NCHA Financial Feature

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CMS Proposes CY 2019 ESRD PPS Update; Contains DMEPOS Changes

The Centers for Medicare and Medicaid Services (CMS) have issued a proposed rule to update payment policies and rates under the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for services furnished on or after January 1, 2019 (calendar year (CY) 2019).

The rule will be published in the July 19th ***Federal Register.*** The 368-page display copy is currently available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-14986.pdf. Of course, this link will be superseded upon publication. A 60-day comment period ending September 10th is provided.

The proposal also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). Further, it proposes a rebasing of the ESRD market basket for CY 2019. The rule also proposes to update numerous requirements for the ESRD Quality Incentive Program (QIP).

Finally, this rule proposes changes to bidding and pricing methodologies under the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) competitive bidding program (CBP); adjustments to DMEPOS Fee Schedule amounts; new payment classes for oxygen and oxygen equipment and a new methodology for ensuring that new payment classes for oxygen and oxygen equipment are budget neutral; payment rules for multi-function ventilators or ventilators that perform functions of other durable medical equipment (DME); and payment methodology revisions for mail order items furnished in the Northern Mariana Islands.

Comment

Under the proposed ESRD PPS for CY 2019, Medicare expects to pay approximately $10.6 billion to approximately 7,000 ESRD facilities.

The proposed ESRD payment changes are straight forward and readily understandable. The ESRD quality incentive program is more complex involving changes to total performance scores and various reporting and validation items.

It appears that the Office of Management and Budget (OMB) is spending considerable time between when CMS forwards it proposals to OMB for clearance and when OMB finally clears such. In this case, OMB had this proposed rule for nearly 2½ months before signing off. While providers still have a 60-day comment period, CMS will have less time to fully consider and respond to comments before having to issue a final rule.

Once again, CMS is piggybacking a non-germane item on this proposal. 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 2019 ESRD update. The DMEPOS items are nearly as long as the proposed ESRD changes. The DMEPOS provisions should have been issued as a separate rule.

The ESRD material that follows is abstracted from the proposed rule, while the DMEPOS is from a CMS summary of those changes.

Update to the ESRD PPS Base Rate

The proposed CY 2019 ESRD PPS base rate will be **$235.82,** an increase of $3.45. The current rate is $232.37.

The proposed CY 2019 ESRDB market basket increase factor is 2.2 percent. The 2.2 percent is reduced by the ***Affordable Care Act's*** (ACA) multifactor productivity (MFP) adjustment, estimated for CY 2019 to be 0.7 percent for net update of 1.5 percent.

An application of a wage index budget-neutrality adjustment factor (0.999833), results in the $235.82 update rate ($232.37 x 1.0150 x 0.999833 = $235.82).

Rebasing the ESRD Market Basket and Labor-Related Share:

CMS is proposing to rebase the ESRD market basket to reflect 2016 cost data. The main impact from the proposed rebasing would be an increase in the labor-related share from 50.673 percent (using the 2012-based market basket) to **52.3** percent (using the 2016-based market basket).

Annual Update to the Wage Index and Wage Index Floor:

For CY 2019, CMS is not proposing any changes to the application of the wage index, however CMS is proposing to increase the current wage index floor from 0.4000 to 0.5000, which would increase the wage index value for any areas currently below 0.5000.

The proposed CY 2019 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the proposed CY 2019 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 Web site at: https://go.cms.gov/1JRxS8Q.

Update to the Outlier Policy:

CMS is proposing to update the outlier services fixed-dollar loss (FDL) amounts for adult and pediatric patients and Medicare Allowable Payment (MAP) amounts for adult patients for CY 2019, using 2017 claims data.

Based on the use of more current data, the FDL amount for pediatric beneficiaries would increase from $47.79 to $47.88 and the MAP amount would decrease from $37.31 to $35.62, as compared to CY 2018 values.

For adult beneficiaries, the FDL amount would decrease from $77.54 to $69.73 and the MAP amount would decrease from $42.41 to $40.25. The 1.0 percent target for outlier payments was not achieved in CY 2017. Outlier payments represented approximately 0.8 percent of total payments rather than 1.0 percent.

Update to the Drug Designation Process:

The ESRD PPS provides for a transitional drug add-on payment adjustment (TDAPA) to pay for a new injectable or intravenous product that is not considered included in the ESRD PPS bundled payment, meaning a product that is used to treat or manage a condition for which there is not an existing ESRD PPS functional category.

CMS is proposing to update and revise its designation process and expand the transitional drug add-on payment adjustment (TDAPA) to all new drugs, not just those in new functional categories, and change the basis of determining the TDAPA from pricing methodologies under section 1847A of the Act, (which includes ASP +6) to ASP +0.

CMS proposes to revise § 413.234(c)(1) to reflect that for new renal dialysis drugs and biologicals that fall within a functional category, the TDAPA would apply for only 2 years.

CMS is also proposing that when a new renal dialysis drug or biological falls within an existing functional category at the end of the TDAPA period CMS would not modify the ESRD PPS base rate, but at the end of the 2 years, the drug would be eligible for outlier payment.

CMS is proposing to operationalize this proposed policy no later than Jan. 1, 2020. "This deadline would provide us with the appropriate time to prepare the necessary changes to our claims processing systems."

CY 2019 Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

The CY 2019 proposed ESRD PPS base rate is $235.82, which reflects the proposed ESRD bundled market basket and multifactor productivity adjustment. Accordingly, CMS is proposing a CY 2019 per treatment payment rate of $235.82 for renal dialysis services furnished by ESRD facilities to individuals with AKI.

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

The ESRD QIP will reduce payments to ESRD facilities that do not meet or exceed a minimum total performance score (TPS) by up to 2.0 percent.

Proposals for the PY 2021 ESRD QIP

a. Removal of 4 Measures

CMS is proposing to remove four of the reporting measures that were previously finalized for the PY 2021 ESRD QIP measure set. They are:

- Healthcare Personnel Influenza Vaccination.
- Pain Assessment and Follow-Up.
- Anemia Management.
- Serum Phosphorus.

The table below summarizes the proposed revisions to the PY 2021 ESRD QIP measure set.

Proposed Revisions to the Previously Finalized PY 2021 ESRD QIP Measure

NQF #	Measure Title and Description	Measure Continuing in PY 2021
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple testing tools.	Yes
2496	Standardized Readmission Ratio (SRR), a clinical measure Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.	Yes
2979	Standardized Transfusion Ratio (STrR), a clinical measure Risk-adjusted TrR for all adult Medicare dialysis patients. Number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected	Yes
N/A	A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume (Kt/V) Dialysis Adequacy Comprehensive, a clinical measure Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.	Yes
2977	Hemodialysis Vascular Access: Standardized Fistula Rate clinical measure Measures the use of an AV fistula as the sole means of vascular access as of the last hemodialysis treatment session of the month.	Yes
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.	Yes
1454	Hypercalcemia, a clinical measure Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.	Yes
1463*	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.	Yes
0255	Serum Phosphorus, a reporting measure. Percentage of all adult (≥18 years of age) peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum of plasma phosphorus measured at least once within month.	**Proposed for Removal**
N/A	Anemia Management Reporting, a reporting measure. Number of months for which facility reports erythropoiesis-stimulating agent (ESA) dosage (as applicable) and hemoglobin/hematocrit for each Medicare patient, at least once per month.	**Proposed for Removal**
Based on NQF #0420	Pain Assessment and Follow-Up, a reporting measure. Facility reports in CROWNWeb one of six conditions for each qualifying patient once before August 1 of the performance period and once before February 1 of the year following the performance period.	**Proposed for Removal**
Based on NQF #0418	Clinical Depression Screening and Follow-Up, a reporting measure Facility reports in CROWNWeb one of six conditions for each qualifying patient treated during performance period.	Yes
Based on NQF #0431	National Healthcare Safety Network (NHSN) Healthcare Personnel Influenza Vaccination, a reporting measure. Facility submits Healthcare Personnel Influenza Vaccination Summary Report to the Centers for Disease Control and Prevention's (CDC's) NHSN system, according to the specifications of the Healthcare, Personnel Safety Component Protocol by May 15 of the performance period.	**Proposed for Removal**
N/A	Ultrafiltration Rate, a reporting measure Number of months for which a facility reports elements required for ultrafiltration rates for each qualifying patient.	Yes
Based on NQF #1460	NHSN Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure. The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.	Yes
N/A	NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to CDC.	Yes

b. Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2021 ESRD QIP

CMS says, "at this time, we do not have the necessary data to assign numerical values to those performance standards, achievement thresholds, and benchmarks because we do not yet have complete data from CY 2017. Nevertheless, we are able to estimate these numerical values based on the most recent data available." Those estimates are reflected in the table below.

Estimated Numerical Values for the Performance Standards for the PY 2021 ESRD QIP Clinical Measures Using the Most Recently Available Data

Measure	Achievement Threshold	Benchmark	Performance Standard
Vascular Access Type			
Standardized Fistula Rate	0.518	0.752	0.628
Long-Term Catheter Rate	19.23%	5.47%	12.02%
Kt/V Composite	91.09%	98.56%	95.64%
Hypercalcemia	2.41%	0.00%	0.86%
Standardized Transfusion Ratio	1.683	0.200	0.846
Standardized Readmission Ratio	1.273	0.630	0.998
NHSN BSI	1.598	0	0.740
SHR measure	1.249	0.670	0.967
ICH CAHPS: Nephrologists' Communication and Caring	57.36%	78.09%	67.04%
ICH CAHPS: Quality of Dialysis Center Care and Operations	53.14%	71.52%	61.22%
ICH CAHPS: Providing Information to Patients	73.31%	86.83%	79.79%
ICH CAHPS: Overall Rating of Nephrologists	49.33%	76.57%	62.22%
ICH CAHPS: Overall Rating of Dialysis Center Staff	48.84%	77.42%	62.26%
ICH CAHPS: Overall Rating of the Dialysis Facility	52.24%	82.48%	66.82%

c. Proposed Change to the Scoring Methodology Previously Finalized for the PY 2021 ESRD QIP

The following table reflects the Proposed Domain and Measure Weighting for the PY 2021 ESRD QIP

Proposed Measures/Measure Topics	Proposed Measures/Measure Topics
PATIENT & FAMILY ENGAGEMENT MEASURE DOMAIN	
ICH CAHPS measure	15.00%
	15.00% of TPS
CARE COORDINATION MEASURE DOMAIN	
SRR measure	14.00%
SHR measure	14.00%
Clinical Depression and Follow-Up reporting measure	2.00%
	30% of TPS
CLINICAL CARE MEASURE DOMAIN	
Kt/V Dialysis Adequacy Comprehensive measure	6.00%
Vascular Access Type measure topic*	6.00%
Hypercalcemia measure	3.00%
STrR measure	22.00%
Ultrafiltration Rate reporting measure	3.00%
	40% of TPS

Proposed Measures/Measure Topics	Proposed Measures/Measure Topics
SAFETY MEASURE DOMAIN	
NHSN BSI measure	9.00%
NHSN Dialysis Event reporting measure	6.00%
NHSN Dialysis Event reporting measure	**15% of TPS**

d. Expanded NHSN Validation:

CMS is proposing to expand NHSN validation under the ESRD QIP to 150 facilities in PY 2021 and 300 facilities in PY 2022 to ensure accurate reporting and payment to facilities.

e. Estimated Payment Reduction for the PY 2021 ESRD QIP

CMS is proposing that a facility that achieves a TPS below the minimum TPS that was set for PY 2021 would receive payment reduction based on the estimated TPS ranges indicated in the table below.

Estimated Payment Reduction Scale for PY 2021 Based on the Most Recently Available Data

Total performance score	Reduction (%)
100-57	0%
56-47	0.5%
46-37	1.0%
36-27	1.5%
26-0	2.0%

Proposals for the PY 2022 ESRD QIP

CMS is proposing to adopt two new measures beginning with the PY 2022 ESRD QIP:

- Percentage of Prevalent Patients Waitlisted (PPPW), and
- Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec).

Proposals for the PY 2024 ESRD QIP

CMS is proposing to adopt one new measure beginning with the PY 2024 ESRD QIP:

- Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR).

Changes to The Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Payment Rules:

Proposals for the DMEPOS CBP and Fee Schedule Payment Rules

The rule proposes changes to bidding and pricing methodologies under the DMEPOS CBP; adjustments to DMEPOS Fee Schedule amounts using information from competitive bidding for items furnished from Jan. 1, 2019 through Dec. 31, 2020; new payment classes for oxygen and oxygen equipment and a new methodology for ensuring that all new payment classes for oxygen and oxygen

equipment added since 2006 are budget neutral; special payment rules for multi-function ventilators or ventilators that perform functions of other durable medical equipment (DME); and payment methodology revisions for mail order items furnished in the Northern Mariana Islands.

This rule proposes to:

- Revise the DMEPOS CBP by implementing lead item pricing.
- Revise the definition of composite bid to mean the bid submitted by the supplier for the lead item in the product category.
- Establish a new method for establishing single payment amount (SPAs) under the CBP using maximum winning bids.
- Establish three different temporary fee schedule adjustment methodologies depending on the area in which the items and services are furnished. The details of these methodologies for these three areas are as follows:

    - CMS is proposing a specific fee schedule adjustment methodology for items and services furnished within former CBAs in accordance with sections 1834(a)(1)(F) and 1834(a)(1)(G) of the Act. Specifically, CMS proposes to add a new paragraph (10) under § 414.210(g) that would establish a methodology for adjusting fee schedule amounts paid in areas that were formerly CBAs during periods when there is a temporary lapse in the CBP. CMS proposes to adjust the fee schedule amounts for items and services furnished in former CBAs based on the SPAs in effect in the CBA on the last day before the CBP contract periods of performance ended, increased by the projected percentage change in the CPI for all Urban Consumers (CPI–U) for the 12-month period on the date after the contract periods ended (for example, January 1, 2019). If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day after the contract period ended based on the projected percentage change in the CPI–U for the 12-month period ending on the anniversary date. Finally, with regard to payment for non-mail order diabetic testing supplies in the event of a gap in the CBP, payment would continue at the current SPA rates for mail order diabetic testing supplies as mandated by section 1834(a)(1)(H) of the Act until new rates are established under the national mail order program.

    - This rule takes into account certain information as mandated by the Cures Act in adjusting fee schedule amounts for DMEPOS items and services subject to the CBP that are furnished in non-CBAs. Based on stakeholder input, the higher costs for suppliers in non-contiguous areas, the longer average travel distance for suppliers furnishing items in certain rural areas, the significantly lower average volume that most non-CBA suppliers furnish, and the decrease in the number of non-CBA supplier locations, we are proposing to revise § 414.210(g)(9) and to adjust the fee schedule amounts for items and services furnished in rural and non-contiguous non-CBAs by extending through Dec. 31, 2020, the current methodology which bases the fee schedule amounts on a blend of 50 percent of the adjusted fee schedule amounts and 50 percent of the unadjusted fee schedule amount in accordance with the current methodologies under paragraphs (1) through (8) of § 414.210(g).

    - CMS is proposing to revise the fee schedule adjustment methodology at § 414.210(g)(9) so that for items and services furnished in non-CBAs that are not rural or non-contiguous areas with dates of service from Jan. 1, 2019, through December 31, 2020, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section. However, we request specific comments on the issue of whether the 50/50 blended rates should apply to these areas as well. We plan to continue monitoring health outcomes, assignment rates, and

other information and would address fee schedule adjustments for all non-CBAs for items furnished on or after Jan. 1, 2021, in future rulemaking.

- Add payment classes for portable liquid oxygen equipment only, portable gaseous oxygen equipment only, and high flow portable liquid oxygen contents. It also proposes to establish a new methodology for ensuring that all new payment classes for oxygen and oxygen equipment added since 2006 are budget neutral in accordance with section 1834(a)(9)(D)(ii) of the Act.

- Establish new rules regarding how to pay for certain ventilators that also perform the function of other items of durable medical equipment (DME) that are subject to payment rules other than those at section 1834(a)(3) of the Act.

- Amend § 414.210(g)(7) to indicate that beginning on or after the date that contracts take effect for a national mail order competitive bidding program that includes the Northern Mariana Islands, the fee schedule adjustment methodology under § 414.210(g)(7) would no longer apply.

Our Washington liaison, Larry Goldberg of Larry Goldberg Consulting, has provided us with this summary and comments. For questions, please contact Jeff Weegar, NCHA, at 919-677-4231, jweegar@ncha.org or Ronnie Cook, NCHA, at 919-677-4225, rcook@ncha.org.