August 24, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-1782-P: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

Dear Administrator Brooks-LaSure:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for the opportunity to comment on the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), Quality Incentive Program (QIP), and End-Stage Renal Disease Treatment Choices (ETC) Model proposed rule. The ESRD Medicare Benefit and the ETC Model shape critical components of kidney care for the nearly 800,000 Americans with kidney failure, including more than 550,000 individuals who are dependent on maintenance dialysis or a kidney transplant to live.

Kidney diseases are the ninth leading cause of death in the United States, resulting in more deaths than breast cancer, and, given the heightened risk of cardiovascular disease associated with chronic kidney disease (CKD), kidney diseases contribute to millions of additional deaths in the United States from other causes. Unfortunately, kidney diseases and kidney failure are more common among Black, Hispanic or Latinx, and Native or Indigenous Americans, Asians, Hawaiians and other Pacific Islanders, people with lower incomes, and older adults; these are populations that also have been disproportionately affected by the COVID-19 pandemic, exacerbating existing disparities.

Black Americans are 3.8 times more likely to develop kidney failure than White Americans, and Latinx Americans are 2.1 times more likely to develop kidney failure than White Americans. One out of every eleven Black American males will require dialysis during their lifetime. Further, Black, Indigenous, and Latinx Americans are less likely to receive a kidney transplant or initiate home dialysis when requiring dialysis for kidney failure. These and other factors are why the Medicare ESRD program and the ETC Model, Kidney Care Choices (KCC) Model, as well as other models and reforms, must promote health equity.

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This letter addresses ASN's general recommendations to the ESRD program:

Prospective Payment System (PPS)

I. Challenges of the Market Basket to Reflect Actual Inflationary Costs and TDAPA
II. Pediatric Transitional Add-On Payment Adjustment (TPEAPA)
III. ESRD PPS Topics
  a. *Discarded Renal Dialysis Drug and Biological Products*
  b. *"Time on Machine"*

Quality Incentive Program (QIP)

I. Facility Commitment to Health Equity
II. COVID-19 Vaccination Coverage Rate Among Healthcare Personnel
III. Clinical Depression Screening and Follow-Up
IV. Ultrafiltration Rate
V. Standardized Fistula Rate
VI. Screening for Social Drivers of Health

Prospective Payment System (PPS)

I. Challenges of the Market Basket to Reflect Actual Inflationary Costs

a. *Inflationary Pressures*

The Centers for Medicare and Medicaid Services (CMS) proposes a 1.7% base payment rate increase which will raise dialysis provider payments from $265.57 to $269.9. While ASN is not a dialysis provider, providing high quality, lifesaving dialysis care to patients with kidney failure is a priority for ASN members. ASN members are concerned with the impact of inflationary pressures on access to high quality dialysis for patients living with kidney failure.

As with multiple sectors of the US health care system, the kidney community faces an unprecedented workforce crisis in multiple health care settings, including dialysis facilities. Many facilities are struggling to find qualified health care professionals, including nurses, dieticians, and dialysis technicians, as they compete with other sectors of health care with more resources and with non-health care employers who offer lower stress workplaces and higher wages. The sharp increases in labor costs have impacted the ability of these facilities to not only maintain the staff that patients need in order to receive dialysis treatments but also to retain more experienced staff who provide high quality care while training the next generation of dialysis facility personnel. ASN believes market basket adjustments in the ESRD PPS are insufficient to deal with the current crisis, with last year's market basket adjustment far below the actual increases in the costs of operating a dialysis facility. USRDS data show that Medicare spending for patients with ESRD has decreased across a range of spending

categories and by essentially 10 percent in aggregate between 2010-2020[i] even before the inflationary impact of the last several years.

ASN believes the crisis is having a negative impact on patients' access to dialysis services, both at home and in-center. ASN is concerned the situation will likely lead to greater inequities for dialysis patients the majority of whom are people of color and many of whom live in medically underserved areas or have low incomes. ASN members are reporting that hospitals are having difficulty finding outpatient unit availability for dialysis patients when trying to discharge them from a hospital stay and emphasize that many patients have lingered in the hospital for days or even weeks until a spot becomes available. While the exact number is unclear, it has been reported that more than 400 dialysis facilities have closed their doors entirely since 2019 for a variety of reasons but in part because they could not properly staff the facility. ASN members highlight the diminishing number of evening shifts at dialysis facilities, timeslots that are critical for people with kidney failure seeking to maintain employment. Finally, dialysis availability at post-acute facilities (skilled nursing facilities, rehabilitation, long-term acute care etc.) is also significantly curtailed by staffing challenges, resulting in delayed hospital discharges and negative impacts on clinical outcomes. There are additional downstream impacts to hospital dialysis capacity, resulting in the need for increased inpatient dialysis staff that can shift staff away from outpatient and post-acute settings. This results in more spending of Medicare Part A dollars to provide in-patient dialysis instead of using Medicare Part B funds for outpatient dialysis.

ASN joins others in the kidney community in asking CMS to apply an ESRD PPS forecast error adjustment – as was done in the skilled nursing facility (SNF) PPS – to correct part of the problem and to concurrently address market basket inadequacies. Without a combined approach, ASN is concerned that gaps in access to in-center dialysis will leave some patients facing delayed access to care, more transportation challenges, and risk of not receiving the right care in the right setting. In addition, there may be a greater concentration of dialysis facilities among fewer providers as small to mid-size providers exit the market.

b. ESRD PPS Transitional Drug Add-on Payment Adjustment (TDAPA)

CMS proposes creating a new add-on payment adjustment for certain new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period that would be both case mix adjusted and set at 65 percent of expenditure levels for the given renal dialysis drug or biological product. It would be applied to all ESRD PPS payments for an additional post-TDAPA period of three years.

ASN remains concerned that the post-TDAPA add-on remains insufficient to ensure access to new therapies. Without certainty that new drugs will be accessible to dialysis patients long-term, clinicians are hesitant to prescribe new agents. Many clinicians have noted that it is easier to not start something than it is to take it away. Additionally, without confidence that new drugs will be used in the dialysis space, innovators will

move to other areas where the potential for a financial return is greater, further disadvantaging kidney patients.

ASN supports CMS' outlined goals for the post-TDAPA add-on payment adjustment that seek to ensure that "payment after the TDAPA is not a barrier to Medicare beneficiaries' access to such new products" and the agency's desire "to support ESRD facilities' long-term planning with respect to continuing to budget and plan for new renal dialysis drugs and biological products that ESRD facilities have incorporated into their businesses during the TDAPA period."[ii] However, ASN believes that there is a difference between promoting efficiencies and providing inadequate funding for a program that results in serious access issues for patients.

ASN has previously commented that there is a need to adjust payments for patients who require more resource intensive clinical treatments than average. In other words, the post-TDAPA payment add on adjustment needs to be tailored to follow the patient while also adding new money. An example of this approach is found in the Hospital Outpatient Prospective Payment System (HOPPS) by defining payment in terms of clinically and resource comparable payment groups – in other words, link payment to the individual patient and their needs while remaining within a prospective payment system.[iii] The current lack of alignment may deter facilities from administering new therapies. This counters the need for CMS to advance greater equity in the Medicare ESRD program, which CMS describes as "disproportionately young, male, and African American, have disabilities and low income as measured by eligibility for both Medicare and Medicaid (dual eligible status), and reside in an urban setting." CMS goes further to state that it is seeking to "address health equity for beneficiaries with ESRD who are also members of underserved communities, including but not limited to those living in rural communities, those who have disabilities, and racial and ethnic minorities."[iv]

Therefore, ASN recommends CMS adopt the following policies to address the inequity in access to innovation faced by individuals who require dialysis:

> (1) Calculate the adjustment amount using the number of treatments with claims for the TDAPA drug as the denominator and apply the add-on payment amount only to claims for patients who actually receive the product, especially when a small portion of the ESRD population medically requires the drug. This modification would more closely align the amount reimbursed with the cost of providing the drug.
>
> (2) Allow the post-TDAPA adjustment to apply on an ongoing basis, similar to the way CMS applies the complexity adjustment in the hospital outpatient department setting using new money.

These steps help alleviate the pressures on nephrologists to avoid prescribing new and innovative therapies when they know that they will need to discontinue the treatment when the TDAPA pass through period ends if this new add-on adjustment period is inadequate.

II. Transitional Pediatric Add-On Payment Adjustment (TPEAPA)

CMS proposes establishing TPEAPA, a new add-on payment adjustment of 30 percent of the per treatment payment amount to all renal dialysis services furnished to pediatric ESRD patients effective January 1, 2024, for calendar years (CYs) 2024, 2025, and 2026. With pediatric patients representing 0.14% of total ESRD patients in 2022, CMS is uncertain exactly how much more expensive pediatric patients are so CMS proposes the payment adjustment as a trial.

ASN applauds CMS' decision to address the long-standing problem that current pediatric adjustments in the PPS do not provide adequate funding to support the unique specialization and costs associated with pediatric care teams. As such, ASN recognizes the need for this three-year adjustment to allow CMS the time it needs to update the pediatric cost report and collect data to develop a more accurate method of establishing the appropriate adjuster to support this population. ASN agrees that these youngest of patients do need additional support that increases the cost of providing services. Given that CMS has committed to developing a more accurate methodology and amount, ASN supports this interim approach. Critically, ASN highlights that, just because younger patients require more support, it does not mean that adults requiring dialysis require less support than they are already receiving. These concepts are inherently unrelated. Accordingly, ASN requests that CMS revisit the issue of whether these adjustments must be undertaken in a budget neutral manner and believes CMS has the authority to take on these adjustments without requiring budget neutrality.

III. Multiple ESRD PPS Issues

c. Discarded Renal Dialysis Drug and Biological Products

CMS proposes several activities for which ASN requests additional information regarding CMS' overall objective or intent and the need for further clarity and guidance. CMS proposes a reporting policy for unused and discarded amounts of renal dialysis drugs and biological products paid for under the ESRD PPS. Facilities would be required to report information on ESRD PPS claims about the total number of billing units of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS, using the JW modifier or a JZ modifier for the same renal dialysis drugs and biological products when there is no discarded amount. ASN is requesting clarity on what is CMS' intent for the use of this data. The two primary drivers of these proposals seem to be related to whether or not patients are being overcharged for their 20 percent coinsurance under Medicare Part B and to evaluate proper payment in the TDAPA program. ASN takes these concerns seriously and simply wishes to better understand how this data would be used to address those concerns, particularly given the already stretched dialysis workforce and additional reporting requirements related to health equity as well as social drivers of health that have been forecasted.

d. Time on Machine

CMS also expresses its interest in adopting a "time on machine" reporting requirement to apply to in-center hemodialysis. ASN agrees that if CMS were to adopt such a requirement, it should not be applied to home dialysis patients, as CMS proposes. CMS states that it is seeking this "patient-level reporting on resource use involved (time on machine) in furnishing hemodialysis treatment in-center in ESRD facilities… for use in the case-mix adjustment."[v]

CMS established patient-level adjustment factors in the CY 2016 ESRD PPS final rule (80 FR 68968, at 68973 through 68984), for age, body surface area (BSA), low body mass index (BMI), sex, four co-morbidity categories (pericarditis; gastrointestinal tract bleeding with hemorrhage; hereditary hemolytic or sickle cell anemias; and myelodysplastic syndrome), and the onset of renal dialysis.[vi] In the current proposed rule, CMS writes "We believe time on machine data would provide the insights we need to develop (and propose) potential amendments to the payment multipliers for the current, and potential future, patient-level adjustments, including new SDOH factors or health conditions (such as profound post-dialytic exhaustion) as patient-level adjustments. More immediately, however, time on machine data would significantly enhance CMS's insight into whether our current payment adjusters are appropriately aligning with actual resource use for individuals and communities who are underserved or disadvantaged and who may have multiple patient-level characteristics that necessitate longer renal dialysis times."[vii]

ASN supports efforts to provide accurate case-mix adjustment; however, it is important to remain focused on those adjustments as a way to ensure patients with these characteristics and co-morbidities are, indeed, provided patient-centered care. ASN is also concerned about the scale of the proposed "time on machine" requirements, which further divert staff time spent on direct patient care. CMS is proposing requiring "time on machine" reporting for tens of millions of dialysis treatments per year. Instead, CMS could limit this data collection to a subset of dialysis facilities or treatments, while still gathering the necessary data for case-mix adjustments.

Quality Incentive Program (QIP)

Proposals for Payment Year 2026:

CMS is proposing to add the Facility Commitment to Health Equity reporting measure to the ESRD QIP measure set beginning with PY 2026. This measure, which was first adopted for use in the Hospital Inpatient Quality Reporting (IQR) Program in the FY 2023 IPPS/LTCH PPS final rule, assesses an ESRD facility's commitment to health equity based on its responses to five equity related attestation-based questions.

- ASN appreciates CMS's commitment to further health equity among patients with kidney disease and that this measure has been adopted by hospitals. We do have concerns regarding the effectiveness and measurable impact of this

attestation measure and advocate for further investment in strategies shown to close gaps in health care disparities.

CMS is proposing to update the COVID-19 Vaccination Coverage Rate Among Healthcare Personnel (HCP) reporting measure beginning with PY 2026 to align with updated measure specifications developed by the CDC. The update reflects the status of COVID-19 transmission in the U.S., recommendations from the CDC and FDA that eligible individuals be up to date on their vaccination, and real-world data demonstrating vaccine efficacy.

- ASN supports this proposal.

CMS is proposing to convert the Clinical Depression Screening and Follow-Up reporting measure to a clinical measure beginning with PY 2026. CMS is also proposing to update the scoring methodology so that the measure is better aligned with current clinical guidelines for depression screening and follow-up.

- ASN recognizes that identifying and treating mental health conditions, particularly depression and anxiety, among patients receiving dialysis are critical to ensuring optimal health and clinical outcomes. We have major concerns about the ability of dialysis units to treat depression in isolation, without additional support and resources. Nephrologists are often not trained in or comfortable prescribing anti-depressants, and certainly are not trained or able to provide cognitive behavioral therapy (CBT). The typical dialysis encounter, where patients are often distracted with their treatments and where privacy is limited, is a suboptimal setting for addressing all aspects of depressive illness. Access to mental health services continues to be a challenge across all populations, and, particularly in the Medicare, Medicaid, and Medicare Advantage populations. Given the current workforce crisis and inflationary pressures, most dialysis facilities are unable to implement additional mental health treatments in the absence of increased financial resources.

  As a first step in improving mental health care for dialysis patients, ASN proposes that CMS consider clarifying opportunities for and supporting expanded access to mental health services for dialysis patients, that can occur either on-site in the dialysis facility (e.g., in a private room before or after their treatments) or via telemedicine. For example, in addition to social workers, some dialysis providers employ psychologists and/or other behavioral health specialists to provide counseling and CBT during dialysis treatments or at a separate time. ASN seeks clarification on a reimbursement pathway for these services.

  ASN does not support the movement of the Clinical Depression Screening and Follow-Up to a clinical measure in the absence of additional resources to support depression management.

CMS is proposing to remove the Ultrafiltration Rate reporting measure from the ESRD QIP measure set beginning with PY 2026. CMS is proposing to remove this measure from the program measure set under measure removal factor 2 (performance or improvement on a measure does not result in better or the intended patient outcomes) because documentation of a patient's ultrafiltration rate through the current measure may not indicate the quality of a patient's ESRD treatment, and therefore a facility's performance on the measure may not accurately reflect the quality of care provided.

- ASN supports removal of this measure, highlighting that this version of the metric was not endorsed by the NQF and that it has been misinterpreted clinically. While high ultrafiltration rates are associated with worse clinical outcomes, lowering ultrafiltration rates may result in unintended consequences such as chronic fluid overload, and has not been shown to improve outcomes. ASN notes that this measure does have utility in patient-level quality assessment and performance improvement activities and hopes that facilities do continue to look at individual patient-level UFR data during QAPI meetings.

CMS is proposing to remove the Standardized Fistula Rate clinical measure from the ESRD QIP measure set beginning with PY 2026. CMS is proposing to remove this measure from the program measure set under measure removal factor 3 (a measure no longer aligns with current clinical guidelines or practice) because updated vascular access treatment guidelines indicate a preference toward increased flexibility in the choice of arteriovenous (AV) access (either AV fistula or AV graft) where appropriate and urge providers to consider what would be most appropriate for the individual patient.

- ASN has concerns about removing the Standardized Fistula Rate clinical measure, given there is strong evidence that AVF utilization of hemodialysis is associated with better clinical outcomes, and that AVF, when achievable, is superior to an AVG, both of which are superior to tunneled catheters. At the same time, we strongly support the need to individualize care based on overall clinical trajectory. To better achieve this balance, ASN recommends CMS consider lowering the performance standard for the AV fistula measure, using a clinically derived level that is substantially lower than the CY 2023 performance standard. This would indirectly make the use of AV grafts less punitive, without eliminating the fistula measure, thereby allowing for individualized care and incentivizing the optimal access for each patient. This approach also would enhance the ability of clinicians to provide patient-centered care while still promoting quality. ASN would be happy to work with CMS on developing clinically relevant performance standards and improvement thresholds that are not dependent on national rates but rather serve to balance optimal access goals with individualized care.

  ASN highlights that CMS has the authority to make this change. The Medicare Improvements for Patients and Providers Act (MIPPA) is deliberately non-specific on this point, stating that "the Secretary shall develop a methodology for

assessing the total performance of each provider of services and renal dialysis facility based on performance standards with respect to the measures selected…" Additionally, Title 42 (IV)(B)(413)(H)(413.178)(12) defines performance standards as "the performance levels used to award points to an ESRD facility based on its performance on the measure." While the achievement threshold and benchmark are defined in this regulation as the 15th and 90th percentiles, this is defined in regulation rather than statute, thereby allowing for flexibility in QIP scoring.[viii]

In the interim, while developing these performance levels, one suggestion is to decrease the weight of the AV fistula metric on the QIP TPS, for example dropping it to 4% of the TPS, with the catheter measure weighted at 8%.

ASN also notes that elimination of the AV fistula measure leaves only the catheter measure in the QIP for vascular access. The catheter measure does not account for patient preference, is unadjusted, and has minimal exclusions. Given that AV grafts can achieve patency more quickly (in fewer than 90 days) while successful AV fistula creation takes four or more months from surgery to use. Given a 90-day threshold for catheters, the additional impact of the proposed QIP further promotes AV grafts. In the absence of fully accountable care (where potentially higher costs associated with grafts due to more frequent interventional procedures are borne by the provider), grafts become markedly incentivized as compared to AV fistulas. While the intent of eliminating the AV fistula measure is appreciated, drawing on the Catheter Last philosophy, Fistula First is still the best option for many hemodialysis patients. The new incentives as a result of this QIP change likely will result in a dramatic and inappropriate reduction in fistula utilization with adverse consequences. The net effect is a very non-patient centered category within the QIP.

Proposals for Payment Year 2027:

CMS is proposing to add the Screening for Social Drivers of Health reporting measure to the ESRD QIP measure set beginning with PY 2027. This health-equity-related measure, which was first adopted for use in the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule, assesses the percent of patients 18 years of age and older screened for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety. If finalized as proposed, CMS plans to begin using the Screening for Social Drivers of Health reporting measure for payment purposes as part of the ESRD QIP beginning with PY 2027 and beyond.

CMS is also proposing to add the Screen Positive Rate for Social Drivers of Health reporting measure to the ESRD QIP measure set beginning with PY 2027. This health-equity related measure, which CMS first adopted for use in the Hospital Inpatient Quality Reporting (IQR)Program in the FY 2023 IPPS/LTCH PPS final rule, assesses the percent of patients 18 years of age and older who screen positive for one or more of the listed five health-related social needs. CMS proposes to begin using the Screen

Positive Rate for Social Drivers of Health reporting measure for payment purposes as part of the ESRD QIP beginning with PY 2027 and for subsequent years.

- ASN applauds CMS's commitment to addressing health care disparities and is supportive of these measure concepts. We are concerned about the feasibility of data collection and reporting at the dialysis units, particularly with the staffing constraints mentioned above. There is also considerable variation in electronic heath records (EHRs) and training of staff, which will require investment. ASN urges CMS to consider supporting dialysis units with resources in order to adequately and completely collect and report these data and then act on SDOH gaps identified. Additionally, we would like to have a better vision of how these data will be used by CMS in the future, prior to implementation of new instruments, as well as the intervals for collecting this data. For example, ASN urges CMS not to use the Screen Positive Rate as a performance measure in the future, because this would disincentivize facilities from caring for socially vulnerable patients. ASN asks CMS to closely monitor the impact of this measure moving forward.

Conclusion

ASN thanks CMS for its work to protect and incentivize quality care for these extremely vulnerable individuals. In so doing, ASN urges CMS to apply an ESRD PPS forecast error adjustment and to concurrently address market basket inadequacies. ASN also urges CMS to monitor the consequences of the proposed measures and steps in the ESRD QIP. To discuss the contents of this letter, please contact David L. White, ASN's Regulatory and Quality Officer, at dwhite@asn-online.org.

Sincerely,

Michelle A. Josephson, MD, FASN
President

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[i] USRDS. Annual Report 2022. Figure 9.6a.
[ii] Proposed Rule Display Copy page 93.
[iii] 42 C.F.R. § 419.31(a)(1).
[iv] Display Copy page 6
[v] https://www.govinfo.gov/content/pkg/FR-2023-06-30/pdf/2023-13748.pdf
[vi] (80 FR 68968, at 68973 through 68984)
[vii] https://www.govinfo.gov/content/pkg/FR-2023-06-30/pdf/2023-13748.pdf
[viii] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-413/subpart-H/section-413.178