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FACT SHEET

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End Stage Renal Disease (ESRD) and Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) CY 2020 Proposed Rule (CMS-1713-P)

On July 29, 2019, 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, 2020. 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).

In addition, this rule proposes 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 would also make amendments to revise existing policies related to the competitive bidding program for DMEPOS. This proposed rule would also streamline the requirements for ordering DMEPOS items, and create 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 would also include requests for information on data collection resulting from the ESRD PPS technical expert panel, on possible updates and improvements to the ESRD PPS wage index, and on new rules for the competitive bidding of diabetic testing strips.

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

Update to the ESRD PPS base rate: The proposed CY 2020 ESRD PPS base rate is $240.27, an increase of $5.00 to the current base rate of $235.27. This proposed 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 (1.004180).

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 is proposing to update 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 proposing to update 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 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 FDL amount would decrease from $65.11 to $52.50 and the MAP amount would decrease from $38.51 to $36.60. The 1 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. CMS believes using CY 2018 claims data to update the outlier MAP and FDL amounts for CY 2020 would 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 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 (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: We are continuing 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 are 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 3rd calendar quarter after we begin applying the TDAPA. We would no longer apply the TDAPA for a new renal dialysis drug or biological product beginning no later than 2 calendar quarters after we determine 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 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 has proposed to provide a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS, as part of our goal to spur innovation to encourage the uptake of the latest renal dialysis treatments by ESRD facilities. 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 January 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 (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures. We are 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. We would pay the TPNIES for 2 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.

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

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, as well as feedback received by TEP participants, is presented in the proposed rule for public comment. 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: 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.

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 1.9 percent, while for freestanding facilities, the projected increase in total payments is 1.5 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 proposing to update the AKI 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 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),), and publicly reports the results.

Proposals for the PY 2022 and 2023 ESRD QIP: This proposed rule proposes several programmatic updates to the ESRD QIP, which include but are not limited to the following:

- Updating the scoring methodology for the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure so that new facilities and facilities with an approved ECE can receive a score on the measure. CMSCMS does not believe that the current policy appropriately accounts for the effort made by these facilities to report these data for the months in which they are eligible to report. In addition, if a facility is aware that it will not be eligible to receive a score on this measure, CMSCMS is concerned that the facility will not be incentivized to report data at all for that payment year.

- Converting the STrR clinical measure (NQF #2979) into a reporting measure in response to concerns raised about the measure's validity. CMSCMS would like to ensure that the Program's scoring methodology results in fair and reliable STrR measure scores because those scores are linked to dialysis facilities' TPS and possible payment reductions. CMSCMS believes that this approach is the most appropriate way to continue fulfilling the statutory requirement to include a measure of anemia management in the Program while ensuring that dialysis facilities are not adversely affected during our continued examination of the measure.

- Adding new regulation text that would codify automatic adoption of the baseline period

and performance period for each payment year; data submission requirements for calculating measure scores; and requirements for the Extraordinary Circumstances Exception (ECE) process, including a new option for facilities to turn down an ECE granted by CMS under certain circumstances. The new regulation text will provide clear guidance to the public on these program requirements.

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 based on average reasonable charges from a historic base period, increased by annual update factors and adjusted by a productivity adjustment factor. 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 or items paid under Healthcare Common Procedure Coding System (HCPCS) codes for miscellaneous items. 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.

Proposals for the DMEPOS Fee Schedule Payment Rules

CMS believes that establishing a set framework and basis for identifying comparable items in regulation would improve the transparency and predictability of establishing fees for new DMEPOS items. Therefore CMS undertook a review of the major components and attributes of DMEPOS items that are evaluated when determining whether items are comparable in order to develop and propose a standard for when and how fees for comparable items would be used to establish fees for new items. CMS identified five main categories upon which new DMEPOS items can be compared to older DMEPOS items: physical components; mechanical components; electrical components (if applicable); function and intended use; and additional attributes and features.

As shown in Table 1, a comparison can be based on, but not limited to, these five main components and various attributes falling under the five main components. When examining whether an item is comparable to another item, the analysis can be based on the items as a whole or its subcomponents. A new product does not need to be comparable within each category, and

there is no prioritization of the categories. The attributes listed in Table 1 under the five main components are examples of various attributes CMS evaluates within each category.

TABLE 1: Comparable Item Analysis (Any combination of, but not limited to, the categories below for a device or its subcomponents)

Components	Attributes
Physical Components	Aesthetics, Design, Customized vs. Standard, Material, Portable, Size, Temperature Range/Tolerance, Weight
Mechanical Components	Automated vs. Manual, Brittleness, Ductility, Durability, Elasticity, Fatigue, Flexibility, Hardness, Load Capacity, Flow-Control, Permeability, Strength
Electrical Components	Capacitance, Conductivity, Dielectric Constant, Frequency, Generator, Impedance, Piezoelectric, Power, Power Source, Resistance
Function and Intended Use	Function, Intended Use
Additional Attributes and Features	"Smart", Alarms, Constraints, Device Limitations, Disposable Parts, Features, Invasive vs. Non-Invasive

CMS is proposing to include in regulations how Medicare pricing is determined for new DMEPOS items. For new DMEPOS items without a pricing history, we propose to establish five main categories of components or attributes of DMEPOS items (as shown in Table 1) that would be evaluated to determine if a new item is comparable to older existing item(s) for gap-filling purposes. If it is determined that the new item is comparable to the older existing item(s), CMS is proposing to use the fee schedule amounts for the older existing item(s) to establish the fee schedule amounts for the new item. CMS is also proposing that 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, more accurate sources of commercial pricing data to establish Medicare payments -- such as internet retail prices or information from supplier invoices -- deflated to the fee schedule base period and updated by the covered item update factors. If supplier or commercial price lists are not available or verifiable or do not appear to represent a reasonable relative difference in supplier costs of furnishing the new DMEPOS item relative to the supplier costs of furnishing DMEPOS items from the fee schedule base period, CMS proposes to use technology assessments that determine the relative costs of the newer DMEPOS items compared to older DMEPOS item(s) to establish the fee schedule amounts for the newer DMEPOS items.

CMS recognizes that the gap-filling method of using supplier prices could result in excessive fee schedule amounts in cases where the market for the new category of items is not yet competitive due to a limited number of manufacturers and suppliers. CMS believes that if supplier or commercial prices are used to establish fee schedule amounts for new items, and the prices then go down once the market for the new items is more established, that Medicare should adjust its rates based on the new, updated prices. Thus, if the supplier or commercial prices used to establish fee schedule amounts for a new DMEPOS item decrease by no more than 15 percent within 5 years of establishing the initial fee schedule amounts are established, CMS believes a one-time adjustment to the fee schedule amounts using the new, lower prices is a reasonable adjustment. CMS does not believe that a similar adjustment is necessary to account for increases in prices since the fee schedule calculation methodology already includes an annual covered item update to address increases in costs of furnishing items and services over time.

CMS is proposing a one-time adjustment based on decreases in prices because in many cases, fee schedule amounts may be gap-filled using manufacturer prices or prices from other payers for new technology items that may only be made by one manufacturer with limited competition. In these situations, competition from other manufacturers or increases in the volume of items paid for could bring down the market prices for the item within a relatively short period of time after the initial fee schedule amounts are established. CMS does not believe that the reverse would be common where prices increase within a short period of time after the item comes on the market and fee schedule amounts are initially established for the item. CMS therefore is not proposing similar one-time increases in fee schedule amounts established using supplier or commercial prices, however, we invite comments on this issue. In cases where supplier or commercial prices used to establish original gap-filled fee schedule amounts increase or decrease by 15 percent or more after the initial fee schedule amounts are established, this would generally mean that the fee schedule amounts are now grossly excessive or deficient as compared to when the fee schedule amounts were initially established. In such circumstances we believe that an adjustment to the fee schedule amounts could be considered in accordance with regulations at § 405.502(g). We can also consider whether changes to the regulations at § 405.502(g) should be made in the future to specifically address situations where supplier or commercial prices change by 15 percent or more and how this information could potentially be used to adjust fee schedule amounts established using supplier or commercial prices.

Conditions of Payment to be Applied to Certain DMEPOS Items

CMS proposes to simplify our DMEPOS payment requirements so that practitioners can focus their attentions on caring for Medicare beneficiaries. To help with this effort, CMS is proposing to streamline the requirements for ordering DMEPOS items, and also propose to develop a single list of DMEPOS items potentially subject to a face-to-face encounter and written orders prior to delivery, and/or prior authorization requirements.

In an April 2006 final rule (71 FR 17021), we established face-to-face examination and written order prior to delivery requirements for 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, based on criteria currently outlined in § 410.38. 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.

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

The rule further proposes to harmonize and simplify requirements by adopting the structure of a "Master List", as conceptually introduced under the prior authorization process, to also apply in the context of face-to-face encounter and written order prior to delivery requirements. The proposal would harmonize the three lists resulting from the former rules and develop one Master List of items potentially subject to prior authorization and/or the face-to-face encounter and written order prior to delivery requirement. It would also update the prior authorization program to more nimbly adapt to changes in billing, and to likewise recognize and offer relief when specific suppliers demonstrate billing compliance.

CMS believes streamlining requirements would further the agency's efforts to reduce waste, fraud, 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 is requesting public comments on other potential sources of data (sources other than the Office of Inspector General), that fulfill the data requirements set forth in section 1847(b)(10)(A) of the Act. CMS is requesting comments on other potential sources of data because the word "multiple" in the phrase "multiple sources of data" could mean that we should use more than one source of data, and that the OIG is one source of data. Therefore, CMS is requesting comments from the public on other potential sources of data through this request for information.

DMEPOS CBP CHOW Process

CMS is proposing to no longer require contract suppliers to notify CMS 60 days in advance of a CHOW. We are proposing this change as we believe it is not always necessary or possible to be notified 60 days in advance of a CHOW. Instead, we are requiring notification no later than 10 days after the effective date of the CHOW. Additionally, we are proposing to remove the distinction of a "new entity" in its entirety, and retain the successor entity requirements as we are aligning the CHOW requirements for all entities, regardless of whether a "new" entity is formed as a result of the CHOW.

The proposed rule is displayed in the July 29, 2019 Federal Register and can be downloaded at: http://www.federalregister.gov/inspection.aspx.

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