American Kidney Fund®

August 28, 2017

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

Re: CMS–1674–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; Request for Information on Medicare Flexibilities and Efficiencies

Dear Administrator Verma:

The American Kidney Fund (AKF) appreciates the opportunity to provide comments on the proposed rule regarding the "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." We also provide comments on the Request for Information on Medicare flexibilities and efficiencies that CMS included in the proposed rule.

The American Kidney Fund is the nation's leading independent nonprofit organization working on behalf of the 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 more than 20 cities nationwide; 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. We also fight tirelessly on Capitol Hill for legislation and policies supporting the issues that are important to the people we serve.

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.

11921 Rockville Pike | Suite 300 | Rockville, MD 20852
301.881.3052 voice | 301.881.0898 fax | 800.638.8299 toll-free | 866.300.2900 Español
Member: CFC 11404 | www.**KidneyFund**.org

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

As an organization that not only works to prevent kidney disease, but also provides direct support to low-income and financially struggling individuals currently on dialysis, we encourage PPS policies that ensure adequate access, high quality care, and transparency for the patient. Adequate reimbursement rates and quality measures are critical for patients to have options in choice of providers.

AKF supports the proposal to apply any pricing methodology available under section 1847A of the Social Security Act (the Act) for eligible outlier drugs and biologicals, *consistent with CMS' decision to use such pricing policy for the transitional drug add-on payment adjustment*. We appreciate CMS' recognition of the importance of implementing policies that ensure patient access to new drugs and biologicals. Given that new drugs and biologicals that come to the market can be exceedingly expensive, it is essential that those drugs be appropriately applied under the ESRD PPS outlier policy. However, with regards to the proposal to not count a drug or biological toward the outlier calculation when it cannot be priced under section 1847A of the Act, *we recommend that CMS instead use contract pricing in the outlier calculation*. We agree with CMS that drugs and biologicals approved by the Food and Drug Administration and being sold in the United States nearly always have at least a wholesale acquisition cost (WAC) published in pricing compendia. But it is important to ensure beneficiary access to life saving drugs and biologicals, including in the unlikely scenario that there is no average sales price (ASP) or WAC available.

AKF supports the increase in the ESRD PPS base rate. Correct reimbursement rates to a health care team for the care of ESRD patients is paramount to ensuring resources that facilitate positive outcomes for patients. Dialysis patients are living with a life-threatening condition that requires them to have treatment at least three times per week; any policies that result in underpayment to providers may have the result of limiting options for dialysis patients if centers close, reduce hours or cutback staffing. When payments do not adequately reflect the actual costs of caring for dialysis patients, we have concerns that outcomes can be adversely impacted and patients hurt.

However, AKF remains concerned about the lack of transparency in the use of data regarding the factors used in calculating payments. Although we appreciate that CMS has made more data available, there continue to be differences in the calculations between what providers believe is the correct amount to adequately care for ESRD patients and the ESRD PPS base rate. The best way to resolve the differences would be through full transparency by releasing all data and calculations used in development of payment rates and adjusters.

AKF also continues to have concerns that the current case-mix adjusters used in the PPS inappropriately reduce reimbursement rates. We reiterate our recommendation that the determining factor in choosing adjusters should be which adjusters will best impact the policy goal of improving patient access. The case-mix adjusters were meant to reimburse providers at a rate that promotes excellent care and that offers no disincentive to treat sicker patients. The adjusters change the base payment and include aspects such as patient weight, body mass index,

comorbidities, length of time on dialysis, age, race, ethnicity and other factors that CMS deems appropriate. The choice of adjusters should take into consideration the fact that some adjusters can work in tandem with each other while others may potentially cancel each other out. We therefore request that CMS continue to work with the kidney community to ensure that the adjusters used and the methods of calculating impact truly cover the costs of providing care for those patients with more health care needs.

End-Stage Renal Disease Quality Incentive Program (QIP)

The American Kidney Fund continues to support the Quality Incentive Program (QIP) as a way to incentivize providers to give the highest level of care to dialysis patients. However, as the program continues to evolve, we remain concerned about certain aspects of the program, particularly the number of measures, relevance of certain measures to optimal patient outcomes and measure design. Since inception of the program, there have been a number of measures added. The growing number of measures reduces the importance of the measures that best reflect patient health status, and increases the significance of less relevant quality measures. AKF invites CMS to work with us and others in the kidney community to pinpoint the most important measures, to reduce the total number and to design measures that are based on National Quality Forum (NQF) principles.

Accounting for Social Risk Factors in the ESRD QIP

AKF appreciates the opportunity to comment on whether CMS should account for social risk factors in 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.

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."[1] 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.[2] One such future strategy deserving of further study could include adding a health equity measure to the ESRD QIP with a linked payment adjustment to incentivize improved care for beneficiaries with social risk factors.[3]

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 Change to the Performance Score Certificate Beginning with the Payment Year (PY) 2019 ESRD QIP

AKF is opposed to CMS' proposed changes to the Performance Score Certificate (PSC) beginning in PY 2019. We believe that public reporting of more detailed performance data is crucial to providing complete and meaningful information for patients so that they can make informed choices.

---

[1] 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

[2] 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

[3] Id.

We appreciate CMS' objective to make the PSC a more approachable and useful document for patients and their families. However, we believe that providing less information in the PSC is not in the best interest of program transparency and the patients who may want more detailed information. If CMS is seeking ways to make the Total Performance Score (TPS) and PSC easier to understand, we recommend that CMS eliminate the ESRD Star Rating Program and instead use the ESRD QIP methodology to assign stars to the TPS. We provide greater detail on this recommendation in the section below responding to CMS' Request for Information.

Proposed Requirements Beginning with the PY 2020 ESRD QIP

We support KCP's submitted comments on the QIP measure set. We also provide our own comments on the following specific measures and issues related to the proposed requirements for the PY 2020 ESRD QIP. Please note that these comments also apply to the proposed requirements for the PY 2021 ESRD QIP.

- **Solicitation of Comments on the Inclusion of Acute Kidney Injury (AKI) Patients in the ESRD QIP:** *AKF opposes requiring facilities to report data on AKI patients under the ESRD QIP*. The clinical treatment goals and outcomes for AKI can be very different depending on the patient and specific nature of the AKI. The quality measures applied to ESRD patients are fundamentally different than what may be appropriate measures for AKI, and therefore, the ESRD QIP would not be a proper program to evaluate the quality of care for AKI individuals. In addition, the statute establishing the program applies only to ESRD beneficiaries and not AKI patients. We agree that CMS should continue to monitor patients with AKI on dialysis, especially since more work and data is needed to better understand when and how AKI morphs into ESRD. However, incorporating AKI patients into the ESRD QIP is not the appropriate method to do so.

- **Kt/V Dialysis Adequacy Measure**: *AKF reiterates our concerns about including all dialysis populations in a single dialysis adequacy measure*. AKF supports 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, is problematic because of the small numbers of pediatric patients. AKF recommends that CMS calculate scores for each group and then roll them up into a single score. We also recommend that CMS follow recommendations of the NQF Standing Renal Committee.

- **Hypercalcemia Measure:** As we have stated in previous letters, *AKF is concerned about the inclusion of the hypercalcemia measure in the ESRD QIP*. We understand that CMS has been directed by the Protecting Access to Medicare Act (PAMA) to adopt measures that are specific to conditions treated with oral-only drugs, and thus CMS has included hypercalcemia as a measure in the ESRD QIP. However, CMS recognizes that the hypercalcemia measure may not be the most appropriate measure. We concur with this assessment, 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 and to the extent that the current hypercalcemia measure continues to be used, AKF urges CMS to adopt NQF recommendations.

- **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 only and that the problems with the reliability of the measure be resolved prior to implementing it as a clinical measure.

- **Serum Phosphorus Measure**: *AKF supports the inclusion of the Serum Phosphorus reporting measure, but we recommend CMS work with the kidney community to identify a more appropriate measure to comply with the Protecting Access to Medicare Act*. NQF has indicated the measure is topped out, and therefore no longer the best indicator of care in this area.

- **ICH CAHPS Measure**: *AKF urges CMS 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. AKF would welcome the opportunity to work with CMS and other stakeholders to identify solutions to this issue.

Request for Information on Medicare Flexibilities and Efficiencies

AKF appreciates the opportunity to provide comments on improvements to the Medicare program that could reduce unnecessary burdens on patients and providers and increase the quality of care, lower costs, improve program integrity, and make the health care system more effective, simple and accessible. Within the Medicare ESRD program, we recommend the following:

Incorporate Star Ratings into the ESRD QIP

AKF recommends that CMS eliminate the Dialysis Facility Compare star ratings program and instead apply star ratings to the Total Performance Scores in the ESRD QIP. We direct CMS to

Kidney Care Partners' comment letter to the Request for Information for further detail on this recommendation. We also reproduce below KCP's example of how stars could be awarded based on the TPS:

Total Performance Score	Reduction	Star
100-61	0%	✓✓✓✓✓
60-51	0.5%	✓✓✓✓
50-41	1.0%	✓✓✓
40-31	1.5%	✓✓
30-21	2.0%	✓

AKF fully supports the public reporting of providers' performance on appropriate quality metrics and conveying that information in a quality rating that is meaningful and useful for patients and their families. And we commend CMS for all its efforts in quality initiatives and value-based payment in the Medicare program. However, having two separate ESRD quality programs with different measures and methodologies has led to confusion for patients. Specifically, the different micro-specifications in the ESRD QIP and the star ratings program lead to inconsistent publicly reported information that then translates to confusing quality performance results. Being on dialysis is a uniquely challenging time in an individual's life, and we urge CMS to help patients make informed decisions about their choice of dialysis clinic. Simplifying the rating system would greatly assist dialysis patients and their families in making these decisions.

The Medicare Payment Advisory Commission (MedPAC) has also called for "greater simplicity and clarity" in the ESRD quality measurement process and cautioned in 2014 that "moving to two system creates greater uncertainty."[4] We believe that aligning the purpose and process of the two ESRD quality programs and incorporating star ratings into the statutorily mandated QIP is the best approach to providing simplicity and clarity for patients.

Improve Sharing of Patient Information between Hospitals and Nephrologists and Dialysis Centers

To improve quality of care, AKF recommends that CMS require hospitals to provide patient information to nephrologists and dialysis centers in a timely fashion. The first step in improving care for chronic kidney disease and ESRD patients is improving communications among health care providers. When an ESRD patient goes into the hospital, it can be very difficult for the dialysis center or the nephrologist to learn what happened in the hospital. To ensure optimal care, it is extraordinarily important for the dialysis team to know the specific reason for the hospitalization, medications administered, diagnostic tests performed, procedures performed,

[4] Medicare Payment Advisory Commission, comment letter on "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies," August 15, 2014. http://medpac.gov/docs/default-source/comment-letters/medpac-comment-on-cms-s-proposed-rule-entitled-medicare-program-end-stage-renal-disease-prospective-.pdf?sfvrsn=0

and diagnostic findings. Based on the information, the dialysis care team can modify the existing treatment plan to best meet the needs of the patient post-hospitalization.

Protect Patient Choice in Coverage

As we have stated in other comment letters to CMS, *we urge the department implement a policy that would require insurers to accept direct and indirect third party payments made by charitable organizations like AKF for individuals with chronic conditions*. Action by CMS/HHS is critical to protecting and facilitating the individual preferences of patients, especially those with ESRD.

AKF is very concerned about the access issues that many patients with ESRD are increasingly facing as a result of policies imposed by some insurance plans to discourage or even prevent people with ESRD and other chronic diseases from enrolling in commercial plans. After being diagnosed with ESRD, most patients are entitled to Medicare coverage. However, the Medicare Secondary Payer (MSP) statute also allows patients to choose to continue with commercial coverage as primary insurer for thirty months if they prefer. Many patients choose to retain coverage that they may have had prior to their diagnosis rather than immediately enrolling in Medicare. Valid reasons for this choice include maintaining a single-family plan, continuing with an established network of providers, or lower out-of-pocket costs (for example, in roughly half of the states, ESRD patients under 65 do not have guaranteed access to Medigap). The MSP statute has protected this choice for decades; however, it is charitable assistance that makes this choice a realistic option for many low-income patients. AKF urges CMS to affirmatively protect the right for this vulnerable group of patients by requiring insurers to accept charitable premium payments on behalf of patients.

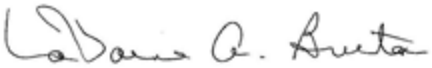
Medicare should also protect these patient rights because doing so results in better patient outcomes and lower Medicare costs. Patients who choose to remain in commercial plans often have a better transition into dialysis care as their health care plans have an incentive to prepare and support their transition. This leads to reduced infection and lower hospitalization rates. There is little financial incentive for insurers to provide support for patients who will leave their rolls to enroll in Medicare shortly after diagnosis with ESRD. Additionally, patients may continue to maintain their commercial coverage as long as possible because there is evidence to show that the chances of getting a kidney transplant are greater for people on private insurance as opposed to noncommercial insurance.[5]

---

[5] *See* Jesse D. Schold et al., *Barriers to Evaluation and Wait Listing for Kidney Transplantation*, 6 CLINICAL J. AMER. SOCIETY OF NEPHROLOGY 1760 (2011), http://cjasn.asnjournals.org/content/6/7/1760.full and A.M. Reeves-Daniel, A.C. Farney, et al., *Ethnicity, medical insurance, and living kidney donation*, http://www.ncbi.nlm.nih.gov/pubmed/23781870; U.S. News & World Report, *Black Medicaid Recipients Less Likely to Get Living-Donor Kidney: Study* (June 26, 2013), http://health.usnews.com/health-news/news/articles/2013/06/26/black-medicaid-recipients-less-likely-to-get-living-donor-kidney-study

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

Sincerely,



LaVarne A. Burton
President and CEO