CAHPS, NHSN Bloodstream Infection). Fewer scored measures could adversely impact TPS calculations and payments for these facilities and limit the amount of quality outcome information available to beneficiaries when choosing dialysis treatment options and facilities.

By way of background, CMS provides information about the temporal trends in the use of home hemodialysis. Home dialysis steadily declined from over 40 percent in 1973 to about 2 percent by 2016, but interest in dialyzing at home as an ESRD treatment option is reportedly increasing among patients and nephrologists. The vast majority of home dialysis is delivered as peritoneal dialysis rather than hemodialysis. CMS cites evidence to support reduced Medicare expenditures without decreases in survivability for home dialysis compared to in-center hemodialysis, attributable to factors including decreased infections and hospitalizations and lower operating costs for home dialysis providers. Home dialysis rates are the basis for incentive payments to facilities and nephrologists during the early years of the ongoing ESRD Treatment Choices (ETC) Model.[39]

CMS also asked for input about how it can support more equitable access to home dialysis across different ESRD populations. CMS states that in 2018, 72 percent of Black ESRD patients received in-center hemodialysis versus only 57 percent of White patients. This data point may indicate that a greater number of White ESRD patients receive home dialysis than Black patients. Further, CMS notes that once patients are stable on a specific dialysis modality (in-center versus home, peritoneal versus hemodialysis), they seldom change and may in fact be unaware that they may choose to change.

In this final rule, CMS summarizes feedback received. The agency does not provide general or specific responses and indicates only that feedback will be considered during development of future home dialysis expansion initiatives. Excerpts of comments from the rule are provided below (see section IV.G.1. of the rule for the full summary).

- Develop an experience-of-care survey separate from ICH-CAHPS or modify ICH-CAHPS to reflect distinct features of home dialysis;
    - alternatives include adopting the Home Dialysis Care Experience tool or adding a measure of Activities of Daily Living to CAHPS.[40]
- Add measures of home dialysis and home dialysis retention rates by modality and in total;
    - account for patient transition to in-center dialysis plus deaths and transplants;
    - consider use of rate and retention measures developed by the Kidney Care Quality Alliance.[41]

[39] More information on the ETC model is available at https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model.
[40] The Home Dialysis Care Experience tool was developed by researchers at the University of Washington.
[41] More information about the Kidney Care Quality Alliance and its measures is available at https://kidneycarepartners.org/quality-priorities/kidney-care-quality-alliance/.

- Create home dialysis measures by modifying certain current measures to reflect home dialysis practices and facilitate reporting; suggestions include the NHSN Bloodstream Infection, Kt/V dialysis adequacy, and inpatient readmission rates along with development of performance standards specific to home dialysis.
- Address existing barriers to equitable access through expanded chronic kidney disease screening and education (e.g., as part of the Welcome to Medicare visit), patient assistance with health-related social needs that impede home dialysis (e.g., housing insecurity, health literacy), and new coverage for nurse or caregiver services for home dialysis patients.
- Leverage telehealth and remote patient monitoring to support home dialysis patients.
- Stratify home dialysis quality measure reports by race and ethnicity.

2. RFI: Potential Future Inclusion of Two Social Drivers of Health Measures

In the proposed rule, CMS requested information about the potential addition to the ESRD QIP measure set of two measures that target screening for social drivers of health in 5 core domains: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. These domains represent health-related social needs (HRSN) of patients that when unmet could contribute to poor clinical outcomes from ESRD. Because chronic condition risks (e.g., ESRD) are associated with HRSNs, screening could provide data useful to ESRD facilities and health systems in addressing persistent outcome disparities within the ESRD population. CMS also believes that the measure data, especially results stratified for HRSNs, would support targeted care coordination initiatives (e.g., identify needs for assistance with transportation to routine dialysis treatments). The two measures discussed in this RFI, shown below, have been finalized for adoption into the Hospital Inpatient Quality Reporting Program beginning with voluntary reporting for FY 2023 and mandatory reporting starting in FY 2024.

- *Screening for Social Drivers of Health.* This measure would assess the proportion of a facility's adult patient population who are screened for 1 or more of the 5 core HRSNs.
- *Screen Positive Rate for Social Drivers of Health.* This measure would assess the proportion of a facility's adult patient population who screen positive for 1 or more of the 5 core HRSNs.

CMS provides a summary of the many comments received, which included the following:

- Many commenters were supportive of adding a HRSN screening initiative and the two potential measures to the ESRD QIP.
- Data gathered could inform actionable planning at the facility level and illuminate care continuity needs of under-resourced communities.
- CMS must address how the data would be used to link patients to community-based services based on their identified HRSNs.
- The measures should be adopted only as reporting measures or for voluntary reporting.
- The Accountable Health Communities HRSN screening tool developed by CMS has not been NQF-reviewed for appropriate use in a penalty (pay-for-performance) program.
- CMS should establish standards for screening timeframe, data collection, and data use.

- Provider burden must be considered and CMS should leverage existing HRSN data sources.

CMS does not provide specific responses but agrees that HRSN screening as part of the ESRD QIP could provide useful information for providers and align with the agency's commitment to health equity. Feedback received will be considered during future policy development.

3. RFI: Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

In the proposed rule, CMS requested feedback about its ongoing initiatives to advance health equity through its quality measurement programs including the ESRD QIP. This RFI continues the discussion started during CY 2022 ESRD PPS rulemaking: "Closing the Health Equity Gap in CMS Hospital Quality Programs" (86 FR 61928 through 61937). The agency's goal for the current request is to obtain input into setting priorities and expectations for using measure stratification as a tool to identify and resolve ESRD care disparities.

Topics for comment and supporting information are grouped around 5 key considerations, listed below, that CMS will take into account when addressing disparities through quality measure development and stratification in the ESRD QIP. A full set of discussion topics and complete background material are found in section IV.G.3. of the rule.

- Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification in the ESRD QIP
- Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting
- Principles for Social Risk Factor and Demographic Data Selection and Use
- Identification of Meaningful Performance Differences
- Guiding Principles for Reporting Disparity Results

CMS provides a summary of the many comments received, from which highlights are provided below. The full summary is found at section IV.G.3.g. of the rule.

- Many commenters supported applying stratification to ESRD QIP measures as a potential approach to identifying the impact of disparities on health outcomes of ESRD patients.
- CMS should work with stakeholders to identify evidence-based measurable solutions to addressing health disparities.
- Minimizing provider burden requires that CMS put in place valid data collection and analytic procedures.
- Patients should be able to opt out of participation in data collection related to disparities.
- Both the within- and between-provider disparity methods to present stratified ESRD facility-level quality measure results received support.
- Measures to be prioritized should leverage existing data sources especially self-reported data, have large sample sizes, have been shown to be linked to disparities, and be actionable.
- CMS should prioritize valid and reliable ESRD QIP clinical quality measures over reporting measures.

- CMS should clarify definitions of care access and care appropriateness measures and then prioritize these types of measures.
- CMS should take a stepwise approach to applying stratification and consider starting with dual eligibility status.
- Risk adjustment should control for legitimate reasons for performance variation (e.g., biological based such as age).
- Thresholds and benchmarking methods were supported; rank ordering and percentile were not.
- Confidential results reporting to providers was supported as was publicly available de-identified aggregate data reporting; concerns were raised about public reporting of facility-specific results.

CMS does not provide specific responses to comments. The agency will consider all input received during future policy development and expansion of its strategic vision for health equity.

V. End-Stage Renal Disease Treatment Choices (ETC) Model (§§512.300–512.397)

A. Overview

CMS finalizes an update to the model's Performance Payment Adjustment (PPA) scoring methodology; no changes are made to the model's Home Dialysis Payment Adjustment (HDPA). CMS also finalizes that qualified staff who provide kidney disease education (KDE) services to patients using the model's Medicare program waivers cannot be leased employees of or in any other way related to dialysis facilities. Finally, CMS confirms its plans to publicly report ETC Model performance results.

ETC is a mandatory payment model administered by the Centers for Medicare and Medicaid Innovation (CMMI) under which payment adjustments are being made to incentivize greater uptake by ESRD beneficiaries of home dialysis and kidney transplantation as treatment options. Model participants are (1) dialysis facilities and (2) clinicians who bill for monthly, bundled ESRD professional services ("managing clinicians"). Participants were chosen from randomly selected hospital referral regions nationwide. The model also includes waivers intended to expand access to Medicare's KDE benefit (e.g., coinsurance waiver). KDE includes information about ESRD treatment options.

The ETC model test began January 1, 2021 and performance year 5 will end December 31, 2025. Payment adjustments under the model are applicable to claims with dates from January 1, 2021 through June 30, 2027. Both achievement and improvement scores are factored into payment adjustments. HDPAs, which are positive adjustments based on home dialysis rates, have been applied to payments beginning with January 1, 2021 claims and will continue through December 31, 2023. PPAs may be positive or negative and are based on a participant's home dialysis and transplant rates during rolling 12-month Measurement Year (MY) periods. PPA adjustments to payments started with July 1, 2022 claims.

B. Finalized ETC Model Changes for 2023 and Subsequent Years

1. Revising the PPA Achievement Scoring Methodology

For MY5 through MY10 (January 1, 2023 through June 30, 2026),[42] CMS finalizes as proposed the assignment of achievement scores for the home dialysis rate or transplant rate for each MY only to those participants whose aggregation groups have rates exceeding zero for that MY.[43]

CMS received supportive comments about this change. Additional comments addressed topics judged out of scope of this rule (e.g., new measures of achievement).

This change will preclude the possibility of awarding of PPA achievement points to participants with home dialysis or transplant rates of zero. This unwanted possibility arose as a consequence of CY 2022 rulemaking that introduced stratified benchmarking for aggregation groups based on beneficiary dual eligibility status or Part D Low Income Subsidy enrollment. Benchmarking stratification caused performance percentile redistribution within the comparison region data from which achievement benchmarks are derived. Stratified benchmarking will otherwise be continued as previously adopted to support more equitable benchmark setting.

2. Revised Requirements for Clinical Staff Furnishing KDE Services

CMS finalizes adding language at §512.397(b)(1) stating that clinical staff who furnish KDE services under the direction of and incident to the services of a managing clinician may not be leased from or otherwise provided by an ESRD facility or related entity.[44] This prohibition will begin with MY5 and will apply whether or not the managing clinician has chosen to reduce or waive the beneficiary coinsurance requirement for the KDE services.

Current regulations provide that clinical staff furnishing KDE services under the ETC model's KDE-related waivers cannot be leased from or otherwise provided by an ESRD facility or related entity only in the scenario where the managing clinician also is waiving some or all of the beneficiary coinsurance amount.

Some commenters supported the change. Several opposed the change because it could reduce access to KDE services by reducing the numbers of healthcare personnel permitted to provide KDE services. They suggested CMS could address beneficiary steering concerns by mandating use of educational material templates created by the agency.

CMS disagrees, stating that beneficiary steering during educational interactions can take multiple and sometimes subtle forms (e.g., ESRD facility logos on educators' uniforms) that would not be mitigated by templated educational materials.

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[42] Model years are rolling periods that are not strictly aligned with calendar year periods.
[43] Provider aggregation groups are used in this model to increase measurement reliability by smoothing out variability in results caused by small participant subgroup sizes when calculating home dialysis and transplant rates.
[44] For the purposes of the ETC model's KDE-related waivers, "clinical staff" means a licensed social worker or a registered dietician/nutrition professional.

3. Public Reporting of ETC Model Results

CMS sought comments on its plans, described in the proposed rule, to publicly report ETC Model performance results on the model's website. Public performance reporting will be separate from and in addition to the formal, independent, overall model evaluation reports required by statute. Planned for public release are home dialysis and transplant rates and results for their component variables (e.g., beneficiary months on nocturnal dialysis or on the transplant waitlist) as well as the number of living donor transplants performed. Data will be provided at the aggregation group level and lists of aggregation group members will be posted (facilities or managing clinicians, as applicable). Results will not be posted until after the model's process for targeted results review when requested by participants has been completed.

Supportive comments were received. Some commenters requested that CMS provide the results to facilities and managing clinicians during a specified "pre-review" period prior to results being posted publicly.

CMS declines to add a "pre-review" period. It views the model's established targeted review process (see §512.390(c)) as a sufficient opportunity for model participants to examine their performance data prior to public posting.

VI. Regulatory Impact Analysis

A. Impact of Changes in ESRD PPS Payments

CMS estimates that the revisions to the ESRD PPS would increase payments to ESRD facilities by approximately $300 million in 2023—the net result of a $300 million increase from the payment rate update, approximately $2.5 million in estimated TPNIES[45] and $2.3 million in TDAPA payment amounts These amounts are from CMS' modeling of payment rate changes holding utilization, case-mix and other variables constant. CMS estimates beneficiary coinsurance payments to be approximately $60 million.

Considering changes in utilization and other factors, Medicare program payments for ESRD facilities in 2023 are estimated to total $7.9 billion, reflecting an expected 3.5 percent decrease in fee-for-service Medicare dialysis beneficiary enrollment. (The final rule does not address the reasons for a projected enrollment decline, but it is notable that beginning in 2021, Medicare ESRD beneficiaries may elect to enroll in a Medicare Advantage plan, pursuant to section 17006 of the 21st Century Cures Act (P.L. 114-255)).

Table 31 in the final rule shows the estimated impact on ESRD payments in 2023 by various types of ESRD facilities. The estimates are based on 2021 data from the Part A and Part B Common Working Files as of July 30, 2022. A portion of that table is reproduced below. The omitted rows display facility impact by region, urban/rural location, and percentage of pediatric patients.

[45]This estimate is based on the continue TPNIES for Tablo hemodialysis system for 2023.

Overall, CMS estimates the combined effects of all the policies in the final rule would be an increase in payments—again, holding utilization, case mix and other factors constant—of 3.1 percent across all ESRD facilities.

Impact of Changes in 2023 Payment to ESRD Facilities (from Table 31)						
Facility Type	**Number of Facilities**	**Number of Treatments (millions)**	**Changes to Outlier Policy**	**Change to Labor Related Share**	**Wage Index Changes**	**Total Percent Change**
All Facilities	7,882	35.5	0.0%	0.0%	0.0%	3.1%
Type						
Freestanding	7,506	34.1	0.0%	0.0%	0.0%	3.0%
Hospital-based	376	1.4	0.1%	0.0%	0.0%	3.1%
Ownership						
Large dialysis organization	6,109	27.9	0.0%	0.0%	0.0%	3.0%
Regional chain	902	4.2	0.0%	0.2%	0.1%	3.4%
Independent	474	2.0	0.0%	0.3%	-0.1%	3.2%
Hospital-based	376	1.4	0.1%	0.0%	0.0%	3.1%
Facility Size (Treatments)						
Less than 4,000	1,310	1.7	0.0%	-0.2%	-0.2%	2.6%
4,000 to 9,999	3,375	11.3	0.0%	-0.2%	-0.1%	2.7%
10,000 or more	3,163	22.5	0.0%	0.1%	0.1%	3.2%

B. Estimated Impact of ESRD QIP

1. Impacts for PY 2023 and PY 2024

CMS estimates that available data will be sufficient to calculate a TPS for 7,847 Medicare-enrolled ESRD facilities and insufficient for 325 for PY 2023. CMS further estimates that 10.1 percent of all enrolled facilities (795/7847) will receive payment reductions for PY 2023, of whom 62 percent will receive the smallest possible reduction (0.5%). Total payment reductions to the 795 facilities are now estimated at $5.5 million. The estimated distribution of reductions is shown in Table 33 of the rule, reproduced below. Facilities that do not receive a TPS do not receive payment reductions. A more detailed presentation of reduction impacts for PY 2023 by facility size, location, and ownership type is not provided.

TABLE 33: Estimated Payment Reduction Distribution for PY 2023 (Includes only facilities for whom a TPS can be calculated)		
Reduction	**Facilities (Total n=7522)**	**Percent of Facilities (%)**
0.0%	6727	89.43
0.5%	492	6.54
1.0%	127	1.69
1.5%	82	1.09
2.0%	94	1.25

No updates are provided in this rule to prior impact estimates for PY 2024 of $17.1 million in reduced payments to be received by a total of 1,788 facilities (86 FR 62006 through 62009). However, PY 2024 impacts appear likely to be close to those above for PY 2023.

2. Impacts for PY 2025 and PY 2026

Table 35 in the Regulatory Impact Analysis, reproduced below, shows the estimated distribution of payment reductions resulting from the PY 2025 ESRD QIP changes finalized in this rule, including measure and domain reweighting. CMS estimates that 3,592 facilities (47.87 percent of the 7,504 facilities having sufficient data to allow TPS calculations) will experience PY 2025 payment reductions, in aggregate totaling $32.5 million. Of those 3,592 facilities, 55.21 percent are expected to receive the lowest level payment reduction: 0.5 percent. Facilities that do not receive a TPS do not receive payment reductions, estimated to be 343 for PY 2025.

TABLE 35: Estimated Payment Reduction Distribution for PY 2025 ESRD QIP (Includes only facilities for whom a TPS can be calculated)		
Reduction	**Facilities (Total n=7504)**	**Percent of Facilities (%)**
0.0%	3912	52.13
0.5%	1983	26.43
1.0%	1190	15.86
1.5%	369	4.92
2.0%	50	0.67

Table 37 of the rule, reproduced in part below, shows PY 2025 payment reduction impacts according to facility size, geography, and type. CMS cautions that the true impacts may be very different than shown because the performance period used for these calculations differs from the performance period to be used for the PY 2025 ESRD QIP (related to data availability).

Based on 7,847 Medicare-enrolled ESRD facilities, CMS estimates the payment reductions will represent about 0.37 percent of total ESRD payments in PY 2025. Reductions are shown to be largest for independently-owned facilities and those located in the US Territories. Costs to facilities associated with reporting of data for the ESRD QIP through the EQRS system are estimated to total $220 million for PY 2025. Taken together, reporting costs and payment reductions are estimated to have an impact of $252 million on ESRD facilities for that year.

Identical estimates are provided for PY 2026 in Tables 38 (payment reduction distribution) and 40 (payment reductions by facility characteristics).

Estimated Impact of QIP Payment Reductions to ESRD Facilities for PY 2025 (from Table 37)			
Facility Type	**Number of Facilities with QIP Score**	**Number of Facilities Expected to Receive a Payment Reduction**	**Payment Reduction as Percent of Total ESRD Payments**
All Facilities	7,504	3,592	-0.37%

Estimated Impact of QIP Payment Reductions to ESRD Facilities for PY 2025 (from Table 37)			
Facility Type	**Number of Facilities with QIP Score**	**Number of Facilities Expected to Receive a Payment Reduction**	**Payment Reduction as Percent of Total ESRD Payments**
Facility Type			
Freestanding	7,168	3,405	-0.37%
Hospital-based	336	187	-0.49%
Ownership Type			
Large Dialysis	5,843	2,631	-0.33%
Regional Chain	881	471	-0.45%
Independent	437	301	-0.68%
Hospital based (non-chain)	336	187	-0.49%
Geography (Census Region)			
Northeast	1,041	518	-0.39%
Midwest	1,657	819	-0.39%
South	3,404	1,743	-0.41%
West	1,342	466	-0.24%
US Territories	60	46	-0.64%

Finally, CMS provides trend data for aggregate payment reductions for PY 2018 through PY 2026 in Table 41 of the rule, re-ordered and reproduced below with rounded dollar amounts. In response to the COVID-19 PHE, a special scoring methodology was applied for the PY 2022 ESRD QIP such that no facilities were assigned TPS values.

Table 41: Estimated ESRD QIP Aggregate Payment Reductions PYs 2018-2026	
ESRD QIP Payment Year	**Estimated Reductions ($ million)**
PY 2018	$11.6
PY 2019	$15.5
PY 2020	$31.6
PY 2021	$32.2
PY 2022	$0
PY 2023	$5.5
PY 2024	$17.1
PY 2025	$32.5
PY 2026	$32.5

C. Estimated Impact on the ETC Model

The finalized change to KDE clinical staff requirements does not affect the previous Medicare savings impact estimate for the ETC Model.

The finalized change to the PPA achievement scoring methodology beginning with MY5 was analyzed in detail for potential impacts on savings using the simulation methodology previously created for the model by the CMS Office of the Actuary.[46] Updated itemized impacts of the

[46] A detailed description of the methodology is found at 86 FR 62012 through 62014.

model are shown in Table 42 of the rule, reproduced below in part. The results in the table represent the average of 400 simulations under the assumption that benchmarks are rolled forward with a 1.5-year lag as provided for in the model's design. The finalized PPA achievement scoring methodology revision does not change the estimated net impact to Medicare spending from the ETC Model, which remains at $28 million in savings over the life of the model (January 1, 2021 through June 30, 2027).

Table 42: Estimates of Medicare Program Savings for ETC Model (Rounded $M)								
	Year of Model							
	2021	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**Total***
Net Impact Medicare Spending	15	9	-1	-9	-12	-19	-9	-28
*Total may not sum due to rounding and from effects of beneficiaries having dialysis treatment spanning multiple years.								