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September 23, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6082-NC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1713-P: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements

Dear Administrator Verma:

The American Kidney Fund appreciates the opportunity to provide comments on the proposed rule that would update and make revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2020 and update requirements for the ESRD Quality Incentive Program (QIP).

The American Kidney Fund (AKF) fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. Through programs of prevention, early detection, financial support, disease management, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator and the Platinum Seal of Transparency from GuideStar.

AKF is also a member of Kidney Care Partners (KCP), an alliance of members of the kidney care community. In addition to our comments below, we support the comments that KCP has submitted.

Proposed Update to Requirements Beginning with the PY 2022 ESRD QIP

Proposed Update to the Scoring Methodology for the National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure

CMS proposes to update the scoring methodology for the NHSN Dialysis Event reporting measure, beginning with the PY 2022 ESRD QIP, by removing the measure's exclusion of facilities with fewer than 12 eligible reporting months. CMS would assess facilities based on the number of months they are eligible to report the measure. Specifically, facilities would receive credit for scoring purposes based on the number of months they successfully report data out of the number of eligible months.

AKF supports this proposed change to the NHSN Dialysis Event measure. We agree with CMS that accurately capturing NHSN data enables facilities to implement their own quality improvement initiatives and enables the Centers for Disease Control and Prevention (CDC) to design and disseminate prevention strategies. Therefore, encouraging new facilities or facilities granted an Extraordinary Circumstances Exception to report this data for the months in which they are eligible to report will provide a more complete picture of NHSN data.

AKF also recommends that CMS submit the NHSN Dialysis Event measure to the National Quality Forum (NQF) for review.

Proposal to Convert the Standardized Transfusion Ratio (STrR) Clinical Measure to a Reporting Measure

CMS proposes to convert the STrR clinical measure to a reporting measure while it continues to examine concerns raised by stakeholders regarding the measure's validity. Specifically, there are concerns that due to the new level of coding specificity required under ICD-10, many hospitals may not be accurately coding blood transfusions.

AKF supports the proposal to convert the STrR clinical measure to a reporting measure as CMS further examines the validity concerns. We also reiterate our prior recommendation that a hemoglobin less than 10 measure (Hgb < 10 g/dL), once fully endorsed by NQF, would be a preferable anemia outcome measure because it would be actionable by physicians since they have access to hemoglobin data in the facility; they do not have access to STrR data. A more actionable anemia outcome measure will have a greater positive effect on patient care.

Proposed Update to the MedRec Reporting Measure's Scoring Methodology

CMS proposes to change the Medication Reconciliation (MedRec) reporting measure's scoring equation before its introduction in PY 2022 to use the term "facility-months" instead of "patient-months." CMS notes that facility-months is consistent with the scoring methodology used for all reporting measures that require monthly reporting.

AKF recommends that CMS maintain the use of patient-months in the MedRec measure's scoring equation, as that would align with the specifications reviewed and endorsed by NQF.

Other AKF Comments on the PY 2022 ESRD Measure Set

In addition to our comments on CMS' proposed updates to the measures above, AKF would also like to reiterate concerns and recommendations on the following measures in the PY 2022 ESRD measure set:

- **Kt/V Dialysis Adequacy Measure:** AKF remains concerned about including all dialysis populations in a single dialysis adequacy measure, which has been rejected by NQF. We support the use of dialysis adequacy measures in the QIP. However, the Kt/V Dialysis Adequacy measure proposed for PY 2022 and future years, which pools adult and pediatric hemodialysis and peritoneal patients into a single denominator, is problematic because it masks important differences in performance among specific patient populations and dialysis modalities. Therefore, patients may not be able to accurately discern a facility's performance on the different dialysis modalities, which is concerning given the Administration's emphasis on encouraging the use of home dialysis. AKF recommends that CMS instead use other NQF-endorsed dialysis adequacy measures that allow patients to better understand a facility's performance on different dialysis modalities.
- **Hypercalcemia Measure:** As we have stated in previous letters, AKF remains concerned about the inclusion of the hypercalcemia measure in the ESRD QIP. We understand that CMS has a statutory requirement to include a mineral metabolism measure. However, the hypercalcemia measure may not be the most appropriate, given that nephrologists agree that the metric is not the best measure to affect patient outcomes and the NQF has concluded the measure is topped out. AKF encourages CMS to work with the kidney community to find an appropriate replacement measure. In the interim, we recommend that the hypercalcemia measure be removed from the QIP while replacing it with the serum phosphorus measure.
- **National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) Measure:** AKF opposes the inclusion of the NHSN BSI measure as a clinical measure until its validity and reliability are determined. AKF commends CMS for its continued efforts to encourage reduction in blood stream infections in the dialysis patient population. Decreasing infections is a very important factor in improved patient outcomes and decreased hospitalizations. AKF does not believe, however, that the NHSN BSI measure is valid. This concern has been corroborated by various sources, including CMS and the measure developer. Until the validity issues, caused primarily by under reporting, are resolved, we recommend that the NHSN BSI measure be used as a reporting measure and that the problems with the reliability of the measure be resolved prior to implementing it as a clinical measure.
- **In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems Survey and Experience of Care (ICH CAHPS) Measure:** AKF urges CMS to continue to work with the kidney community to improve the ICH CAHPS measure and make modifications that reduce the burden on patients and encourage patient participation. Acquiring and maintaining an accurate record of the patient experience is essential to improving care and outcomes. However, the current ICH CAHPS measure response rate is very low, due in large part to patient survey fatigue. Our recommendations to address the fatigue problem and the low

response rates include dividing the survey into three sections that are independently tested and administering the survey once a year instead of twice a year.

We also want to stress the importance of ensuring the survey is accurately administered and is available through different delivery modes. Given that minority groups are disproportionately affected by ESRD, it is important that the lingual translations of the surveys are accurate so that foreign language speakers can provide meaningful responses. Also, allowing patients to respond to ICH CAHPS via a mobile device would help improve the response rate, especially for those patients who may use a smartphone as their main connection to the internet.

AKF also encourages CMS to work with stakeholders to develop an additional CAHPS survey for home dialysis patients, especially given the Administration's emphasis on encouraging the use of home dialysis. It is critically important that the patient experience in home dialysis is formally captured.

- **Percentage of Prevalent Patients Waitlisted (PPPW):** AKF fully supports the inclusion of meaningful transplant measures in the QIP. As we have noted in the past, there are areas for improvement for both dialysis facilities and transplant centers that CMS should examine. For example, it is important to incorporate transplant measures in the QIP to help improve transplantation rates, and it is important that the measures be actionable by dialysis facilities to have an impact on patient access to a transplant. However, the Percentage of Prevalent Patients Waitlisted measure is not actionable by dialysis facilities since the decision to add a patient to the transplant waitlist is made by the transplant center. Also, the measure has not been endorsed by the NQF because it does not meet the scientifically based criteria used to evaluate measures. CMS should work with the kidney community towards developing a facility-level measure that includes referring a patient to a transplant center and assisting a patient in securing and attending their first appointment. This type of measure would better capture actions that the facility can be held accountable, while also encouraging prompt evaluation of patients.

Thank you for your consideration of AKF's comments and recommendations.

Sincerely,



LaVarne A. Burton
President and CEO