PG Bulletin
January 9, 2020

CMS Issues CY 2020 ESRD Final Rule

Janus Pan (Bradley Arant Boult Cummings LLP)

This Bulletin is brought to you by AHLA's Regulation, Accreditation, and Payment Practice Group.

On November 8, 2019, the Centers for Medicare & Medicaid Services (CMS) published changes to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS). The changes include creating transitional add-on payment adjustments for certain new ESRD equipment and supplies; updating the scoring methodology and other programmatic changes to the ESRD Quality Incentive Program; and revising the ESRD PPS base rates and base rates for individuals with Acute Kidney Injuries. This Bulletin briefly overviews the ESRD PPS history, then summarizes CMS' Calendar Year (CY) 2020 updates and associated practical implications.

Background of ESRD Rule

In 2011, CMS implemented the ESRD PPS for renal dialysis services furnished by ESRD facilities.[1] CMS updates the ESRD PPS each calendar year to modify payments based on an ESRD market basket factor and adjust payments based on a productivity factor equal to the U.S. Health and Human Services Secretary's projected ten-year moving average of changes in economy-wide productivity.[2]

ESRD Updates in CY 2020 Final Rule

CMS revises the ESRD PPS for CY 2020

CMS updates the CY 2020 ESRD PPS base rate to $239.33 per treatment, an increase of $4.06 from the CY 2019 base rate of $235.27.[3] The ESRD PPS base rate represents the average per treatment Medicare Allowable Payment (MAP) for composite rate and separately billable services.[4] To calculate the per treatment rate, CMS first updates the ESRD PPS base rate based on a market basket percentage increase of 1.7% and modest wage index budget neutrality adjustment factors.[5] CMS then adjusts the ESRD PPS base rate for the characteristics of both adult and pediatric patients, in categories such as age, body surface area, body mass index, dialysis onset, and dialysis modalities.[6] CMS also adjusts the ESRD PPS base rate for facility-level adjustments, including volume of dialysis treatments, rural geographic locations, and differences in area wage levels.[7] Finally, CMS adjusts the ESRD PPS base rate for outlier payments

to high-cost patients and training add-ons under 42 C.F.R. § 413.237 and 42 C.F.R. § 414.335(b).[8]

CMS updates the ESRD PPS wage index using the latest hospital wage data and latest core-based statistical area (CBSA) delineations.[9]

CMS updates the outlier policy and outlier services fixed-dollar loss (FDL) amounts and MAP amounts for adult and pediatric patients, using 2018 claims data.[10] Under 42 C.F.R. § 413.237, an ESRD facility is eligible for an outlier payment if its actual or imputed MAP amount exceeds a certain threshold.[11] CMS has consistently lowered the MAP amount each year under the ESRD PPS.[12] For CY 2019, outlier payments represented only 0.5% of total ESRD payments, and CMS believes that using CY 2018 claims data to update the outlier MAP and FDL amounts for CY 2020 will increase payments to ESRD beneficiaries requiring higher resource utilization, in line with a target 1% outlier percentage.[13]

CMS excludes certain non-innovative drugs approved by the Food and Drug Administration (FDA) from eligibility for the Transitional Drug Add-on Payment Adjustment (TDAPA) and modifies other programmatic details of the TDAPA[14]

Specifically, "[a] new renal dialysis drug used to treat or manage a condition for which there is an ESRD PPS functional category is not eligible for payment using the transitional drug add-on payment adjustment . . . if the drug is approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or the new drug application (NDA) for the drug is classified by FDA as Type 3, 5, 7, or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the parent NDA is a Type 3, 5, 7 or 8 . . . ."[15]

These categories include generic drugs and drugs with new dosages or reformulations,[16] drugs previously marketed but without FDA approval, and prescription and over-the-counter drugs.[17] The TDAPA pays for new injectable or intravenous products that are not included in the ESRD PPS bundled payment.[18]

CMS finalizes a reduction to the TDAPA calcimimetics payment for CY 2020, from Average Sales Price (ASP) plus 6% to 100% of the ASP.[19]

CMS requires sufficient months of ASP data to apply the TDAPA.[20] Specifically, CMS will not apply the TDAPA for a new renal dialysis drug or biological product if CMS does not receive a full calendar quarter of ASP data within 30 days of the last day of the third calendar quarter after CMS begins applying the TDAPA for that product.[21] CMS also will not apply the TDAPA for a new renal dialysis drug or biological product beginning no later than two calendar quarters after CMS determines a full calendar quarter of ASP data is not available.[22] CMS also will not apply the TDAPA for a new renal dialysis drug or biological product if CMS does not receive the latest full calendar quarter of ASP data for the product, beginning no later than two calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.[23] If ASP data is not

available for new renal dialysis drugs and biological products, then CMS will use Wholesale Acquisition Cost (WAC), or invoice pricing if WAC is not available.[24]

CMS establishes a transitional add-on payment adjustment (TPNIES) to support ESRD equipment and supplies

ESRD equipment and supplies must meet the following criteria to qualify for TPNIES: (1) is designated by CMS as a renal dialysis service under 42 C.F.R. § 413.171, (2) is new, meaning it is granted marketing authorization by the FDA on or after January 1, 2020, (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) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular calendar year, (5) is innovative, meaning it meets the criteria specified in 42 C.F.R. § 412.87(b)(1), and (6) is not a capital-related asset that an ESRD facility has an economic interest in through ownership.[25] CMS will consider whether a given new renal dialysis supply or equipment meets these eligibility criteria,[26] as well as whether the equipment or supply "represent[s] an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries."[27]

CMS will pay the TPNIES based on 65% of the price established by the Medicare Administrative Contractors (MACs) for two calendar years, after which the equipment or supplies qualifies as an outlier service under the ESRD PPS.[28] CMS provides the application instructions to obtain TPNIES payment for calendar year 2021 at 84 Fed. Reg. 60648, 60698 (Nov. 8, 2019). Applications for TPNIES payment in calendar year 2021 are due by February 1, 2020.[29]

CMS discontinues the erythropoiesis-stimulating agent (ESA) monitoring policy (EMP) under the ESRD PPS[30]

CMS updates Medicare coverage and dialysis services furnished to individuals with Acute Kidney Injuries (AKI)

Under Social Security Act § 1834(r)(1) and 42 C.F.R. § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under Social Security Act § 1881(b)(14), updated by the ESRD bundled market basket and multifactor productivity adjustment, and adjusted by geographic factors under Social Security Act § 1881(b)(14)(D)(iv)(II).[31] In CMS' 2020 ESRD Final Rule, CMS finalizes a CY 2020 payment rate of $239.33 per renal dialysis service furnished by ESRD facilities to individuals with AKI, the same rate as the CY 2020 ESRD PPS base rate.[32]

CMS finalizes several updates to the ESRD Quality Incentive Program (QIP), which establishes incentives for dialysis facilities to meet or exceed CMS performance standards

Under the ESRD QIP program, CMS assesses the total performance of each facility on measures specified per payment year and applies an appropriate payment reduction to each facility that does not meet a minimum total performance score (TPS).[33] Specifically, "CMS defined the minimum TPS in [its] regulations at [42 C.F.R.] § 413.178(a)(8) as, with respect to a payment year, the TPS that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national performance on all clinical measures and the median of national ESRD facility performance on all reporting measures."[34] CMS codified at 42 C.F.R. § 413.177 "payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the minimum TPS . . . ."[35]

For performance year (PY) 2022, CMS estimated that a facility must meet or exceed a minimum TPS of 54 in order to avoid a payment reduction.[36] Table 11 below reflects the percentage reduction in payments associated with each decrease in performance score:[37]

TABLE 11—FINALIZED PAYMENT REDUCTION SCALE FOR PY 2022 BASED ON THE MOST RECENTLY AVAILABLE DATA

Total performance score	Reduction (%)
100–54	0
53–44	0.5
43–34	1.0
33–24	1.5
23–0	2.0

CMS updates scoring methodology for the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure to allow new eligible facilities to report data.[38]

CMS automatically advances the performance period and baseline period for each payment year by one year from the previous year, beginning with the PY 2024 payment year.[39]

CMS codifies at 42 C.F.R. § 413.178(d)(3) requirements for the Extraordinary Circumstances Exception (ECE) process, which grants facilities exceptions to certain reporting requirements in the QIP.[40]

CMS converts the Standardized Transfusion Ratio (STrR) clinical measure to a reporting measure[41] while it examines the validity of the STrR clinical measure for future rulemaking.[42] Specifically, the National Quality Forum raised concerns before the CY 2020 ESRD PPS proposed rule regarding the variability in hospital coding practice of the STrR clinical measure.[43]

CMS finalizes payment reductions of up to 2% for the PY 2022 ESRD QIP. The total payment reduction for the approximate 1,871 out of 7,386 Medicare-enrolled dialysis facilities expected to receive a payment reduction is approximately $18.2 million.[44]

Practical Takeaways

ESRD providers can take advantage of CMS' new payment opportunities and evaluate CMS' new payment requirements, including:

- Applying for the new ESRD TPNIES payment adjustment for renal dialysis services granted marketing authorization by the FDA after January 1, 2020; and
- Monitoring payment reductions for the PY 2022 ESRD QIP.

Because CMS projects total Medicare spending for ESRD facilities in CY 2020 to be higher than the spending in CY 2019 by 1.6% for freestanding facilities and 2.1% for hospital-based ESRD facilities, providers should ensure that any deviations between expected payments and received payments in CY 2020 can be explained by CMS' new ESRD policies.

---

[1] 84 Fed. Reg. 60648, 60649 (Nov. 8, 2019).
[2] 84 Fed. Reg. 60648, 60649 (Nov. 8, 2019); 42 U.S.C.A. § 1395ww(b)(3)(B)(xi)(II).
[3] 84 Fed. Reg. 60648, 60649 (Nov. 8, 2019).
[4] 84 Fed. Reg. 60648, 60707 (Nov. 8, 2019).
[5] 84 Fed. Reg. 60648, 60707 (Nov. 8, 2019).
[6] 84 Fed. Reg. 60648, 60652 (Nov. 8, 2019); 42 C.F.R. § 413.235.
[7] 84 Fed. Reg. 60648, 60652 (Nov. 8, 2019); 42 C.F.R. §§ 413.231-233.
[8] 84 Fed. Reg. 60648, 60676 (Nov. 8, 2019).
[9] 84 Fed. Reg. 60648, 60649 (Nov. 8, 2019).
[10] 84 Fed. Reg. 60648, 60649 (Nov. 8, 2019).
[11] 84 Fed. Reg. 60648, 60704 (Nov. 8, 2019).
[12] 84 Fed. Reg. 60648, 60704 (Nov. 8, 2019).
[13] 84 Fed. Reg. 60648, 60649 (Nov. 8, 2019).
[14] 84 Fed. Reg. 60648, 60649 (Nov. 8, 2019).
[15] 84 Fed. Reg. 60648, 60804 (Nov. 8, 2019).
[16] 84 Fed. Reg. 60648, 60656 (Nov. 8, 2019).
[17] 84 Fed. Reg. 60648, 60657 (Nov. 8, 2019).
[18] 84 Fed. Reg. 60648, 60652 (Nov. 8, 2019).
[19] 84 Fed. Reg. 60648, 60650 (Nov. 8, 2019).
[20] 84 Fed. Reg. 60648, 60650 (Nov. 8, 2019).
[21] 84 Fed. Reg. 60648, 60650 (Nov. 8, 2019).
[22] 84 Fed. Reg. 60648, 60650 (Nov. 8, 2019).
[23] 84 Fed. Reg. 60648, 60650 (Nov. 8, 2019).
[24] 84 Fed. Reg. 60648, 60650 (Nov. 8, 2019).
[25] 84 Fed. Reg. 60648, 60691 (Nov. 8, 2019).
[26] 84 Fed. Reg. 60648, 60691 (Nov. 8, 2019) (to be codified at 42 C.F.R. § 413.236).
[27] 84 Fed. Reg. 60648, 60650 (Nov. 8, 2019).
[28] 84 Fed. Reg. 60648, 60650 (Nov. 8, 2019).
[29] 84 Fed. Reg. 60648, 60697 (Nov. 8, 2019).
[30] 84 Fed. Reg. 60648, 60650 (Nov. 8, 2019).
[31] 84 Fed. Reg. 60648, 60712 (Nov. 8, 2019).

[32] 84 Fed. Reg. 60648, 60713 (Nov. 8, 2019).
[33] 84 Fed. Reg. 60648, 60725 (Nov. 8, 2019).
[34] 84 Fed. Reg. 60648, 60725-26 (Nov. 8, 2019).
[35] 84 Fed. Reg. 60648, 60726 (Nov. 8, 2019).
[36] 84 Fed. Reg. 60648, 60727 (Nov. 8, 2019).
[37] 84 Fed. Reg. 60648, 60727 (Nov. 8, 2019).
[38] 84 Fed. Reg. 60648, 60650 (Nov. 8, 2019).
[39] 84 Fed. Reg. 60648, 60803 (Nov. 8, 2019).
[40] 84 Fed. Reg. 60648, 60714 (Nov. 8, 2019) (to be codified at 42 C.F.R. § 413.178(d)(3)-(7)).
[41] 84 Fed. Reg. 60648, 60720 (Nov. 8, 2019). CMS will award from zero to ten points to each ESRD facility on a reporting measure based on the degree to which, during the applicable performance period, the ESRD facility reports data and completes other actions specified by CMS with respect to that measure (42 C.F.R. § 413.178(e)(1)(vi), effective Jan. 1, 2020).
[42] 84 Fed. Reg. 60648, 60721 (Nov. 8, 2019).
[43] 84 Fed. Reg. 60648, 60720 (Nov. 8, 2019).
[44] 84 Fed. Reg. 60648, 60794 (Nov. 8, 2019).