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August 28, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244–1850

Re: CMS-1749-P - Medicare Program; 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.

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 proposing changes in the ESRD Treatment Choices (ETC) Model. We also appreciate CMS providing the opportunity to provide feedback on the Requests for Information (RFIs) on the PPS, QIP, and ETC Model, and we commend the agency on its concerted efforts to improve health equity in kidney care.

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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 Flexibilities for the ESRD QIP in Response to the COVID-19 PHE

AKF supports CMS' proposed ESRD QIP flexibilities in response to the COVID-19 public health emergency (PHE), including the proposed measure suppression policy and the measure suppression factors; the proposed suppression of four ESRD QIP measures for PY 2022; and the proposed special scoring methodology and payment policy for the PY 2022 ESRD QIP.

We agree with CMS' concerns that the ESRD QIP "measure scores that are calculated using data submitted during the PHE for COVID-19 will be distorted and will result in skewed payment incentives and inequitable payments, particularly for dialysis facilities that have treated more COVID-19 patients than others." The ESRD QIP is intended to assess the quality of care, and we appreciate CMS' recognition of the distortion of measure scores due to the COVID-19 pandemic. We believe CMS' proposed flexibilities would help avoid inequitable payments that would unfairly penalize facilities and affect patient care.

In addition to CMS' proposed suppression of the Standardized Hospitalization Measure (SHR), Standardized Readmissions Ratio Measure (SRR), In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration Measure, and the Long-Term Catheter Rate Measure, we recommend CMS also suppress the Standardized Fistula Rate measure and the Percentage of Prevalent Patients Waitlisted (PPPW) measure. Like the other four measures CMS proposes for suppression, both measures should be suppressed under proposed factor 1, significant deviation in national performance on the measure during the COVID-19 PHE.

For several months, it was unclear whether an AV fistula placement (which the Standardized Fistula Rate measure assesses) was considered an elective surgery; CMS had delayed all elective surgeries during the PHE. Patients had also avoided in-person medical appointments during the pandemic. These factors, taken together with the fact that the Standardized Fistula Rate measure is linked to the Long-Term Catheter Rate measure, leads us to recommend its suppression.

Similarly, the PPPW measure will be impacted due to the COVID-19 PHE as UNOS registry data has shown significant decreases in waitlist additions in the first months of the PHE, including an overall 25 percent decrease at the end of April 2020 compared to January and February 2020.[1] Data has also shown more significant decreases in waitlist additions and transplants in certain UNOS regions. Given these significant deviations during the COVID-19 PHE, we believe suppression of the PPPW measure is warranted.

[1] Cholankeril, George et al. "Early Impact of COVID-19 on Solid Organ Transplantation in the United States." *Transplantation* vol. 104,11 (2020): 2221-2224. doi:10.1097/TP.0000000000003391

Proposed Updates to Requirements Beginning with the PY 2024 ESRD QIP

CMS does not propose any measure changes for the PY 2024 ESRD QIP measure set. As such, AKF would like to reiterate our concerns and recommendations on certain measures that we have previously commented on:

- **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, 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.

  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.

- **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 National Quality Forum (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, which 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.

- **Hypercalcemia Measure:** AKF remains concerned about the inclusion of the hypercalcemia measure in the ESRD QIP. We understand that CMS has a statutory requirement to include a mineral metabolism measure. However, the hypercalcemia measure may not be the most appropriate, given that nephrologists agree that the metric is not the best measure to affect patient outcomes and the NQF has concluded the measure is topped out. AKF encourages CMS to work with the kidney community to find an appropriate replacement measure.

- **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.

- **Standardized Transfusion Ratio (STrR) Reporting Measure:** AKF recommends that CMS remove the STrR measure from the QIP and 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 would be actionable by facilities since they already have access to hemoglobin data. A more actionable anemia outcome measure will have a greater positive effect on patient care, particularly Black ESRD patients who tend to have lower hemoglobin 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.

- **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. For example, it is

[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

important to incorporate transplant measures in the QIP to help improve transplantation rates, and it is important that the measures be actionable by dialysis facilities to have an impact on patient access to a transplant. 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, while also encouraging prompt evaluation of patients.

Requests for Information (RFIs) on Topics Relevant to the ESRD QIP

Closing the Health Equity Gap in CMS Quality Programs RFI

Addressing longstanding health disparities and advancing health equity is a central part of AKF's work. We commend CMS' commitment to achieving equity in health care outcomes for beneficiaries and appreciate the opportunity to provide comments on CMS' ongoing efforts in closing the health gap in CMS quality programs, specifically the ESRD QIP. The following are our comments on the topic areas in which CMS seeks comment.

Future potential stratification of quality measure results by dual eligibility and race/ethnicity

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. As recommended by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) in their reports on social risk factors in Medicare value-based purchasing programs, quality measure stratification by social risk should be part of a comprehensive approach to reward and support better outcomes for beneficiaries with social risk factors. ASPE recommended, and AKF agrees, that the first strategy should include "collecting data on social risk and reporting quality measures by patient social risk to identify and address patients' social needs and reduce health disparities. Separately reporting quality measures for those patients with and without social risk will assess progress toward closing the performance gap between these two groups of patients."[3]

AKF supports the potential stratification of facility-specific reports for ESRD QIP measure data by dual eligibility status and race/ethnicity. In line with our recommendations in our response to the 2018 ESRD PPS and QIP rulemaking, we recommend the following measures for potential stratification by dual eligibility status and race/ethnicity: Standardized Readmission Ratio (SRR),

[3] U.S. Department of Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation (ASPE), Summary of Report to Congress, *Social Risk and Performance in Medicare's Value-Based Purchasing Programs*: https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195036/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report-3-Pager.pdf

Standardized Transfusion Ratio (STrR), Standardized Mortality Ratio (SMR), and Standardized Hospitalization Ratio (SHR). There is evidence that social risk factors may be a factor in the performance of these measures in other health care settings, in particular readmission measures. Therefore, these measures would be appropriate candidates for potential stratification by social risk factors in the ESRD QIP.

As we noted in our comments on the ESRD QIP measure set, CMS should continue to work with the kidney community to improve the ICH CAHPS measure and make modifications that reduce the burden on patients, encourage patient participation and increase the survey response rate. Once steps are taken to address those priorities, potential stratification of the ICH CAHPS measure by dual eligibility status and race/ethnicity could be an important step in addressing disparities. Acquiring and maintaining an accurate record of the patient experience is essential to improving care and outcomes. Being able to identify potential differences in the patients' experience of care between dual eligible and non-dual eligible beneficiaries and patients of different race/ethnicity can allow for CMS and providers to develop strategies to address disparities in patient experience and health outcomes.

The vascular access measures, the Standardized Fistula Rate and the Long-Term Catheter Rate clinical measures, are appropriate measures for potential stratification by dual eligible status and race/ethnicity, but we also recommend stratification of these measures by insurance status at the time of dialysis initiation. Stratifying these measures by these social risk factors can give us a clearer sense of the challenges certain groups of patients may face in accessing appropriate pre-dialysis care and timely vascular access placement.

The PPPW measure is also appropriate for potential stratification by social risk factors. While AKF has raised concerns with the PPPW and has recommended CMS work with the kidney community to develop a transplant measure that is more actionable by dialysis facilities, we believe stratification by social risk factors is appropriate for any waitlisting measure. Data has shown that individuals from communities of color have lower rates of kidney transplantation. There are nearly 108,000 Americans on the organ transplant waiting list, with 93,000 of them—86%—waiting for a kidney. In 2020 45% of all kidney transplant recipients in the U.S. were White, 27% were Black, and 18% were Hispanic.[4]

In 2018, the total number of incident ESRD patients who received transplants in the same calendar year was 3,732, with 76.9% of them White and 9.6% Black.[5] Given these disparities in transplant access, it is imperative for CMS and providers to identify any differences in waitlisting when stratified by social risk factors. In addition to stratifying by dual eligibility status and race/ethnicity, we also recommend stratification by geographic area. There is significant

[4] Data from Organ Procurement and Transplantation Network: https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#

[5] United States Renal Data System (USRDS), Data Query Tools, ESRD Incident Count: https://www.usrds.org/data-query-tools/esrd-incident-count/

geographic variation in transplantation access and waitlist criteria at transplant centers, and it would be informative to see these differences through stratified reporting of the measure.

Improving Demographic Data Collection

AKF agrees with CMS that self-reported data on race, ethnicity and disability status is the best approach to classifying individuals by those demographics. We support efforts that aim to improve the collection and sharing of a standardized set of social risk data elements by ESRD facilities using structured, interoperable electronic data standards for the purposes of measure stratification and advancing equity. In conjunction with these efforts, AKF urges CMS to take into account the ASPE recommendation to consider providing "targeted technical assistance to facilities that disproportionately serve beneficiaries with social risk factors to improve quality and ensure they can successfully participate in the reporting required for the ESRD QIP." As CMS noted in the RFI, additional resources such as data collection and staff training may be necessary to ensure the conditions are created in which all patients are comfortable answering demographic questions and that preferences for a non-response from an individual is maintained.

AKF also recommends the collection and use of Z-codes to improve the collection and reporting of social determinants of health (SDOH) data such as housing insecurity, lack of caregiver or family support, and other issues related to psychosocial circumstances. As CMS has noted in a January 2020 Data Highlight, the prevalence of chronic kidney disease (CKD) among the 33.7 million Medicare fee-for-service (FFS) beneficiaries in 2017 was 24%. Among the 467,136 Medicare FFS beneficiaries with Z-code claims in 2017, 38% had CKD.[6] Clearly, there is an opportunity to utilize Z-codes to identify disparities among beneficiaries for whom SDOH may be impacting their health outcomes and to implement strategies to improve their care.

Potential creation of ESRD Facility Equity Score

AKF supports the potential creation and confidential reporting of an ESRD Facility Equity Score to synthesize results across multiple social risk factors and disparity measures. In our comments to the 2018 ESRD PPS and QIP rulemaking, we noted that creating a health equity measure was worthy of further study. ASPE had also presented it for CMS consideration in their 2016 report, noting that "a measure of health equity may play an important role in ensuring that pay-for-performance programs help to incent, rather than disincent, improving care for beneficiaries with social risk factors."[7] Developing an ESRD Facility Equity Score would need to be carefully constructed, tested, and validated prior to its use, and we would encourage CMS to work closely with stakeholders and experts, including patient groups, in any future development of a score.

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[6] CMS Data Highlight, January 2020, *Z Codes Utilization among Medicare Fee-for-Service (FFS) Beneficiaries in 2017*: https://www.cms.gov/files/document/cms-omh-january2020-zcode-data-highlightpdf.pdf

[7] U.S. Department of Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation (ASPE), December 2016, Report to Congress, *Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs*: https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//171041/ASPESESRTCfull.pdf

End-Stage Renal Disease Treatment Choices (ETC) Model

Achievement Benchmark Stratification by Dual-Eligible and Low-Income Subsidy (LIS) Status

AKF supports CMS' proposal to stratify achievement benchmarks based on the proportion of beneficiary years attributed to the ETC participant's aggregation group for which attributed beneficiaries were dually-eligible for Medicare and Medicaid or received the LIS. We believe it does address some of the concerns that socioeconomic factors may impact a beneficiary's likelihood to receive alternative renal replacement modalities, which would lower the transplant rate and home dialysis rates for ETC participants who provide services to low-income beneficiaries. However, we suggest CMS consider using either a lower cutpoint of 40%, rather than 50%, for the dual-eligible/LIS prevalence threshold, or use multiple thresholds that could be used to stratify the benchmarks based on dual-eligible or LIS status. Using these alternate cutpoints would result in more reliable benchmarks. We direct you to KCP's comment letter on the ETC model for a more detailed analysis.

We also recommend that in conjunction with stratifying achievement benchmarks by dual-eligibility and LIS status, CMS should modify the benchmark calculation by adopting a population-weighted benchmark using patient months. Doing so will allow facilities with larger patient populations, who tend to be in urban areas serving more beneficiaries from communities of color, to better move along the achievement tiers, thereby creating more incentive to improve their home dialysis and transplant rates. Again, we direct you to KCP's comment letter for more a more detailed analysis.

Proposed changes to Improvement Benchmarking and Scoring - Health Equity Incentive

AKF supports CMS' proposal to add a Health Equity Incentive to the improvement scoring methodology, which would result in a 0.5-point increase on the improvement score for ETC participants who demonstrate sufficient improvement on the home dialysis rate and/or transplant rate for attributed beneficiaries who are dual-eligible or LIS recipients. We agree with CMS that a Health Equity Incentive would benefit beneficiaries who, due to socioeconomic factors, may need extra assistance from ESRD facilities or managing clinicians to use alternative renal replacement modalities. A Health Equity Incentive would encourage ETC participants serving dual-eligible and LIS beneficiaries to implement strategies that address disparities in accessing alternative renal replacement modalities for these beneficiaries.

However, instead of the 5 or more-percentage point increase in the home dialysis and/or transplant rate from the benchmark year to the measurement year (MY) that CMS would require in awarding the Health Equity Incentive, we recommend awarding the incentive when the increase in home dialysis and/or transplant rates in dual-eligible and/or LIS patients is above the previous year's benchmark by 1% or more every two MYs, beginning for MY3. This improvement benchmark is more realistic and achievable for ETC participants and would better encourage

them to assist their dual-eligible and LIS patients with accessing alternative renal replacement modalities. We direct you to KCP's comment letter for more a more detailed analysis on this recommendation.

Proposed Kidney Disease Patient Education Services Telehealth Waiver

AKF supports CMS' proposal to add a waiver of certain telehealth requirements to provide qualified staff the flexibility to furnish kidney disease patient education services via telehealth. Specifically, we fully support the proposal to waive the geographic and site of service originating site requirements for kidney disease patient education services furnished via telehealth. AKF had recommended this flexibility in our comments to the 2019 ETC model proposed rule, stating back then that expanding the use of telehealth to more beneficiaries will allow patients to receive kidney disease patient education services in a manner that may be more convenient for them. The COVID-19 PHE has also shown the importance of this telehealth flexibility for the patient's health and safety. We appreciate that CMS sees the benefit of extending the telehealth flexibility beyond the PHE with this proposed waiver, as it would increase access to kidney disease patient education services for people who may lack transportation or who may not feel comfortable attending in-person individual or group sessions, even after the PHE ends.

Kidney Disease Patient Education Services Beneficiary Coinsurance Waiver

AKF strongly supports CMS' proposal to permit ETC participants the flexibility to reduce or waive the 20% coinsurance requirement for kidney disease patient education services (referred to as the "kidney disease patient education services coinsurance patient incentive"). We had recommended this flexibility in our comment letter to the 2019 ETC model proposed rule, as it would help make the kidney disease patient education services more accessible to beneficiaries for whom the 20% coinsurance is cost prohibitive.

While we understand CMS' reasoning for proposing to limit the kidney disease patient education services coinsurance patient incentive to beneficiaries who do not have secondary insurance, we recommend that CMS permit the incentive to all beneficiaries for whom kidney disease patient education services are clinically appropriate. Given the historically low percentage of eligible beneficiaries who have been provided kidney disease patient education services and the importance of pre-dialysis education to help patients make informed treatment decisions, expanding the coinsurance waiver to more beneficiaries would help improve the uptake of this important benefit.

Additionally, AKF supports CMS waiving Medicare requirements such that CMS would pay the full amount of the kidney disease patient education services, rather than just 80% of the amount—an option that CMS notes they considered but did not ultimately propose. We believe CMS paying 100% of the payment amount for kidney disease patient education services would remove the administrative burden that accompanies an ETC participant having to maintain the required records, as outlined in the proposed rule, when offering the kidney disease patient education

services coinsurance patient incentive. By removing that administrative burden, it would help increase the number of beneficiaries who receive kidney disease patient education services.

Requests for Information

TDAPA and TPNIES polices must ensure adequate incentives to encourage long-term adoption of innovative products for patients

AKF supports and appreciates CMS' efforts to drive greater innovation in kidney care and to encourage the development of new products that can improve the treatment of kidney disease, specifically the transitional drug add-on payment adjustment (TDAPA) and the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES).

However, to ensure the long-term adoption of innovative treatments for ESRD patients via TDAPA, we recommend that CMS return to its previous policy of requiring two to three years of TDAPA and reimbursement at average sales price (ASP) + 6%. We also recommend that in the post-TDAPA period, CMS should make incremental adjustments to the PPS base rate as needed to ensure adequate reimbursement and patient access to treatments, including TDAPA drugs and biologicals that are in existing functional categories. These recommended changes would ensure that CMS collect at least two full calendar years of data to assess a drug's utilization more accurately before it is incorporated into the ESRD bundle. The changes would also better incentivize innovation and ensure access to truly innovative products that can improve patient health.

Similarly, AKF recommends CMS apply TPNIES for three years to collect adequate utilization data and use that information to assess a device's potential incorporation into the ESRD bundle with an appropriate incremental adjustment to the PPS base rate. We also recommend CMS remove the TPNIES offset that, when combined with the pre-adjusted per treatment amount based on 65% of the price established by Medicare Administrative Contractors, undervalues innovative devices that meet the qualifying criteria for TPNIES. We believe TPNIES policy should be structured in a way that incentivizes long-term innovation and ensures patient access to devices that can improve their care and health outcomes.

In addition, we strongly urge CMS to take steps to align TDAPA and TPNIES policies in traditional Medicare and Medicare Advantage (MA) by ensuring proper reimbursement for TDAPA drugs and TPNIES devices in MA. While MA plans are required to provide the same services and items offered in traditional Medicare, inadequate reimbursement in MA for TDAPA drugs and TPNIES devices could lead to patient access issues for MA enrollees. As all Medicare ESRD beneficiaries now have the option to enroll in an MA plan, it is important that there is equal access to innovative treatments in both traditional Medicare and MA if this is going to be a truly viable option for these beneficiaries.

Calculation of the Low-Volume Payment Adjustment (LVPA)

AKF appreciates CMS' request for information on LVPA, and we share the concerns that have been voiced by other stakeholders that the current LVPA needs improvements to better target ESRD facilities that serve patients in remote or isolated areas. AKF supports replacing the current LVPA and rural adjusters and implementing a single low-volume facility adjuster with two tiers—the first tier for facilities providing less than 4,000 treatments per year and the second tier for facilities providing less than 6,000 treatments per year. These adjusters would include mechanisms to prevent bad actors from gaming the system to restrict their patient caseload, such as population attestations that can be confirmed with claims data. We believe this approach will better target funds to facilities that need it the most and that serve vulnerable populations.

CMS also seeks comment on an alternative approach to the LVPA that would use census tracts to identify geographic areas with low demand. We do not support this approach because as presented by the 2020 ESRD PPS Technical Expert Panel (TEP), this alternative lacks transparency and could be unnecessarily complicated. Also, developing an adjuster based on zip codes may not appropriately target facilities with actual low volume.

Calculation of the Case-Mix Adjustments

Patient-level adjustments must be targeted to truly high-cost patients to ensure access to quality patient care. AKF appreciates the opportunity to provide the following feedback on CMS' request for information on the ESRD PPS case-mix adjustments:

- *Comorbid case-mix adjusters*: Analyses have shown the comorbid case-mix adjusters are being claimed at low rates, which means the money withheld to fund them are being removed from the system and are not being used for patient care. Therefore, we recommend CMS remove the comorbid case-mix adjuster and instead redirect those funds so they can be better utilized on patient care and improving outcomes.

- *Age adjuster*: The age adjuster needs modification to address the current statistical noise found in published runs of the ESRD-PPS model and to have the adjuster be meaningful. An essential modification is to have the adjuster differentiate between adult and pediatric patients.

- *Weight adjusters*: The weight adjusters currently include body mass index (BMI) and body surface area (BSA). However, these two adjusters interact in a way that cancel each other out in certain instances. We recommend CMS only use BSA as a weight adjuster because physicians tend to use BSA in tailoring treatments, since BMI does not account for a patient's muscle mass.

- *Onset of dialysis adjuster*: AKF supports this adjuster in its current form.

Calculation of the Outlier Payment Adjustment

The outlier payment adjustment has consistently paid out less than the 1% that is withheld to fund the outlier pool, typically between 0.5% and 0.6%. That is problematic because the unused outlier funds are not returned to the ESRD PPS system and are therefore not used for patient care. Given the disproportionate impact of ESRD on people from communities of color, it is important to ensure these resources are used to improve patient care and address the longstanding health disparities seen among Medicare ESRD beneficiaries.

We recommend CMS align the outlier withhold with the amount that has historically been paid out. We also recommend that in the event there are remaining outlier funds that are not paid out, CMS should reallocate those funds to services that help address health disparities in the Medicare ESRD population, such as educational or pilot programs that improve health outcomes for patients from communities of color, rural areas, and low-income patients.

Calculation of the Pediatric Dialysis Payment Adjustment

AKF agrees with KCP and the American Society of Pediatric Nephrology (ASPN) that 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 must be addressed. AKF recommends the following:

- Instead of using duration of treatment, which is not a valid proxy for composite rate costs, CMS should use a combination of age, weight, and pediatric-specific comorbidities as a proxy. These comorbidities should include:
    - Failure to thrive/feeding disorders
    - Congenital anomalies requiring subspecialty intervention (cardiac, orthopedic, colorectal)
    - Congenital bladder/urinary tract anomalies
    - Solid organ or stem cell transplant
    - Neurocognitive impairment
    - Global developmental delay
    - Cerebral palsy
    - Seizure disorder
    - Chronic lung disease (and ensuing dependency on CPAP and ventilators)
    - Inability to ambulate or transfer

- To account for the differences in resource use to treat younger pediatric patients, the cost of care should be reflected in the following age group categories: <6 years old, 6-11 years old, and 12-18 years old.

- Given the very small number of pediatric patients, they should not be included in the estimation of multipliers for both adult and pediatric populations.

- To improve the collection and reporting of data on pediatric ESRD patients in the hospital setting, cost report requirements should be streamlined and made consistent with state Medicaid and private payer reporting requirements.

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

Sincerely,

LaVarne A. Burton
President and CEO