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August 26, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244–1850

Re: CMS–1805–P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, 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 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 Market Basket Update

The proposed ESRD market basket update for CY 2025 is 1.8 percent, after accounting for the productivity adjustment. AKF is concerned that the ESRD 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 disparities, and the continued misalignment between the market basket and actual inflation only

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exacerbates those health disparities 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 quality care.

Based on an analysis by Health Management Associates (HMA) that is also presented in KCP's comment letter, the underestimating of the actual increase in cost since 2019 has led to a cumulative difference between the market basket update and actual increase in cost of nearly 7 percent (see Table 1).

Table 1. Base-Rate Update Math for ESRD-PPS 2025

MB Base Year	2016				2020		
ESRD PPS Final Rule	2019	2020	2021	2022	2023	2024	Cumulative
Unadjusted Final MB Update	2.1	2	1.9	2.4	3.1	2.4	114.7%
Actual MB Inflation	2.3	1.9	3.1	5.1	4.2	3.3	121.6%
Final MB Update Compared to Actual (Forecast Error)	-0.2	0.1	-1.2	-2.7	-1.1	-0.9	-6.9%

This cumulative forecast error represents 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.

We also urge CMS to work with the kidney community to evaluate and consider ways to revise the market basket to address methodological issues that may be contributing to the misalignment between the update and actual increase in cost. HMA conducted an analysis that compared the cost categories, weights and price proxies of the ESRD market basket and other Medicare payment systems—specifically the Inpatient Prospective Payment System (IPPS) and the SNF PPS.

We direct you to KCP's letter for more detail, but in summary, the analysis found that capital costs and "All Other Goods and Services" are weighted significantly more in the ESRD PPS than in the IPPS and SNF PPS, while the labor-related share of payments in the IPPS (a two-tier share of 67.6% and 62.0%) and SNF PPS (70.10%) are significantly higher than in the ESRD PPS (55.20%). Refining categories, blending proxies, and adjusting the weighting amounts could better reflect changes in cost and lead to a more accurate ESRD market basket update, and we ask that CMS work with the kidney community to further evaluate these potential changes to the market basket methodology.

Proposed CY 2025 Update to the Outlier Policy

CMS proposes to change the definition of ESRD outlier services to include drugs and biological products that were or would have been included in the composite rate prior to the establishment of the ESRD PPS. The proposal would expand outlier eligibility to longstanding drugs and biological products that were historically included in the composite rate, as well as newer drugs and biological products that are currently included in the calculation of the post-TDAPA add-on payment adjustment, which for CY 2025 would include Korsuva, the only renal dialysis drug with a TDAPA period ending in CY 2024.

We agree that composite rate drugs and biological products should be eligible for outlier payments, but we have concerns that CMS's proposed technical modifications to the inflation factors used for the outlier calculations could lead to outlier payments that exceed the 1 percent target for the outlier pool. To calculate the inflation factor for outlier eligible drugs and biological products, CMS proposes to create and use an ESRD specific drug index instead of the market basket price proxy for pharmaceuticals. CMS calculates this would result in a projected inflation factor of -0.7 percent, which would result in lower FDL and MAP amounts, but it would also increase the number of claims that could be eligible for outlier payments and the amount of outlier payments that would be paid on each claim. However, we are concerned that if the projected inflation factor using this new drug index is incorrect and prices instead increase in 2025, the outlier pool could well exceed the 1 percent outlier pool threshold, which could necessitate a decrease in the ESRD base rate to compensate.

For outlier eligible laboratory tests and supplies, CMS proposes a different approach to calculating the inflation factor, in which the CPI projection for labs and supplies would be replaced with the equivalent market basket proxies. CMS calculates the effect would be similar to the proposed modification for drugs and biological products: lower FDL and MAP amounts, but an increase in the number of claims that could be eligible for outlier payments and the amount of outlier payments that would be paid on each claim. Again, our concern is the same as with the proposed changes to the inflation factor for drugs and biological products, which is that the outlier pool could exceed the 1 percent threshold. We recommend CMS reevaluate these proposed technical modifications before finalizing them to address this concern.

We also want to emphasize that although we agree that composite rate drugs and biological products should be eligible for outlier payments, expanding eligibility for outlier payments is not a suitable substitute for meaningful payment policy that ensures patient access to innovative drugs, biological products, and devices while maintaining the stability of the ESRD PPS to ensure access to other renal dialysis services in the bundle. The example of Korsuva under the proposed outlier policy demonstrates this.

In HMA's analysis, under the proposed outlier policy, facilities would lose approximately $70 per treatment for each patient receiving Korsuva, which costs $150 per treatment. If the entire 16

percent of the population that is estimated to suffer from severe pruritus were to receive the drug, the total outlier payment for that one drug would be $350 million for CY 2025, more than three times the current outlier pool. That would mean CMS would have to decrease the ESRD base rate by approximately $9 per treatment to align the outlier pool with the budget neutrality requirement, jeopardizing access to other renal dialysis services for beneficiaries.

As we outlined in our comment letter to last year's proposed rule, ensuring patient access to innovative drugs and biological products requires a post-TDAPA add-on payment adjustment that is permanent and applied to the base rate for new drug and biological products that are in an existing functional category; applied immediately at the end of TDAPA; applied in a non-budget neutral manner; uses the most recent average sales price (ASP) and utilization data in calculating the add-on payment adjustment and set the final amount at 65% of that calculated amount; updated annually to account for inflationary changes; and applied only to claims for patients who receive the new renal dialysis drug or biological product.

Inclusion of Oral-Only Drugs into the ESRD PPS Bundled Payment

AKF appreciates CMS soliciting comment on the extent to which 100 percent of ASP is appropriate for TDAPA payment for phosphate binders and whether there are any costs associated with the inclusion of phosphate binders into the ESRD bundled payment that may not be accounted for by 100 percent of ASP. As CMS notes, "unlike drugs and biological products for which payment is already included in the ESRD PPS base rate, including all other drugs and biological products in existing functional categories, dispensing fees and other costs are not currently included in the ESRD base rate for phosphate binders."

As ESRD facilities, patient groups and others in the kidney community have noted, and which the the Government Accountability Office (GAO) detailed in its 2023 report, there will be significant costs associated with including phosphate binders in the ESRD bundled payment due to several factors, including: the high volume of phosphate binders prescribed; the complexity of dispensing phosphate binders; updating of information technology systems; hiring additional staff; establishing storage space, adjusting drug supplies when a physician changes a patient's prescription to another product; mailing fees and pharmacy charges; and complying with state pharmacy laws.

Given these operational costs, we urge CMS to adopt a dispensing fee using a rate of ASP + 6 percent for phosphate binders. Doing so would align with the policy CMS used for calcimimetics during its TDAPA period, and it would align with the ASP + 6 percent dispensing fee policy currently used in other payment systems, including for hospital outpatient departments and ambulatory surgical centers.

While we recognize CMS's intention to proceed with including oral-only phosphate lowering drugs in the ESRD bundled payment in CY 2025, we want to reiterate our concern that doing so will negatively impact patient access to these critical therapies due to the operational challenges

described above, particularly for smaller dialysis providers. For patients who are experiencing food insecurity or live in food deserts, and therefore lack access to nutritious, low phosphorus foods, moving phosphate-lowering therapies into the ESRD bundled payment may create access barriers that could further complicate management of serum phosphorus. Also, given that people of color are disproportionately represented among the ESRD population, and because of the relatively high percentage of Medicare Part D beneficiaries with ESRD receiving phosphate binders (63.3% of HD patients and 56.6% of PD patients[1]), adverse effects on patient access to these therapies are concerning from a health equity standpoint.

Proposed Changes to the Low-Volume Payment Adjustment (LVPA)

AKF appreciates that CMS's proposed two-tiered LVPA using scaled adjusters is a step toward refining the LVPA with an approach that has been recommended by several stakeholders, including AKF, KCP and MedPAC. Although we have recommended in previous comment letters a two-tiered LVPA, with 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, we now recommend a three-tiered LVPA. The first tier would be facilities providing fewer than 4,000 treatments per year, the second tier would be facilities providing 4,001-5,000 treatments, and the third tier would be facilities providing 5,001-6,000 treatments. These are the same three-tiers recommended by MedPAC. We are recommending these tiers because they are consistent with analysis from HMA that identified cut points in which these low-volume facilities have higher costs. Also, as MedPAC has noted, these three tiers "reduce the all-or-nothing application of the [current] LVPA and better match the higher cost per treatment for facilities with relatively low volume."[2]

We are concerned that in CMS's proposed changes to the LVPA, the rural payment adjustment would remain in the ESRD PPS. We reiterate our recommendation from previous comment letters that in conjunction with a three-tiered LVPA, the rural payment adjustment should be eliminated. MedPAC has also recommended this, finding that the rural adjustment does not target low-volume and isolated facilities, with about 50 percent of rural facilities being high-volume, furnishing more than 6,000 treatments.[3] High-volume facilities have, on average, lower adjusted costs per treatment than low-volume freestanding facilities.[4] HMA's analysis of CMS's proposed two-tiered LVPA finds that both tiers would significantly overlap with the rural adjustment.

[1] https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/10-prescription-drug-coverage-in-patients-with-esrd
[2] https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch7_reporttocongress_sec.pdf
[3] https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/default-document-library/dialysis-oct-2019-public.pdf
[4] Ibid.

Table 2. Low Volume / Rural Overlap

	# of Facilities	% rural 2025	% rural 2024
Low Volume Tier 1 (0-2999)	202	48.5%	50.0%
Low Volume Tier 2 (3000-3999)	128	44.5%	46.1%

Eliminating the rural adjustment would allow those resources to be reallocated to a refined LVPA that better targets funding to ESRD facilities that serve a small number of patients in underserved areas so that patient access to care is maintained. Removing the rural adjustment would also negate the need to apply a significant budget neutrality calculation, as CMS does in its LVPA proposal with the rural adjustment still in place.

Although we recommend different categories of LVPA tiers than CMS proposes, we do support CMS's proposal to determine an ESRD facility's LVPA tier based on the median treatment count volume of the last three cost reporting years, rather than using a single year treatment count. We agree that this would smooth payments over years, increasing stability and predictability in payments to low-volume facilities, and help address the issue of payment cliffs between the tiers.

Proposal to Allow Medicare Payment for Home Dialysis for Beneficiaries with AKI

AKF strongly supports the proposal to extend the home dialysis benefit to beneficiaries with acute kidney injury (AKI), for either peritoneal dialysis (PD) or hemodialysis (HD). As CMS notes, the literature clearly shows a high correlation between the use of PD for beneficiaries with AKI and positive clinical outcomes related to fluid management, infection rates, and mortality. We believe this proposal is a much-needed step to improve patient-centered care and ensure beneficiaries with AKI receive the necessary care to improve their condition and recover kidney function.

However, we urge CMS to not adopt a budget neutrality adjustment to account for a home dialysis training add-on payment adjustment for beneficiaries with AKI. The ESRD PPS base rate, which would be the same payment amount for home dialysis for AKI beneficiaries, already includes a budget neutrality adjustment for the home dialysis training add-on payment adjustment. Applying a separate budget neutrality adjustment to the home dialysis training add-on payment for AKI beneficiaries would be unnecessary and redundant.

Additionally, as outlined by the example provided by CMS, a reduction in the AKI base rate due to the budget neutrality adjustment for the home training add-on payment could disincentivize ESRD facilities from treating patients with AKI, since the ESRD PPS base rate would not be equal to the AKI dialysis payment rate. While we strongly support the proposal to allow Medicare payment for home dialysis for AKI beneficiaries, we urge CMS to not adopt a budget neutrality adjustment that would hinder this positive step toward improved patient-centered care for AKI beneficiaries.

Proposed Updates to the ESRD Quality Incentive Program (QIP)

AKF supports the proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic, which would be comprised of four individual Kt/V measures for adult HD, adult PD, pediatric HD, and pediatric PD. As we have expressed in the past, the Kt/V Dialysis Adequacy measure, 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. We agree with CMS that by replacing this measure with Kt/V Dialysis Adequacy Measure Topic CMS "would be able to assess Kt/V performance more accurately based on whether the patient is an adult or child and what type of dialysis the patient is receiving."

AKF supports the proposal to remove the NHSN Dialysis Event reporting measure based on the analysis that NHSN dialysis event data are being reported consistently by most facilities, and the measure is not likely to drive improvements in care.

We would also like to take this opportunity to reiterate our concerns with the NHSN Bloodstream Infection (BSI) clinical measure. Research by the measure developer and others, including CMS, have demonstrated that the measure is not reliable or valid, caused primarily by under reporting. Decreasing infections is a very important factor in improved patient outcomes and decreased hospitalizations, and there should be a measure that encourages reduction in bloodstream infections in the dialysis patient population. As an interim step, AKF recommends CMS convert the NHSN BSI measure to a reporting measure while it convenes a technical expert panel (TEP) to identify the problem with the measure, propose solutions, and submit a measure that would meet the validity requirements of endorsement to the consensus-based organization.

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:

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KCP Recommendations for Distributing Measures Across the QIP and DFC

QIP	Dialysis Compare
Bloodstream Infection in HD Patients Rate Clinical Measure (replaced with one that is valid and reliable)	Medication Reconciliation Reporting Measure
ICH-CAHPS Clinical Measure (with suggested modifications and including home dialysis questions)	Clinical Depression Screening and Follow-Up Reporting Measure
Standardized hospitalization rate measure (current ratio measure modified to a true risk-standardized rate)	COVID-19 Vaccination Coverage Among Healthcare Personnel
Standardized readmissions rate measure (current ratio measure modified to a true risk-standardized rate)	Facility Commitment to Health Equity Reporting Measure
Transplant referral and percentage of referred patients waitlisted measure set	Screening for Social Drivers of Health Reporting Measure
Hgb < 10 g/dL	Screen Positive Rate for Social Drivers of Health Reporting Measure
Long-Term Catheter Rate Clinical Measure	
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	

Request for Public Comment on Future Change to the Scoring Methodology to Add a New Adjustment that Rewards Facilities Based on their Performance and the Proportion of their Patients Who are Dually Eligible for Medicare and Medicaid

AKF supports the development and implementation of a Health Equity Adjustment (HEA) bonus in the ESRD QIP based on a facility's performance and the proportion of their patients who are dually eligible for Medicare and Medicaid, and we believe it would be a valuable addition to the program. Studies have documented the association between low income or poverty status and increased risk factors for chronic kidney disease (CKD).[5] Additionally, a person with ESRD may become too sick to continue working, especially if they have comorbidities and other complex medical conditions, leading to less income. These factors, along with Medicare coverage that most people with ESRD become eligible for because of their ESRD, contribute to a higher percentage of dually eligible beneficiaries with ESRD when compared to non-ESRD Medicare beneficiaries. In 2021, 45% of Medicare beneficiaries with ESRD were dually eligible for Medicare and Medicaid, whereas 19% of all Medicare fee-for-service beneficiaries were dually eligible.[6] An HEA bonus in the ESRD QIP would be a valuable tool to ensure high-performing facilities that serve a higher proportion of complex and vulnerable patients have the resources they need to continue to advance health equity.

As a starting point for the development of a future HEA in the ESRD QIP, we recommend the following points for consideration:

- Similar to the recent HEA CMS has recently finalized for the Hospital Value-Based Purchasing (VBP) program, an HEA bonus in the ESRD QIP should be applied to a facility's TPS and calculated based on their performance on the QIP measure domains and the percentage of their patients who are dually eligible.
- Because the QIP is not a budget neutral program, an HEA bonus should not be budget neutral. The purpose of an HEA is to reward high-performing facilities serving disadvantaged populations with bonus points to their TPS, which is likely to result in a reduction in the number and size of QIP penalties in the ESRD program. CMS should not seek to increase QIP penalties through other policy changes.
- Given the increase in the number of ESRD beneficiaries enrolled in Medicare Advantage (MA), the calculation of the number of dually eligible patients served by a facility should include those who are in Medicare fee-for-service and MA.

AKF looks forward to working with CMS as it continues to consider and develop a potential HEA in the ESRD QIP.

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[5] Crews, D.C., Gutiérrez, O.M., Fedewa, S.A. *et al.* Low income, community poverty and risk of end stage renal disease. *BMC Nephrol* 15, 192 (2014). https://doi.org/10.1186/1471-2369-15-192

[6] https://www.medpac.gov/wp-content/uploads/2024/01/Jan24_MedPAC_MACPAC_DualsDataBook-508_SEC.pdf

ESRD Treatment Choices (ETC) Model Request for Information

AKF appreciates the opportunity to provide feedback on the following questions from CMS's request for information on the ETC Model.

- *How should any future Innovation Center model that incorporates home dialysis incorporate what the community has learned from the ETC Model?*

  Any future model that incorporates home dialysis should continue to focus on the importance of patient education on their modality choices and encouraging shared decision-making. One policy tool that we have commented on previous comment letters is expanding the use of the Medicare Kidney Disease Education (KDE) benefit. While we strongly support CMS granting KDE flexibilities within the ETC Model, we believe it should ideally be implemented throughout the Medicare program, but at the very least should be expanded further through future Innovation Center models. For example, we believe it would be beneficial to extend the KDE benefit to beneficiaries with stage 3b chronic kidney disease (CKD) so that more patients would be able learn about future treatment modality options and interventions that can help slow their disease progression.

  In talking to people living with ESRD, AKF has heard numerous accounts where people with ESRD were not adequately educated on their treatment options and were not aware that home dialysis or a preemptive transplant might be a good option for them until they researched it themselves or went to a different clinician. Given the importance of patient education in empowering patients to make the right modality choice for them, continuing to eliminate barriers to the Medicare KDE benefit is an important step in increasing the rate of home dialysis.

- *What barriers to home dialysis could be addressed through the ESRD Prospective Payment System (PPS)?*

  We reiterate our recommendation for CMS to adopt the set of home dialysis measures developed by the Kidney Care Quality Alliance (KCQA), of which AKF is a member. The measures, which have been considered for endorsement, are:

  - The home dialysis rate measure: percent of all dialysis patient-months in the measurement year in which the patient was dialyzing via a home dialysis modality.
  - The home dialysis retention measures: percent of all new home dialysis patients in the measurement year for whom >=90 consecutive days of home dialysis was achieved.

  This measure set is more useful than current metrics because they hold facilities accountable for starting patients on home dialysis modalities as well as ensuring that these individuals remain on home dialysis. Given the importance of addressing barriers to

home dialysis, CMS should adopt this measure set to better evaluate the effectiveness of facility performance on the use of home dialysis among their patients.

- *What approaches could CMS consider to increase beneficiary access to home dialysis modalities in Medicare Advantage?*

  As we have noted previously, given the significant growth in MA enrollment among beneficiaries with ESRD, it is critical that MA enrollees have access to an adequate network of dialysis facilities, nephrologists, and other specialists in their MA plan, and we reiterate our recommendation that CMS restore MA time and distance network adequacy standards for dialysis providers. Patients who want to do home dialysis still need access to dialysis facilities and other specialists at certain times, and establishing strong network adequacy standards will ensure patients have access to the necessary providers for their care.

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

Sincerely,

LaVarne A. Burton
President and CEO