Issue Brief

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CMS Releases Proposed CY 2020 ESRD PPS Update; DMEPOS Changes

The Centers for Medicare & Medicaid Services has issued a proposed rule to update payment policies and rates under the End-Stage Renal Disease Prospective Payment System for services furnished on or after Jan. 1, 2020, calendar year 2020.

This proposed rule also includes payment items for (1) renal dialysis services furnished to individuals with acute kidney injury (AKI), (2) the ESRD Quality Incentive Program (QIP) and, (3) the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) proposed amendments, and the regulations governing DMEPOS orders, face-to-face encounters, and prior authorization.

The rule will be published in the Aug. 8 *Federal Register*. The 327-page display copy currently is available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-16369.pdf. Of course, this link will be superseded upon publication.

A 60-day comment period ending Sept. 27 is provided.

COMMENT

The overall impact of the proposed CY 2020 changes is projected to be a 1.6 percent increase in payments. Hospital-based ESRD facilities have an estimated 1.9 percent increase in payments compared with freestanding facilities with an estimated 1.5 percent increase.

Medicare expects to pay approximately $11.1 billion to approximately 7,000 ESRD facilities for the costs associated with furnishing renal dialysis services.

CMS estimates that the proposed revisions to the ESRD PPS would result in an increase of approximately $210 million in payments to ESRD facilities in CY 2020, which includes the amount associated with updates to the outlier thresholds, payment rate update, updates to the wage index, and the proposal to change the basis of payment for the transitional drug add-on payment adjustment (TDAPA) for calcimimetics from ASP+6 percent to ASP+0 percent. This reflects a $230 million increase from the payment rate update and a $40 million increase due to the updates to the outlier threshold amounts, and a $60 million decrease from the proposal to change the basis of payment for the TDAPA for calcimimetics from ASP+6 percent to ASP+0 percent.

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As noted above, there is a comment period ending Sept. 27. This means that CMS will have only 34 days to respond to comments, prepare a final rule, have OMB approve such, and have it published. Something appears amiss with this rule's timeframe. One wonders about how much review CMS can give to comments.

Once again, CMS is piggybacking a non-germane item onto this rule. While piggybacking maybe a convenience to the government, it is not helpful to those whose only concern is the major item in question, in this case, the CY 2020 ESRD update. The DMEPOS items are as long as the ESRD changes. This analysis is only centered on the ESRD items. CMS says that DMEPOS issues will be made a separate rule in the future.

Proposed CY 2020 ESRD PPS Update

The proposed CY 2020 ESRD PPS base rate would be $240.27, an increase of $5.00 to the current base rate of $235.27. This proposed amount reflects a reduced marketbasket increase as required by Section 1881(b)(14)(F)(i)(I) of the Act (1.7 percent) and application of the wage index budget-neutrality adjustment factor (1.004180).

This marketbasket increase is calculated by starting with the proposed CY 2020 ESRDB marketbasket percentage increase factor of 2.1 percent and reducing it by a proposed multifactor productivity (MFP) adjustment (the 10-year moving average of MFP for the period ending CY 2020) of 0.4 percent.

For the CY 2020 ESRD payment update, CMS proposes to continue using a labor-related share of 52.3 percent for the ESRD PPS payment.

Proposed CY 2020 ESRD PPS Wage Indices

The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under Sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. The proposed CY 2020 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the proposed CY 2020 wage index values for rural areas are listed in Addendum B (Wage Indices for Rural Areas). Addenda A and B are located on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html.

The CY 2020 proposed wage index budget-neutrality adjustment factor is 1.004180.

Proposed CY 2020 Update to the Outlier Policy

For CY 2020, CMS proposes to update the outlier services Medicare Allowable Payment (MAP) amounts and fixed-dollar loss (FDL) amounts to reflect the utilization of outlier services reported on 2018 claims.

Based on the use of the latest available data, the proposed FDL amount for pediatric beneficiaries would decrease from $57.14 to $44.91, and the MAP amount would decrease from $35.18 to $33.82, as compared to CY 2019 values.

For adult beneficiaries, the proposed FDL amount would decrease from $65.11 to $52.50, and the MAP amount would decrease from $38.51 to $36.60.

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The 1.0 percent target for outlier payments was not achieved in CY 2018. Outlier payments represented approximately 0.5 percent of total payments rather than 1.0 percent.

CY 2020 Payment for Renal Dialysis Services Furnished to Individuals with AKI

As required by Section 1834(r) of the Act, CMS is proposing to update the Acute Kidney Injury dialysis payment rate for CY 2020 to equal the proposed CY 2020 ESRD PPS base rate and to apply the proposed CY 2020 wage index. For CY 2020, the proposed AKI dialysis payment rate is $240.27.

PROPOSED CHANGES TO THE ESRD QIP

The ESRD QIP is authorized by Section 1881(h) of the Act. Under the program CMS assesses the total performance of each facility on measures specified for a payment year and, applies an appropriate payment reduction to each facility that does not meet a minimum total performance score (TPS) and publicly reports the results.

1. PY 2022 ESRD QIP Measure Set

The PY 2022 ESRD QIP measure set includes 14 measures. (Refer to the rule's table 3).

2. Estimated Performance Standards for the PY 2022 ESRD QIP

The performance standards must include levels of achievement and improvement, as required by Section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by Section 1881(h)(4)(C) of the Act.

Estimated Performance Standards for the PY 2022 ESRD QIP Clinical Measures Using the Most Recently Available Data

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Vascular Access Type			
Standardized Fistula Rate	52.61%	63.69%	76.11%
Catheter Rate	18.24%	11.15%	5.02%
Kt/V Comprehensive	92.98% (92.75%)*	96.88% (96.83%)*	99.14% (99.10%)*
Hypercalcemia	1.81%	0.57%	0.00%
Standardized Readmission Ratio	1.268 (1.273)*	0.998	0.629 (0.642)*
Standardized Transfusion Ratio	1.684 (1.695)*	0.840	0.194
NHSN Bloodstream Infection	1.477	0.694 (0.698)*	0
Standardized Hospitalization Ratio	1.248	0.967 (0.971)*	0.670 (0.687)*
PPPW	8.75%	17.77%	34.29%
ICH CAHPS: Nephrologists' Communication and Caring	58.09%	67.81%	78.53%
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.16%	62.34%	72.03%
ICH CAHPS: Providing Information to Patients	73.90% (73.89%)*	80.38%	87.08%
ICH CAHPS: Overall Rating of Nephrologists	49.33% (47.85%)*	62.22% (60.37%)*	76.57% (74.50%)*
ICH CAHPS: Overall Rating of Dialysis Center Staff	49.12% (49.10%)*	63.04% (63.03%)*	77.48%
ICH CAHPS: Overall Rating of the Dialysis Facility	53.98% (53.97%)*	67.93%	82.48% (82.34%)*

* If the PY 2022 final numerical value is worse than the PY 2021 finalized value, we will substitute the PY 2022 final numerical value for the PY 2021 finalized value. We have provided the PY 2021 finalized value as a reference for clinical measures whose PY 2022 estimated value is worse than the PY 2021 finalized value.

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Proposed Update to the Eligibility Requirements for the PY 2022 ESRD QIP

CMS is proposing to remove the requirement that to be eligible to receive a score on the NHSN Dialysis Event reporting measure, new facilities must have a CCN Open Date before October 1 prior to the performance period that applies to the payment year.

Estimated Payment Reduction for the PY 2022 ESRD QIP

For PY 2022, CMS estimates using available data that a facility must meet or exceed a minimum TPS of 53 in order to avoid a payment reduction.

Under CMS' current policy, a facility that achieves a TPS below 53 would receive a payment reduction based on the TPS ranges indicated in the table below.

Total Performance Score	Reduction (%)
100-53	0%
52-43	0.5%
42-33	1.0%
32-23	1.5%
22-0	2.0%

Proposals for the PY 2023 ESRD QIP

CMS is continuing all measures from the PY 2022 ESRD QIP for PY 2023. CMS is not proposing to adopt any new measures beginning with the PY 2023 ESRD QIP.

ELIGIBILITY CRITERIA FOR THE TRANSITIONAL DRUG ADD-ON PAYMENT ADJUSTMENT (TDAPA)

CMS is proposing revisions to the drug designation process regulation for new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. Specifically, CMS is proposing to exclude drugs approved by the Food and Drug Administration under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and drugs approved under Section 505(c) of the FD&C Act that are classified by FDA as new drug application (NDA) Types 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, Type 5 in combination with Type 2, or Type 9 when the "parent NDA" is Type 3, 5, 7 or 8 — from being eligible for the TDAPA, effective Jan. 1, 2020.

PROPOSAL TO CONVERT THE STANDARDIZED TRANSFUSION RATIO (STrR) CLINICAL MEASURE TO A REPORTING MEASURE

CMS finalized the adoption of the STrR clinical measure to address gaps in the quality of anemia management, beginning with the PY 2018 ESRD QIP.

CMS also is proposing that, beginning with PY 2022, CMS would score the STrR reporting measure as follows: facilities that meet previously finalized minimum data and eligibility requirements will receive a score on the STrR reporting measure based on the successful reporting of data, not on the values actually reported. CMS

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is proposing that to receive 10 points on the measure, a facility would need to report the data required to determine the number of eligible patient-years at risk and have at least 10 eligible patient-years at risk. A patient-year at risk is a period of 12-month increments during which a single patient is treated at a given facility. A patient-year at risk can be comprised of more than 1 patient if, when added together, their time in treatment equals a year. For example, if 1 patient is treated at the same facility for 4 months and a second patient is treated at a facility for 8 months, then the two patients would combine to form a full patient year.

BASIS OF PAYMENT FOR THE TRANSITIONAL DRUG ADD-ON PAYMENT ADJUSTMENT (TDAPA) FOR CALCIMIMETICS

CMS is continuing to pay the TDAPA for calcimimetics for a third year in CY 2020 to collect sufficient claims data for rate setting analysis, but CMS is proposing to reduce the basis of payment for the TDAPA for calcimimetics for CY 2020 from the average sales price plus 6 percent (ASP+6) methodology to 100 percent of ASP.

AVERAGE SALES PRICE (ASP) CONDITIONAL POLICY FOR THE APPLICATION OF THE TDAPA

CMS is proposing to no longer apply the TDAPA for a new renal dialysis drug or biological product if CMS does not receive a full calendar quarter of ASP data within 30 days of the last day of the third calendar quarter after CMS begins applying the TDAPA. CMS would no longer apply the TDAPA for a new renal dialysis drug or biological product beginning no later than two calendar quarters after it determines a full quarter of ASP data is not available. CMS is also proposing to no longer 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.

NEW AND INNOVATIVE RENAL DIALYSIS EQUIPMENT AND SUPPLIES UNDER THE ESRD PPS

CMS has proposed to provide a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS. The proposed policy would provide a payment adjustment for renal dialysis equipment and supplies (with the exception of capital-related assets) that are: new, meaning they are granted marketing authorization by FDA on or after Jan. 1, 2020, and innovative, meaning they meet substantial clinical improvement (SCI) criteria similar to those used for IPPS's NTAP, as well as commercially available, and have a Healthcare Common Procedure Code System application submitted in accordance with the official Level II HCPCS coding procedures. CMS is proposing that the payment for TPNIES would be based on 65 percent of the price established by the Medicare Administrative Contractors (MACs), using the information from the invoice and other relevant sources of information. CMS would pay the TPNIES for two calendar years, after which the equipment or supply would qualify as an outlier service and no change to the ESRD PPS base rate would be made.

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DISCONTINUING THE APPLICATION OF THE ERYTHROPOIESIS-STIMULATING AGENT MONITORING POLICY UNDER THE ESRD PPS

CMS is proposing to discontinue the application of the ESA EMP under the ESRD PPS. Currently, beneficiaries, physicians, and ESRD facilities are required to submit additional documentation to justify medical necessity, and any outlier payment reduction amounts are subsequently reinstated when documentation supports the higher hematocrit or hemoglobin levels. Under the proposed policy, ESRD facilities would no longer have to go through the EMP appeal process and submit additional documentation regarding medical necessity. In addition, CMS no longer believes the EMP is necessary because ESAs are now bundled into the per treatment payment amount and overutilization and the incentive for overutilization has been eliminated from the ESRD PPS.

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

Requests for Information

Data Collection

A CMS data contractor conducted a Technical Expert Panel (TEP) on Dec. 6, 2018 to discuss options for improving data collection to refine the ESRD PPS case-mix adjustment model. The data contractor presented the participants in the TEP with several options for optimizing data collection on composite rate items and services, and each option was specifically formulated to minimize reporting burden for ESRD facilities where possible. The information presented in the TEP, as well as feedback received by TEP participants, is presented in the proposed rule for public comment.

Wage Index Solicitation

Stakeholders have frequently commented on certain aspects of the ESRD PPS wage index values and their impact on payments. CMS is soliciting comments on concerns stakeholders may have regarding the wage index used to adjust the labor-related portion of the ESRD PPS base rate and suggestions for possible updates and improvements to the geographic wage index payment adjustment under the ESRD PPS.