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August 27, 2018

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

Re: CMS 1691-P Medicare Program; 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) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendment to Correct Existing Regulations Related to the CBP for Certain DMEPOS

Dear Administrator Verma:

The American Kidney Fund (AKF) 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) 2019 and update requirements for the ESRD Quality Incentive Program (QIP).

The American Kidney Fund is the nation's leading independent nonprofit organization working on behalf of the more than 30 million Americans with kidney disease. For the past half-century, AKF has existed to help people fight kidney disease and live healthier lives. We provide a complete spectrum of programs and services: top-rated education materials; free kidney disease screenings in numerous cities across the nation; clinical research funding; and need-based financial assistance enabling one in five U.S. dialysis patients to access lifesaving medical care, including dialysis and transplantation.

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.

End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

Solicitation of Information on Transplant and Modality Requirements

AKF strongly believes in patients choosing the modality and treatment choice that best suits their health needs and their individual circumstances, whether it is in-center hemodialysis, home dialysis, or transplantation. We appreciate and support CMS efforts to facilitate patient access to modality options and to address the disparities that exist among different demographics of patients. Those efforts have included

aligning payment for in-center and home dialysis treatment, making changes to the home dialysis training add-on, and establishing the current Conditions for Coverage (CfC) requirements in which dialysis facilities must provide transplant evaluation and referrals and patient modality education.

CMS is seeking input on ways to increase kidney transplant referrals and improve the tracking process for patients on the waitlist. 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 critically important that the measures be actionable by dialysis facilities to have an impact on patient access to a transplant. However, CMS is proposing to include two measures in PY 2022 and 2024, respectively, that AKF believes are not appropriate for inclusion in the QIP: Percentage of Prevalent Patients Waitlisted (PPPW) and Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR). The decision to add a patient to the transplant waitlist is made by the transplant center and is not a decision controlled by the dialysis facility, and therefore these measures are not actionable by the dialysis facility. In addition, the PPPW and SWR have not been endorsed by the National Quality Forum (NQF) because they do not meet the scientifically based criteria used to evaluate measures, which is another key reason we are unable to support their inclusion in the QIP.

Instead, CMS should work 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.

For transplant centers, we believe CMS should work with them to streamline the waitlist criteria and the registration process to decrease the administrative complexity that patients must go through to improve their chances of finding a match. In addition, CMS must ensure that transplant centers are evaluated on outcomes-based metrics that do not encourage patient cherry-picking.

With regard to modality education and ensuring equal access to dialysis modalities, the Kidney Disease Education (KDE) benefit is an important tool that can help patients with chronic kidney disease (CKD) learn about their treatment options. Medicare covers up to six sessions of KDE services for beneficiaries with Stage IV CKD. Physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certain providers in rural areas can provide KDE services. Unfortunately, the KDE benefit has been underutilized since its implementation in 2011 and its usage has declined in recent years. About 4,200 Medicare beneficiaries were provided KDE services in both 2011 and 2012 compared with about 3,500 beneficiaries in both 2015 and 2016.¹ For context, there were about 83,000 fee-for-service beneficiaries who were new to dialysis in 2016.²

In a 2015 report, the Government Accountability Office (GAO) recommended that “the administrator of CMS should examine the Kidney Disease Education Benefit and, if appropriate, seek legislation to revise

¹ Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Medicare Payment Policy*, Ch. 6, Outpatient dialysis services (March 2018):

http://medpac.gov/docs/default-source/reports/mar18_medpac_ch6_sec.pdf?sfvrsn=0

² Ibid.

the categories of providers and patients eligible for the benefit.”³ At the time of the report’s release, HHS responded that it did not concur with that recommendation. AKF urges CMS and HHS to reconsider that decision and look for ways to increase the use of the KDE benefit. We echo the statement from GAO that “it is important for HHS to help ensure that Medicare patients with chronic kidney disease understand their condition, how to manage it, and the implications of the various treatment options available, particularly given the central role of patient choice in dialysis care.”⁴

Specifically, AKF recommends that CMS should consider waiving the 20 percent coinsurance requirement that accompanies KDE as a Part B benefit. This would help make the KDE benefit more accessible to beneficiaries for whom the 20 percent coinsurance is cost prohibitive. In the long run, this will be cost efficient for Medicare as patients will be better prepared to begin dialysis. We also recommend that CMS consider a pilot program that would allow dialysis facilities to provide the KDE benefit under certain circumstances and to expand beneficiary eligibility to patients with Stage V CKD but who have not yet started dialysis. The results of this pilot would help inform CMS and Congress about the efficacy of making these changes to the KDE benefit permanent.

End-Stage Renal Disease Quality Incentive Program (QIP)

Accounting for Social Risk Factors in the ESRD QIP

AKF appreciates CMS providing a summary on the recent work that has been done to examine social risk factors and their effect on health outcomes. As CMS continues to work with stakeholders on the issue of accounting for social risk factors in its quality programs, AKF reiterates our comments from last year regarding social risk factors and the ESRD QIP. We fully support CMS’ core objective to improve beneficiary outcomes, including reducing health disparities, and ensuring that those with social risk factors receive high quality care. We also believe that CMS must ensure that the quality of care provided by facilities is assessed fairly while also safeguarding beneficiary access to excellent care.

AKF believes that the measures used in the ESRD QIP should continue to be studied to determine the appropriateness of adjusting for social risk factors, also referred to as sociodemographic status factors (SDS). We direct CMS to Kidney Care Partners’ comment letter for a more detailed explanation, but we want to reiterate the recommendation that the Standardized Readmission Ratio (SRR), Standardized Transfusion Ratio (STrR), Standardized Mortality Ratio (SMR), and Standardized Hospitalization Ratio (SHR) be assessed for possible SDS adjustments; the Vascular Access Type clinical measures be examined for possible adjustment for insurance status at the time of dialysis initiation; and the Kt/V Dialysis, Hypercalcemia and National Healthcare Safety Network (NHSN) Bloodstream Infection clinical measures, as well as the reporting measures, not be adjusted for social risk factors. Like KCP, we are uncertain of the impact of SDS factors on In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey responses, and we believe CMS should review and make public the data required to evaluate the impact of SDS factors before a decision is made. Also, as the CMS continues to consider adopting transplantation-related measures, we recommend that CMS engage with the kidney community to assess the SDS factors that clearly affect transplant referrals and patient placement on organ waitlists.

³ Government Accountability Office (GAO), *End-Stage Renal Disease: Medicare Payment Could Promote Increased Use of Home Dialysis* (October 2015): <https://www.gao.gov/assets/680/673140.pdf>

⁴ Ibid.

In accounting for social risk factors, it is imperative that any possible adjustments to measures be combined with public reporting stratified by patient characteristics. Like CMS, AKF is concerned that adjusting measures could mask health disparities and minimize incentives to improve the outcomes for disadvantaged and minority populations. This risk is especially concerning for the patients we serve, as individuals with ESRD are disproportionately of racial and ethnic minority descent, and AKF's financial assistance programs serve a population that is nearly two-thirds racial and ethnic minority. But as the National Academies of Sciences, Engineering, and Medicine described in its work *Accounting for Social Risk Factors in Medicare Payment*, "showing quality information for different subgroups within health care providers and health plans is the only strategy that makes disparities visible... therefore, such stratified public reporting must be part of any approach that seeks to monitor and reduce disparities."⁵ By stratifying measures by social risk factors and patient characteristics, CMS and clinicians will be able to identify differences in performance for socially at-risk beneficiaries and develop strategies to address health disparities and achieve health equity.⁶ One such future strategy deserving of further study could include adding a health equity measure to the ESRD QIP.⁷

CMS seeks comment on which social risk factors should be considered for possible measure adjustment or stratification. We believe that income (i.e., dual eligibility/low-income subsidy), race and ethnicity, geographic area of residence, and insurance status at dialysis initiation are the most appropriate at this time. However, this list is by no means exhaustive, and we would look forward to working with CMS and the kidney community to consider other social factors that may affect outcomes and quality of care provided.

Proposed Update to Requirements Beginning with the PY 2021 ESRD QIP

AKF supports KCP's submitted comments on the QIP measure set, and we provide comments on the following specific measures and issues related to the updated requirements for the PY 2021 ESRD QIP.

- **Kt/V Dialysis Adequacy Measure:** AKF remains concerned about including all dialysis populations in a single dialysis adequacy measure. We support the use of dialysis adequacy measures in the QIP. However, the Kt/V Dialysis Adequacy measure proposed for 2019 and future years, which pools adult and pediatric hemodialysis and peritoneal patients into a single denominator, is problematic because of the small numbers of pediatric patients. This could mask important differences in performance among the larger adult population and the smaller pediatric population at a facility. Also, the pooled measure masks facilities' performance on home dialysis from patients and can unfairly penalize facilities that primarily provide home dialysis. Both of those unintended consequences would create a disincentive for the use of home dialysis. AKF recommends that CMS calculate scores for each group and then roll them up into a single score.

⁵ National Academies of Sciences, Engineering, and Medicine, *Accounting for Social Risk Factors in Medicare Payment, Key Questions and Answers* (January 2017): <http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2017/SES-Medicare-5/medicare-key-questions-answers.pdf>

⁶ Assistant Secretary for Planning and Evaluation (ASPE), *Report to the Congress: Social Risk Factors and Performance under Medicare's Value-Based Purchasing Programs* (Dec. 2016), 320: <https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf>

⁷ Ibid.

We also recommend that CMS follow recommendations of the NQF Standing Renal Committee, which had recommended against endorsement of the measure.

- **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. We reiterate KCP's recommendations to address the fatigue problem and the low response rates, which include dividing the survey into three sections that were 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.

Finally, we encourage CMS to continue considering an additional CAHPS survey for home dialysis patients.

- **Proposal to Refine and Update the Factors Used for ESRD QIP Measure Removal and Proposed New Measure Removal Factor:** AKF generally supports CMS' proposed adjustments to the factors that will determine whether a measure is removed from the program. We also encourage CMS to

add an additional factor in which measures that do not meet the scientifically accepted measure evaluation and testing criteria of NQF should be removed from the QIP.

- **Proposed Removal of Four Reporting Measures:** AKF supports the proposed removal of the following measures from the QIP: Healthcare Personnel Influenza Vaccination, Pain Assessment and Follow-Up, and Anemia Management. We believe CMS' proposed removal of these measures is appropriate based on its measure factors and within the context of the Meaningful Measures Initiative. However, we recommend that the Serum Phosphorus measure remain in the QIP, and as noted above, the Hypercalcemia measure should be removed. Serum Phosphorus is a more appropriate measure that would comply with the statutory requirement to include a mineral metabolism measure, and physicians rely upon it to make clinical decisions.

In addition to removing the Anemia Management reporting measure, we also recommend the STrR measure be removed and replaced with a hemoglobin less than 10 measure. There are serious concerns regarding the validity of the STrR measure and underreporting of transfusions by hospitals after the switch from ICD-9 to ICD-10. A lower hemoglobin measure, once fully developed and 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 Requirements for the PY 2022 ESRD QIP and Proposed Requirements Beginning with the PY 2024 ESRD QIP

CMS is proposing to include two transplant measures in PY 2022 and PY 2024, respectively: Percentage of Prevalent Patients Waitlisted (PPPW) and Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR). We fully support the inclusion of meaningful transplant measures in the QIP, but as noted in our above comments we oppose the inclusion of PPW and SWR because the measures are not actionable by dialysis facilities and the NQF has not endorsed them. 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.

Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

CMS is seeking comment on improving a Medigap patient's understanding of his or her out-of-pocket costs prior to receiving services, especially with respect to the following questions:

How does Medigap coverage affect patients' understanding of their out of pocket costs before they receive care? What challenges do providers and suppliers face in providing information about out-of-pocket costs to patients with Medigap? What changes can Medicare make to support providers and suppliers that share out-of-pocket cost information with patients that reflects the patient's Medigap coverage? Who is best situated to provide patients with clear Medigap coverage information on their out-of-pocket costs prior to receipt of care? What role can Medigap plans play in providing information to patients on their expected out-of-pocket costs for a service? What

state-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?

AKF appreciates CMS' requests for information and we agree there needs to be greater transparency with respect to prices, charges, and consumer costs in the health care system. However, in our experience as a nonprofit patient organization that provides financial assistance to low-income ESRD patients that enables them to afford their Medicare Part B and Medigap coverage, patients do not lack an understanding on the costs of their care. They know all too fully that without their Medigap coverage, they would be financially liable for the 20 percent of medical care costs that Medicare does not cover, and with no out-of-pocket maximum. Without Medigap coverage, they know that they may have to spend down their assets to qualify for Medicaid and become dually eligible. ESRD patients know very well that because of their complex health needs, they have high health care costs and face high out-of-pocket costs. Average out-of-pocket costs for ESRD patients on Medicare are \$7,000. Of the Medicare patients with average out-of-pocket costs close to \$12,000, 45 percent are ESRD patients.

We also know from our experience that Medigap plans continue to use tactics to try to disenroll ESRD patients who receive financial assistance from AKF. Therefore, while we appreciate CMS' questions about improving a Medigap patient's understanding of their out-of-pocket costs, we believe the more pertinent question is: what can policymakers and CMS do to protect Medigap coverage for vulnerable individuals with ESRD?

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

Sincerely,



LaVarne A. Burton
President and CEO