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OVERVIEW:

On July 11, 2018, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule 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, 2019. 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 changes to the ESRD Quality Incentive Program (QIP).

The ESRD and Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) proposed rule is one of several rules for calendar year (CY) 2019 that reflect a broader Administration-wide strategy to relieve regulatory burdens for providers, support the patient-doctor relationship in healthcare, and promote transparency, flexibility, and innovation in the delivery of care.

CMS is committed to transforming the healthcare delivery system – and the Medicare program – by putting a strong focus on patient-centered care, so providers can direct their time and resources to patients and improve outcomes. In addition, this rule also proposes changes to bidding and pricing methodologies under the DMEPOS competitive bidding program (CBP); adjustments to DMEPOS Fee Schedule amounts using information from competitive bidding for items furnished on or after January 1, 2019; new payment classes for oxygen and oxygen equipment and a new methodology for ensuring that the classes 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.

CMS has yet to begin the process for recompeting DMEPOS CBP contracts, and the current DMEPOS CBP contract periods of performance will end on December 31, 2018. Beginning on January 1, 2019, beneficiaries may receive DMEPOS items from any willing supplier (until new contracts are awarded under the DMEPOS CBP). CMS will provide additional information about the DMEPOS CBP in the future.

In addition to the proposals in the rule, CMS is soliciting comments in a request for information (RFI) on the gap-filling process for establishing fees for new DMEPOS items. Specifically, CMS is soliciting comments for information on how the gap-filling process could be revised in terms of what data sources or methods could be used to estimate historic allowed charges for new technologies in a way that satisfies the exclusive payment rules for DMEPOS items and services, while preventing excessive overpayments or underpayments for new technology items and services.

PROPOSED CHANGES AND UPDATES TO THE ESRD PPS FOR CY 2019:

ESRD PPS BACKGROUND: Section 1881(b)(14) of the Social Security Act (the Act) requires the implementation of a bundled PPS for renal dialysis services furnished to Medicare beneficiaries for the treatment of ESRD effective January

1, 2011. The bundled payment under the ESRD PPS includes all renal dialysis services furnished for outpatient maintenance dialysis, including drugs and biologicals (with the exception of oral-only ESRD drugs until 2025) and other renal dialysis items and services that were formerly separately payable under the previous payment methodologies. The bundled payment rate is case-mix adjusted for a number of factors relating to patient characteristics. There are also facility-level adjustments for ESRD facilities that have a low patient volume, for facilities in rural areas, and for the wage index. For high-cost patients, an ESRD facility may be eligible for outlier payments. Under the ESRD PPS for CY 2019, Medicare expects to pay approximately \$10.6 billion to approximately 7,000 ESRD facilities for the costs associated with furnishing chronic maintenance dialysis services.

Update to the ESRD PPS base rate: The proposed CY 2019 ESRD PPS base rate is \$235.82, an increase of \$3.45 to the current base rate of \$232.37. This proposed amount reflects a reduced market basket increase as required by section 1881(b)(14)(F)(i)(I) of the Act (1.5 percent) and application of the wage index budget-neutrality adjustment factor (0.999833).

Rebasing of the CMS ESRD Bundled Market Basket and Labor-Related Share:

For CY 2019, we are proposing to rebase the ESRD Bundled market basket to reflect 2016 cost data. We periodically rebase the CMS market baskets in order to reflect more up-to-date cost structures faced by facilities. The main impact from the proposed rebasing of the ESRD Bundled market basket 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). From 2012 to 2016 the data indicate a relative increase in compensation costs and a relative decrease in all other costs, particularly drug costs.

Annual Update to the Wage Index and Wage Index Floor: The ESRD wage indices are adjusted on an annual basis using the most current hospital wage data and the latest Core-Based Statistical Area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. 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.

Update to the Outlier Policy: CMS annually updates the outlier policy using the most current data. 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 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. We believe using CY 2017 claims data to update the outlier MAP and FDL amounts for CY 2019 would increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1 percent outlier percentage.

Expansion of the Transitional Drug Add-on Payment Adjustment (TDAPA): In order to provide beneficiaries with more choices, promote innovation, and lower prices through competition, CMS is proposing to revise the drug designation process to allow all new renal dialysis drugs and biologicals as of January 1, 2019 regardless of whether they fit into an existing functional category, to be eligible for the TDAPA. However, after the end of the TDAPA period, modifications to the ESRD PPS base rate would not be available for new drugs that fall within existing functional categories.

Burden Reduction Related to the Comorbidity Adjustment: In response to our burden reduction RFI last year, stakeholders commented that CMS should reduce the documentation burden for obtaining the comorbidity payment adjustment to make the requirement consistent with other payment systems or eliminate the comorbidity payment adjustments altogether. CMS is proposing to rely on the International Classification of Diseases (ICD) official guidelines and general documentation requirements with regard to the comorbidity adjustment, consistent with other payment systems. These guidelines provide clear direction on the coding and sequencing of diagnosis codes and we would continue to monitor claims data to observe diagnosis reporting trends.

Impact Analysis: CMS projects that the updates for CY 2019 will increase the total payments to all ESRD facilities by 1.7 percent compared with CY 2018. For hospital-based ESRD facilities, CMS projects an increase in total payments of 1.8 percent, while for freestanding facilities, the projected increase in total payments is 1.7 percent.

PAYMENT FOR RENAL DIALYSIS SERVICES FURNISHED TO INDIVIDUALS WITH ACUTE KIDNEY INJURY (AKI):

As required by the Trade Preferences Extension Act of 2015, CMS is proposing to update the AKI dialysis payment rate for CY 2019 to equal the proposed CY 2019 ESRD PPS base rate and to apply the proposed CY 2019 wage index. For CY 2019, the proposed AKI dialysis payment rate is \$235.82.

PROPOSED CHANGES TO THE END-STAGE RENAL DISEASE QUALITY INCENTIVE PROGRAM (ESRD QIP)

ESRD QIP Background: Section 153(c) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended the Social Security Act to require CMS to establish an ESRD QIP that selects measures, establishes performance standards, specifies a performance period for each payment year (PY), assesses the total performance of each facility, applies an appropriate payment reduction to each facility that does not meet a minimum TPS, and publicly

reports the results. The ESRD QIP is intended to promote high-quality care by dialysis facilities treating beneficiaries with ESRD. This program changes the way CMS pays for the treatment of ESRD patients by linking a portion of payment directly to facilities' performance on quality measures. The ESRD QIP will reduce payments to ESRD facilities that do not meet or exceed a minimum TPS by up to two percent.

Proposals for the PY 2021 ESRD QIP

Removal of Four Reporting Measures: We propose removing four Reporting measures from the PY 2021 ESRD QIP's measure set to align with the Meaningful Measures Initiative. Our rationale for removing these four measures is based on the factor "The cost associated with a measure outweighs the benefit of its continued use in the program". The four Reporting measures that we propose removing are:

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

The proposals to remove these measures are consistent with CMS' commitment to using a smaller set of more meaningful measures. CMS is focusing on measures that provide opportunities to reduce both paperwork and reporting burden on providers and patient-centered outcome measures, rather than process measures. To accomplish these goals, CMS is proposing to adopt a new measure removal factor and to update the ESRD QIP Program's measure set.

New Domain Structure and Weights: We also propose restructuring the ESRD QIP's domains and measure weights to align with the Meaningful Measures Initiative. If finalized, the ESRD QIP will score participating facilities in four quality domains:

- Patient & Family Engagement,
- Care Coordination,
- Clinical Care, and
- Safety.

Expanded NHSN Validation: We also propose expanding 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.

Proposals for the PY 2022 ESRD QIP

New Measures: We propose adopting 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

New Measure: Finally, we also propose adopting 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:

Background for the DMEPOS CBP and Fee Schedule Payment Rules

The Medicare payment rules for durable medical equipment (DME) are set forth in section 1834(a) of the Act and 42 CFR part 414, subpart D of our regulations. Section 1834(a) of the Act governs payment for DME covered under Part B and under Part A for a home health agency and provides for the implementation of a fee schedule payment methodology for DME furnished on or after January 1, 1989. General payment rules for DME are set forth in section 1834(a) of the Act and § 414.210 of our regulations, and § 414.210 also contains paragraphs relating to payment for maintenance and servicing of items and replacement of items. Sections 1834(a)(2) through (a)(7) of the Act set forth separate payment categories of DME and describe how the fee schedule amounts for items under each of the categories are established. The payment rules for these categories are different and in some cases mutually exclusive. The Medicare payment basis for DME is equal to 80 percent of either the lower of the actual charge or the fee schedule amount for the item. The beneficiary coinsurance is equal to 20 percent of either the lower of the actual charge or the fee schedule amount for the item.

Section 1847(a) of the Social Security Act (the Act), as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires the Secretary of the Department of Health and Human Services (the Secretary) to establish and implement competitive bidding programs in competitive bidding areas (CBAs), referred to as the DMEPOS CBPs, throughout the United States for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services.

Section 16008 of the 21st Century Cures Act (the Cures Act) (Pub. L. 114-255) was enacted on December 13, 2016, and amended section 1834(a)(1)(G) of the Act to require, in the case of items and services furnished on or after January 1, 2019, that in making adjustments to the fee schedule amounts in accordance with sections 1834(a)(1)(F)(ii)

and (iii) of the Act, the Secretary shall: (1) solicit and take into account stakeholder input; and (2) take into account the highest bid by a winning supplier in a CBA and a comparison of each of the following factors with respect to non-CBAs and CBAs:

- The average travel distance and cost associated with furnishing items and services in the area.
- The average volume of items and services furnished by suppliers in the area.
- The number of suppliers in the area.

Proposals for the DMEPOS CBP and Fee Schedule Payment Rules

This 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 January 1, 2019 through December 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 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:
 - We are 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, we propose 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. We propose 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 December 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).
 - We are 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 January 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 January 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.

We are soliciting comments on these provisions.

Request for Information for the DMEPOS CBP and Fee Schedule Payment Rules

CMS is considering if changes should be made to the gap-filling process for establishing fees for newly covered DMEPOS items paid on a fee schedule basis. The gap-filling process allows Medicare to establish fee schedule amounts for new DMEPOS items that align with the statutory basis for the DMEPOS fee schedule. We are soliciting comments for information on how the gap-filling process could be revised in a way that complies with the exclusive statutory payment rules, but also prevents excessive overpayments or underpayments for new technology items and services.

The proposed rule was published in the July 11, 2018 Federal Register and can be downloaded from the Federal Register at: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-14986.pdf>.

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