August 26, 2024

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

**RE: CMS-1805-P: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model**

Dear Administrator Brooks-LaSure,

On behalf of the more than 37,000,000 Americans living with kidney diseases and the nearly 22,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to provide comments on the proposed End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Quality Incentive Program (QIP). Currently, more than 800,000 Americans have kidney failure from ESRD, including more than 550,000 receiving dialysis and more than 200,000 living with a kidney transplant. The high prevalence of kidney failure is partly attributable to the increase of diabetes and hypertension, increasingly pervasive chronic diseases that are the leading risk factors for ESRD.

Kidney diseases represent the eighth leading cause of death in the United States, resulting in more deaths than breast cancer. These deaths occur in part to increased risk of cardiovascular disease (CVD) associated with chronic kidney disease (CKD), as well as progression to kidney failure. Unfortunately, kidney diseases and kidney failure disproportionally impact historically marginalized populations including Black, Hispanic or Latinx, and Native or Indigenous Americans, Asians, Hawaiians and Other Pacific Islanders, people with lower incomes, and older adults, underlying and exacerbating existing disparities. Black Americans are 3.7 times more likely to develop kidney failure than White Americans, and Latinx Americans are 1.5 times more likely to develop kidney failure than non-Hispanic or non-Latinx Americans. Remarkably one out of every eleven Black American males will require dialysis during their lifetime. Further, Black, Indigenous, and Latinx Americans have a lower likelihood of receiving a kidney transplant or initiating home dialysis to treat kidney failure. These and other factors explain why it is critical that the Medicare ESRD program and the ETC Model, Kidney Care Choices (KCC) Model, and the newly proposed Increasing Organ Transplantation Access (IOTA) Model, promote equitable access to optimal kidney care.

## Summary of ASN Recommendations in this Comment Letter

- Finalize Site of Care Proposal for Individuals with Acute Kidney Injury
- Revise proposed Add-on Payment Adjustment for Training
- Support Proposed Conditions for Coverage for Dialysis Facilities but Need to Go Further
- Address Dialysis Bundled Payment Shortcomings
  a) Payment Policy for Innovation does not Equate to the Outlier Policy – Do Not Finalize
  b) Dispensing Fees for Orals in the Bundle are Needed if Oral-Only Agents are Included in the PPS
  c) Address the Policy of the Current Base Rate Does Not Include Dispensing Fees for Phosphate Binders
- Convene Community to Improve the Proposed Health Equity Adjustment
- Support replacing the Kt/V Dialysis Adequacy Comprehensive Clinical Measure with Four Separate Measures
- Address Additional ESRD Quality Incentive Program Issues
  a) In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems Survey Administration (clinical measure)
  b) Standard Readmission Ratio (SRR) (clinical measure)
  c) Standardized Transfusion Ratio (STrR) (clinical measure)
  d) Standardized Hospitalization Ratio (SHR) (clinical measure)
  e) Clinical Depression Screening and Follow-up (reporting measure)
  f) National Healthcare Safety Network (NHSN) Dialysis Event (reporting measure)
  g) NHSN Bloodstream Infection (BSI) in Hemodialysis Patients (clinical measure)
  h) Screen Positive Rate for Social Drivers of Health (reporting measure)

## ASN Applauds CMS' Decision to Expand Site of Care for Individuals with Acute Kidney Injury (AKI)

*a) Site of Care Change*

CMS proposes to extend the home dialysis benefit as defined in 42 CRF 410.52 to beneficiaries with AKI for either peritoneal dialysis (PD) or home hemodialysis (HHD). ASN is supportive of this proposal, having advocated for such a change for many years. ASN also advocates for nephrologists treating AKI requiring kidney replacement with home dialysis as patients transition to home (from hospital, post-acute facility or in-center transitionary dialysis), and the corresponding Medicare payment should be allowed when the nephrologist determines that an AKI patient can safely dialyze at home.

In the past, CMS reasoned that these patients require supervision by qualified staff during dialysis and close monitoring with laboratory tests to ensure that they are receiving the necessary care to support their condition and stop dialysis when clinically indicated (i.e. patients show evidence of kidney recovery). ASN views home therapies as supervised care that is of at least similar quality and intensity to in-center hemodialysis and highlight the commitment to ensuring the success of all patients with AKI-D, regardless of whether they are receiving dialysis in the home or in a hemodialysis facility. In these circumstances, intensive training for home dialysis should also be reimbursed by Medicare, via the addition of training codes (CPT 90989 and 90933, since there is no RVU value attached to this code, clinicians who are dependent on the RVU system to quantify their clinical work have a difficult time receiving credit for the work they perform in the supervision of home dialysis training) being added to the telehealth list.

ASN believes that incident AKI patients are medically complex and the clinical decision regarding the next stage of treatment should be evaluated by their physician and agreed upon mutually among the patient, care partners, and physician.

Importantly, the entire armamentarium of treatment options must be available in order to provide the most patient-centered care and allow for the best outcomes. Peritoneal dialysis in particular may be learned quickly, reduces rapid hemodynamic changes that may potentiate kidney injury and impede kidney recovery, and does not require a high-risk central venous catheter. ASN thanks CMS for creating a treatment pathway and reimbursement for the treatment of an AKI patient with home dialysis if deemed medically appropriate, noting that this will most often occur with peritoneal dialysis.

*b) Concerns regarding the Add-on Payment Adjustment for Training*

CMS proposes that the payment amount for home dialysis for AKI patients would be the same amount as the proposed payment amount for 2025 for in-center dialysis for the same individuals, consistent with payment parity within the ESRD PPS: $273.20. However, CMS also proposes to extend the add-on payment adjustment for home and self-dialysis training at the same rate as ESRD patients, on a budget neutral basis, which results in a proposed AKI CY 2025 base rate (for all dialysis modalities) of $264.70 ($273.20 - $8.50, with $8.50 being the estimated add-on training adjustment). ASN has multiple concerns regarding this proposal, including the methodology used by CMS to make these calculations.

- *Methodologic Assumptions:* Using fourth quarter data 2022 ESRD Public Use File (PUF), the average monthly percentage of dialysis treatments furnished via home dialysis was 15.4%. Data indicate that there were 279,000 AKI dialysis treatments in 2023. Based on that, CMS estimates that the same percentage of beneficiaries with AKI would choose a home modality as did beneficiaries with ESRD, therefore they estimate that 42,966 AKI dialysis treatments would be performed in a home setting. Using USRDS ADR data, CMS estimates the average beneficiary using a home PD

modality would receive 15 PD training treatments. From fourth quarter 2022 AKI PUF, CMS calculates 10,802 first time beneficiaries with AKI.

- Cost of training= $2,370,498.90 (10,802 x 0.154 x 15 x $95.57) or $8.50 ($2,370,498.98/279,000) per AKI treatment.[i]

ASN has reviewed these assumptions with practicing clinicians (including the clinicians contributing to these comments), and there is consistent alignment with the perspective that peritoneal dialysis (PD) will be a relatively rarely used therapy for AKI-D, counter to the assumption that forms the foundation of the above methodology. It is highly unlikely that the AKI home dialysis rate will equal the overall ESRD home dialysis rate, especially not in the first years of this new policy.

Nephrologists ASN polled, including many home dialysis champions, feel that it is highly unlikely that there will be a significant number of individuals with AKI initiating home peritoneal dialysis. In fact, incident peritoneal dialysis patients with AKI will likely number fewer than 100 across the United States – but for these handful of patients, peritoneal dialysis is an important patient-centered option. Critically, patients engaging in home dialysis does not make providing care to those patients receiving in-center hemodialysis for AKI less expensive, particularly given that Medicare, based on MedPAC, already reimburses at or below the cost of therapy for many providers. AKI-D patients are reimbursed lower than incident ESRD patients, reflecting non-inclusion of the incident patient modifier. While this is required by law, it emphasizes that further deductions from the reimbursement for hemodialysis for AKI-D would be financially unviable.

Conceptually, there are three likely outcomes for individuals with AKI-D receiving home dialysis: 1. Recovery of kidney function, which most nephrologists think will be more likely with peritoneal dialysis and ultimately will be cost-saving; 2. Death or transfer to in-center hemodialysis (with possible later kidney transplantation); or 3. Continuation of PD as an ESRD patient. In scenario 1, home dialysis for AKI-D is likely net cost-saving to CMS. In scenario 3, the beneficiary will have already been trained and, therefore, they will not require additional training, such that the training payment is merely shifted earlier in time. This is cost neutral. Of note, in scenario 3, CMS, through its support of the ETC model, has expressed a preference for PD being cost saving, and, therefore, this should also lead to a net financial benefit for Medicare. Given this, ASN opposes the large, proposed adjustment for training to the AKI-D payment. If our belief that peritoneal dialysis for AKI-D being an uncommonly used therapy is incorrect, ASN would support CMS considering the adjustment in future years based on actual usage, but ASN is certain that the proposed adjustment is exceptionally excessive and will prove harmful to other AKI-D beneficiaries, potentially resulting in more beneficiaries being classified as ESRD earlier in their dialysis courses. Additionally, ASN supports that the initial training fee is not available for individuals transitioning from home AKI-D to home dialysis with an ESRD designation. ASN does note that ‘home’ hemodialysis may be used in nursing home settings for incident dialysis patients and supports that a training payment is not applicable to these individuals unless they are training to transition to home dialysis outside of a nursing facility. ASN is volunteering its AKI Now task force to work with CMS on accurate predictions of the uptake of home dialysis for AKI-D.

*c) Conditions for Coverage (CfCs) for Dialysis Facilities*

CMS correctly points out that "ESRD" and "AKI" are not interchangeable and that the CfCs need to be aligned with the changes proposed in this rule. ASN believes the CfCs need updating – last updated in 2008 – and urges CMS to engage the kidney care community in a broader dialogue on a range of potential updates to the CfCs. In general, CMS proposes "revising the phrase 'ESRD' to say 'kidney failure;' by revising the phrase 'ESRD care' to say 'dialysis care;' by revising the phrase 'management of ESRD' to say 'management of their kidney failure;' by revising the phrase 'serve ESRD patients' to say 'serve patients with kidney failure;' and lastly by revising the phrase 'provider of ESRD services' to say 'provider of dialysis services.' "[ii] ASN finds these proposals to be reasonable and supports them. However, as noted above, ASN believes that the CFCs are outdated and that some sections act as impediments to innovations that could enhance high-quality patient-centered dialysis at home or in-center. Thus, ASN believes that CMS should take this opportunity to revise not just the AKI-relevant sections of the CfCs, but also several other sections of the CfCs that could help address barriers in access to home dialysis and high-quality dialysis, such as the section on dialysis adequacy. ASN looks forward to discussions regarding proposals for updates to the CfCs.

**<u>Dialysis Bundled Payment Shortcomings</u>**

ASN is concerned that multiple factors have led to an inadequate Medicare bundled payment for dialysis. In its March "Report to the Congress," MedPAC estimated a margin of zero for 2024.[iii] MedPAC's finding means that there are many facilities with a margin below zero. Given the significantly increasing costs, it is impossible for many facilities to be able to adjust to unexpected events when they occur, or, in some cases, to be able continue providing services at their historic levels. As ASN noted in its comment letter last year, hundreds of facilities have ceased to operate and even more have reduced the number of shifts, particularly evening shifts used by people trying to work, making it difficult for some patients to access care. A decrease in access to dialysis presents a grave concern for all patients regardless of payor. ASN would like to address some concerning issues in the proposed rule.

*a) Payment Policy for Innovation does not Equate to the Outlier Policy*

The ESRD PPS system as currently structured stifles innovation for a population that already experiences extreme health disparities and issues of access. As a result of recent policies, patients with CKD-associated pruritis (CKD-aP) are not able to access the only FDA-approved treatment indicated specifically to treat this disease. ASN does not believe that difelikefalin (Korsuva) is a "substitute" for or results in the "same effect" as diphenhydramine (Benadryl), and notes that this presumption contradicts the FDA labeling of both products. The manufacturer of Korsuva has indicated it will cease all research and development in the area of chronic kidney disease, reflecting low use due to payment policy.[iv] In addition, the manufacturer of daprodustat (Jesduvroq), a

medication to treat anemia that also received TDAPA status, has indicated it will no longer market this product,[v] which is indicated only for individuals with ESRD receiving dialysis and is particularly useful for those practicing home dialysis. Current payment policy has deterred access to medically necessary therapies for patients. Equally important, the experiences with these agents will deter future innovators from investing in the health and wellbeing of people dependent on dialysis. This outcome could be especially problematic for patients from communities of color or those with low-income status, who comprise a large share of all beneficiaries with ESRD.

CMS' proposal to address innovative payment by expanding products eligible for outlier payments does not represent a sustainable ESRD PPS payment policy for adequate funding for innovative drugs, biologicals, and devices. As MedPAC stated, the outlier policy is essentially stop-loss insurance, and it is not meant to establish accurate and adequate payment for new medically necessary services. The goal of "*protecting patients' access to medically necessary care through a payment adjustment that more fully recognizes unusual variations in the type or amount of such care*" requires a policy that seeks to cover the average cost of that medically necessary care at the individual patient level. The outlier policy is simply not designed to address the disincentives inherent in a prospective payment system to provide "new renal dialysis drugs and biological products (that) are likely to be drivers of cost, because these drugs are typically more expensive."[vi]

While ASN understands that Congress designed the ESRD PPS to be a single disease-specific payment system and that the offset policies used in the hospital inpatient and outpatient payment systems will not work, ASN still believes that expanding coverage through the outlier payments is unworkable. The example of difelikefalin (Korsuva) that CMS highlights in the preamble establishes this point. The cost of difelikefalin is currently $150 per administration, and it is administered thrice weekly at an in-center hemodialysis session. Under the post-TDAPA policy, the base rate for all ESRD claims is increased by $0.4047. For a facility to cover the cost of providing Korsuva to a single patient, it would require the facility to treat 370 patients, which is beyond the capacity of all dialysis facilities in the United States. While the large dialysis organizations may be able to manage this situation by distributing the cost across multiple facilities, it ignores the reality that the medium and smaller organizations certainly cannot. As evidenced by the significant percentage of patients for whom difelikefalin is indicated (roughly 16 percent of dialysis patients) not being able to access the product, it is clear that the payment system has prevented patient access to an important treatment option for the vast majority of patients who would benefit from receiving it.

ASN supports the proposal outlined in section 201 of S. 4469, "The Chronic Kidney Disease Improvement in Research and Treatment Act of 2024." This proposal would require CMS in a non-budget neutral manner to:

- Establish a permanent post-TDAPA add-on adjustment to the base rate for a new drug or biological product that comes within an existing functional category.

- Calculate the post-TDAPA add-on adjustment using the most recent 12-month period of utilization data for the product and the most recent available full calendar quarter of average sales price (ASP).
- Calculate the adjustment as the expenditures for the new drug or biological product divided by the total number of dialysis services during which the drug or biological product was administered.
- Set the final amount of the adjustment at 65% of that calculated amount.
- Update the adjustment amount annually to account for inflationary changes.
- Apply the adjustment amount immediately upon the expiration of the TDAPA period.

*b) Dispensing Fees for Orals in the Bundle are Needed if Oral-Only Agents are Included in the PPS*

ASN has repeatedly voiced its concerns to CMS about including oral-only phosphate binders and other phosphate-lowering drugs in the ESRD PPS payment for many reasons and supports efforts in Congress to delay that occurrence. Therefore, we will not repeat our previously stated objections. Rather, we simply indicate our support for a dispensing fee should CMS feel compelled to proceed as proposed.

CMS has requested comments "*on the extent to which 100 percent of ASP is appropriate for TDAPA payment amount for phosphate binders and whether there are any costs associated with the inclusion of phosphate binders into the ESRD PPS bundled payment that may not be accounted for by 100 percent of ASP*."[vii] To maintain consistency with the treatment of calcimimetics during their first two years of TDAPA, to align with the way Medicare reimburses for drugs and biologicals under the Hospital Outpatient PPS's pass-through payment policy, and minimize administrative burden on CMS and providers, ASN recommends that CMS adopt the methodology outlined in the Social Security Act § 1847A. This methodology sets payment at the ASP+6 percent; if ASP is not available, the payment is based on the Wholesale Acquisition Cost (WAC).

As ASN has made clear in earlier letters and meetings with CMS, ASN believes that adding phosphate binders and phosphate lowering drugs to the bundle will have a negative impact on patients. Phosphate binders and phosphate lowering drugs must be taken outside of the facility, typically when a patient eats. The dosage is difficult to manage because it can vary with the size of snacks and meals that a patient consumes. The situation is complicated by the fact that there is no "average" patient when it comes to dosing these drugs. The decision to incorporate these products into the bundle does not correspond with the clinical realities that kidney care providers and individuals who require these products actually experience. The Congress has recognized the challenges of including these drugs in the ESRD PPS when it has repeatedly restricted CMS from adding them. Also, there will not be an actionable solution present for distribution of phosphate lowering agents to patients residing in nursing homes or other facilities. ASN highlights that this policy is likely to increase financial strains on all dialysis providers, but particularly on smaller and medium-sized providers who are

already struggling financially. This will result in further consolidation among dialysis providers and a loss in choice for patients with ESRD.

c) *The Current Base Rate Does Not Include Dispensing Fees for Phosphate Binders*

CMS recognizes in the Proposed Rule's preamble, "dispensing fees and other costs are not currently included in the ESRD PPS base rate for phosphate binders."[viii] As the Governmental Accountability Office (GAO) found in its 2023 report, dialysis facilities will incur significant costs if phosphate binders are added to the ESRD PPS bundled reimbursement that are not included in the base rate. These costs include:

- Paying pharmacy charges to obtain the drugs through them.
- Mailing fees either in terms of obtaining the drugs from pharmacies or sending the drugs directly to patients' home, which is where they are taken.
- Storage costs associated with maintaining the drugs at the dialysis facility if the decision is to distribute the drugs to patients during their dialysis treatment sessions.
- Complying with state pharmacy laws. For example, some states, like Alabama, do not allow dialysis facilities to distribute oral drugs so there are additional contracting costs incurred.
- Supporting the provision of a significant volume of pills to patients so they have the amount they need to take their medication at every meal and snack.
- Adjusting drug supplies when a physician changes a patient's prescription to another product (which often occurs)
- Absorbing costs of unused medications when patients are hospitalized, transfer to other facilities, die, or receive a kidney transplant.

It is important to recognize that 100 percent of ASP does not cover the cost of acquiring these products either. Because of the sequestration cut, 100 percent of ASP is really ASP minus 1.6 percent. Many medium and small dialysis organizations do not have the economies of scale and must purchase drugs at a significant percentage above the ASP. As a result, 100 percent of ASP is actually less than the acquisition cost of these drugs. Therefore, ASN recommends the adoption of a dispensing fee using a rate of ASP+6 percent for phosphate binders to align the ESRD PPS policies with those applied to other Medicare providers. Critically, Medicare only reimburses 80% of costs. For patients who are dual eligible receiving Medicaid, this remaining 20% goes unreimbursed, which, following sequestration, equates to 78.4%. Similar results will occur for patients without a secondary insurance if they are unable to pay the remaining 20% out-of-pocket.

Both the Medicare Part D and Medicaid programs provide for dispensing fees. Under Part D, the dispensing fees are set through negotiations between the plan and pharmacy. Medicaid amounts are significantly higher and in the range of $9 to $12 per prescription, which would translate into a $0.69-$0.92 per treatment amount in the context of the ESRD PPS according to the analysis prepared by Health Management

Associates (HMA). Medicare Part B includes a $24 dispensing fee, which would be approximately $1.85 per treatment in the ESRD PPS context.[ix]

CMS also provides a dispensing fee to hospital outpatient departments (HOPD) and ambulatory surgical centers (ASC) but relies upon ASP+6 percent rather than a flat rate. CMS decided to maintain the ASP+6 percent policy in the HOPD and ASC settings after conducting a multi-year analysis of hospital cost reports. Adopting an ASP+6 policy as the basis of a dispensing fee rate would also align with the treatment of drugs in these other payment systems. HMA's analysis of phosphate binders demonstrates that the increase in per treatment payment for a 30-day supply of a phosphate binder could range from $1.46-$8.03. These amounts are not significantly different than those CMS finds acceptable in the HOPD/ASC setting or the other dispensing fee programs.[x]

ASN recommends that CMS adopt the straightforward and transparent ASP+6 percent policy that it relies upon in other parts of the Medicare program. As an alternative, CMS could consider using the same flat rate supply fee used for other oral Part B drugs that are supplied as part of a physician service. This approach would also support the agency's timeline to add phosphate binders to the ESRD PPS bundled rate for CY 2025.

**Health Equity Adjustment is Important but Needs More Work**

CMS added three new health-equity focused quality measures in the CY 2024 ESRD PPS final rule (88 FR 76437 through 76446; 76466 through 76480) to the ESRD QIP.[xi] CMS is now soliciting feedback on the creation of a Health Equity Adjustment (HEA) and is "considering updating our scoring methodology in future rulemaking to add Health Equity Adjustment bonus points to a facility's TPS that would be calculated using a methodology that incorporates a facility's performance across all five domains for the payment year and its proportion of patients with dual eligibility status (DES), meaning those who are eligible for both Medicare and Medicaid coverage."[xii]

CMS details how it has recently finalized a Health Equity Adjustment scoring policy for the Hospital Value-Based Purchasing (VBP) Program (88 FR 59092 through 59106) and the Skilled Nursing Facility (SNF) VBP Program (88 FR 53304 through 53316).[xiii] The differences in approaches to those programs are significant. The hospital system is based on the hospital's performance on four measure domains and its proportion of patients with dual eligibility status (DES). The SNF program is based on the facility's performance on each measure and its proportion of patients with DES. CMS posed two questions, discussed below.

Question 1. Would a Health Equity Adjustment be valuable to the ESRD QIP?

a) If a Health Equity Adjustment would be valuable to the ESRD QIP, how should it be structured?

b) If a Health Equity Adjustment would not be valuable to the ESRD QIP, why not?

Question 2. Are there other approaches that the ESRD QIP could propose to adopt to effectively address healthcare disparities and advance health equity?

ASN applauds CMS for its efforts to improve health equity among the ESRD population receiving facility-based dialysis, given long-standing disparities among this population. ASN has engaged with and written to CMS on an ongoing basis regarding the issues of equity and disparity in the kidney health space. ASN does not believe the brief discussion of the two approaches in the proposed rule provided sufficient insight into CMS' thinking or time to design a well-researched approach to such an important issue. However, ASN appreciates that CMS is commissioning a Technical Expert Panel (TEP) to allow for a more nuanced discussion about these issues. In the interim, ASN provides a few preliminary suggestions for the TEP and CMS to consider:

1) ASN is concerned that a HEA performance adjustment may be insufficient as a means to address health disparities. As the ESRD QIP only has penalties and does not provide any bonuses to dialysis facilities, we are concerned that a performance adjustment could inadvertently suggest that dialysis facilities with more dual eligible beneficiaries are allowed to have poorer health outcomes. CMS reminded readers in the proposed rule that in a 2016 Report to Congress on Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) reported that beneficiaries with social risk factors had worse outcomes and were more likely to receive a lower quality of care. Given these known disparities, ASN suggests that CMS consider a positive payment adjustment to facilities that improve outcomes for dual eligible beneficiaries, similar to that of the health equity incentive in the ETC and IOTA models.
2) ASN is concerned that states that did not expand Medicaid may be differentially impacted by a HEA in the QIP. One suggestion may be to expand eligibility for the HEA to include low-income subsidy recipients as well as dual eligible beneficiaries.

**ASN supports replacing the Kt/V Dialysis Adequacy Comprehensive Clinical measure with four separate measures.**

ASN applauds CMS' proposal to disaggregate the Kt/V Dialysis Adequacy measure into four distinct components, each evaluated against its own performance standards. This approach acknowledges the complexity of dialysis adequacy and allows for a more nuanced assessment. By distinguishing among various aspects of Kt/V, this proposal facilitates a more accurate reflection of patient-specific needs and treatment efficacy. However, ASN has longstanding concerns about the application of Kt/V in assessing peritoneal dialysis (PD) adequacy, particularly considering existing guidelines and patient outcomes.

*a) Concerns Regarding Kt/V in Peritoneal Dialysis*

Despite the positive aspects of the proposed disaggregation, ASN remains concerned about the application of Kt/V as a measure of dialysis adequacy for patients undergoing peritoneal dialysis (PD). The International Society for Peritoneal Dialysis (ISPD) 2020 guidelines highlight significant limitations of Kt/V as a measure for PD adequacy and have suggested moving away from Kt/V as it may limit patient choice. Specifically, Kt/V may not adequately capture the nuances of dialysis adequacy in adult PD patients.

The ISPD guidelines indicate that Kt/V may not always be the most suitable metric for assessing dialysis adequacy in adult peritoneal dialysis (PD) patients, particularly in patients who are new to dialysis and who have residual kidney function. In many countries, Kt/V is not the primary measure for evaluating PD adequacy. For instance, in Canada, Kt/V is seldom assessed. The Canadian approach acknowledges that relying exclusively on Kt/V can oversimplify the complexities of peritoneal dialysis, which involves a variety of factors impacting patient outcomes. Kt/V may overlook important aspects such as patient-reported outcomes, quality of life, and overall life participation. Additionally, Kt/V measurement in some PD patients can potentially lead to inappropriate discontinuation of PD as the patient's preferred dialysis modality. Given the current treatment guidelines, an excessive and sole focus on Kt/V as a quality measure for PD may undermine the principles of patient-centered care by neglecting broader, patient-focused considerations.

In future rulemaking, ASN urges CMS to explore alternative methods for comprehensively evaluating peritoneal dialysis (PD) adequacy. For example, there is recent literature highlighting alternative pathways CMS could explore to allow for clinicians to use the new ISPD guidelines to provide high-quality goal-directed PD for patients within the US[xiv]. However, to allow clinicians to adopt these guidelines, it is crucial that CMS provide guidance in rulemaking that takes into account both the ISPD guidelines and international practices and standards. This approach will help ensure that quality measures for PD are more comprehensive and patient-centered, reflecting a broader range of factors that impact patient well-being.

## **Additional ESRD Quality Incentive Program Issues and Comments**

a) *In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration (clinical measure)*

ASN continues to express concern over the low response rate to the ICH CAHPS. ASN urges CMS to review the recommendations from recent technical expert panels and emerging from contractors' work in order to reduce the number of questions in the survey.

Studies have indicated that there are significant differences between patients who complete the ICH CAHPS survey and those who do not, which could lead to an inaccurate representation of patient experiences at dialysis facilities. A 2019 study on ICH CAHPS response rates revealed that non-responders were more likely to be men,

non-white, younger, single, dual Medicare/Medicaid eligible, less educated, non-English speaking, and inactive on the transplant list. These findings highlight the underrepresentation of key groups among in-center hemodialysis patients, particularly those with fewer socioeconomic advantages and higher illness burdens. Such disparities may introduce biases into facility-level ICH CAHPS survey results, especially considering the overall low response rates, potentially missing crucial opportunities to assess and enhance the patient experience for the most vulnerable hemodialysis patients.

To reduce the burden on patients, ASN requests that CMS field the survey once a year and not twice. We also recommend that CMS exclude patients experiencing homelessness to whom the survey cannot be distributed given that facilities are not allowed to provide it directly to patients, although we realize that an individual's housing status is often not tracked by the facility.

Finally, to empower patients, CMS should allow facilities to see de-identified results of the surveys so they can respond to the specific patient concerns with some level of patient permission. Patient members of several TEPs have recommended this step.

*b) Standard Readmission Ratio (SRR) (clinical measure)*

ASN remains concerned that the SRR might mislead patients, care partners, and healthcare providers due to its wide confidence interval. This variability can lead to inaccurate facility classifications and fail to accurately reflect actual performance.

The QIP should utilize a true risk-standardized rate measure, rather than a ratio multiplied by a national median, which does not represent a true risk-standardized rate. The risk adjustment for the standardized hospitalization ratio measure (SHR) and the SRR is reliant on billing codes, meaning that one needs admissions records, and the codes attached to them in order to adequately risk adjust. This may be problematic when estimating SHR, where many patients included in the standardization process may not have been hospitalized. This poses a problem for patients covered under Medicare Advantage (MA) as the inpatient codes are not always as robust as for Medicare Fee for Service beneficiaries.

The current measure also poses challenges for small facilities, as their scores can be heavily influenced by random variability. ASN urges CMS to transition to the use of the underlying readmission rate, which can be properly risk-adjusted in the same way the standardized mortality rate has been and allow within facility year-to-year comparisons. The confusion surrounding the ratio measure can mislead patients and their physicians who rely on readmission metrics for making informed healthcare decisions. As CMS has noted in previous rulemaking, rate measures are more transparent and easier for patients and care partners to understand. ASN stands ready to work with CMS on this issue.

*c) Standardized Transfusion Ratio (STrR) (clinical measure)*

ASN remains concerned that the STrR measure lacks validity and believe it should be suppressed. While we appreciate that CMS has acknowledged this concern, we remain troubled that CMS has not addressed the low reliability of the data on transfusions. ASN believes that this measure has limitations as most transfusions are due to bleeding, chemotherapy, and sickle cell disease, and the ascertainment of transfusion is poor as it is not consistently coded properly during hospitalizations. ASN stands ready to work with CMS on this issue.

*d) Standardized Hospitalization Ratio (SHR) (clinical measure)*

ASN agrees that hospitalization rates are crucial indicators of quality for both patients and providers but also strongly urges CMS to implement a genuinely risk-standardized hospitalization rate measure to prevent misclassifying facilities and misleading patients. The current SHR measure lacks reliability and fails to accurately reflect performance. For example, it remains problematic to use the weight from the 2728 form (which is the BMI at ESRD incidence). In addition, if Medicare Advantage patients are included, the ascertainment of prevalent comorbidities will not be accurate. The same concerns mentioned in SRR apply to the SHR as well. The situation can result in misleading information that does not effectively or accurately capture the true quality of care.

*e) Clinical Depression Screening and Follow-up (reporting measure)*

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 antidepressants, 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 onsite 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.

Given the concerns discussed above, ASN recommends removing this measure from the QIP program.

*f) National Healthcare Safety Network (NHSN) Dialysis Event (reporting measure)*

ASN is supportive of CMS' proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set beginning with PY 2027. ASN supports CMS' rationale that this reporting measure is topped out, and ASN supports any proposal by CMS to remove measures that no longer serve to measure and enhance quality in the ESRD QIP program.

*g) NHSN Bloodstream Infection (BSI) in Hemodialysis Patients (clinical measure)*

Research from the CDC, the measure's developer, as well as from CMS and other sources, indicates that the measure lacks both validity and reliability. Consequently, it fails to provide accurate data to patients and providers. When a measure inaccurately reports a facility as having fewer bloodstream infections (BSIs) than it does, it compromises the ability of patients, care partners, and other providers to make well-informed healthcare decisions.

Previously, ASN has recommended that CMS transition the NHSN BSI measure to a reporting measure while forming a Technical Expert Panel (TEP) to address its shortcomings. This panel would be tasked with identifying the issues with the current measure, proposing improvements, and developing a measure that meets the endorsement validity requirements set by consensus-based organizations.

Research also suggests that underreporting may stem from the fact that hospitals, rather than dialysis facilities, hold the relevant data. This creates a burden on both hospitals to provide the data and on facilities to obtain it. Implementing a valid measure could alleviate this burden for both parties.

*h) Screen Positive Rate for Social Drivers of Health (reporting measure)*

ASN applauds CMS' commitment to addressing health care disparities and supporting these measure concepts. ASN strongly supports the implementation of screening measures for social drivers of health for dialysis patients, recognizing their potential to improve patient care. However, ASN also encourages CMS to evaluate the impact of variations in electronic heath records (EHRs) and staff training on this effort.

ASN has significant concerns about the public reporting of the percentage of patients in each dialysis facility who screen positive in various domains. ASN fears that this publicity may lead patients to either avoid answering or provide inaccurate responses, especially within the close-knit environment of a dialysis facility. With relatively small patient populations in individual facilities, there is a high risk of compromising patient privacy around very sensitive issues. The potential for identifying individuals based on aggregated screen positive data raises serious privacy issues. It is crucial to balance

the benefits of screening with the need to protect patient confidentiality and ensure that data reporting does not inadvertently lead to privacy breaches. In asking these important questions to patients, if results are publicly reported, nephrologists queried by ASN feel compelled to notify patients that the number of individuals in the facility screening positive to each question will be publicly available.

ASN feels very strongly that this will impact dramatically the number of truthful responses. Additionally, public reporting of these data may further stigmatize dialysis facilities serving a high proportion of vulnerable patients, resulting in those with fewer social risk factors selecting different facilities based on preconceptions. This runs the risk of substantial financial impacts on facilities treating a high number of individuals with social risk factors and may have unintended consequences, such as lesser availability of dialysis slots for these individuals. To summarize, ASN strongly supports collecting these data as they are critical for treating patients but sees little benefit and potential for substantial harm with reporting facility level screen positive rates.

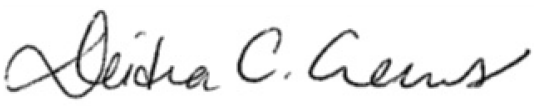
The current logistics for the three Health Equity Measures, which require assessment within the first three months of each year, present a challenge due to their integration into the annual CfC mandated care plans with other elements of the social worker assessment. Since care plans, which are time intensive, are distributed throughout the year, aligning the Health Equity Measures with a calendar year creates inconsistencies. To address this issue, it would be more effective to evaluate whether these measures were assessed within the last 12 months of each patient's care plan rather than adhering to a fixed calendar year. This adjustment would better align with the staggered scheduling of care plans and ensure that assessments are more accurately integrated into each patient's individual care cycle.

## Conclusion

Going into effect January 1, 2011, the ESRD bundle turns 14 years old in January, 2025. And like most individuals of that age, there are serious growing pains. ASN believes the bundle is in need of refinements that may need to be both statutory and regulatory. ASN strongly encourages CMS to join the kidney community in a dialogue about areas of concern in the program as the community also engages Congress in a similar dialogue. For any questions regarding this letter, please contact David White, ASN Regulatory and Quality Officer at dwhite@asn-online.org.

Thank you for your consideration of these comments.

Sincerely,



Deidra C. Crews, MD, ScM, FASN
President

[i] www.govinfo.gov/content/pkg/FR-2024-07-05/pdf/2024-14359.pdf
[ii] www.govinfo.gov/content/pkg/FR-2024-07-05/pdf/2024-14359.pdf
[iii] MedPAC. *Report to the Congress: Outpatient Dialysis Services* (Mar. 2024).
[iv] Cara Therapeutics Statement (January 2024) ("Following careful consideration, we have decided to discontinue our work in advanced chronic kidney disease (CKD). I would like to thank the patients and investigators who have participated in our advanced CKD clinical program, as well as our employees for their commitment to transforming the lives of CKD patients suffering from pruritus.")
[v] Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (fda.gov)
[vi] MedPAC. *Report to the Congress: Outpatient Dialysis Services* (Mar. 2024).
[vii] www.govinfo.gov/content/pkg/FR-2024-07-05/pdf/2024-14359.pdf
[viii] *Id*
[ix] Health Management Associates. Drug Overhead Cost (July 17, 2024).
[x] *Id*
[xi] www.govinfo.gov/content/pkg/FR-2024-07-05/pdf/2024-14359.pdf
[xii] *Id*
[xiii] *Id*
[xiv] Maliha G, Weinhandl ED, Reddy YNV. Deprescribing the Kt/V Target for Peritoneal Dialysis in the United States: The Path Toward Adopting International Standards for Dialysis Adequacy. J Am Soc Nephrol. 2023 May 1;34(5):751-754. doi: 10.1681/ASN.0000000000000101. Epub 2023 Feb 14. PMID: 36787755; PMCID: PMC10125636.