American Society of Nephrology

August 29, 2025
The Honorable Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20001

Re: CMS-1830-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 Oz,

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 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 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 proposed rule.

Chronic kidney disease (CKD) is a progressive condition characterized by the gradual loss of kidney function[i]. It affects approximately 37 million Americans, or about 1 in 7 adults, and its prevalence is projected to rise[ii]. CKD poses an increasing public health crisis resulting in considerable morbidity and growing health care expenditures. The U.S. Medicare program spends more than $150 billion each year managing kidney diseases, including $50 billion for kidney failure patients alone[iii]. ASN believes that it is essential as a nation to reduce the burden of kidney diseases on individuals, their families, and the health care system overall; and this aligns with the Trump Administration's chronic disease prevention efforts to Make America Healthy Again (MAHA).

PROSPECTIVE PAYMENT SYSTEM (PPS)

a. Reliance on Medicare

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The Medicare ESRD program created by Congress in 1972 sought to provide Americans with kidney failure access to life-sustaining treatments (dialysis and kidney transplantation) that otherwise would be largely inaccessible to most Americans. As a result, any American with kidney failure has the opportunity to enroll in Medicare to access these treatment options, regardless of their age.

However, the reliance on the federal government has grown disproportionately large, especially in the last several years as commercial insurers pushed their enrollees to shift to Medicare primary coverage. The U.S. Renal Data System (USRDS) reports that since insurers began these practices, the percentage of patients relying on commercial coverage between 2012 and 2022 has fallen by more than 36 percent. ASN believes that this downward trend will only continue now that the Supreme Court in *Marietta Memorial Hospital Employee Health Benefit Plan v. DaVita Inc*., has re-interpreted the Medicare Secondary Payer Act (MSPA) to allow insurers to eliminate in-network coverage for locally available treatments for kidney failure. There are several negative consequences to this dynamic. First, private insurers are de-incentivized to invest in screening and new therapies to slow progression of kidney disease and prevent kidney failure, knowing these patients can be transferred to Medicare's bottom line once they reach kidney failure (at which point care costs dramatically rise). Second, if the patient carries the insurance policy for the entire family, shifting them to Medicare often leaves family members under 65 without coverage.

b. *Streamlining and Leveraging Technology RFI*

ASN is also pleased that the Administration is requesting ideas about streamlining and leveraging technology solutions to improve information about patients and hold providers accountable for patient outcomes. ASN provided some input earlier this year when responding to the request for information (RFI) from the Centers for Medicare and Medicaid Services (CMS) and the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC Health IT) on ways to improve the health technology ecosystem. That response is attached to this letter, which will also elaborate on those recommendations and others.

c. *Forecast Error*

The ESRD PPS faces forecast errors, particularly in capturing the actual costs associated with labor and other factors, leading to potential underfunding for dialysis providers. These errors arise because the system relies on historical data to forecast annual payment updates, which can be inaccurate during periods of economic uncertainty like the recent rise in inflation and labor shortages. This can result in dialysis providers not receiving adequate reimbursement to cover their operational costs, including the rising expenses for attracting and retaining skilled staff. This error can lead to further consolidation of dialysis providers – which is already consolidated to the point

of only two companies providing care for more than 80 percent of all patients with kidney failure. These annual forecast errors contribute to a cumulative difference of nearly 7% between the market basket update and actual cost increases since 2019.

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

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

[iv]

The need for adequate adjustments to the payment rates remains critical because the current rates often do not cover the cost of providing the most basic care. As the latest MedPAC report demonstrates, facility margins for Medicare patients, at best, are “break even” and often negative. Payment rates have essentially stagnated over time, despite government data showing that costs have risen significantly during the last 10 years. The substantial increases in the cost of labor, medical supplies, devices, and medications have consistently been higher than the inflation predicted by the ESRD market basket. This chronic underfunding and associated impacts of consolidation have left patients with kidney failure behind and resulted in higher overall costs to the Medicare program and out-of-pocket expenses. More than 71 percent of individuals with kidney failure rely on Medicare for their health insurance coverage. The program is not sustainable for patients unless it is significantly reformed.

ASN welcomes the opportunity to work with CMS and Congress to comprehensively reform the Medicare ESRD PPS so that it empowers patients to access solutions to better manage their chronic kidney disease and navigate the complexities of the health care system while also giving their providers access to better information and treatment options and holding them accountable for patient outcomes. Given your deep understanding of the need to incentivize and support innovative treatment options to drive meaningful improvement in patient outcomes and ultimately lower overall health care spending, and hope that you will partner with ASN and the broader kidney care community so that those living with kidney diseases are not left behind. ASN pledges to work with CMS and the broader kidney care community to provide a blueprint to address the future viability of the ESRD program.

d. Innovation

The Medicare ESRD Program’s approach to payment for innovation is broken. CMS’ two programs for innovation payments, Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPINES) and Transitional Drug Add-on

Payment Adjustment Patients (TDAPA) have not had robust results and patients who could have benefited from innovative therapies cannot access them because the payment system fails to adequately adjust the payment rate to account for such new therapies.

There is a dearth of research and development for advancing treatments for patients with kidney failure, while research and development in other disease states (including earlier stages of CKD not reimbursed under the ESRD PPS) have seen substantial treatment innovations. These innovations have led to improved patient outcomes and quality of life. For example, in 2024, cancer care research received an estimated ten times more funding, and heart disease research 1.5 times more funding than kidney care research. Private innovative companies and investors are also often unwilling to support even the most promising research addressing kidney failure because Medicare fails to provide a sustainable reimbursement pathway for such innovations.

i. TDAPA Eligibility Criteria

ASN agrees that TDAPA should apply to truly new products and generally supports providing a 3-year window in which a manufacturer could submit a TDAPA application; and encourage CMS to refine this timeframe. Specifically, ASN requests that TDAPA applications be accepted up to three years after FDA approval of a new ESRD indication for use as a dialysis drug or biologic product. In other words, if a manufacturer obtains a new FDA approval for a new ESRD indication, then the manufacturer should have three years from that new indication to apply for TDAPA. Given the lack of investor interest in supporting new renal dialysis-related drugs and biological products, ASN encourages CMS to avoid adoption of another policy that will create more barriers to patients having access to innovative therapies related to treating kidney failure. ASN agrees that the implementation date for the proposed changes should not be before January 1, 2028.

ASN appreciates CMS seeking comments on how TDAPA could be improved. The current TDAPA policy, coupled with the lack of a sustainable permanent reimbursement pathway after the TDAPA period ends, not only stifles access to investment in new innovation, but also discourages drug manufacturers from studying ways existing drugs and biological products may support individuals living with kidney failure. The TDAPA period for new drugs or biological products in or outside of an existing functional category should closely mirror the ESRD transition policy applied in the hospital outpatient department and ambulatory surgical centers for price bundling--a period of at least three years. Three years would provide at least 24 months of utilization and pricing information to allow for a more accurate inclusion of the new product into the bundled payment – an improvement over current policy, though it may still underestimate the potential long-term uptake of innovative therapies.

ii. Additional Recommendations Related to the Drug Designation Process

ASN also requests CMS take two additional steps:

- Revising the drug designation process to make sure it is more transparent and involve input from the broader community.
- Reconsidering the use of functional categories to support innovation, and foster competition as intended.

The current CMS process for determining whether a new drug or biological product is designated a renal dialysis service or fits within a functional category or warrants a new one, lacks transparency and meaningful stakeholder engagement. These determinations directly impact patient access and shape reimbursement pathways, such as TDAPA duration, post-TDAPA adjustments, and whether new funding is integrated into the bundle base rate.

At present, CMS conducts internal reviews of FDA materials and Healthcare Common Procedure Coding System (HCPCS) applications without public input. Manufacturers and dialysis organizations learn of decisions through letter or policy transmittals. While outcomes may be referenced in the ESRD rule preamble, they are not subject to public comment or formal review. This closed process creates uncertainty for stakeholders, limits their ability to anticipate or contribute to coverage and payment decisions, and delays efforts to adapt and respond to the decisions. It also discourages investment in innovative therapies due to the unpredictability of reimbursement outcomes. ASN believes CMS should adopt a more structured and transparent approach, modeled after the HCPCS code application process.

ASN believes that the reliance on functional categories as a proxy for defining innovation has become a serious barrier to patient access to medically necessary treatments. This construct is not only misaligned with the federal government's own definitions of innovation—such as those outlined by the FDA and HHS, which emphasize clinical advancement and addressing unmet medical needs—but it also fails to foster the meaningful competition CMS has identified as a key policy goal.

By equating innovation with functional "newness", the policy creates a structural disincentive for the development of new therapies that may offer substantial clinical benefit but share superficial characteristics with older, less effective treatments. This misalignment has a chilling effect on innovation and represents a missed opportunity to improve patient outcomes. Moreover, the current reimbursement model actively undermines competition as is the case with Korsuva.

Korsuva is the first and only FDA-approved therapy for CKD-associated pruritus (CKD-aP), a condition affecting approximately 35 percent of kidney failure patients. Despite its demonstrated clinical value, Korsuva was placed in a functional category alongside

antihistamines like Benadryl—an agent approved in 1946 and widely regarded as ineffective for pruritus. As a result, no meaningful reimbursement mechanism exists to support Korsuva's continued use. Physicians reported withholding Korsuva prescriptions due to concerns about long-term sustainability, despite recognizing the drug's efficacy and the lack of viable alternatives. This policy failure has led to a stark mismatch between clinical need and utilization: fewer than 1 percent of eligible patients have received Korsuva, despite the condition's considerably higher prevalence.

CMS's proposed post-TDAPA add-on adjustment does not resolve the core issue. The methodology—distributing reimbursement across all dialysis treatments rather than those involving the drug—results in a payment of just $0.26 per treatment for a product with an average sales price (ASP) of approximately $50. This approach not only fails to support access to Korsuva, but actively disincentivizes providers from stocking or prescribing it. A more patient-centered approach—such as the one proposed by ASN and the kidney care community—would ensure that reimbursement follows the patient and supports the continued use of effective, innovative therapies like Korsuva.

iii. Barriers to innovation with TPNIES

Innovation in dialysis treatments is lagging behind that of other chronic diseases. The primary difference is that the federal government serves as the primary insurer for most individuals who require dialysis, while commercial insurers cover the majority of patients with other chronic conditions. Medicare reimbursement rates for dialysis have long been underfunded, further limiting progress.

ASN urges CMS to address the flaws in the current policies during the CY 2027 rulemaking cycle. ASN recommends CMS extend the TPNIES period to at least three years and provide an alternative pathway for TPNIES eligibility for devices designated by the FDA as Breakthrough Devices. ASN also requests that CMS expand TPNIES to include capital-related assets. ASN would welcome the opportunity to discuss how these policies could be implemented this winter so that meaningful proposals could be included in the CY 2027 proposed rule.

e. Proposed Payment Adjustment for ESRD Facilities in Certain Non-Contiguous States and Territories

CMS is proposing a new payment adjustment for ESRD facilities in Alaska, Hawaii, and the U.S. Pacific Territories due to higher non-labor costs in these remote areas. The adjustment would increase the non-labor portion of the ESRD PPS base rate, capped at 25%. Under the proposal, facilities in Alaska and the Pacific Territories would receive the full 25% increase, while those in Hawaii would receive a 21% increase.

Under this proposal, CMS would reduce the CY 2026 ESRD PPS base rate by

approximately 0.1%, or $0.40, to maintain budget neutrality. While these numbers may seem small, relative to the totality of all payments in the United States, the impact on care quality and staffing adequacy in the affected areas will be much larger. ASN believes that this payment adjustment should be made outside of the mandated boundaries of budget neutrality.

QUALITY INCENTIVE PROGRAM (QIP)

a. The removal of health-related social needs measures

ASN supports the Administration's focus on improving health care by addressing health-related factors such as nutrition, wellbeing, and the early identification and management of chronic conditions before they progress to more serious diseases. These factors are critical to preventing and slowing the progression of kidney disease and seamlessly align with the Make America Healthy Again initiative to "address the root causes of America's chronic disease crisis". ASN is committed to working with the Administration to strengthen these dimensions of care for individuals living with CKD and kidney failure.

At the same time, ASN recognizes that the collection of the two health-related social needs (HRSNs) screening measures could create administrative burden for dialysis facilities, and so the kidney community understand the rationale for their removal from the QIP measure set. However, ASN wishes to emphasize that improving health through nutrition, wellbeing, and disease management cannot be fully achieved unless HRSN are identified and addressed. ASN encourages continued efforts to incorporate HRSN data collection, especially data on access to healthy nutrition, into kidney care quality initiatives in ways that are meaningful for patients.

b. Modifications to the ICH CAHPS measure

ASN appreciates the ongoing efforts to address the burden of the ICH CAHPS measure on patients and supports the changes outlined in the proposed rule. In previous comment letters, ASN has supported the modification to the questions included in the instrument. ASN has also encouraged CMS to implement these changes within the ESRD QIP. Administering the current measure has created such a high level of patient burn-out with completing the lengthy survey twice a year that the measure is no longer valid.

ASN has long maintained that administering ICH CAHPS twice a year creates additional burden and may lower representativeness, since the same patients could be surveyed twice. ASN believes the survey should be administered once a year to reduce patient burden while still allowing sufficient time to act on results before the next administration. Response rates have remained low, averaging around 30 percent since the survey's implementation, which limits the utility of the measure and underscores the need for a

process that allows facilities to meaningfully use the data. There is no data indicating that survey accuracy would be compromised if facilities were required to field it only annually, and indeed some biases in survey responses may be reduced.

ASN is pleased that CMS is developing a survey equivalent to ICH CAHPS to capture the experiences of home dialysis patients. As the number of home dialysis patients continues to rise due to federal initiatives such as the Kidney Care Choices Model and other payment models and policy changes implemented under the Executive Order on Advancing American Kidney Health, the need for a home dialysis equivalent to ICH CAHPS has never been more urgent. Several dialysis facilities have successfully adapted the ICH-CAHPS instrument for home dialysis patients. Notably, a recent study by Rivara et al. led to the development of the Home Dialysis Care Experience instrument, the first rigorously developed, content-valid, English-language tool designed to measure patient experiences in home dialysis[v]. If CMS intends to continue prioritizing patient-centered care, developing a validated patient-reported experience measure tailored to home dialysis is essential.

ASN reiterates its outstanding request that CMS adopt a CAHPS survey specifically designed to be administered to home patients or a similarly designed tool and that CMS obtain endorsement of the new measure, which MedPAC and others in the community also have consistently requested. It is important that patients who select home dialysis modalities have the same opportunity to provide their input on their experience with the care they receive.

c. Modernize the ESRD QIP to more effectively hold providers accountable for quality outcomes

ASN has long recommended streamlining the QIP and urged CMS to prioritize parsimony when evaluating measures in the QIP and to streamline the measures used in the ESRD QIP, in the Five Star/Dialysis Facility Compare (DFC) program, and by ESRD Networks. The following chart below details the overlapping measure and inconsistencies in the specifications.

To streamline this effort, ASN recommends that CMS use the following measures in the ESRD QIP.

i. **Standardized hospitalization rate measure (replacing the current ratio measure)**
ii. **Standardized readmissions rate measure (replacing the current ratio measure)**
iii. **Long-term catheter use**
iv. **Patient Experience of Care: In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey**

Clinical Measure (modified to incorporate the experience of home dialysis patients as well)

v. **Serum phosphorous**
vi. **Adult Hemodialysis Kt/V Adequacy Measure**
vii. **Adult Peritoneal Dialysis Kt/V Adequacy Measure**
viii. **Pediatric Hemodialysis Kt/V Adequacy Measure**
ix. **Pediatric Peritoneal Dialysis Kt/V Adequacy Measure**
x. **Percentage of patient months of pediatric in-center hemodialysis patients with documented monthly nPCR measurements**
xi. **Clinical Depression Screening and Follow-Up Measure**
xii. **Medication Reconciliation Reporting Measure**

The stars ratings should be awarded based on the QIP methodology and assigned based on the five tiers that are already delineated in the QIP program. Given that CMS proposes to eliminate the social determinant of health-related measures in the upcoming proposed rulemaking, as it has done for the Part A providers, ASN has not included them in either program. ASN also urges CMS to eliminate the hypercalcemia measure, which the kidney care community has noted for several years is no longer relevant to the current reimbursement system (which incentivizes underutilization, not overutilization of Vitamin D analogues). ASN also urges CMS to eliminate the transplant waitlist measures, which more accurately measure transplant centers than dialysis facilities that have little influence over hospital waitlist criteria or whether a patient is listed for transplant. ASN would welcome the opportunity to work with CMS on a transplant access measure to test and ultimately have incorporated into one of the quality programs.

Within the DFC program, ASN requests that CMS eliminate the following measures:

i. **Standardized Emergency Department Encounter Ratio (SEDR) for Dialysis Facilities**
ii. **Standardized Ratio of Emergency Department Encounters Occurring Within 30 Days of Hospital Discharge (ED30) for Dialysis Facilities**
iii. **Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR)**

ASN remains concerned that these measures have validity and reliability problems.

Summary of Inconsistencies in ESRD Quality Programs

Measure	Differences
BSI	Positive blood cultures (PBCs) are considered BSIs in NHSN and only the SIR (observed PBCs / predicted PBCs) is used by CMS for QIP and Five Star. The Network uses variable definitions.
ICH CAHPS	Star ratings updated twice per year, while QIP follows a calendar-year (CY) survey. Different timeframes can lead to incongruent results where clinic can perform well in one program but poorly in another.
Hospitalizations	The SHR measure is the same for both QIP and Five Star; however, there are a few differences related to assessing performance. **QIP Only**: For facility exclusions, calculations will exclude the months covered by a granted ECE (see Section 3.4). - See 2.13.7 of the CMS ESRD Measures Manual (https://www.cms.gov/files/document/esrd-measures-manual-v101.pdf). **Five-Star Only:** 2.13.16 Flagging Rules for Dialysis Facility Measures. Per CMS Measures manual: "As currently implemented for Dialysis Facility Measures, for reporting purposes we identify outlier facilities from amongst those with at least five patient-years at risk during the time period. If the 95% interval lies entirely above the value of 1.00 (i.e., both endpoints exceed 1.00), the facility is said to have outcomes that are 'worse than expected'. On the other hand, if the 95% interval lies entirely below the value 1.00, the facility is said to be better than expected. If the interval contains the value 1.00, the facility is said to have outcomes that are 'as expected'."
	There are no specifications when hospitalization is part of a Network program.
Readmissions	SRR has two separate measures for QIP and Five-Star. Slight differences in the measure specifications (detailed below) lead to differences in SRR for QIP and Five-Star. For example, SRR for Five-Star was 26.4 and 25.87 in QIP (expressed as rates). While the measure name, description, rationale, and type are similar - Five-Star uses "ratio" only whereas QIP states "A lower rate/ratio indicates better quality." in Sections 2.10.5 and 2.11.5. Additionally, QIP includes a statement in the Facility exclusions that states: "Calculations of index discharges will exclude the months covered by a granted ECE (see Section 3.4)."

Measure	Differences
	The numerator and denominator statements are the same. However, the Index Discharge Exclusions vary. QIP also has a patient exclusion section that is not included in the Five-Star measure: "Patient with a functioning transplant on the date of the index discharge. Patient is determined to have a functioning transplant on the discharge date when the discharge date occurs on or between the transplant start and end dates." Mapping to facilities is essentially the same with one addition in QIP: "ESRD QIP assigns to the CCN the facility used as of date of discharge." Defining Readmissions section has several variances as well, specifically related to classification of planned/unplanned admission (QIP refers you to Section 2.11.17, Five-Star continues the conversation in that same section). Note: Both QIP & Five-Star use the same algorithm for determining planned admissions: Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation (YNHHSC/CORE). However, they are similar in the 4-30 day timeframe for unplanned readmissions. QIP also includes a definition of the calculation of the National Average whereas Five-Star does not. Finally, the risk adjustment approach used in the model for the SRR was adapted from CMS' Standardized Hospitalization Ratio (SHR) and CMS' Hospital-Wide Readmission (HWR) measure is the same for both QIP & Five-Star.
	There are no specifications when hospitalization is part of a Network program.
Mortality	Five Star removes patient deaths which occur 30 days after the patient was last dialyzed in a facility. Claims-based measures continue to count those deaths.

Measure	Differences
PPPW/Waitlist	The PPPW measure is the same for both QIP and Five Star; however, there are a few differences related to assessing performance: **QIP only:** For facility exclusions & denominator statement, calculations will exclude the months covered by a granted ECE (see Section 3.4). - See 2.16.7 of the CMS ESRD Measures Manual. **Five-Star only:** 2.16.14 Creating Interval Estimates "The 95% confidence interval gives a range of plausible values for the true waitlist percentage. The upper and lower limits of the confidence interval enclose the true percentage approximately 95% of the time if this procedure were to be repeated on multiple samples. A two-sided Wald test (0.05 significance level) is used to measure the statistical significance of (or evidence against) the hypothesis that the PPPW for a facility is the same as (neither higher nor lower than) that from the national average percentage waitlisted. A p-value of less than 0.05 is usually taken as evidence that the facility PPPW differs from the national PPPW." **Five-Star only:** 2.16.15 Flagging Rules for Dialysis Facility Compare "Facilities were classified as "Better than expected", "As expected", or "Worse than expected" based on their Z score of the logit of PPPW. The z score value is much more likely to follow a normal distribution than PPPW itself, due to the symmetry and lack of range restrictions of the transformed version" Additionally, Five-Star has an additional waitlist measure that is not included in QIP: Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) Measure.

e. Center for Medicare and Medicaid Innovation (CMMI) Models

i. CMS is proposing to terminate the End-Stage Renal Disease Treatment Choices (ETC) Model at the end of this year. CMS states:

The ETC Model performance since 2021 has not been shown to enhance the quality-of-care in ETC regions on the key model measures of home dialysis modalities, transplant waitlisting, and living donor transplantation versus the control group. CMS then proceeds to outline the final dates for data collection and sharing. ASN regrets the course of events that has led to this course of action. In ASN's letter to the CMMI on February 22, 2024 (attached), ASN outlined factors impacting the model and urged additional rulemaking to try to preserve it. ASN will continue to support CMS's efforts to provide models for improvements and cost savings in kidney care.

ASN does wish to thank CMMI for implementing the new Increasing Organ Transplant Access (IOTA) Model, for which ASN supported and contributed substantial input.

ii. Hurricane Helene and the ETC Model

CMS discusses that while it proposes no changes to the schedule and methodologies for the ETC Model Performance Payment Adjustment (PPA) due to the Hurricane Helene, it could have made adjustments. CMS seeks comments on whether it should make retroactive adjustments for this emergency. ASN's response to this invitation for comment is an emphatic: YES, this should be undertaken. Hurricane Helene resulted in massive supply chain disruptions to peritoneal dialysis fluid availability through its largest manufacturer. For a period of time, the manufacturer did not ship supplies to any new patients starting on peritoneal dialysis. ASN led efforts to guide dialysis facilities during this public health emergency and standardized a protocol for peritoneal dialysis fluid stewardship. Despite these efforts by ASN, supply chain shortages may have led to attrition of patients on peritoneal dialysis. Taken together, the PPA in the ETC Model was almost certainly impacted by Hurricane Helene, which should be accounted for.

iii. KCC

In contrast to the ETC Model, CMS notes the "promise" of the KCC Model. Results of the PY 2022 evaluation for the KCC Model demonstrate promising strides towards the aforementioned shared goals with the ETC Model, and more specifically, a statistically significant increase in home dialysis rates for aligned beneficiaries in aggregate. KCC participants increased the proportion of patients receiving PD in a given month by 2.3 percentage points. This statistically significant relative increase represents about 26 percent of the pre-KCC mean. Additionally, Comprehensive Kidney Care Contracting (CKCC) model participants increased the proportion of patients receiving PD in a given month by 0.74 percentage points. This statistically significant relative increase represents about 8 percent of the pre-KCC mean. ASN will further provide comments to CMMI as ASN believes the accomplishments of the model contradict the steps CMMI took this year to dismantle key components of the incentive structures which enabled these improvements to occur.

f. Other RFIs: Interoperability Measure Concept; Well-Being Measure Concept; Nutrition Measure Concept; Physical Activity Measure Concept; and Chronic Kidney Disease Measure Concept

i. Interoperability

ASN appreciates CMS's commitment in interoperability as was the case in the first Trump Administration. The questions asked in the RFI, however, are vast in scope and require a much larger commitment of time and resources to address than a 60-day comment period. ASN encourages HHS and the White House to commit the time, resources, and workforce worthy of a Presidential Blue-Ribbon panel to address this across a vast range of healthcare delivery systems along with information from the Administration's AI efforts. ASN urges the Administration to undertake this effort with clarity and serious parameters to capture the true scope of resources needed.

ii. The Importance of Nutrition

ASN appreciates CMS's request for feedback on the development of nutrition-related quality measures for the ESRD PPS QIP. Nutrition is a critical component of care for patients with end-stage renal disease, as it directly impacts health outcomes, the effectiveness of dialysis treatments, and overall quality of life. Proper nutrition supports symptom management, helps maintain a healthy weight, prevents complications, and may even slow disease progression. Efforts to address patient nutrition also align with the Make America Healthy Again initiative to "address the root causes of America's chronic disease crisis [including] poor diets… to empower individuals and communities with access to healthier lifestyles".

ASN encourages CMS to ensure that any new nutrition-related measures are carefully aligned with existing programs and requirements, such as the ESRD Conditions for Coverage and associated Interpretive Guidance, to avoid duplication and maintain consistency in patient care standards. Current regulations already require facilities to have an interdisciplinary team, including a registered dietitian, complete a patient assessment, and develop a corresponding plan of care that addresses the evaluation and management of the patient's nutritional status and risk for renal bone disease. Facilities are also required to measure, analyze, and track quality indicators related to these areas.

Although critically important, nutrition presents unique challenges for quality measurement. Nutritional requirements vary considerably across patients, making it inherently complex to establish standardized measures that accurately capture patient needs. Within the ESRD population, these challenges are compounded by gaps and variation in the research, which limit the development of robust, evidence-based measures. Examples of tools currently in use include:

- Subjective Global Assessment (SGA): a nutrition assessment tool that refers to an overall evaluation of a patient's history and physical examination and uses structured clinical parameters to diagnose malnutrition
- Malnutrition Inflammation Score (MIS): a tool used to assess the nutritional status and inflammation in patients, particularly those with chronic kidney disease (CKD) and those undergoing hemodialysis

- Nutritional Risk Screening (NRS-2002): designed to identify patients at nutritional risk who may benefit from nutritional support therapy and has been officially adopted by the European Society of Parenteral and Enteral Nutrition.

At present, the Conditions for Coverage and the ESRD QIP do not specify a standard instrument, leaving the choice to individual facilities. This lack of a recommended uniform tool results in variation across clinics. ASN recognizes CMS's adoption of the Global Malnutrition Composite Score (GMCS) into the Hospital Inpatient Quality Reporting program in 2024 as an important step toward elevating the role of nutrition in quality programs by promoting standardized, evidence-based interventions across the care team in the hospital setting. However, before pursuing a similar approach within the ESRD QIP, ASN urges CMS to thoroughly examine the current state of nutritional status measurement in the ESRD population, given the absence of a universally accepted tool and the resulting inconsistency in practice. ASN recommends that CMS convene a Technical Expert Panel (TEP) composed of registered dietitians, nephrologists, patients, caregivers, and other members of the ESRD care team to evaluate both the current state of nutritional guidelines in ESRD care and the status of measurement practices within the ESRD program.

Registered dietitians play a critical role in the care of patients with ESRD, and any new measures should be designed to support, rather than duplicate, the work of these professionals. ASN looks forward to continued collaboration with CMS to ensure that quality measures enhance patient-centered care while building on existing frameworks that already promote optimal nutrition and outcomes for patients with ESRD.

iii. Chronic Kidney Disease Measure Concepts

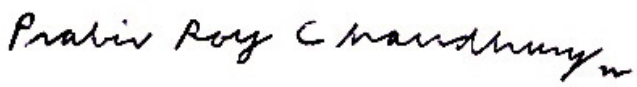
Over the past five years, ASN has led significant work to evaluate existing CKD quality measures and identify priorities for future measure development. ASN conducted an environmental scan which revealed a paucity of measures for early CKD treatment and delaying progression to ESRD.[vi] Furthermore, CKD quality measures remain absent in primary care-focused programs such as the CMS Universal Foundation, Alternative Payment Model (APM) Performance Pathway, and the Optimizing Chronic Disease Management Merit-based Incentive Payment System (MIPS) Value Pathway. ASN previously partnered with CMS to advance CKD quality measurement by co-developing the *Optimal Care for Kidney Health* MIPS Value Pathway.[vii]

While measures for CKD care fall outside the scope of the ESRD PPS, ASN looks forward to partnering with the administration on efforts to incentivize chronic kidney disease prevention and management, as well as increase access to new evidence-based treatments for CKD.

CONCLUSION

ASN applauds the Trump Administration's commitment to addressing the burdens of kidney diseases on patients, their families, and the federal government and pledges to work with CMS to improve the ESRD benefit and its quality outcomes. To discuss this letter, please contact David L. White, ASN Senior Regulatory and Quality Officer, at dwhite@asn-online.org.

Sincerely,



Prabir Roy-Chaudhury, MD, PhD, FASN
President

[i] Chronic kidney disease - Symptoms and causes - Mayo Clinic
[ii] Kidney Disease Statistics for the United States - NIDDK
[iii] Kidney Disease Statistics for the United States - NIDDK
[iv] https://www.kidneyfund.org/sites/default/files/media/documents/AKF%20comment%20letter%20-%20ESRD%20PPS%20and%20QIP%20CY%202025%20-%20Aug%202024%20Final.pdf
[v] https://pubmed.ncbi.nlm.nih.gov/38261328/
[vi] https://pubmed.ncbi.nlm.nih.gov/32054692/
[vii] https://pubmed.ncbi.nlm.nih.gov/37400103/