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Contact	press@cms.hhs.gov

CMS Proposed Updates to Policies and Payment Rates for End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (CMS 1674-P)

On June 29, 2017, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would 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, 2018. In addition, 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.

The ESRD PPS proposed rule also proposes changes to the ESRD Quality Incentive Program (QIP), including for payment years (PYs) 2019, 2020, and 2021, under which payment incentives are made to dialysis facilities to improve the quality of care that they provide. The proposed rule includes updates to the ESRD QIP Extraordinary Circumstances Exception Policy (ECE), Performance Score Certificate, National Healthcare Safety Network (NHSN) dialysis event data validation sampling methodology, and quality measures. The proposed rule also requests comments on how to include individuals with AKI in the ESRD QIP and the feasibility and appropriateness of accounting for social risk factors in the program.

The ESRD PPS proposed rule is one of several rules for calendar year (CY) 2018 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 to the proposed rule, CMS is releasing a Request for Information (RFI) to welcome continued feedback on the Medicare program. CMS is committed to maintaining flexibility and efficiency throughout the Medicare program. Through transparency, flexibility, program simplification, and innovation, we aim to transform the Medicare program and promote the availability of high value and efficiently-provided care for its beneficiaries.

CMS would like to start a national conversation about improving the healthcare delivery system, and how Medicare can contribute to making the delivery system less bureaucratic and complex, and how we can reduce burden for clinicians, providers, and patients in a way that increases quality of care and decreases costs – thereby making the healthcare system more effective, simple and accessible while maintaining program integrity and preventing fraud.

CMS is soliciting ideas for regulatory, sub-regulatory, policy, practice, and procedural changes to better accomplish these goals. Ideas could include recommendations regarding payment system re-design, elimination, or streamlining of reporting, monitoring and documentation requirements, operational flexibility and feedback mechanisms and data sharing that would enhance patient care, support the doctor-patient relationship in care delivery, and facilitating patient-centered care within the End Stage Renal Disease Program. Ideas could also include recommendations regarding when and how CMS issues regulations and policies, and how CMS can simplify rules and policies for Medicare beneficiaries, clinicians, providers and suppliers.

In responding to the RFI, CMS should be provided with clear and concise proposals that include data and specific examples. If the proposals involve novel legal questions, analysis regarding CMS' authority is welcome. CMS will not respond to RFI comment submissions in the final rule, but rather will actively consider all input in developing future regulatory proposals or future sub-regulatory guidance.

PROPOSED CHANGES AND UPDATES TO THE ESRD PPS FOR CY 2018:

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 wage index. For high-cost patients, an ESRD facility may be eligible for outlier payments. Under the ESRD PPS for CY 2018, Medicare expects to pay approximately \$10.0 billion to approximately 6,750 ESRD facilities for the costs associated with furnishing chronic maintenance dialysis services.

Update to the ESRD PPS base rate: The proposed CY 2018 ESRD PPS base rate is \$233.31, an increase of \$1.76 to the current base rate of \$231.55. This amount reflects a reduced market basket increase as required by section 1881(b) (14)(F)(i)(I) of the Act (0.7 percent) and application of the wage index budget-neutrality adjustment factor (1.000605).

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 2018, CMS is not proposing any changes to the application of the wage index, and we propose to continue to apply the current wage index floor (0.4000) to areas with wage index values below the floor.

Update to the Outlier Policy: Consistent with the proposal to annually update 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 2018 using 2016 claims data. Based on the use of more current data, the FDL amount for pediatric patients would decrease from \$68.49 to \$49.55 and the MAP amount would decrease from \$38.29 to \$38.25. For adult patients, the FDL amount would increase from \$82.92 to \$83.12 and the MAP amount would decrease from \$45.00 to \$42.70. In CY 2016, outlier payments were 0.78 percent of total ESRD PPS payments, slightly less than the 1.0 percent target for outlier payments. Using CY 2016 claims data to update the outlier MAP and FDL amounts for CY 2018 would increase outlier payments for ESRD beneficiaries requiring higher resource utilization.

In order to have pricing options for certain drugs and biologicals that do not have an average sales price (ASP), CMS is proposing to expand pricing options for drugs and biologicals to all methodologies available under Section 1847A of the Act. In addition to the ASP methodology for pricing drugs and biologicals under Part B, section 1847A of the Act provides Medicare Administrative Contractors other pricing options if the ASP is unavailable during the first quarter of sales, such as the Wholesale Acquisition Cost or Average Manufacturer Price.

Impact Analysis: CMS projects that the updates for CY 2018 will increase the total payments to all ESRD facilities by 0.8 percent compared with CY 2017. For hospital-based ESRD facilities, CMS projects an increase in total payments of 1.0 percent, while for freestanding facilities, the projected increase in total payments is 0.8 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 rate for CY 2018 to equal the proposed CY 2018 ESRD PPS base rate and to apply the proposed CY 2018 wage index. For CY 2018, the proposed AKI base rate is \$233.31.

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

ESRD QIP Background: Section 1881(h) of the Social Security Act requires the implementation of an ESRD QIP that selects measures, establishes performance standards, specifies a performance period for each PY, assesses the total performance of each facility, applies an appropriate payment reduction to each facility that does not meet a minimum Total Performance Score (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 by up to 2 percent if they do not meet or exceed a minimum TPS.

Comments on the treatment of AKI patients in ESRD QIP: The Trade Preferences Extension Act of 2015 (TPEA) provides coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Social Security Act to an individual with AKI.

As a result of this change in the law, we believe that we now have authority to include this population in the measures we use for the ESRD QIP. We believe that it is vitally important to monitor and measure the quality of care AKI patients receive. We are seeking comment in this proposed rule on whether and how to adapt any of our current measures to include this population. We are also seeking comment on the types of measures that might be appropriate for future inclusion in the program that would address the unique needs of beneficiaries with AKI.

Comments on the inclusion of social risk factors in ESRD QIP: We are seeking comment on whether we should account for social risk factors in the ESRD QIP and, if so, which social risk factors (examples of which include, but are

not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic areas of residence) might be most appropriate for stratifying measure scores and/or potential risk adjustment of a particular measure.

Proposals Beginning with the PY 2019 ESRD QIP

Updates to the Performance Score Certificate (PSC): Beginning in PY 2019, we are proposing to shorten the Performance Score Certificates (PSCs) for the ESRD QIP to make the document simpler and easier to understand. Specifically, we are proposing that the revised PSC would indicate the facility's TPS for the applicable payment year, information sufficient to identify the facility, and information showing how well the facility performed compared to the national average.

Proposals Beginning with to the PY 2020 ESRD QIP

We are proposing to change the ESRD QIP Extraordinary Circumstances Exception (ECE) policy to better align with the ECE policy adopted by other CMS Medicare quality programs. Specifically, we are proposing to require that the facility submit the ECE form within 90 days following the event and to expand the reasons for which an ECE can be requested to include an unresolved issue with a CMS data system which affected the ability of the facility to submit data. We are also proposing that the facility would not need to be closed to request an ECE exception, as long as the facility could show that its normal business operations were significantly affected due to an extraordinary circumstance beyond the control of the facility.

Updates to the sampling method used to validate National Healthcare Safety Network (NHSN) dialysis event data: Beginning with PY 2020, we are proposing to continue conducting the same NHSN dialysis event validation study that we finalized in the CY 2017 ESRD PPS final rule for PY 2019 (81 FR 77894). However, we are proposing to adjust the sampling method used to select the 35 facilities in order to ensure that a more-representative sample of high-performing and low-performing facility data can be analyzed.

Proposals for the PY 2021 ESRD QIP

Replacement of Existing Measures with New and Improved Measures: The proposed PY 2021 ESRD QIP measure set includes eight measures in the Clinical Measure Domain, two measures in the Safety Measure Domain, and six measures in the Reporting Measure Domain. These 16 measures address anemia management, dialysis adequacy, vascular access type, patient experience of care, infections, mineral metabolism management, safety, pain management, depression management, and hospital readmissions. Similar to what we finalized for PY 2020, we are proposing to apportion 75 percent of a facility's TPS to the Clinical Measure Domain, 15 percent to the Safety Measure Domain, and 10 percent to the Reporting Measure Domain for PY 2021.

We are proposing to remove the current Vascular Access Type clinical measures in PY 2021, and to replace them with new measures—Standard Fistula Rate and Long-Term Catheter Rate—that were recently endorsed by with National Quality Forum (NQF). Further, CMS proposes to use CROWNWeb, rather than Medicare claims data, as the primary data source these new measures.

Likewise, we are proposing revisions to the Standardized Transfusion Ratio clinical measure so that the specifications for that measure are consistent with the specifications that were endorsed by the NQF.

The proposed rule will be published in the July 5, 2017 Federal Register and can be downloaded from the Federal Register at: <http://www.federalregister.gov/inspection.aspx>.

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