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August 19, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Center for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS–1768–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 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.

AKF appreciates that CMS, in addition to its annual proposed rulemaking on the Medicare End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Quality Incentive Program (QIP), is continuing to seek stakeholder feedback on addressing health disparities and achieving health equity in kidney care. Advancing health equity is a key pillar of AKF's work, and we are pleased to offer our comments on the various topics raised in the requests for information (RFIs) in the proposed rule.

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.

Flexibilities for the ESRD QIP in Response to the Public Health Emergency (PHE) Due to COVID-19

AKF supports CMS' ESRD QIP flexibilities in response to the COVID-19 public health emergency (PHE), including the measure suppression policy and the measure suppression factors, which remain the same as from the CY 2022 ESRD PPS and QIP final rule. We appreciate and agree with CMS that the policy allows the agency to "account for the impact of changing conditions that are beyond participating facilities' control" and helps "ensure that facilities are not affected negatively when their quality performance suffers not due to the care provided, but due to external factors, such as the COVID-19 PHE."

AKF supports the proposal to suppress the following six measures for Performance Year (PY) 2023: Standardized Hospitalization Ratio measure (SHR), Standardized Readmissions Ratio measure (SRR), In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration measure, Long-Term Catheter Rate measure, the Kt/V Dialysis Adequacy measure, and the Percentage of Prevalent Patients Waitlisted measure, which we had recommended for suppression in CY 2022 rulemaking.

Additionally, we recommend that CMS also suppress the Standardized Fistula Rate (SFR) measure under CMS' Measure Suppression Factor 1, significant deviation in national performance on the measure during the COVID-19 PHE. In explaining the reason for suppressing the Long-Term Catheter Rate measure, CMS noted it has observed a steady and significant increase in catheter rates in 2021. CMS noted its concern that the COVID-19 PHE continues to impact the ability of ESRD beneficiaries to seek treatment from medical providers regarding their catheter use, possibly due to the risks of COVID-19 and patient reluctance to seek medical treatment and risk exposure. Given that the SFR measure is linked to the Long-Term Catheter Rate measure, COVID-19 PHE factors that could be increasing catheter use would also affect AV fistula placement and lead to a decrease in the fistula rate. Therefore, we recommend the suppression of the SFR measure.

AKF also recommends that CMS not score facilities on the remaining measures nor implement penalties for PY 2023 as it did for PY 2022. AKF strongly supports CMS' long-standing effort through the QIP to link payments to healthcare quality in the dialysis setting. We also support CMS' stated policy of publicly reporting suppressed measure data with appropriate caveats on data limitations due to the COVID-19 PHE in order to provide transparency to consumers and to uphold safety. However, scoring facilities on the remaining unsuppressed measures and assessing penalties will not produce a meaningful representation of a facility's quality performance during the COVID-19 PHE because the total performance score (TPS) will be skewed. For example, scoring the remaining measures would shift the weight of the Clinical Depression reporting

measure from 2 percent to 35 percent. The measure reports on whether a facility screens a patient for depression but does not measure a clinical outcome. Tying a facility's payment penalty to the resulting skewed TPS does not further the goal of incentivizing and driving quality care.

Technical Updates to the SRR and SHR Clinical Measures Beginning with the PY 2024 ESRD QIP

AKF supports the proposal to express the SRR and SHR as rates instead of ratios. We agree with CMS that doing so will improve the ability of facilities to track and compare their performance on the measures year over year, and help patients and providers better understand a facility's performance. To ensure this proposal achieves these objectives, we recommend CMS use a consistent denominator, which will better allow facilities to compare their performance and take steps to improve patient outcomes.

Proposed Updates to Requirements Beginning with the PY 2025 ESRD QIP

- **Proposal To Adopt the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Reporting Measure Beginning with the PY 2025 ESRD QIP**

AKF supports the proposal to add a new measure, the COVID-19 Vaccination Coverage among HCP, to the QIP beginning with PY 2025. People on dialysis are at high risk for developing complications from COVID-19, and facilities have implemented additional infection-control policies and procedures in accordance with CMS and CDC recommendations to protect high-risk ESRD beneficiaries and employees during the COVID-19 pandemic.¹ We believe the addition of this reporting measure will be another useful tool to protect essential healthcare workers, patients on dialysis, caretakers, and the broader community.

- **Proposed Updates to the standardized Transfusion Ratio (STrR) Reporting Measure Beginning with PY 2025**

While we appreciate CMS' efforts to address ongoing validity concerns of stakeholders about the STrR measure, AKF remains concerned about its use in the QIP and reiterate our recommendation to instead use a hemoglobin less than 10 measure (Hgb < 10 g/dL). Facilities do not have access to transfusion data because it is maintained by hospitals and outpatient departments, and facilities encounter difficulties in obtaining the information when they request it. Hgb < 10 g/dL would be a preferable anemia outcome measure because it is actionable by facilities since they have ready access to hemoglobin data. A more actionable anemia outcome measure will have a greater positive effect on patient care and outcomes, particularly Black ESRD patients who tend to have lower hemoglobin

¹ HHS Office of Inspector General, "Selected Dialysis Companies Implemented Additional Infection Control Policies and Procedures to Protect Beneficiaries and Employees During the COVID-19 Pandemic," May 2022: <https://oig.hhs.gov/oas/reports/region5/52000052.pdf>

levels compared to White ESRD patients. According to the U.S. Renal Data System (USRDS), 27.2% of Black hemodialysis and 30.6% of Black peritoneal dialysis patients have hemoglobin levels less than 10 g/dL, compared to 23.8% of White hemodialysis and 22.7% of White peritoneal dialysis patients.² Using the HgB < 10 g/dL measure gives facilities a more actionable measure to manage a patient's anemia and address health disparities.

- **Proposal To Convert the Hypercalcemia Clinical Measure to a Reporting Measure Beginning with PY 2025**

We appreciate that CMS recognizes the concerns that AKF and other stakeholders have voiced regarding the role of the hypercalcemia clinical measure in the ESRD QIP as a bone mineral metabolism measure. The National Quality Forum (NQF) has determined that the hypercalcemia measure is topped out, and CMS noted other analyses that show it is very close to being topped out. While CMS' proposal to convert the hypercalcemia clinical measure to a reporting measure beginning in PY 2025 is a more appropriate step than keeping the status quo, AKF recommends that CMS instead use the NQF approved (#0255) serum phosphorus measure starting in PY 2025. Although it is in reserve status (as is the hypercalcemia measure), physicians still use the serum phosphorus measure in their clinical decision-making. We believe the serum phosphorus measure would be a more appropriate one to use while CMS works with the kidney community to find an appropriate replacement measure for bone mineral metabolism.

Additional AKF comments on ESRD QIP measures

Although in the proposed rule CMS does not propose any changes to the following ESRD QIP measures, AKF would like to reiterate our concerns and recommendations from previous comment letters:

- **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 (approximately 35 percent), due in large part to patient survey fatigue. Our recommendations to address the fatigue problem and the low response rates include dividing the survey into three sections that are independently tested and administering the survey once a year instead of twice a year.

² United States Renal Data System (USRDS) 2020 Annual Data Report, Chapter 2, Clinical Indicators and Preventive Care: <https://adr.usrds.org/2020/end-stage-renal-disease/2-clinical-indicators-and-preventive-care>

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.

AKF also encourages CMS to work with stakeholders to develop an additional CAHPS survey for home dialysis patients, especially given the Administration's emphasis on encouraging the use of home dialysis. It is critically important that the patient experience in home dialysis is formally captured. We also strongly urge CMS to obtain NQF endorsement to the new measure.

- **Kt/V Dialysis Adequacy Measure**

AKF remains concerned about including all dialysis populations in a single dialysis adequacy measure which has not been endorsed by the NQF. We support the use of dialysis adequacy measures in the QIP. However, the Kt/V Dialysis Adequacy measure proposed for PY 2024 and future years, 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. This is concerning given the Administration's emphasis on encouraging the use of home dialysis. AKF recommends that CMS instead use NQF-endorsed dialysis adequacy measures that allow patients to better understand a facility's performance on different dialysis modalities, specifically the separate adult and pediatric hemodialysis and peritoneal dialysis adequacy measures.

- **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 bloodstream 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 CMS rely on the NHSN Dialysis Event reporting measure to inform patients on whether a facility is reporting bloodstream infections. This would be an interim step while the problems with the reliability of the BSI measure are resolved prior to implementing it as a clinical measure.

- **Percentage of Prevalent Patients Waitlisted (PPPW)**

AKF fully supports the inclusion of meaningful transplant measures in the QIP. There are areas for improvement for both dialysis facilities and transplant centers that CMS should examine. Appropriate transplant measures in the QIP can promote patient access to transplantation if actionable by dialysis facilities and meets NQF criteria for validity and reliability. However, the PPPW measure is not actionable by dialysis facilities since the decision to add a patient to the transplant waitlist is made by the transplant center. Also, the measure has not been endorsed by the NQF because it does not meet the scientifically based criteria used to evaluate measures. CMS should work with the kidney community towards developing an NQF-endorsed facility-level measure that may include 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 for, while also encouraging prompt evaluation of patients.

Request for Information on Quality Indicators for Home Dialysis Patients

CMS seeks comments on strategies to monitor and assess quality of care to patients who receive home dialysis. We urge 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 submitted to the NQF 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.

We refer CMS to the KCP comment letter for further details on the measures.

We also reiterate our recommendation for CMS to work with stakeholders to develop a patient satisfaction survey for home dialysis patients, as noted above.

CMS also seeks comment on how to support more equitable access to home dialysis across different ESRD patient populations. As AKF noted in our February 2022 comment letter on CMS' RFI on the kidney care ecosystem, home dialysis has traditionally seen low rates of utilization in the United States, with 13.1% of all dialysis patients using home dialysis in 2019.³ With studies showing that home dialysis for certain patients can lead to better health outcomes,⁴ there is

³ United States Renal Data System, Annual Data Report, 2020. Volume 2, Chapter 1, Incidence, Prevalence, Patient Characteristics, and Treatment Modalities: <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>

⁴ Rivara, M. B., & Mehrotra, R. (2014). The changing landscape of home dialysis in the United States. *Current opinion in nephrology and hypertension*, 23(6), 586–591. doi:10.1097/MNH.000000000000066

clearly an opportunity and a need to increase its utilization, and AKF has been supportive of federal efforts to do so.

Increasing access to home dialysis is particularly important for communities of color, who see disproportionately lower rates of its use. For example, 58% of all dialysis patients (both in-center and home dialysis) in 2018 were White, 33% were Black, and 19% were Hispanic.⁵ However, 66% of peritoneal dialysis (PD) patients were White, 24% were Black, and 16% were Hispanic.⁶ For home hemodialysis (HHD), 50.8% of HHD patients were White, 24.2% were Black, and 16% were Hispanic.⁷ A study has also found that Blacks and Hispanics were 30% and 19% less likely, respectively, than Whites to start on PD.⁸ Additionally, the study found communities of color (particularly Hispanic and Asian patients) were 7% to 35% less likely to initiate HHD compared with White patients, though the difference for Black patients was not statistically significant.⁹

For these disparities in home dialysis initiation, the study found socioeconomic factors played a significant role.¹⁰ Another study examining the reasons why patients start but then exit from a HHD program found that the primary reasons included lack of caregiver support and housing insecurity due to losing a home or being evicted.¹¹

There are various policy tools that could be used to address the low rate of home dialysis in communities of color, and one we want to highlight is expanding the use of the Medicare Kidney Disease Education (KDE) benefit. While we support CMS granting KDE flexibilities within the ESRD Treatment Choices (ETC) Model, we believe it should be implemented throughout the Medicare program. Additionally, 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, eliminating barriers to the Medicare KDE benefit is an important step in increasing the rate of home dialysis and transplantation, especially in communities of color.

⁵ United States Renal Data System (USRDS): <https://usrds.org/data-query-tools/esrd-prevalent-count/>

⁶ Ibid.

⁷ Shen, Jenni I. et al. Socioeconomic Factors and Racial and Ethnic Differences in the Initiation of Home Dialysis, *Kidney Med.* 2(2):105-115. Published online February 11, 2020. DOI: <https://doi.org/10.1016/j.xkme.2019.11.006>

⁸ Ibid.

⁹ Ibid.

¹⁰ Ibid.

¹¹ Paterson B, Fox DE, Lee CH, et al. Understanding Home Hemodialysis Patient Attrition: A Cohort Study. *Canadian Journal of Kidney Health and Disease.* January 2021. doi:10.1177/20543581211022195

Another policy tool that we urge Congress and CMS to support is including kidney disease screening in the “Welcome to Medicare” preventive visit. For many people with kidney failure, they were not aware of their CKD until they “crashed” into dialysis. Because a person with CKD usually does not have any symptoms until their kidneys are badly damaged, having access to a kidney disease screening is critical for early detection. By detecting their CKD earlier on in the process, before they reach ESRD, patients and their providers can work together on ways to slow the progression and discuss treatment modalities, including preemptive transplantation.

Request for Information on Potential Future Inclusion of Two Social Drivers of Health Measures

AKF strongly supports CMS’ commitment to helping facilities advance health equity and to identify and eliminate health disparities that disproportionately affect people with ESRD. As CMS noted, health-related social needs (HRSNs) are significant risk-factors associated with worse health outcomes and increased health care utilization and costs, and we agree that identifying them is crucial to address disparities and implement focused quality improvement initiatives.

In its request for information on the potential future inclusion of a Screening for Social Drivers of Health measure and a Screen Positive Rate for Social Drivers of Health measure, CMS does not provide measure specification information or detail on how these measures would be implemented into the QIP. Without this information, AKF is unable to provide informed comments, and we request that CMS provide this information to help stakeholders offer more substantive feedback before proceeding.

We agree with CMS that screening for social drivers of health would help inform facilities and providers of the impact of HRSNs in people with ESRD, which can help them tailor and initiate quality improvement strategies that help advance health equity. We support efforts to use quality measures to identify and address health disparities, particularly the use of measure stratification in the ESRD QIP. However, based on the limited information in the RFI, we are concerned that the social drivers of health measures could exacerbate disparities that they are meant to address, depending on the specifications of the measures and how the measures are used in a penalty-based program like the QIP. Another major concern is the potential time and effort required for administration and completion of questionnaires or surveys. As CMS continues to consider these potential measures in the QIP and works with stakeholders to provide feedback, we must ensure that their potential inclusion would not inadvertently and adversely affect underserved populations.

Request for Information on Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

AKF commends CMS for its continued efforts on quality measure stratification as part of its commitment to achieve health equity in healthcare outcomes for beneficiaries. As we have stated in previous letters, AKF believes that stratification of quality measure results by social risk

factors, including dual eligibility status and by race/ethnicity, is a key element of advancing health equity, and it should be part of a comprehensive approach to reward and support improved outcomes for beneficiaries with social risk factors. AKF provides the following comments on the key considerations in five specific areas that could inform CMS' approach in the use of measurement and stratification as tools to address health disparities and advance health equity.

- **Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification in ESRD QIP**

In developing methods to measure disparities in care, AKF supports CMS' goal to provide actionable and useful results to dialysis providers. Identifying and measuring disparities in care using measure stratification is a critical step toward developing effective interventions that address the reasons for the disparities and improve patient care.

We support the use of the “within-provider” and “across-provider” approaches to measuring disparities, which have been recommended by the Assistant Secretary of Planning and Evaluation (ASPE) in their 2020 Report to Congress. As CMS noted, using both methods is important to the provision of a more complete picture of disparities in care.

AKF appreciates CMS' sensitivity to the need to ensure all disparity reporting avoids measurement bias and we support CMS' intention to carefully examine stratified results and methods to mitigate the potential for drawing incorrect conclusions from results. Because ESRD disproportionately affects people from communities of color and underserved areas, it is important to be cognizant of potential measurement bias throughout the process.

- **Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting**

AKF generally agrees with and supports the guiding principles outlined by CMS in selecting and prioritizing measures for disparity reporting: prioritizing validated clinical quality measures, prioritizing measures with identified disparity in treatment or outcomes for selected social or demographic factors, prioritizing measures with sufficient sample size, and prioritizing outcome measures and measures of access and appropriateness of care. As CMS acknowledges in the RFI, measurement of access and appropriateness is a growing field and quality measures in these areas are currently limited. We look forward to engaging with CMS and other stakeholders on these measures as they continue to be developed, and to have future opportunities to provide further comment.

- **Principles for Social Risk Factor and Demographic Data Selection and Use**

As CMS noted, patient-reported data are considered the gold standard for evaluating care for patients with social risk factors and the most accurate way to attribute social risk.

However, as various efforts are underway to further develop collection of self-reported patient social risk and demographic variables, CMS has in the interim outlined three sources of social risk and demographic information that it is considering using to report stratified measure results. Based on the strengths and limitations of each data source outlined by CMS in the RFI, and like ASPE in its report to Congress, we agree that dual eligibility status is the most effective indicator of social risk and support its use in social risk factor analysis. We also encourage CMS to work with stakeholders on a coordinated effort to increase the use of ICD-10 Z-codes, to improve the collection and reporting of social determinants of health data such as housing insecurity, lack of caregiver or family support, and other issues related to psychosocial circumstances. As CMS noted, Z-codes represent an important opportunity to document patient-level social risk factors in Medicare beneficiaries, but they are underutilized in clinical practice.

- **Identification of Meaningful Performance Differences**

AKF does not support the use of rank ordering and percentiles to identify meaningful differences in performance because, as CMS noted in the RFI, it can mask the actual performance between top and bottom ranked facilities even if a measure shows a large disparity in care for patients based on a given factor. In general, the use of statistical differences, thresholds, and benchmarking are more appropriate approaches to identifying meaningful differences.

- **Guiding Principles for Reporting Disparity Results**

AKF appreciates CMS' pragmatic explanation of how it is exploring optimal methods of reporting disparity results. We agree that initially, confidential reporting may be a prudent approach to allow facilities and providers the opportunity to understand the stratification methodology and the stratified results, and to implement programs to address disparities. De-identified aggregate reporting of disparity results may also be an appropriate way to share results beyond the facility level during an initial period. Eventually, making the data on disparities publicly available will be an important step to consider to promote transparency and accountability and to address health disparities. AKF looks forward to working with CMS and other stakeholders in the future on this consideration.

Request for Information on an Add-On Payment Adjustment after the TDAPA Period Ends

AKF thanks CMS for its consideration of whether to establish an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after their Transitional Drug Add-on Payment Adjustment (TDAPA) period ends. AKF has recommended in previous comment letters that to ensure the long-term adoption of innovative treatments for ESRD beneficiaries via TDAPA, CMS should make incremental adjustments to the PPS base rate as needed after the TDAPA period to ensure adequate reimbursement and patient

access to treatments, including TDAPA drugs and biologicals that are in existing functional categories.

AKF provides the following responses to CMS' specific RFI questions:

Is an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends needed? If so, why? What criteria should CMS establish to determine which renal dialysis drugs or biological products would be included in the calculation for an add-on payment adjustment after the TDAPA period ends?

While it would be different than an adjustment to the PPS base rate, we support the concept of a post-TDAPA add-on payment methodology, which is necessary to protect beneficiary access to innovative treatments that can improve quality of care. When the ESRD PPS bundled payment rate was established, it reflected the drug and biological products available to ESRD beneficiaries prior to 2008. This has contributed to the lack of access to innovative products among ESRD beneficiaries when compared to the non-ESRD population.

CMS has stated previously that the outlier policy and annual updates to the ESRD market basket are tools that can address beneficiary access issues after a TDAPA period ends. However, using the outlier pool for new drugs in existing functional categories post-TDAPA would lead to a significant increase in the outlier threshold, which would adversely affect access to other products that traditionally qualified for the outlier pool and impact the care of high-cost outlier beneficiaries. Also, because the outlier policy is budget neutral, there would be cuts to dollars that cover the cost of treatments for the average ESRD beneficiary on dialysis.

Regarding annual updates to the ESRD market basket, it cannot be assumed that updates will ultimately result in an adequate reimbursement rate that ensures access to new products post-TDAPA. Analysis has shown that the current base rate is inadequate to support the cost of new products (see KCP letter for more detail), and the drug proxies CMS has used have not adequately accounted for the price of the majority of non-ESA drugs in existing functional categories. While we hope CMS' proposed use of a different drug proxy helps address this issue, it would still be inaccurate to assume the update to the ESRD market basket will ensure beneficiary access to innovative products. For these reasons, an add-on payment adjustment is needed, and we recommend that all new drugs that receive TDAPA should be included for an add-on payment adjustment after the TDAPA period ends.

If an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period is needed, are the methods discussed in section II.D.4 of this proposed rule sufficient to address the add-on payment adjustment? Which method would be most appropriate? Are there changes to the methodologies that CMS should consider to improve our ability to align payment for renal dialysis services with resource utilization?

AKF believes the methods outlined by CMS in the second and third bullets are the most appropriate for further consideration. These two options provide for an incremental adjustment that accounts for the adjustment by directly attributing it to the new product that is being added to the bundle. We support the approach outlined in these two options that would reconcile the average expenditure per treatment for the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in expenditures for other formerly separately billable renal dialysis drugs or biological products. While the two options differ in how the reduction is determined, we recommend that the approach should use the primary indication on the FDA label to determine the clinical association between the new product and other formerly separately billable renal dialysis products. This approach should then be combined with evidence using dialysis claims data that shows a statistically significant difference in the utilization of the formerly separately billable renal dialysis product during the TDAPA period for the new product.

We thank CMS again for its consideration and for seeking feedback on a potential add-on payment adjustment after the TDAPA period for renal dialysis drugs and biologicals in existing functional categories. This is an important issue that would address beneficiary access to innovative products, as well as taking a step to advance health equity, since communities of color are disproportionately affected by ESRD.

Proposed Revision to the Definition of Oral-Only Drug

CMS indicates in the preamble that they intend to proceed with incorporating oral-only drugs, which at the present time would be phosphate binders, into the ESRD PPS starting January 1, 2025. AKF is concerned that this policy would have negative effects on patient care, and we recommend CMS use its regulatory authority to continue the delay of including oral-only drugs in the ESRD PPS.

Phosphate binders and phosphate lowering drugs must be taken daily with meals and snacks, and there would be difficulty in administering these drugs in the facility due to the varying dosage that is required per patient and that is based on the size of meals and snacks a patient consumes. The clinical and practical realities of administering phosphate binders and phosphate lowering drugs and the need to ensure quality patient care, requires further delay of incorporating oral-only drugs in the ESRD PPS. However, if CMS does proceed with including oral-only drugs in the ESRD PPS starting January 1, 2025, we support the use of TDAPA for at least two years and for CMS to modify the base rate after the TDAPA period, as CMS indicates in the preamble.

Regarding CMS' proposed revision to the definition of oral-only drug, we ask for clarification on whether comparing the end action effect of drugs to determine functional equivalence will be made at the class or subgroup level or if it will be applied across the functional category level. We recommend that CMS clarify that comparisons of end action effects will be made at the class or subgroup level.

Health Disparities Faced by Pediatric Patients Receiving Renal Dialysis Services within the ESRD PPS

AKF agrees with KCP and the American Society of Pediatric Nephrology (ASPN) regarding the recommendations that are needed to address the health disparities faced by pediatric patients receiving dialysis, which mirror the disparities faced by adults on dialysis. Particularly, social determinants of health play a significant role in driving health disparities. To address the disparities and advance health equity, we support and reiterate the following recommendations made by KCP and ASPN:

- Provide housing assistants for families with children with kidney failure.
- Support adult care partners to allow children to dialyze at home.
- Address food insecurity and promote access to nutritious foods by expanding access to nutrition assistance programs and making sure that these programs cover the nutrition supplements that children with kidney disease need.
- Establish Medicare reimbursement for care coordination services.
- Enhance telehealth payments for pediatric nephrology visits to help address the shortage of pediatric nephrologists.

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

Sincerely,



LaVarne A. Burton
President and CEO