CY 2023 Medicare End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Final Rule (CMS-1768-F)

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INTRODUCTORY SUMMARY AND BACKGROUND

On October 31, 2022, The Centers for Medicare and Medicaid Services (CMS) issued a final rule to update payment policies and rates under the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for renal dialysis services furnished to beneficiaries on or after January 1, 2023.

This rule finalizes proposed updates to the Acute Kidney Injury (AKI) dialysis payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI. There are also finalized updates to the requirements for the End-Stage Renal Disease Quality Incentive Program (ESRD QIP), including a continued measure suppression policy for the duration of the COVID-19 public health emergency (PHE) that was previously finalized, as well as updates for CY 2024 and 2025. Changes to the ESRD Treatment Choices (ETC) Model are also included in this final rule, including addition of a parameter to the Performance Payment Adjustment (PPA) achievement scoring methodology.

ESRD Final Rule

The CY 2023 final rule is located in its entirety at the following link:
https://public-inspection.federalregister.gov/2022-23778.pdf?utm_source=federalregister.gov&utm_medium=email&utm_campaign=pi+subscription+mailing+list

This document in PDF form is 472 pages in length. The format of the information is intended to summarize the changes so readers are encouraged to view the document in its entirety for further details.

FINALIZED CHANGES TO ESRD PPS

Under ESRD PPS for CY 2023, Medicare expects an increase in 2023 expenditures of $300 million as compared to CY 2022. The overall impact of the CY 2023 changes is projected to be a 3.1 percent increase in payments. This includes over 7,800 hospital-based ESRD facilities as well as freestanding ESRD facilities. Section 1881 of the Act requires the implementation of a bundled PPS for renal dialysis services provided to Medicare beneficiaries. A single per-treatment payment is made to an ERSD facility for all the renal dialysis services as defined in the Act. The bundled payment rate is case-mix adjusted for factors relating to:

1) Adult patient case-mix characteristics including age, body surface area, low body mass index, onset of dialysis, four comorbidity categories (pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, myelodysplastic syndrome); and

2) Pediatric patient-level adjusters consisting of two age categories (under age 22 years or 22-26) and two dialysis modalities (peritoneal or hemodialysis).

There are three facility-level adjustments for low patient volume ESRD facilities, those in rural areas and for differences in area wage levels in the wage index. The ESRD PPS also provides a training add-on payment adjustment for home and self-dialysis; transitional drug add-on payment adjustment (TDAPA); and transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES). For high cost patients, outlier payments may be applicable.

ESRD Quality Incentive Program (ERSD QIP)

The ESRD Quality Incentive Program (ERSD QIP) focuses on improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by CMS.

These performance standards have been impacted by the COVID-19 PHE in terms of validity and reliability of the measures, performance scores and payment policies. Because of this, CMS finalized a suppression policy for the duration of the COVID-19 PHE in CY 2022. There were no changes to this suppression policy.

For CY 2023, CMS finalizes its proposal to suppress the use of six ESRD QIP clinical measures for scoring and payment adjustment purposes. The suppression policy focuses on a short-term approach and is not intended for long-term or infinite application:

1) Standardized Hospitalization Ratio (SHR) clinical measure;
2) Standardized Readmission Ratio (SRR) clinical measure;
3) In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) clinical measure;
4) Long-Term Catheter Rate clinical measure;
5) Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure;
6) Kt/V Dialysis Adequacy Comprehensive clinical measure; and
7) Standardized Fistula Rate clinical measure.

Other finalized proposals based on addressing the impact of the COVID-19 PHE include adopting special scoring and payment policies for CY 2023 so that no facility would receive a payment reduction; and calculating the performance standards for CY 2023 using CY 2019 data, which is the most recently available full calendar year of data. CMS believes using CY 2019 data is appropriate given the circumstances of CY 2020.

For CY 2024, technical specification updates are being finalized for certain clinical measures in order to express results as rates rather than ratios. For CY 2025, multiple changes are being finalized, including conversion of the Hypercalcemia (currently a clinical measure) to a reporting measure; conversion of the Standardized Transfusion Ratio (STrR) (currently a reporting measure) to a clinical measure; creation of a new reporting measure domain; and re-weighting of current measure domains. Currently, there are no new requirements for the CY 2026 ESRD QIP.

CMS requested comments from stakeholders for future potential classification of quality indicators for home dialysis patients, expansion of quality reporting programs to provide information for healthcare equality issues under the ESRD PPS, and possible inclusion of two social drivers of health screening measures. CMS is considering all comments for future development and expansion of home dialysis, and advancing their vision for health equality.

ESRD Treatment Choices (ETC) Model

The ESRD Treatment Choices (ETC) Model is a mandatory Medicare payment model which focuses on additional payment for new and innovative capital-related assets – mainly, home dialysis machines when used in a residence for a single ESRD patient. Further defined, "home dialysis machines" are hemodialysis machines and peritoneal dialysis cyclers in their entirety. The FDA provides a separate marketing authorization for equipment intended for home use. In addition to the use of home dialysis machines, the ETC Model also encourages kidney transplantation, beneficiary care modality choice, and preservation and enhancement of quality of care, all while reducing Medicare costs. The ETC model began January 1, 2021, and will end June 30, 2027.

For CY 2023, this final rule will make certain changes to the ETC Model, including modification of the home dialysis rate and transplant rate; addition of a parameter to the Performance Payment Adjustment (PPA) achievement scoring methodology; addition of a supplemental protection related to flexibilities for furnishing and billing kidney disease patient education services by ETC Participants; and clarification of the requirements of qualified staff to furnish and bill kidney disease education services under the ETC Model's Medicare waiver programs.

Base Rate Update

Historically the term "market basket" describes the mix of goods and services used for ESRD treatment; however, this term is also used to indicate the input price index - cost categories, their respective weights and prices combined. Therefore, the term ESRD bundled (ESRDB) market basket refers to the ESRDB input price index.

CMS is finalizing their proposal to rebase and revise the ESRDB market basket to a 2020 base year, which reflects the most recent and complete set of Medicare cost report data, as well as other publicly available data. Additionally, CMS is proposing an update to the labor-related share of the base rate which reflects the 2020 labor-related cost share weights with 21 detailed cost categories, including specific overhead expenses and capital-related expenses

Under the ESRD PPS, a single per-treatment payment is made to an ESRD facility for all the renal dialysis services defined in section 1881 of the Act. The finalized CY 2023 ESRD PPS base rate is $265.57, which applies to both ESRD and AKI patients receiving renal dialysis services. This amount is an increase of $7.67 from the 2022 base rate of $257.90. It is also reflective of the application of the finalized wage index budget-neutrality adjustment factor (0.999730) to the proposed base rate of $257.90, and a productivity-adjusted market basket increase (3.0 percent) as required by the Act, equaling $265.57: ($257.90 x 0.999730) x 1.030 = $265.57.

Wage Index Update

The wage index is updated annually based on the most current hospital wage data and the latest core-based statistical area (CBSA) delineations that account for varied wage levels in ESRD facility areas. The wage index is applied to the labor-related share of the payment rate and is budget neutral. The finalized labor-related share is 55.2 percent, based on the 2020-based ESRDB market basket.

For CY 2023, CMS is finalizing their proposal to update the wage index values based on the latest available data and continuing the 2-year transition to the Office of Management and Budget (OMB) delineations as described in the September 14, 2018, OMB Bulletin No. 18–04.

Other CMS finalized changes regarding the wage index for CY 2023 include application of a permanent 5-percent cap on any ESRD facility's wage index decrease from the prior year's wage index, regardless of the reason for the decline. This means an ESRD facility's wage index for CY 2023 would not be less than 95 percent of its final wage index for CY 2022. This wage index cap will not apply to ESRD facilities that are new in CY 2023.

A wage index floor value (0.5000) is applied to areas with very low wage index values. For CY 2023, CMS is finalizing an increase of the wage index floor from 0.5000 to 0.6000 for wage index values below the wage index floor. Currently, only rural Puerto Rico and 8 urban Core-Based Statistical Area Codes (CBSAs) in Puerto Rico receive the wage index floor of 0.5000. Under this proposal, all CBSAs in Puerto Rico would be subject to the wage index floor of 0.6000 as well as any area that may fall below the wage index floor.

Revision of Oral-Only Drugs Definition

Based on observations regarding ESRD drug usage and spending, and upcoming changes related to oral-only drugs under ERSD PPS, CMS is finalizing its proposal to revise the definition of oral-only drugs to include the word *functional.* The current definition states "that an oral-only drug is a drug or biological product with no injectable equivalent or other form of administration other than oral form." Under the finalized definition, an oral-only drug would be defined as "drug or biological product with no *functional* equivalent or other form of administration other than an oral form." This revision refers to functional equivalence which falls in line with the current drug designation process based on ESRD PPS functional categories. This change will take effect January 1, 2025.