American Kidney Fund®
FIGHTING ON ALL FRONTS

August 28, 2025

The Honorable Mehmet Oz
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-1830-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 Oz:

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

The American Kidney Fund (AKF) fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 1 in 7 American adults 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 CY 2026 Market Basket Update and Payment Rate Update

AKF is deeply concerned that the ESRD Bundled (ESRDB) market basket continues to not accurately reflect the changes in the goods and services included in renal dialysis services and continues to underestimate the increases in health care inflation and the cost of labor that ESRD facilities face. Medicare beneficiaries with ESRD already confront significant health challenges, and the continued misalignment between the market basket and actual inflation only exacerbates those health challenges for the ESRD population. Appropriate payment to providers is critical to ensure facilities can hire and retain the clinical staff that is necessary to provide

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quality care. We have heard from many patients that have experienced high staff turnover at their dialysis clinic, including ones that are considered high performing facilities. This turnover has a practical effect on the patient experience, because patients and clinical staff are unable to establish a relationship that allows staff to be more attuned to the individual needs of the patient. Or a patient is able to establish a relationship with a nurse or technician, but then that staff person moves on to another job in a different health care setting or a different industry that is able to pay a higher salary.

The proposed ESRD Bundled (ESRDB) market basket update for CY 2026 is 1.9%, which is equal to the 2.7% ESRDB market basket percentage increase reduced by a proposed 0.8 percentage point productivity adjustment. The proposed CY 2026 ESRD PPS base rate—after accounting for the ESRDB market basket percentage increase, the productivity adjustment, the wage index budget neutrality adjustment factor, and the proposed non-contiguous areas payment adjustment (NAPA) budget neutrality factor—is $281.06, a 2.6% increase from the CY 2025 ESRD PPS base rate.

An analysis by Health Management Associates (HMA) using publicly available CMS data continues to show significant forecast errors year after year (see Table 1). For 2023, the CMS contractor reports that the actual market basket update was 4.1%, but the market basket update used in the CY 2023 final rule was 3.1%. For 2024, the contractor reports that the actual market basket update was 3.3%, while the market basket update used in the CY 2024 final rule was 2.4%. For 2025, the contractor reports a market basket update of 3.2%, but the update used in the CY 2025 final rule was 2.3%. The cumulative difference between the forecasted market basket update and the actual increase in costs, from 2019-2025, is 8%.

Table 1. Market Basket Forecast Error 2019-2025

MB Base Year	2016				2020			Cumulative
ESRD PPS Final Rule	2019	2020	2021	2022	2023	2024	2025	
Unadjusted Final MB Update	2.1	2	1.9	2.4	3.1	2.4	2.3	117.40%
Actual MB Inflation	2.3	1.9	3.1	5.1	4.1	3.3	3.2	125.40%
Final MB Update Compared to Actual (Forecast Error)	**-0.2**	**0.1**	**-1.2**	**-2.7**	**-1.0**	**-0.9**	**-0.9**	**-8.00%**

These forecast errors represent resources that should have been available to provide necessary and quality care for Medicare beneficiaries receiving dialysis. We recognize that CMS has chosen not to adopt a forecast error adjustment in the ESRD PPS that is similar to the one used in the Skilled Nursing Facility (SNF) PPS, and which we have recommended in previous rulemaking cycles. However, given the continued evidence that the current ESRD market basket has

significant flaws that result in reduced resources for Medicare beneficiaries on dialysis and who disproportionately face health disparities, we urge CMS to reconsider our recommendations on adopting a forecast error adjustment in the ESRD PPS.

Proposed Modification to the Eligibility Timeframe for the TDAPA

CMS proposes to modify the regulatory language of §413.234 to reflect that a transitional drug add-on payment adjustment (TDAPA) application must be submitted within three years of FDA approval for a new renal dialysis drug or biological product to be eligible for the TDAPA. AKF agrees that the TDAPA should be applied to truly new and innovative products, and we support a three-year time frame to apply for the TDAPA with a CY 2028 implementation date. However, we urge CMS to further modify the language to also allow for a three-year TDAPA application window that would be applied to products that receive a new FDA approval for a new ESRD indication. This would help bolster CMS's stated goal of focusing Medicare resources on new and innovative products by encouraging manufacturers to study existing drugs and biological products for potential efficacy in the treatment or management of a condition of conditions associated with ESRD. Given the barriers that exist within the ESRD PPS that can hinder patient access to new and innovative renal dialysis drugs and biological products, CMS should ensure that policies do not also pose a barrier to discovering new indications for existing FDA-approved products that could help people living with ESRD.

In the proposed rule, CMS also welcomes any suggestions on how TDAPA policies could be improved in future rulemaking. We would like to take this opportunity to reiterate our past recommendations on the TDAPA and post-TDAPA add-on payment adjustment:

- The TDAPA period should be for at least three years for new renal dialysis drugs and biological products that are in or outside existing functional categories; this would allow for at least 24 months of utilization and pricing data that would ensure more accurate inclusion of the product into the ESRD bundled payment.
- The post-TDAPA add-on payment adjustment should be permanent and applied immediately at the end of TDAPA in a non-budget neutral manner.
- The post-TDAPA add-on payment adjustment should be applied only to claims for patients who receive the new renal dialysis drug or biological product.
- The post-TDAPA add-on payment adjustment amount should be calculated by multiplying the most recent 12-month utilization for the product by the most recent full quarter of ASP (or WAC or manufacturer's invoice) divided by the total number of services when the product was administered; the final amount should then be set at 65% of that calculated amount and updated annually to account for inflationary changes.

Proposed Non-Contiguous Areas Payment Adjustment

CMS proposes a new facility-level payment adjustment for ESRD facilities in Alaska, Hawaii, and the U.S. Pacific Territories, which CMS has found to have higher non-labor costs when compared to ESRD facilities in the contiguous U.S. This proposed payment adjustment, the non-contiguous areas payment adjustment (NAPA), would be capped at 25% and applied only to the non-labor portion of PPS reimbursements to facilities in these selected geographic areas. CMS also proposes to apply the NAPA in a budget neutral manner; for CY 2026, the ESRD PPS base rate would be reduced by approximately 0.1%, or $0.40, to maintain budget neutrality.

AKF appreciates CMS's analysis of the higher non-labor costs associated with ESRD facilities that serve Medicare beneficiaries in remote non-contiguous areas. We support efforts to ensure facilities that serve these populations have adequate resources to deliver high quality care. However, if CMS finalizes the proposed NAPA, we urge the agency to not apply it in a budget neutral manner. This would be consistent with how CMS applies payment policies related to Critical Access Hospitals, super rural ambulance reimbursement, and the physician fee schedule 1.0 geographic practice cost index (GPCI) practice expense floor for frontier states. Applying the NAPA in a non-budget neutral manner would also ensure that the already limited resources in the ESRD PPS bundle are not further impacted in a way that could jeopardize beneficiaries' access to renal dialysis services.

We recommend that CMS provide further analysis that recalculates the rural payment adjuster and low-volume payment adjuster (LVPA) for those facilities predicted to receive the proposed NAPA and the rural adjuster or LVPA. Doing so will help CMS and stakeholders better understand any possible changes to those adjusters that may be needed to account for any covariance. An analysis by HMA finds that of the 59 facilities predicted to receive a NAPA, 18 are rural, 1 is low volume, and 1 is both rural and low volume.

AKF also recommends that CMS conduct an analysis that uses claims data to calculate the NAPA, in addition to the cost report data and the average case-mix adjustment multiplier that was used as one of the control variables in CMS's logarithmic regression. Using claims data will provide better insight into whether particular co-morbidity adjusters are predictive of higher costs at NAPA facilities. It will also help ensure the proposed NAPA is properly addressing higher non-labor costs associated with furnishing renal dialysis services in non-contiguous areas, including non-salary costs associated with capital, administration, drugs, supplies and laboratory tests.

Proposed Updates to the ESRD Quality Incentive Program (QIP)

AKF supports the proposed removal of the Facility Commitment to Health Equity Reporting Measure beginning with the PY 2027 ESRD QIP. As we stated in our comment letter for the CY 2024 ESRD PPS and QIP proposed rule, we shared 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 systemic level. We also stated that 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).

AKF supports the proposed removal of the two social drivers of health reporting measures beginning with the PY 2027 ESRD QIP. As we stated in our CY 2024 comment letter, 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 while also taking into consideration the administrative burden that will accompany any added social drivers of health measure, CMS and other stakeholders need to ensure that social drivers of health measures will truly drive improved health outcomes and address health disparities.

AKF supports the proposal to update the ICH CAHPS clinical measure beginning with the PY 2028 ESRD QIP. AKF has previously recommended that CMS 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 believe the proposed modifications to the ICH CAHPS survey, including the removal of certain questions, are a step in the right direction to help address the length of the survey and the survey fatigue problem. To further address this problem, we also want to restate our previous recommendation to administer the survey once a year instead of twice a year.

We appreciate CMS noting in the proposed rule that it is working on a modified survey to include questions that address the experience of care for patients on home dialysis modalities. AKF has recommended in previous rulemaking cycles—and reiterate again here—that CMS should work with stakeholders to develop a CAHPS survey specifically for home dialysis patients, especially given the agency's emphasis on encouraging the use of home dialysis. It is critically important that the patient experience in home dialysis is formally captured in a survey measure that is endorsed by the CBE.

Finally, AKF restates our strong support for the purpose of the QIP to drive improvement in the quality of patient care and we 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 (DFC) 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. Below is the list of measures that KCP recommends (and which we strongly support) be included in the QIP and which should be available in Dialysis Facility Compare:

QIP:

- Standardized hospitalization rate measure (replacing the current ratio measure)
- Standardized readmissions rate measure (replacing the current ratio measure)
- Catheter > 90 Days Clinical Measure
- Bloodstream infection measure (updated to address the underlying validity issues)
- Patient Experience of Care: In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Clinical Measure (modified to incorporate the experience of home dialysis patients as well)
- Hgb < 10 g/dL (replacing the standardized transfusion ratio measure)
- Serum phosphorous

DFC:

- Adult Hemodialysis Kt/V Adequacy Measure
- Adult Peritoneal Dialysis Kt/V Adequacy Measure
- Pediatric Hemodialysis Kt/V Adequacy Measure
- Pediatric Peritoneal Dialysis Kt/V Adequacy Measure
- Percentage of patient months of pediatric in-center hemodialysis patients with documented monthly nPCR measurements
- Clinical Depression Screening and Follow-Up Measure
- Medication Reconciliation Reporting Measure

Request for Information on Measure Concepts Under Consideration for Future Years

CMS seeks stakeholder feedback on potential future measure concepts that would address well-being, nutrition, and physical activity, as well as measures related to chronic kidney disease (CKD) that would encourage early detection and treatment and delaying the progression to ESRD.

CMS describes well-being as a comprehensive approach to disease prevention and health promotion that integrates mental, social, and physical health while emphasizing preventative care to proactively address potential health issues. While well-being is important for all people, including Medicare beneficiaries living with ESRD, attempting to assess their overall health, happiness, and satisfaction in life through a measure in the ESRD QIP would be outside the scope of the program. The ESRD QIP assesses the quality of care provided by dialysis facilities and nephrologists based on clinical and reporting measures for the renal dialysis services they provide and for the outcomes they can directly impact. Attributing a patient's happiness and satisfaction

in life to the renal dialysis services provided by their facility is outside the scope of the ESRD QIP. We urge CMS to not consider a well-being measure for the ESRD QIP for future years.

Adequate nutrition and nutritional support are important for the health of people living with ESRD and receiving dialysis. Nutrition-related concerns for this population include maintaining acceptable weight and serum proteins (e.g., albumin), minimizing renal bone mineral disease, and reducing cardiovascular risk. Over the years, various groups in the kidney community have explored a potential nutrition measure but could not reach a consensus. While there are metrics related to albumin, they would not be appropriate as a measure of nutrition for people on dialysis. This is due to challenges of assessing albumin based on different dialysis modalities and the interaction of other conditions that can muddle the results. A more appropriate avenue for a potential nutrition measure would be as a pre-dialysis CKD measure, given the important role nutrition can play in slowing CKD progression.

As CMS notes, there are several barriers to physical activity that a person on dialysis may encounter, including physical, structural, psychological, and practical barriers. And the extent of these barriers can vary from patient to patient based on their individual circumstances. In terms of the available research, there is no clinical literature to support the development of a measure of physical activity specific to individuals receiving dialysis. There is no consensus about what type of physical activity should be measured, how long the activity should last, or how to quantify the effort exerted during the activity. Given all of these factors, we urge CMS to not consider a physical activity measure in the ESRD QIP for future years.

Encouraging early detection of CKD and earlier treatment of CKD to slow its progression is critical to addressing the prevalence of CKD and kidney failure. However, given the structure of the Medicare ESRD program, in which beneficiary coverage starts on the first day of the fourth month of receiving dialysis treatments, measures related to early detection and treatment of CKD would not be applicable in the ESRD QIP. We support efforts to develop reliable, valid and actionable CKD measures for other physician quality programs. We also urge CMS to work with the kidney community and other health care stakeholders to consider other ways to improve and encourage more upstream kidney care, including potential payment models.

Thank you for the opportunity to provide comments on this proposed rule.

Sincerely,

LaVarne A. Burton
President and CEO