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**Re: CMS–1782–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, and End-Stage Renal Disease Treatment Choices Model**

Dear Administrator Brooks-LaSure:

The American Kidney Fund appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule referenced above.

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.

In this letter, we focus our comments on certain proposals and requests for information on the prospective payment system (PPS) and the Quality Incentive Program (QIP). For our comments on the proposed CY 2024 market basket update and the proposed new add-on payment adjustment for certain new renal dialysis drugs and biological products after the transitional drug add-on payment adjustment (TDAPA) period ends, please see our August 14<sup>th</sup> comment letter.

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.

## **Requests for Information on Modification of Low-Volume Payment Adjustment (LVPA) and Development of a New Payment Adjustment Based on Geographic Isolation**

AKF appreciates CMS' requests for information (RFI) seeking input about potential approaches to refine the ESRD PPS LVPA methodology. We share the concerns that have been voiced by other stakeholders that the current LVPA needs improvements to better target funding to ESRD facilities that serve a small number of patients in underserved areas so that patient access to care is maintained. As we noted in our CY 2022 ESRD PPS comment letter, AKF supports replacing the current LVPA and rural adjusters with a single low-volume facility adjuster with two tiers—the first tier for facilities providing fewer than 4,000 treatments per year and the second tier for facilities providing between 4,001 and 6,000 treatments per year. This two-tiered LVPA would be a straightforward and transparent approach that would better target facilities that need it the most and prevent the closure of low-volume facilities that serve vulnerable populations. The second tier would eliminate the payment cliff that occurs with the current one-tiered methodology, thereby encouraging low-volume facilities to accept more patients and ensuring patient access to care.

In conjunction with this two-tiered LVPA, it is important to retain two guardrails currently in place to prevent gaming. The first is requiring facilities to attest to meeting the number of required treatments in each of the three cost reporting years preceding the payment year, which helps ensure a facility is consistently treating a low volume of patients. The second guardrail is requiring the aggregate number of treatments furnished by a facility to also include the treatments furnished by other facilities that are under common ownership and that are 5 miles or less from the facility in question. This disincentivizes the opening of multiple facilities in close geographic proximity to reduce the number of treatments each facility provides and targets the LVPA to facilities that would create patient access issues if they were to close.

Conversely, we believe the four-tiered and eight-tiered LVPA models, the continuous function, and a new payment adjustment based on the local dialysis need (LDN) methodology, as presented in the RFI, are not appropriate approaches to address the needs of low-volume facilities and the patients they serve. These approaches are overly complicated, not well targeted to facilities that truly need the adjustment, vulnerable to gaming, and lack transparency when compared to the two-tiered approach with guardrails described above that would replace the current LVPA methodology and rural adjuster.

## **Proposal for an Exception to the Current LVPA Attestation Process for Disasters and Other Emergencies**

AKF supports the proposed exception to the LVPA treatment threshold for ESRD facilities that accept patients from a facility affected by a disaster or other emergency, and the proposed exception to the LVPA closure provision for facilities affected by a disaster or other emergency. We agree with CMS that adding these flexibilities during disasters or other emergencies would ensure access to care for vulnerable populations served by low-volume facilities.

## **Proposed Transitional Pediatric ESRD Add-On Payment Adjustment for Pediatric Patients with ESRD Receiving Renal Dialysis Services**

AKF appreciates CMS' attention to the shortcomings of the current pediatric adjustments in the ESRD PPS. As we have noted in previous comment letters, the magnitude of total costs and pediatric multipliers does not reflect ESRD facilities' actual incurred costs for pediatric ESRD patients. Given the specialized staffing and resource needs that are required to provide quality care to pediatric patients, the current undervaluation of pediatric ESRD care needs to be addressed.

We support the adoption of a three-year transitional pediatric ESRD add-on payment adjustment (TPEAPA), which will give CMS time to update the pediatric cost report and collect the needed data to develop a more appropriate adjuster for the pediatric population. However, we recommend CMS reconsider its proposal to make the TPEAPA budget neutral. Medicare beneficiaries with ESRD are disproportionately impacted by health disparities, and it seems inappropriate to cut payment rates for vulnerable populations in a PPS that has continually seen inadequate market basket updates that fail to take into account the actual increase in health care inflation.

### **Proposed Clarification to TDAPA average Sales Price (ASP) Policy**

AKF supports CMS' clarification that for the purposes of the TDAPA conditional policy, in circumstances where a manufacturer submits ASP data reflecting zero or negative sales during the TDAPA period, CMS will consider it to have received the latest full calendar quarter of ASP data. Therefore, CMS would not discontinue TDAPA payment under the conditional policy. We believe this is an appropriate approach to help ensure patient access to a drug or biological product during the TDAPA period.

Separately, CMS also notes that Korsuva's current TDAPA period will continue through March 31, 2024. However, we recommend that CMS extend Korsuva's TDAPA for an additional two years in the CY 2024 ESRD PPS final rule. As we explained in our August 14<sup>th</sup> comment letter, concerns about long-term funding for Korsuva and providers not wanting to be in a position of ending the prescription when the TDAPA ends has resulted in lower utilization, despite the product's effectiveness. About 1% of patients on hemodialysis have been treated with Korsuva, even though available data describes the prevalence of pruritus at approximately 35% of hemodialysis patients. If CMS proceeds with adopting a post-TDAPA add-on payment adjustment, Korsuva should be granted two additional years of TDAPA so that CMS can collect two full years of utilization and ASP data that more accurately reflect an environment in which providers know there is a post-TDAPA add-on payment adjustment for the product.

### **Proposed Clarifications Regarding CMS' Evaluation of the TPNIES Eligibility Criteria**

AKF supports the proposed clarifications regarding CMS' evaluation of the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES). We also want to take this opportunity to make recommendations on other issues related to TPNIES.

CMS has assigned to the Medicare Administrative Contractors (MAC) the responsibility of determining the claims submission process and communicating those details to ESRD facilities. There has been substantial variation in the level of knowledge and awareness on TPNIES among the MACs, which has

contributed to the denials of submitted TPNIES claims. The confusion and associated administrative burden for ESRD facilities in trying to navigate the opaque TPNIES claims process has led to delayed payments, which hinders the adoption of innovative equipment and devices. We recommend that CMS provide clarification on how the MACs will determine payment rates and process claims in a timely manner to support uptake and patient access to equipment and devices receiving TPNIES.

Given the issues with the claims process and its effect on adoption of TPNIES products, we also recommend that CMS grant an additional year of TPNIES to the Tablo System, whose TPNIES period ends on December 31, 2023.

Additionally, we ask that CMS issue an RFI seeking public feedback on a post-TPNIES add-on payment adjustment, as the agency did previously when it considered a post-TDAPA add-on payment adjustment in its RFI in last year's ESRD PPS proposed rule. Parity in the length of payments for TDAPA and TPNIES, including any finalized post-TDAPA add-on payment adjustment, is critical in supporting access to innovative treatments for people on dialysis. This is especially true considering CMS' descriptions of TDAPA and TPNIES and their shared intent, stating that as "we explained in prior ESRD PPS rules establishing the TDAPA and TPNIES, ESRD facilities face unique challenges in incorporating new renal dialysis drugs, biological products, equipment and supplies into their businesses and these add-on payment adjustments are intended to support ESRD facilities' use of new technologies during the uptake period for these new products."<sup>1</sup>

### **ESRD Quality Incentive Program**

AKF appreciates the opportunity to comment on the ESRD QIP. We strongly support the purpose of the QIP to drive improvement in the quality of patient care and continue to support many of the QIP measures. However, we recommend CMS continue to engage with the kidney community to ensure the QIP and Dialysis Facility Compare star program include a streamlined set of meaningful measures that drive improvements in clinical outcomes and patient experience while minimizing administrative burden on facility staff who are working to deliver quality care. When facility staff—including physicians, nurses, technicians, social workers, and dieticians—have to spend time on the collection and submission of data on measures that are not endorsed, have validity and reliability concerns, are topped out, or are merely checklist measures, that takes time away from critical patient care and care planning. We look forward to working with CMS on these important issues to ensure ESRD quality measurement leads to quality patient care.

### **Proposal to Adopt the Facility Commitment to Health Equity Reporting Measure Beginning with the PY 2026 ESRD QIP**

AKF commends CMS for its continued commitment to health equity, and we appreciate the intent of this measure, which is "to assess facility commitment to health equity across five domains using a suite of organizational competencies aimed at achieving health equity for all patients." However, we share the concerns of the Measure Applications Partnership (MAP) Health Equity Advisory Group that the measure is more of a checklist measure that may not directly address health inequities at a

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<sup>1</sup> 85 FR 71417 (Nov. 9, 2020)

systemic level. We believe more work needs to be done on the measure before it is included in the QIP, including further evaluation on how it can be linked to clinical outcomes and an endorsement review by the consensus-based entity (CBE).

### **Proposed Modification of the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning with PY 2026**

AKF supports the proposed modification of the COVID-19 vaccination coverage among HCP measure, pending endorsement from the CBE. We agree with CMS that vaccination remains a critical tool to prevent the worst consequences of COVID-19, and it is important to modify the measure to reflect recent updates that explicitly specify for HCP to receive primary series and booster vaccine doses in a timely manner.

### **Proposal to Convert the Clinical Depression Screening and Follow-up Reporting Measure to a Clinical Measure Beginning with the PY 2026 ESRD QIP**

Screening for and addressing clinical depression in people with ESRD is vital for their overall care and health outcomes. However, the current clinical depression screening reporting and follow-up measure is topped out and should not be converted to a clinical measure. We recommend that the reporting measure be moved to Dialysis Facility Compare to provide beneficiaries with the information they can use to compare how facilities perform on screening for and responding to clinical depression.

### **Proposal to Remove the Ultrafiltration Rate Reporting Measure from the ESRD QIP Measure Set Beginning with PY 2026**

We agree with CMS' proposal to remove the ultrafiltration rate reporting measure from the ESRD QIP under measure removal factor 2, performance or improvement on a measure does not result in better or the intended patient outcomes. As CMS notes, recent studies raise concerns that patient body size may be a confounding and possibly explanatory factor for the relationship between higher UFR and increased mortality. Additionally, mortality risk associated with high UFR may be due to the frequency or number of hemodialysis sessions with high UFR. However, we also want to note that the measure has served an important purpose in the QIP by underscoring the value of monitoring UFRs and how a continued discussion of UFRs and other clinical markers of fluid management can be a part of quality improvement strategies.

### **Proposal to Remove the Standardized Fistula Rate Clinical Measure from the ESRD QIP Measure Set**

We agree with CMS' proposal to remove the standardized fistula rate clinical measure from the ESRD QIP beginning with PY 2026. AKF supports measures focused on increasing the number of patients with an AV fistula when appropriate for the patient and reducing the use of catheters. The continued use of the long-term catheter rate clinical measure in the ESRD QIP would effectively achieve these aims. We also urge CMS to continue to monitor the rates of AV fistulas and AV grafts.

**Proposal to Adopt the Screening for Social Drivers of Health Reporting Measure and Proposal to Adopt the Screen Positive Rate for Social Drivers of Health Reporting Measure Beginning with PY 2027**

AKF commends CMS in its continued efforts to address social drivers of health and health-related social needs (HRSNs) and their impact on health disparities and health outcomes of Medicare beneficiaries with ESRD, particularly those from underserved communities. We agree with CMS that the screening for social drivers of health and screen positive rate for social drivers of health reporting measures could help identify gaps in care and develop sustainable solutions at a facility level and community level.

However, we believe more work needs to be done on the measures before they are included in the ESRD QIP, including addressing issues raised by MAP work groups and advisory groups, and an endorsement review by the CBE. Specifically, concerns regarding potential reporting challenges and the potential masking of health disparities in the screening measure, and reliability and validity concerns in the screen positive measure need further exploration.

Given the importance of addressing the social drivers of health, and the administrative burden that will accompany any added social drivers of health measure, CMS and other stakeholders need to ensure that new measures will truly drive improved health outcomes and advance health equity.

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

Sincerely,



LaVarne A. Burton  
President and CEO