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September 3, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS-1732-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program

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) 2021 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 2023 ESRD QIP

Proposed Update to the scoring methodology for the Ultrafiltration Rate reporting measure

CMS proposes to modify the scoring methodology for the Ultrafiltration Rate reporting measure so that facilities would be scored based on the number of eligible patient-months, as opposed to facility-months. AKF supports this proposed

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change, as it would correspond with the National Quality Forum (NQF)-endorsed measure, which uses a patient-month construction. We agree with CMS that this methodology is more objective, will better support CMS' goal of assessing performance on whether a facility is documenting ultrafiltration rate for its eligible patients, and will lead to better patient outcomes.

We also appreciate that CMS reaffirms in the proposed rule that the agency will be using the patient-months methodology for the Medication Reconciliation (MedRec) reporting measure, which AKF recommended in our comment letter on the CY 2020 proposed rule. Using the patient-months construction for both the Ultrafiltration Rate and MedRec reporting measures is consistent with the specifications reviewed and endorsed by NQF, and we support these changes.

Other AKF Comments on the PY 2023 ESRD QIP 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 2023 ESRD QIP measure set:

- **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.

- **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 2023 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 as a reporting 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 bloodstream 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 CMS rely on the NHSN Dialysis Event reporting measure to inform patients on whether a facility is reporting bloodstream infections. This would be an interim step while the problems with the reliability of the BSI measure are resolved prior to implementing it as a clinical measure.

- **Standardized Transfusion Ratio (STrR) Reporting Measure:** AKF supports CMS' prior decision to convert the STrR clinical measure to a reporting measure as CMS further examines the validity concerns related to the coding of blood transfusions under ICD-10. 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.

- **Percentage of Prevalent Patients Waitlisted (PPPW):** AKF fully supports the inclusion of meaningful transplant measures in the QIP. 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 NQF-endorsed facility-level measure that may include 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.

Updates and Revisions to the ESRD PPS for CY 2021

Inclusion of calcimimetics in the ESRD PPS base rate

AKF supports CMS' proposal to modify the ESRD PPS base rate to include calcimimetics in the ESRD PPS bundled payment. While we support the proposed methodology to determine the per treatment rate that will be added to the base rate, we recommend two modifications related to the utilization data and price that are used for the proposed methodology.

Instead of using CY 2018 and 2019 utilization data for calcimimetics, as CMS proposes, we recommend the use of the most recent publicly available 12-month utilization data to establish the utilization rate. The data from 2018 is not an accurate reflection of the utilization of calcimimetics due to challenges related to the implementation of the transitional drug add-on payment adjustment (TDAPA). In particular, data from the first quarter of 2018 is not an accurate reflection of utilization because many patients had a supply of Part D oral calcimimetics from the previous year that they were using at the start of 2018, which reduced utilization under Part B and slowed the adoption of the IV product.

In addition to using data that more accurately captures the utilization of calcimimetics, using the most recent publicly available data would align with the approaches in other Medicare payment systems, such as the inpatient and hospital outpatient prospective payment systems, which use claims data from the most recent year.

With regards to the price used for the methodology, AKF supports the proposal to use the most recent quarter of Average Sales Price (ASP), but instead of ASP+0 percent, as CMS proposes, we recommend ASP+6 percent. This would more accurately reflect the cost providers incur when purchasing and administering these drugs.

We believe these modifications to utilization data and price will better ensure adequate patient access to calcimimetics. This is particularly important for Black ESRD patients on dialysis, who tend to have more severe secondary hyperparathyroidism than other ESRD patients and therefore rely on these medications to manage their parathyroid hormone (PTH) and calcium levels.

Changes to and the expansion of the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES)

AKF supports and appreciates CMS' efforts to drive greater innovation in kidney care and to encourage the development of new products that can improve the treatment of kidney disease. We also believe that more should be done to increase the utilization of home dialysis for patients for whom it is appropriate and who have decided it is the modality that best fits their needs. We therefore support CMS' proposed changes to the eligibility criteria for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) and to expand TPNIES for new and innovative capital-related assets that are home dialysis machines when used in the home for a single patient. We believe these changes create a pathway for innovative products to reach ESRD beneficiaries who want access to them and to improve patient outcomes.

We also urge CMS to work with the kidney community to consider other possible changes to TPNIES in the future, such as expanding TPNIES to other capital-related assets. Broadening the scope of TPNIES to other capital-related assets could encourage the adoption of truly innovative devices and equipment that can improve the care for a greater number of ESRD patients.

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

Sincerely,

LaVarne A. Burton
President and CEO