

CY 2022 Medicare End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Proposed Rule (CMS-1749-P)

W.L. GORE and Associates

INTRODUCTORY SUMMARY AND BACKGROUND

On July 1, The Centers for Medicare and Medicaid (CMS) issued a proposed rule (CMS-1749-P) that proposes 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, 2022.

This rule also proposes updates to the Acute Kidney Injury (AKI) dialysis payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI; and proposes updates to the requirements for the End-Stage Renal Disease Quality Incentive Program (ESRD QIP), including a proposed measure suppression policy for the duration of the COVID-19 public health emergency (PHE). Changes to the ESRD Treatment Choices (ETC) Model are also included in this proposed rule.

ESRD Proposed Rule

The CY 2022 proposed rule is located in its entirety at the following link:

<https://www.federalregister.gov/documents/2021/07/09/2021-14250/medicare-program-end-stage-renal-disease-prospective-payment-system-payment-for-renal-dialysis>

This document in PDF form is 345 pages in length. The format of the information is intended to summarize the proposed changes so readers are encouraged to view the document in its entirety for further details.

PROPOSED CHANGES TO ESRD PPS

Under ESRD PPS for CY 2022, Medicare expects an increase in 2022 expenditures of \$140 million as compared to CY 2021. This includes approximately 7,700 ESRD facilities for renal dialysis services. 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 ESRD 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, resulting performance scores and payment policies for CY 2022. Because of this, CMS proposes to suppress the use of certain ESRD QIP measure data for scoring and payment adjustment purposes, and offer a time extension for facilities to report September-December 2020 data under the Extraordinary Circumstances Exception (ECE) policy. Facilities will now have until September 1, 2021 to report 2020 data.

Other proposals based on addressing the impact of the COVID-19 PHE include adopting special scoring and payment policies for CY 2022 so that no facility would receive a payment reduction; and calculating the performance standards for CY 2024 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.

CMS is seeking comments from stakeholders future potential classification of quality measurements by race, Medicare/Medicaid dual eligible status, disability status, LGBTQ+ and economic status. Comments are also requested on the potential collection of demographic data elements by facilities at the time of admission, and using this data to permit nationwide health information exchange for the purposes of data collection efforts related to quality.

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. 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, preserve and enhance quality of care, all while reducing Medicare costs. The ETC model began January 1, 2021 and will end June 30, 2027.

For CY 2022, CMS has proposed to implement changes to the ESRD Treatment Choices (ETC) model. These proposed modifications include changes to the home dialysis rate, transplant rate, Performance Payment Adjustment (PPA) benchmarking methodology and scoring. These changes are to address the health and socioeconomic differences, which are a major contributor to chronic kidney disease (CKD) and ESRD. CMS is considering a two-tiered approach to address these differences:

- Adding a Health Equity Incentive to the improvement scoring methodology for both home dialysis and transplant rate. With this incentive, ETC participants who demonstrate significant improvement of home dialysis or transplant rates with their dual-eligible Medicare/Medicaid or low-income-subsidy (LIS) beneficiaries could earn additional improvement points.

- Classifying achievement benchmarks by beneficiaries who are dual-eligible Medicare/Medicaid or low-income-subsidy (LIS). ETC participants who see a high volume of these types of patients would not face a negative financial impact as a result.

The most common form of home peritoneal dialysis. CMS believes home dialysis and peritoneal dialysis often lead to greater patient anatomy, better health outcomes and overall improved quality of life. Stakeholders have identified Medicare payment for peritoneal dialysis catheter placement as a barrier to home dialysis. In an effort to better understand this issue, the proposed rule includes CMS' request for information from the public on this topic regarding placement of peritoneal dialysis catheters and home dialysis beneficiary experience measure. to consider potential future modifications to the ETC Model.

Base Rate Update

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 proposed CY 2022 ESRD PPS base rate is \$255.55, which applies to ESRD and AKI patients receiving renal dialysis services. This proposed amount reflects the application of the proposed wage index budget-neutrality adjustment factor (.999546), and a proposed productivity-adjusted market basket increase as required by the Act (1.0 percent), equaling \$255.55 ($\$253.13 \times .999546 \times 1.010 = \255.55).

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 proposed labor-related share is 52.3 percent, which is a continuation of the CY 2019 ESRD PPS final rule.

For CY 2022, CMS is proposing 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.

Submitting Comments

Comments to CMS regarding the ESRD PPS proposed rule must refer to file code CMS-1749-P and must be received no later than August 31, 2021. Electronic and mail submissions are acceptable.