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FACT SHEET

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CY2020 End-Stage Renal Disease/Durable Medical Equipment Final Rule (CMS 1713-F).

On October 31, 2019, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that updates 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, 2020. This rule also updates the acute kidney injury (AKI) dialysis payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI and finalizes changes to the ESRD Quality Incentive Program (QIP).

In addition, this rule finalizes a methodology for calculating fee schedule payment amounts for new Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) items and services and making adjustments to the fee schedule amounts established using supplier or commercial prices if such prices decrease within five years of establishing the initial fee schedule amounts. This rule also revises existing policies related to the competitive bidding program for DMEPOS. This final rule also streamlines the requirements for ordering DMEPOS items, and creates one Master List of DMEPOS items that could potentially be subject to face-to-face encounter and written order prior to delivery and/or prior authorization requirements. Finally, it also includes summaries of responses to requests for information on data collection resulting from the ESRD PPS technical expert panel, possible updates and improvements to the ESRD PPS wage index, and new rules for the competitive bidding of diabetic testing strips.

FINAL CHANGES AND UPDATES TO THE ESRD PPS FOR CY 2020:

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 biological products (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. The ESRD PPS provides a training add-on payment adjustment for home and self-dialysis modalities and, for high-cost patients, an ESRD

facility may be eligible for outlier payments. The ESRD PPS also provides for a transitional drug add-on payment adjustment (TDAPA). Under the ESRD PPS for CY 2020, Medicare expects to pay approximately $10.3 billion to approximately 7,000 ESRD facilities for the costs associated with furnishing renal dialysis services.

Update to the ESRD PPS Base Rate: The final CY 2020 ESRD PPS base rate is $239.33, an increase of $4.06 to the current base rate of $235.27. This amount reflects a reduced market basket 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 (1.000244).

Annual Update to the Wage Index: 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 2020, CMS updated the wage index values based on the latest available data.

Update to the Outlier Policy: CMS annually updates the outlier policy using the most current data. CMS is updating the outlier services fixed-dollar loss (FDL) amounts for adult and pediatric patients and Medicare Allowable Payment (MAP) amounts for adult and pediatric patients for CY 2020, using 2018 claims data. Based on the use of more current data, the FDL amount for pediatric beneficiaries will decrease from $57.14 to $41.04 and the MAP amount will decrease from $35.18 to $32.32, as compared to CY 2019 values. For adult beneficiaries, the FDL amount will decrease from $65.11 to $48.33 and the MAP amount will decrease from $38.51 to $35.78. The 1 percent target for outlier payments was not achieved in CY 2019. Outlier payments represented approximately 0.5 percent of total payments rather than 1.0 percent. CMS believes using CY 2018 claims data to update the outlier MAP and FDL amounts for CY 2020 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1 percent outlier percentage.

Eligibility Criteria for the Transitional Drug Add-on Payment Adjustment (TDAPA): CMS is revising the drug designation process regulation for new renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category by focusing eligibility on those drugs that are innovative. Specifically, CMS is excluding drugs approved by the Food and Drug Administration (FDA) 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 January 1, 2020.

Basis of Payment for the Transitional Drug Add-on Payment Adjustment (TDAPA) for Calcimimetics: CMS will continue to pay the TDAPA for calcimimetics for a third year in CY 2020 in order to collect sufficient claims data for rate setting analysis, but CMS is finalizing a change to 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 finalizing a policy 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 3rd calendar quarter after CMS begins applying the TDAPA. CMS will no longer apply the TDAPA for a new renal dialysis drug or biological product beginning no later than 2-

calendar quarters after CMS determines a full quarter of ASP data is not available. CMS is also finalizing a policy 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 2-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 is establishing a transitional add-on payment adjustment to support the use of certain new and innovative renal dialysis equipment or supplies furnished by ESRD facilities. CMS will pay this adjustment, which is called the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES), for equipment and supplies that: (1) have been designated by CMS as a renal dialysis service, (2) are new, meaning granted marketing authorization by FDA on or after January 1, 2020, (3) are commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, (4) have 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) are innovative, meaning they meet the substantial clinical improvement criteria specified in the Inpatient Prospective Payment System regulations at 42 CFR 412.87(b)(1) and related guidance, and (6) are not capital-related assets. Specifically, the equipment or supply must represent an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular calendar year. The TPNIES will be based on 65 percent of the price established by the Medicare Administrative Contractors, using the information from the invoice and other relevant sources of information. CMS will pay the TPNIES for 2 calendar years, after which the equipment or supply will qualify as an outlier service and no change to the ESRD PPS base rate will be made.

Discontinuing the Erythropoiesis-stimulating Agent (ESA) Monitoring Policy (EMP): CMS is discontinuing the application of the erythropoiesis-stimulating agent (ESA) monitoring policy (EMP) under the ESRD PPS.

Requests for Information:

Data Collection: A CMS data contractor conducted a Technical Expert Panel (TEP) on December 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, feedback received by TEP participants, and a summary of responses from stakeholders on the request for information in the CY 2020 ESRD PPS proposed rule are presented in the final rule. Additional TEP information and materials are available here: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.html.

Wage Index Solicitation: CMS included a request for information in the CY 2020 ESRD PPS proposed rule 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. A summary of responses to the request for information from stakeholders is presented in the final rule.

Impact Analysis: CMS projects that the updates for CY 2020 will increase the total payments to all ESRD facilities by 1.6 percent compared with CY 2019. For hospital-based ESRD facilities, CMS projects an increase in total payments of 2.1 percent, while for freestanding facilities, the projected increase in total payments is 1.6 percent.

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

As required by section 1834(r) of the Act, CMS is updating the AKI dialysis payment rate for CY 2020 to equal the CY 2020 ESRD PPS base rate and to apply the CY 2020 wage index. For CY 2020, the AKI dialysis payment rate is $239.33.

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

ESRD QIP Background: The End-Stage Renal Disease Quality Incentive Program (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).

- **Finalized Policies for the ESRD QIP:** This rule finalizes several programmatic updates beginning with the PY 2022 ESRD QIP, including an updated scoring methodology for the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure so that new facilities and facilities that are eligible to report data on the measure for less than 12 months can receive a score on the measure, and the conversion of the Standardized Transfusion Ratio (STrR) clinical measure (NQF #2979) to a reporting measure while CMS continues to examine concerns raised by stakeholders about the measure's validity. CMS is not finalizing its proposal to revise the scoring methodology for the Medication Reconciliation (MedRec) reporting measure and will continue to score that measure using the methodology it previously adopted.

CMS is also finalizing the performance and baseline periods for the PY 2023 ESRD QIP and that, beginning with the PY 2024 payment year, it will automatically adopt performance and baseline periods that are advanced 1 year from those specified for the previous payment year.

Finally, CMS is updating its regulation text for the program so that it better informs the public of the program's requirements. The updates include a new policy that allows facilities to reject an extraordinary circumstances exception granted by CMS under certain circumstances.

CHANGES TO THE DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS AND SUPPLIES (DMEPOS) FEE SCHEDULE PAYMENT RULES:

Background for the DMEPOS Fee Schedule Payment Rules

Medicare fee schedule amounts for DMEPOS items and services are generally based on average reasonable charges from a historic base period, increased by annual update factors and adjusted

by a productivity adjustment factor. Section 1834 of the Act notes that this is the exclusive payment rule for these items under the statute.

The Medicare payment amount for a DMEPOS item is generally equal to 80 percent of the lesser of the actual charge or the fee schedule amount for the item, less any unmet Medicare Part B deductible. The beneficiary coinsurance for such items is generally equal to 20 percent of the lesser of the actual charge or the fee schedule amount for the item once the deductible is met.

The statute does not specify how to calculate fee schedule amounts when the base reasonable charge data does not exist. Since 1989, CMS has used a process referred to as "gap-filling" to fill the gap in the reasonable charge data for new DMEPOS items, which are newly covered items or technology. . The gap-filling process is used to estimate what Medicare would have paid for the item under the reasonable charge payment methodology during the period of time from which reasonable charge data is used to calculate the fee schedule amounts, or the fee schedule base period (for example, 1986 to 1987 for DME). Various methods have been used by CMS and its contractors to gap-fill DMEPOS fee schedule amounts including use of fees for comparable items, supplier prices, manufacturer's suggested retail prices (MSRPs), wholesale prices plus a markup percentage to convert the prices to retail prices, or other methods.

Changes for the DMEPOS Fee Schedule Payment Rules

This rule finalizes a methodology for determining the fee schedule amounts for new DMEPOS items and services.
If it is determined that the new item is comparable to the older existing item(s), CMS will use the fee schedule amounts for the older existing item(s) to establish the fee schedule amounts for the new item. If it is determined that there are no comparable items to use for gap-filling purposes, the fee schedule amounts for a new item would be based on other sources of commercial pricing data such as retail prices or information from supplier invoices deflated to the fee schedule base period and updated by the covered item update factors. Also, in consideration of comments received, CMS is not finalizing the use of technology assessments to establish the fee schedule amounts for new DMEPOS items at this time in order to have the opportunity to consider additional information on the use of technology assessments. CMS will consider whether to include a revised proposal addressing the use of technology assessments in future rulemaking.

CMS is also finalizing a one-time adjustment to gap-filled fee schedule amounts if, within 5 years of establishing the initial fee schedule amounts for a new item based on supplier or commercial prices, the supplier or commercial prices decrease by less than 15 percent.

Conditions of Payment to be Applied to Certain DMEPOS Items

CMS is simplifying its DMEPOS payment requirements so that practitioners and suppliers can focus their attention on caring for Medicare beneficiaries. CMS is streamlining and harmonizing prior regulatory requirements to help with this effort.

In an April 2006 final rule (71 FR 17021), CMS established face-to-face examination and written order prior to delivery requirements for a list of power mobility devices. In a November 2012 final rule (77 FR 68892), CMS separately created a list of Specified Covered Items to be subject to face-to-face encounter and written order prior to delivery requirements. In a December 2015 final rule (80 FR 81674), CMS created a "Master List" of items that are potentially subject to

prior authorization upon selection. The rule harmonizes the lists created by the former rules, to develop one "Master List" which serves as a library of items from which an item may be selected to be subject to face-to-face encounter and written order prior to delivery and/or prior authorization requirements.

Similarly, while prescription requirements aim to create uniformity and exactness in healthcare delivery, over time the implementation of overlapping instruction created various requirements for written orders/prescriptions, dependent upon the type of DMEPOS being ordered. This may have created unintended confusion for stakeholders. This finalized rule creates one standardized set of required elements for all DMEPOS orders.

CMS believes streamlining requirements furthers the CMS' efforts to reduce fraud, waste, and abuse by promoting a better understanding of Medicare DMEPOS conditions of payment, which may result in increased compliance.

Request for Information for Sources of Market-Based Data Measuring Sales of Diabetic Testing Strips to Medicare Beneficiaries (Section 50414 of the Bipartisan Budget Act of 2018)

The Bipartisan Budget Act of 2018 (BBA) was enacted on February 9, 2018, and section 50414 of the BBA amended section 1847(b)(10)(A) of the Act to establish additional rules for the national mail order DMEPOS Competitive Bidding Program (CBP) for diabetic testing supplies. Section 1847(b)(10)(A) of the Act now requires that for bids to furnish diabetic testing strips on or after January 1, 2019, the volume for such products be determined by the Secretary through the use of multiple sources of data (from mail order and non-mail order Medicare markets), including market-based data measuring sales of diabetic testing strip products that are not exclusively sold by a single retailer from such markets.

The Office of Inspector General (OIG) reports to CMS the Medicare Part B market share of mail order diabetic test strips before each round of the Medicare national mail order CBP, and pursuant to section 1847(b)(10)(A) of the Act, the OIG will now report on the non-mail order diabetic test strip Medicare Part B market. Because section 1847(b)(10)(A) of the Act now requires the use of "multiple sources of data," CMS requested public comments on other potential sources of data (sources other than the OIG), that fulfill the data requirements set forth in section 1847(b)(10)(A) of the Act. CMS requested comments on other potential sources of data because the word "multiple" in the phrase "multiple sources of data" could mean that CMS should use more than one source of data, and that the OIG is one source of data. CMS therefore requested comments from the public on other potential sources of data regarding the mail order and non-mail order Medicare markets for diabetic testing strips through this request for information.

CMS received 6 comments from suppliers, industry representative groups, and others in response to this Comment Solicitation on Sources of Market-Based Data Measuring Sales of Diabetic Testing Strips to Medicare Beneficiaries. Of the comments CMS received, none included data, or readily available sources of data, and were otherwise outside the scope of the request for information. CMS summarized the responses to this request for information in the final rule.

DMEPOS CBP Change of Ownership (CHOW) Process

CMS will no longer require contract suppliers under the DMEPOS Competitive Bidding Program to notify CMS 60 days in advance of a CHOW. CMS is making this change because it is not always necessary or possible to be notified 60 days in advance of a CHOW. Instead, CMS will now require notification no later than 10 days after the effective date of the CHOW. Additionally, CMS removed the distinction of a "new entity" in its entirety, and retained the successor entity requirements as we align the CHOW requirements for all entities, regardless of whether a "new" entity is formed as a result of the CHOW. We are also finalizing a few more changes to the CHOW regulations and the breach of contract regulations at § 414.423.

The final rule is displayed in the October 31, 2019 Federal Register and can be downloaded at: http://www.federalregister.gov/inspection.aspx

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