



August 22, 2022

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

Re: CMS–1768–P: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

Dear Administrator Brooks-LaSure:

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 – many of whom may not survive long enough to receive a life-prolonging transplant.

Kidney diseases are the ninth leading cause of death in the United States, resulting in more deaths than breast cancer. These deaths are due in part to an extremely high risk of cardiovascular disease (CVD) associated with chronic kidney disease (CKD) as well as a high risk of progression to kidney failure. 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 3.7 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 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. ASN provides comments in this

letter outlining support of existing and proposed health equity efforts as well as comments on other aspects of the ESRD PPS, QIP and ETC Model.

ASN applauds the Biden-Harris Administration for its ongoing efforts seeking to improve access to high-quality kidney care and address inequities in the delivery of health care impacting individuals living with kidney disease and kidney failure, as outlined.

This letter addresses CMS' request for information in the following areas:

- Quality indicators for home dialysis
- Health disparities for individuals receiving renal dialysis services
- Health disparities faced by pediatric ESRD patients
- Future inclusion of two Social Drivers of Health measures
- Add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories

The letter also addresses general recommendations to the ESRD program:

- Prospective Payment System
 - a) Modifying Site of Service Provided to Medicare beneficiaries with Acute Kidney Injury (AKI)
 - b) Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)
 - c) Permanent five percent cap on decreases in the ESRD PPS wage index
 - d) Overall payment flexibility in the program
 - e) Changes to the ESRD Treatment Choices (ETC) model
- Quality Incentive Program
 - a) Suppressing Measures for CY 2023
 - b) Updating the PY 2023 performance standards using CY 2019 data
 - c) Technical changes to some rates and clinical measures in outlying years

I. Requesting comments on Quality Indicators for home dialysis.

CMS requests information on quality indicators for home dialysis in the proposed rule and highlights the two general types of dialysis currently in use: hemodialysis (HD) and peritoneal dialysis (PD). While HD can be performed both in-center and at home – and PD can be furnished in both sites of care as well – CMS acknowledges that it is very rare for PD to be performed in-center and that for the purposes of this RFI, CMS considers PD to be exclusively a home modality.

CMS discusses its support of home dialysis, when appropriate, for the patient and the financial stability of the Medicare ESRD program. The agency writes “*we are seeking comments on strategies to monitor and assess the quality of care delivered to patients who receive dialysis at home. We are also seeking comments on how to support more equitable access to home dialysis across different ESRD patient populations.*”

ASN recommends CMS first examine its reliance on Kt/V to determine the adequacy of all dialysis modalities – both HD and PD. Since 2020, the International Society for Peritoneal Dialysis (ISPD) recommends that the adequacy of PD should no longer be determined by Kt/V. Rather, home dialysis should be “goal-directed” to promote high-quality dialysis care that helps patients meet their own individual care goals (e.g., remaining independent at home, maintaining a high quality of life). Given current treatment guidelines, an overreliance on Kt/V as a quality measure for PD runs counter to the spirit of patient reported outcome measure, and thus may encroach on patient-centered care.

ASN recommends that CMS reevaluate the assessment of Kt/V in PD by examining and tailoring the performance standards within the ESRD QIP separately for in-center hemodialysis and PD. Currently, the PD and HD performance standards for Achievement Threshold, Median, and Benchmark Kt/V in dialysis are the same regardless of modality, with a median performance standard of 97.61% estimated for PY 2025 (with an achievement threshold of 94.33% and benchmark of 99.42%). These standards are inappropriate for a substantial proportion of PD patients as discussed in the current PD guidelines. ASN believes that achieving a target Kt/V should be disaggregated for PD and HD, with the application of different performance standards for PD. These can then be reagggregated at the facility level to comprise a revised Kt/V Comprehensive measure that does not disadvantage patients electing for PD and facilities providing PD. This revised strategy would be less discordant with current international guidelines for peritoneal dialysis.

CMS should convene a technical expert panel to evaluate the basic framework for these performance standards through the lens of clinical knowledge and intended to limit unintended consequences and individualize care. For example, in a setting where dialysis prescriptions are optimized and individualized, the proportion of patients at a facility who achieve a given Kt/V threshold for in-center hemodialysis typically will be higher than the proportion for peritoneal dialysis. Reasons for this are multifactorial, including: 1) prescription of care concordant with international guidelines; 2) national and international inconsistency in how Kt/V is determined in patients receiving PD, including uncertain determination of V as well as estimates regarding clearance that assume all exchanges are accomplishing similar small molecule clearance; 3) patient level challenges with accurate 24 hour urine collections; 4) patient level challenges with dialysate effluent collections; and 5) patient burden and inconvenience with repeating collections and delivering them to the dialysis facility within a time frame to meet CMS reporting mandates. Only one of these issues, some uncertainty in V, exists for in-center HD.

ASN recognizes the CMS goal of assessing dialysis dose in all modalities as well as the fact that relatively small numbers of patients treated with PD at many facilities result in a non-viable measure if PD adequacy forms a separate metric. Accordingly, ASN suggest that performance in this measure could be assessed separately within modality and

then be reaggregated at the facility level. This would maintain a comprehensive dialysis adequacy measure, with performance standards more appropriate to PD allowing for more individualized, guideline concordant care while also acknowledging the challenges of rechecking Kt/V assessments in home dialysis. This strategy could also help account for the more frequent adequacy penalties in PD-only facilities or in facilities with both PD and in-center HD as compared to HD-only facilities, further promoting the uptake of home dialysis and aligning with CMS' stated goals.

Coupled with deprioritization of Kt/V, ASN recommends prioritization of outcome measures to focus on relevant clinical outcomes such as reporting peritonitis rate as the number of episodes per patient year, inpatient readmission rates and mortality. Other types of metrics, such as patient-reported outcome measures (PROMs), and patient-reported experience measures (PREMs) are key home dialysis indicators that should also be considered. Work in the PREMs area has been significant, and ASN urges CMS to examine the promising Home Dialysis Care Experience instrument developed by Rivara, et al.¹ CMS should facilitate further testing and evaluation of this instrument to demonstrate sufficient feasibility and validity for use as a potential first PREM for home dialysis. The use of PROMs such as SF-36, KDQOL, and ICHCAHPs has been leveraged for in-center dialysis patients and should be examined for home patients as well.

II. Requesting comments on improving CMS's ability to detect and reduce health disparities for individuals receiving renal dialysis services.

CMI is inviting public comment on the following:

- *What kind of refinements to the ESRD PPS payment policy could mitigate health disparities and promote health equity?*

ASN recommends CMS consider a health equity incentive model, similar to ETC Model, that many respondents discussed in comments to CMS' 2021 RFI in last year's proposed ESRD rule on the stratification of quality metrics. For example, in ETC "sufficiently significant improvement on the home dialysis rate or transplant rate (2.5%) among their attributed beneficiaries who are dual eligible or receive the low-income subsidy (LIS) between the Benchmark Year and the MY. ETC Participants who earn the Health Equity Incentive would receive a 0.5-point increase on their improvement score."

ASN hopes CMS will consider a model with a similarly structured incentive in which a payment adjustment is based on the percentage of dual eligible/LIS patients (to incentivize care of these patients). The model could include add-on payments for higher percentage of dual eligible home dialysis patients or patients with social challenges such as housing and/or food insecurity. ASN believes that collecting information about social determinants of health and paying for potentially higher costs of historically disadvantaged patient populations is critical to improving outcomes equitably. This requires CMS to incentivize healthcare providers to invest financial resources.

As stated earlier, ASN recommends CMS establish payment for assistance for home dialysis for specified interventions selected to help initiate and maintain home dialysis as needed. We recommend that this payment be an add-on, given difficulties related to staffing shortages.

- *Are there specific comorbidities that should be examined when calculating the case-mix adjustment that would help better represent the ESRD population and help address health disparities? Please describe in detail and provide specific data or recommendations for analytical frameworks and data sources that CMS should use in evaluating such comorbidities.*

ASN recommends CMS consider mental health diagnoses (depression-related, bipolar disorder, anxiety, substance abuse), language and communication barriers, physical disabilities (i.e., wheelchair dependency), and social determinants of health including, but not limited to housing and food insecurity.

Patients with disability and mobility challenges are at high risk for inequitable care, due to many challenges including transportation to dialysis. With further restrictions on ambulance utilization, patients requiring any assistance related to transport to in-center hemodialysis facilities are at risk of not being transported to dialysis in a timely manner, remaining inpatient if admitted, or being delayed in receiving appropriate post-acute care including rehabilitation. Addressing transportation factors in the case-mix adjusters could help address resulting disparities. Similarly, CMS should explore broader transportation options beyond ambulance or chair car, which offer medical assistance from vehicles to within a patient's home or dialysis unit to avoid exacerbating existing disparities among those with mobility challenges.

- *Are there specific subpopulations whose needs are not adequately accounted for by the current ESRD PPS payment policy and should be evaluated for potential health disparities?*

See above answer as well as subpopulations of 70 years of age and older, non-English speakers, and those with limited education and/or literacy.

- *What are the challenges, and suggested ways to address, defining and collecting accurate and standardized, self-identified demographic information (including information on race and ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, and language preference) for the purposes of reporting, stratifying data by population, and other data collection efforts that would refine ESRD PPS payment policy.*

ASN supports collection of self-identified demographic information as outlined in the question above. Ensuring self-identification is critical, and challenges include: 1) training of frontline staff to collect data; 2) ensuring adequate EHR functionality to capture data; and 3) ensuring that CMS is collecting demographic data that is comprehensive and reflects self-identification. One strategy is to amend CMS forms (i.e., 2728) to include a

broader range of demographic data and specifying that data must be self-identified or identified by a health care professional (HCP). As ASN has previously discussed in prior letters to CMS, the agency can leverage zip codes as well as proxy for capturing geographic SES variation. For all the data collection questions in this proposed rule, ASN strongly recommends that these efforts are duplicated in Medicare Advantage (MA).

In its August 2021 letter to CMS on the CY 2022 ESRD PPS QIP proposed rule, ASN wrote the following:

“As reported by Kathryn Taylor, RN, MPH and Deidra C. Crews, MD, ScMⁱⁱ in *Toward Antiracist Reimbursement Policy in End-Stage Kidney Disease: From Equality to Equity*, one source of data that CMS could consider in reporting would be to stratify reports based on Zip Code level residential segregation. This approach would allow CMS to use publicly available data on the racial composition of the Zip Code where the facilities are located and show the facilities their data compared to other facilities with a similar neighborhood composition as well as compared to communities with a lower percentage of minority residents (less residential segregation). This step is important as multiple studies have shown that ALL patients (regardless of their individual race) dialyzing at facilities serving a large percentage of Black patients have poorer outcomes.

With respect to the ‘social risks’ that CMS wishes to track, ASN believes that tracking issues, such as housing insecurity and food insecurity, are very important. This section of the proposed rule references housing insecurity, and ASN encourages CMS to include food insecurity. Both would either require new data collection from patients or the use of neighborhood level (Zip Code level) proxy measures.”

ASN re-iterates its support for this approach and its past support for the collection of data through Z codes. ASN continues to recommend that CMS collect data using the Z-codes, such as the following:

- Z55 – Problems related to education and literacy
- Z56 – Problems related to employment and unemployment
- Z57 – Occupational exposure to risk factors
- Z59 – Problems related to housing and economic circumstances
- Z60 – Problems related to social environment
- Z62 – Problems related to upbringing
- Z63 – Other problems related to primary support group, including family circumstances
- Z64 – Problems related to certain psychosocial circumstances
- Z65 – Problems related to other psychosocial circumstances

ASN offers to work with CMS to identify the precise Z-codes that could be collected and analyzed to support a better understanding of how the SDOH impact the ESRD population. This additional work is critical as many nephrologists, while billing the

monthly capitated payment, do not list Z codes or additional comorbid conditions, resulting in limited data on beneficiaries. It is not clear whether CMS intends for nephrologists and facilities to report this data and/or making billing adjustments.

Finally, given staffing shortages affecting all of healthcare, particularly dialysis facilities, requiring this additional data collection will be challenging to operationalize without initial training and financial investment. CMS should consider an initial payment adjustment to facilitate investment in staff training and EHR modification.

++ What impact do SDOHs have on resource use and treatment costs for patients who are medically underserved?

SDOHs contribute to wide health disparities and inequities, including increased risk of CKD and ESKDⁱⁱⁱ and contribute to increased healthcare utilization, lower rates of transplantation, and non-adherence to treatment among ESKD patients as demonstrated by Balhara, et al^{vi}. Overall SDOHs are associated with increased utilization and increased treatment-related costs among patients with kidney disease.

++ Which SDOHs should data collection include?

Dual eligibility is often cited as a proxy for social risk and has been considered as a variable for stratification in identifying patients at risk for socially driven poor health outcomes. A limitation of this indicator is that Medicaid eligibility varies by state, particularly for adults.

As of July 2022, 12 states still had not adopted Affordable Care Act Medicaid expansions which sought to standardize coverage for most low-income adults by expanding Medicaid coverage to 138% of the federal poverty level (FPL) (Alabama, Florida, Georgia, Kansas, Mississippi, North Carolina, South Carolina, South Dakota, Tennessee, Texas, Wisconsin, Wyoming). A 2021 analysis by the Kaiser Family Foundation found that nearly 4 million adults de facto were excluded from new access to Medicaid coverage because they lived in states that did not expand, 2.2 million of whom had incomes <100% FPL.^v Dialysis patients residing in non-expansion states may have higher social needs than those living in expansion states, and yet would be less likely to qualify for Medicaid and could be missed in the event of heavy reliance on dual eligibility as an indicator for social risk. Inclusion of other SDOH, such as LIS eligibility, as has been proposed for the ETC, will be important to address these limitations.

Another consideration is classifying PD patients as disadvantaged with respect to the receipt of rehabilitation and nursing home services. Often, PD patients must transition to HD to enter a nursing home or rehabilitation center. This is a tragedy, resulting in hemodialysis with a catheter and a lack of patient-centered care. ASN urges CMS to collect data in this area and assess the impact as well as to develop programs that would incentivize nursing and rehabilitation facilities to offer peritoneal dialysis. In the current environment, post-acute facilities that are facing staffing shortages, do not have

the financial incentive to train staff in caring for patients on peritoneal dialysis. If the AAKH and ETC Model efforts are successful in increasing rates of home dialysis, these trends will be constrained by the lack of access to post-acute care

++ How should data regarding SDOH be collected? How should such data be used in the ESRD PPS to help mitigate health disparities and promote health equity?

CMS should be collecting data on a range of factors including, but not limited to, housing and food insecurity, zip codes as a proxy for neighborhood poverty, disability status, mobility, employment status, education, smoking status, primary language, race, ethnicity, age, gender identity, sexual orientation. CMS can collect this data through existing CMS forms (2728 for incident ESRD patients) and through billing claims. CMS should partner with the Office of the National Coordinator (ONC) in the Department of Health and Human Services (HHS) to achieve accurate capture of electronic health record (EHR) data to achieve this goal and prioritize the need for self-identification. Additionally, CMS will need to work with the nephrology community to enhance systems to include relevant claims in billing data in a way that does not further increase clinician burden.

● Are there actions CMS could potentially consider under the ESRD PPS to help prevent or mitigate potential bias in renal dialysis technologies, treatments, or clinical tools that rely on clinical algorithms? What are the relevant considerations for evaluating the effectiveness of such actions?

In September 2021, the National Kidney Foundation (NKF) and ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Diseases released its final report, which outlined a new race-free approach to diagnose kidney disease. In the report, the NKF-ASN Task Force recommends the adoption of the new eGFR 2021 CKD EPI creatinine equation that estimates kidney function without a race variable. The task force also recommended widespread adoption of cystatin C combined with serum (blood) creatinine, as a confirmatory assessment of GFR or kidney function.^{vi}

Numerous institutions and laboratories have followed this recommendation. In June 2022, the Organ Procurement and Transplantation Networks' (OPTN's) board endorsed a race free eGFR calculation for all its transplant system participants. ASN and NKF have also requested that OPTN call for the elimination of race in the calculation of the Kidney Donor Risk Index (KDRI) writing "There is no place for race-based variables in the evaluation of organs offered through the organ allocation system."

ASN urges CMS to evaluate its guidance to ensure that it aligns with these recommendations and to work with ASN and NKF in the next year to determine a pathway for a National Coverage Determination regarding the use of serum cystatin C.

III. Asking about health disparities faced by ESRD pediatric patients and Request for Information Regarding Dialysis for Pediatric ESRD Patients.

ASN joins the American Society of Pediatric Nephrology (ASPN) in responding to this RFI and thanks CMS for continuing to engage with the kidney community about the needs of children with ESRD, soliciting comments on health disparities in this population, and how changes to the ESRD PPS, including changes to data collection procedures, may help reduce these disparities. We are providing responses to the following questions:

- *Please provide any information and supporting documentation about whether there are health disparities in this sub-population*

Health inequity in pediatric kidney diseases is pervasive and persistent. Black children are significantly less likely to receive kidney transplants, wait longer to receive transplants, and are disproportionately impacted by chronic kidney disease overall.^{vii} United States Renal Data System (USRDS) data show that the time to 50 percent incidence of kidney transplantation was 30 months in Black children compared to 19 months in White children.^{viii} Disparities in pediatric kidney care also extend to treatment modalities, with all racial and ethnic minorities being significantly less likely to receive home dialysis treatment than white patients.^{ix} ^x Data show that a substantially higher percentage of Black children initiated in-center hemodialysis compared with White children, 55 percent compared to 35 percent.^{xi}

Furthermore, children are always dependent on a caregiver; accordingly, the social determinants of health (SDOH) that impact the adult caregiver also impact the pediatric patient, leading to a cascade effect of disparities. Children are in an environment where both they and their caregivers may be impacted by social determinants of poor health. Lack of access to proper housing is another major concern.

Algorithms designed to optimize the match of kidneys from deceased donors to pediatric kidney transplant recipients include race, even though this inclusion actually increases barriers for donors of African ancestry to provide kidneys to children who need a kidney transplant. In these current algorithms, kidneys from individuals from African ancestry are considered as coming from high-risk donors, thereby decreasing the chances that these kidneys will be used in children, where transplantation from high-risk donors is often avoided. Consequently, overall access to transplantation for children awaiting deceased donor kidneys is negatively impacted. Moreover, wait times until kidney transplantation for kidney recipients from African ancestry are also longer with this algorithm, since there are fewer donors from African ancestry considered appropriate.

- *How could refinements to the ESRD PPS payment policy mitigate health disparities in the pediatric population?*

There are several refinements that could be made to the ESRD PPS payment policy that would help mitigate health inequities and disparities in the pediatric population.

Certain SDOH affect the pediatric population differently than the adult population. As an example, housing assistance could favor children who do not have homes, stable addresses, and are in struggling school districts. Home dialysis is favored in children for many reasons: some children cannot tolerate hemodialysis because of their small size, home dialysis can have fewer side effects, and it is less disruptive for those in school. Yet, many patients do not have a home to support their care. Finally, it may be challenging for children to receive hemodialysis in a dialysis facility predominantly caring for adults for numerous reasons; however, this is often necessary as pediatric facilities are scarce, typically located exclusively at children's hospitals and often require substantial commutes.

Food insecurity and access to proper nutrition have different implications for the health of children with ESRD compared to adults. Proper growth and development are very important for pediatric patients, and often there are concerns with lack of weight gain and growth, oral aversion, and supplement requirements. If certain supplements are not covered by the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) or other nutrition assistance programs, then the patient will not have access. Growth and development are a challenge for many pediatric patients, but these challenges are exacerbated when families are dealing with SDOH or only have a single income source, which is common since in many instances one parent becomes the child's primary caregiver. In many cases, the food required to adhere to a renal diet falls off the list of items that a family can afford. Children may not have access to food with appropriate potassium or sodium levels, as these specialized foods can be more expensive and are not accessible with the Supplemental Nutrition Assistance Program (SNAP). For children who need specialized formulas, WIC or Medicaid may not cover these. It can also be difficult to get approval for more than one base formula in cases where patients need to mix different formulas together to create the correct base. The nationwide formula shortage has further exacerbated the challenge of receiving formulas through WIC. Intradialytic parental nutrition (IDPN), which is used to stabilize weight and prevent weight loss, is also not covered by WIC or Medicaid.

Many of the current adult ESRD payment models are aiming to create a medical home for patients. Pediatric ESRD care is ahead of the curve as pediatric nephrologists and centers already serve as the medical home for pediatric patients, and provide care coordination, particularly for end-stage care. However, pediatric centers are not reimbursed for the care coordination services that they provide. This must be addressed, as it is critical that pediatric patients have access to pediatric nephrologists, who can provide longitudinal care for the patient. For patients with SDOH vulnerabilities who cannot access pediatric nephrologists, this puts them at a further disadvantage as they do not have access to the medical home.

Additionally, there is a limited workforce that provides pediatric ESRD care, with shortfalls in not only pediatric nephrologists but also the entire interdisciplinary team required to provide care for this very vulnerable group. According to American

Academy of Pediatrics data^{xii}, the mean driving distance to see a pediatric nephrologist in 2019 was 29.4 miles; 42 percent of patients had to drive less than 10 miles, 19 percent of patients had to drive between 10 and 20 miles, 16 percent of patients had to drive between 20 and 40 miles, 13 percent of patients had to drive between 40 and 80 miles, and 10 percent of patients had to drive over 80 miles to see a pediatric nephrologist. According to the American Board of Pediatrics' Pediatric Physicians Workforce Data Book for 2020-2021, there are two states without a single pediatric nephrologist and many more with fewer than one per 100,000 children^{xiii}. This is particularly challenging as patients are reliant on a caregiver to drive them to appointments. To improve access to care and adherence, CMS could consider an enhanced telehealth payment for pediatric nephrology visits.

- *Should a pediatric dialysis payment include a specific payment modifier on the claim so that costs for providing pediatric dialysis can be further delineated with alternative payment sub-options (for example, age related, or comorbidity related)?*

ASN recommends that a combination of age, weight, and pediatric-specific comorbidities be used as a proxy for composite rate costs. ASN supports the following list of pediatric comorbidities compiled by ASPN:

- a. Failure to thrive/feeding disorders – 80 percent of children under 6 years of age require a G-tube and feeding pump for management of oral aversion or supplemental enteral nutrition to promote growth and ensure appropriate cognitive development
- b. Congenital anomalies requiring subspecialty intervention (cardiac, orthopedic, colorectal)
- c. Congenital bladder/urinary tract anomalies
- d. Non-kidney solid organ or stem cell transplant
- e. Neurocognitive impairment
- f. Global development delay
- g. Cerebral palsy
- h. Seizure disorder
- i. Chronic lung disease (including dependency on CPAP and ventilators)
- j. Inability to ambulate or transfer

Although these comorbidities significantly impact the provision of pediatric dialysis care, neurocognitive impairment and global developmental delay are often more longitudinally complex as they continue to pose significant management challenges even as the child ages, particularly when there are no treatments or procedures that can readily ameliorate the underlying condition. Adolescents or young adults with profound neurocognitive impairment or global developmental delay continue to require complex care despite their age and size, and often require a much more intensive utilization of staff resources throughout their life.

ASN joined ASPN last year in suggesting to CMS that the costs of pediatric care can be broken down into the following age groups: <6 years old, 6-11 years old, and 12-18 years old. Treating the typical dialysis patient who is a young child of small size usually requires more staff resources and specialized equipment than treating the typical older and larger adolescent dialysis patient. In general, care becomes less resource intensive as the child becomes older and more cognitively mature, and as the child grows and approaches adult body size. Although there are exceptions to this expectation, especially in the setting of patients with global developmental delay, most pediatric dialysis facilities find that younger and smaller children require the most resources, with needs becoming less intense by adolescence.

- *Are there specific comorbidities that should be examined when calculating the case-mix adjuster that would help better represent the pediatric ESRD population and help address inequities? Please describe in detail and provide specific data or recommendations for analytical frameworks and data sources that CMS should use in evaluating such conditions.*

ASN wants to highlight the circumstances of patients with intellectual impairment or who rely on medical equipment, such as ventilators or feeding tubes. These complicated patients face unique circumstances and require additional assistance to receive necessary care. For example, these patients may need to rely on their pediatric centers to arrange transportation, including medical transportation, and will always need an adult to accompany them.

Food insecurity should also be examined with respect to the pediatric population as ASN has previously indicated in this comment letter. Many patients are not able to remain compliant with prescribed 'renal' diets, as foods with the appropriate potassium or sodium levels may be more expensive and not accessible with SNAP.

- *Are there other direct patient care labor categories that should be considered when determining the cost to provide renal dialysis services to pediatric patients, and if so, which ones?*

Yes, the interdisciplinary team includes pediatric trained social workers, dietitians, psychologists, child life specialists, and other team members. These positions all require additional pediatric training, which comes at a higher cost. Allied health professionals need to have more than just a general knowledge of ESRD in order to be able to care for pediatric patients. For example, in Texas, allied health professionals need special pediatric training to provide care to patients under a certain weight limit. Technicians cannot provide care to certain patients due to catheter and size issues. Teachers also play an important role as liaisons with patients' schools to address frequent absences and to coordinate the educational experience.

- *How should CMS revise case-mix categories in the ESRD PPS to better represent the pediatric population?*

As stated above, CMS should revise the pediatric age breakdowns to more accurately reflect the resources required to provide optimal care. ASN joins ASPN in recommending that the costs of pediatric care be broken down into the following age groups: <6 years old, 6-11 years old, and 12-18 years old.

- *Are there SDOH that are specific to the pediatric population?*

Children who lack caregivers are particularly vulnerable, and, as stated earlier, the SDOH of caregivers directly affect a child's SDOH. For patients who do have a parent as a caregiver, at least one parent or caregiver will need to provide full-time care, leading to a potential loss of income that disproportionately impacts disadvantaged populations.

IV. Request for information on potential future inclusion of two Social Drivers of Health measures

- a. CMS is seeking public comment on adding a new measure, Screening for Social Drivers of Health, to the ESRD QIP measure set in the next rulemaking cycle.

The measure would assess the proportion of a facility's patients that are screened for one or more social drivers of health in the five core domains, including food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

- b. CMS is seeking public comment on the possible addition of a new measure, Screen Positive Rate for Social Drivers of Health, to the ESRD QIP measure set in future rulemaking.

The measure would assess the proportion of patients who screen positive for health-related social needs (HRSNs) in the five core domains, including food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

ASN supports both measures conceptually, noting that, without this level of data collection, it is challenging to consistently capture and trend disparities in kidney care delivery. ASN also appreciates the direct association between identifying social drivers of health and care coordination, community resource connection as a means of mitigating disparities.

SDOH may have a dramatic impact on the ability of individuals who require dialysis to select home dialysis options. The lack of a care partner, inadequate space for the home dialysis equipment and supplies, problems with housing and utilities, lack of access to nutritional food and meals, and mental health issues can make home dialysis

a less attractive option. Another practical barrier is the lack of transportation, especially during the period of home dialysis training that requires frequent trips to the home dialysis training location. Some Medicaid programs provide financial support, assistance, or coverage for varying levels of transportation. Others do not.

SDOH also affect care transitions that can negatively impact outcomes and quality of life. Because of the lack of timely referral to nephrology and pre-dialysis care, the first year of dialysis is often the most difficult for patients and presents a significant risk of mortality.

SDOH also affect other patient treatment outcomes. Individuals who lack access to fresh foods or have few options for nutritional meals experience worse outcomes than those who can access healthier food options. Individuals who are obese require longer dialysis sessions, which can affect their cardiovascular system, as well as their quality of life. Current treatments for managing anemia can be more difficult when individuals have cardiovascular diseases, which impacts their outcomes and quality of life.

SDOH have a negative impact on access to transplantation. There are significant gaps in health equity when it comes to access to kidney transplantation. Transplant centers often face challenges when it comes to treating more socially complex patients, the majority of whom are Black or Brown. Despite recent changes, the MS-DRG payment to transplant centers often does not cover the cost of transplant, particularly those more medically or surgically complex patients. There is also little reimbursement for patients needing complex social services after transplantation.

ASN believes that there is an important need to systemically gather evidence on SDOH and the prevalence of social vulnerabilities among ESRD beneficiaries. As CMS proceeds with its planning, ASN encourages the agency to avoid unintended consequences brought on by increased reporting burden. In order to accurately and systematically capture these data, dialysis facility staff will require training. ASN recommends CMS support resourcing and training. In addition, to capture these data accurately, facilities will need to meaningfully change their workflows, adapt their EHRs and educate their staff related to collecting these data. There also needs to be a component designed to assist in explaining to patients why this data is being collected and, if for example, interpersonal safety issues are identified, how to best address the barriers to care along with the identification of certain needs – like interpersonal safety – that require timely follow-up and interventions. These burdens of data collection will be experienced most meaningfully by smaller facilities, more constrained by staffing challenges.

Also, additional funding for care management is not articulated but is necessary to successfully operationalize a positive screening process. Patients in Medicare Advantage (MA) programs or accountable care organizations (ACOs) may have care coordinators assigned to them, but there is no requirement to provide care management elsewhere.

The RFI language is not clear about CMS' intention to stipulate or institute a standardized form or questionnaire and plan for centralized tracking of rates and types of social barriers. It appears logical to ASN that CMS may utilize the Accountable Health Communities (AHC) Health-Related Social Needs (HRSN) instrument. Critically, if included in the ESRD system, both measures should be reporting measures and not used to evaluate performance. In sum, while ASN views this information as valuable, we emphasize that new data collected should be tested in this setting for feasibility, accuracy and validity before any new survey instruments are added to an already instrument-heavy system.

V. Is an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends needed? If so, why?

Yes. ASN believes that an add-on payment adjustment for new drugs and biologicals that come within existing functional categories after the TDAPA period ends is essential to protect access to these innovative products. Two full years of claims data should be used to establish the utilization of the product, which will require at least a three-year TDAPA period, which ASN supports. At least two full years of data are necessary as we have noted in previous letters because, even with all the right incentives in place, it can take time for nephrologists to determine how best to use a new product with their patients. Therefore, the hospital pass-through payments are provided for three years. CMS also used this rationale when it provided TDAPA for three years for calcimimetics. It is important to provide these new functional category drugs and biologicals with at least three years of TDAPA as well, so that CMS has sufficient data (at least two full years of data) to calculate the drug add-on. In terms of determining cost, we support using the most recently available Average Sales Price. This approach aligns with how CMS established the initial base rate when adding formerly separately billed drugs and its policies related to calcimimetics and new drugs not within a functional category.

This has real world implications. For example, the new agent, difelikefalin, may have substantial benefits for the subset of hemodialysis patients suffering from pruritus. Yet, most patients are unable to access this medication because clinicians have no way to ensure that they will be able to continue this medication at the completion of the TDAPA period. This places clinicians in a difficult position of either not prescribing this agent now or discontinuing it in the future, potentially resulting in patients suffering, either now when they are not getting this agent or in the future when this agent is discontinued. This lack of use and inherent uncertainty regarding payment has enormous upstream effects, as innovators will avoid the ESRD space, perpetuating the innovation stagnation that has pervaded dialysis for the past 40 years.

ASN also supports that the comparison to establish a link between a change in the utilization of the formerly separately billed drug or biological and the new TDAPA product be based on reference to a predictable, objective, and transparent source. Just as CMS relies upon the FDA approved indication for determining whether a product fits

in within an existing functional category, it should rely upon the FDA-approved primary indication to assess whether an existing product's change in utilization during the TDAPA period of a new product is clearly attributed to physicians prescribing the new product in lieu of prescribing the existing product. This direct attribution analysis is important because changes in utilization may occur during the TDAPA period of a new product, but not be related to the adoption of the new product. For example, a new product may be additive to the existing products, but changes in utilization could occur because of manufacturing shortages or supply chain problems. Changes in expenditures might not be due to changes in utilization, but a generic coming to market that is in no way related to the new product. It is important that CMS use clear, objective data to determine whether the change in utilization that ultimately changes the per treatment expenditures for the existing drug or biological be directly attributed to the adoption of the new drug or biological.

Critically, the add-on payment adjustment is designed for a treatment that is used in a high proportion of patients within the capitated bundle. For agents that may be costly used by a minority of beneficiaries, this system is not optimal. ASN strongly encourages the addition of new money to pay for innovative treatments for ESRD beneficiaries. For innovations applicable to a high proportion of beneficiaries, this can occur simply with a change in the bundled rate following the TDAPA period, while, for innovations targeting a subpopulation of beneficiaries, ASN would like to work with CMS to ensure that these beneficiaries have access to innovations that will improve their quality of life and/or their health in a way that is fiscally responsible for the ESRD program.

ESRD Prospective Payment System

Modifying Site of Service Provided to Medicare beneficiaries with Acute Kidney Injury (AKI)

In last year's proposed rule CMS wrote: *"CMS is soliciting feedback from the public on the differences in care for patients with AKI versus patients with ESRD and whether it has bearing on the ability of patients with AKI to perform home dialysis safely. We request any additional comments regarding potentially modifying site of renal dialysis services and payment for AKI in the home setting."*

Unfortunately, after soliciting comments last year, this year's proposed rule is silent on the subject. ASN has shared its concerns with CMS repeatedly on the agency's policy preventing nephrologists from treating AKI patients requiring kidney replacement therapy with home dialysis as they transition from the hospital or in-center facilities to home. In the past, CMS reasoned that these patients require supervision by qualified staff during their dialysis and close monitoring through laboratory tests to ensure that they are receiving the necessary care to improve their condition and transition out of dialysis. Quite simply, the members of ASN view home therapies as supervised care that is of at least similar quality and intensity to in-center hemodialysis, and we highlight that we are absolutely and equally dedicated to the success of all patients with AKI-D,

regardless of whether they are receiving dialysis in the home or in a hemodialysis facility.

Medicare payment for home dialysis for AKI patients should be allowed when the nephrologist determines that an AKI patient can safely dialyze at home. Home modalities can be at least equivalent to in-center care, when delivered with proper patient guardrails. In these circumstances, intensive training for home dialysis should also be reimbursed by Medicare, via the addition of training codes (CPT 90989 and 90933) being added to the telehealth list.

As nephrologists, ensuring that these patients are receiving the necessary care to improve their condition and transition out of dialysis is always first and foremost. ASN believes the incident AKI patient is a complex patient, and, as with any patient, particularly those with medical complexity, the clinical decision regarding the next stage of a patient's treatment should be evaluated by their physician and agreed upon mutually among the patient, caregivers, 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.

Nephrologists do not take this responsibility lightly, and ASN sees no reason for CMS to limit clinical decisions for the patient and physician through payment policy. ASN requests that CMS allow 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.

Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)

ASN commends the Biden-Harris Administration for addressing the lack of innovation in kidney care through its support of the Kidney Innovation Accelerator (KidneyX) – a public-private partnership between the US Department of Health and Human Services (HHS).

ASN has made its own \$25,000,000 commitment to KidneyX to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases. Since its launch in 2018, KidneyX has run six prize competitions and supported innovators in 22 states. By accelerating the development of drugs, devices, biologics, and other therapies across the spectrum of kidney care, KidneyX seeks to improve the lives of the 37,000,000 Americans and 850,000,000 people worldwide currently afflicted with kidney diseases. ASN believes payment policies within the ESRD bundle have long been a disincentive for innovation in dialysis care delivery.

TPNIES was created to incentivize the adoption of innovative devices through the use of a pass-through payment in the ESRD bundle. As of January 1, 2021, TPNIES is set for three years from the date of the US Food and Drug Agency (FDA) marketing authorization. The policy has also been expanded to cover “certain capital-related assets when used in the home for a single patient.” ASN supports these steps and commends the administration and CMS for addressing the need for innovation in kidney care.

ASN wrote last year that there are multiple challenges to introducing innovative devices, drugs, biologics, and other therapies into the ESRD PPS. First, there are barriers related to the use of items during the first few years after introduction. Second, there are no current policies to adjust the base bundle rate to account for new products. Third, and most notable, is the challenge raised by the definition and interpretation of substantial clinical improvement (SCI) criteria.

ASN believes the requirements to prove SCI are numerous and expansive in scope. In addition, the data required to demonstrate SCI represent a far greater outlay of resources than the approved 65 percent rate of reimbursement over three years. Finally, the 65 percent rate of reimbursement, for only three years, arguably abrogates the need to prove SCI to the extent posited by CMS in the discussion of the applicants in the current proposed rule. This fact is because, under TPNIES, a large portion of the financial risk associated with new technologies (35% in the first three years and up to 100% thereafter depending on the amount the bundle is adjusted by to account for technology costs) will be shared by the dialysis providers that adopt the new technology.

If the administration fails to address these three challenges, ASN remains concerned that innovation will continue to stagnate, and millions of Americans will receive suboptimal care as a result of a failure of kidney therapies evolving. There needs to be an opportunity to introduce new technologies into the kidney failure space that results in a willingness for innovators to take the risk of investing in the care of kidney failure patients, similar to other areas of medicine such as Oncology and Cardiovascular disease. ASN fears that the current proposal does not present this opportunity.

Improvements in in-center dialysis care and increases in the use of home dialysis are important for improving overall outcomes and the quality of life for people receiving maintenance dialysis. However, ASN believes that the current TPNIES criteria do not sufficiently address the issues that are critical to advancing home dialysis nor do they fully support the second goal of the federal government’s Advancing American Kidney Health (AAKH) initiative of improving access to, and the quality of, person-centered treatment options.

For home dialysis, ASN supports all innovation that:

- Increases access through technical specifications that make home dialysis easier for people disadvantaged due to smaller homes, living alone, poor vision, challenges with dexterity or other physical limitations; or
- Supports modality longevity with a machine or mechanism that helps more people dialyze at home with reduced drop out, including technologies that are:
 - a. Easier for patients and care partners to use
 - b. More reliable than current machines
 - c. Able to boost communication between patients and care teams; or
 - d. Improves quality of dialysis delivered and/or reduces complications.

Regulations require that an item eligible for TPNIES be new (within three years of FDA market authorization) but many of the trials that will be required to definitively meet the SCI criteria, unless there is a clear acknowledgement that surrogate outcomes will be accepted, will be post-approval for devices given the FDA bar for devices. Recognizing the dearth of technological advances in dialysis in the past decades, the exceptionally high bar established here will continue to disincentivize development of new technologies in the dialysis space. Uncertainty about whether these potential benefits from a new device satisfy current SCI criteria, and uncertainty about the level of evidence necessary to demonstrate that it does may deter some entities from investing in kidney technology. ASN encourages CMS to take a broad view of innovation for dialysis, having established a shared-risk system with TPNIES.

Home dialysis suffers from having many layers of complexity because it must empower an individual to administer a life-sustaining procedure in their own home, and almost always that ability is dictated by the individual's own limitations and sense of security. As such, CMS should consider all elements of a new device that increase use or support greater longevity of home dialysis. ASN looks forward to working with CMS and other stakeholders to develop a set of principles to govern the creation of clinical improvement criteria that are specific to home dialysis in order to help bring innovative technologies to the market.

ASN recommends that CMS also apply TPNIES for three years to allow it to assess the effect of adding the device to the PPS bundle and to then evaluate the base rate to determine if an incremental adjustment would be necessary to support ongoing access to the device. Adjusting the base rate for truly innovative products that improve care is essential to expanding innovation to those living with kidney diseases. The statute establishing the payment system anticipated such adjustments, so there is sufficient authority to provide for these incentives.

In addition, ASN asks that CMS coordinate the policy with the Medicare Advantage (MA) program, so that the MA program receives equivalent additional funding for these products to ensure adequate funding exists for innovative products in the MA program as well.

Overall PPS Proposals

Given the foundational role of the PPS in Medicare, which provides coverage to the majority of individuals living with kidney failure, it is important that the Administration continue its efforts to get these payment policies right. Getting the payment system right means supporting the long-term adoption of innovative treatment options, making sure incentives to adopt innovation apply to patients enrolled in MA plans as well as the PPS, targeting case-mix and facility-level adjusters, outlier policies, and similar policies to prevent millions of dollars being trapped within the federal government and not spent on patient care, and providing flexibilities that support care coordination among those health care providers who provide services to individuals living with kidney disease and kidney failure.

ASN supports CMS' proposal to apply a permanent five percent cap on decreases in the ESRD PPS wage index beginning CY 2023. However, it is clear to ASN that the current payment adjustment system for the PPS is not nimble enough to deal with the strong inflationary forces and real-time staffing crisis facing dialysis providers today. ASN urgently calls on the Biden-Harris Administration to deal with current staffing and inflation crisis post haste in order to avoid unwanted effects on the care that patients receive.

Quality Incentive Program

Suppressing Measures for CY 2023

The Quality Incentive Program (QIP) for payment year 2023 is based on treatment data from facilities from calendar year 2021. Due to the ongoing impact of COVID-19 on the operation of dialysis facilities in 2021, CMS is proposing suppressing these six ESRD QIP measures and using CY2019 data as the baseline for other measures.

- a) The Standardized Hospitalization Ratio (SHR) clinical measure;
- b) The Standardized Readmission Ratio (SRR) clinical measure;
- c) The In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) clinical measure;
- d) The Long-Term Catheter Rate (LTCR) clinical measure;
- e) The Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure;
and
- f) The Kt/V Dialysis Adequacy Comprehensive clinical measure.

The remaining measures would be scored for PY2023/CY2021.

- a) The Clinical Depression Screening and Follow-Up reporting measure;
- b) The Standardized Fistula Rate (SFR) clinical measure;
- c) The Hypercalcemia clinical measure;
- d) The Standardized Transfusion Ratio (STrR) reporting measure;
- e) The Ultrafiltration Rate reporting measure;
- f) The Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) reporting measure;
- g) The National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI)

- clinical measure; and
- h) The NHSN Dialysis Event reporting measure.

As CMS has observed, the impact of the COVID-19 pandemic on the health care remains substantial, which the HHS Secretary most recently recognized by extending the public health emergency (PHE) an additional three months. Individuals living with kidney disease are particularly at-risk for infection, re-infection, and experiencing complications from the disease. While the kidney care community has joined together and worked diligently to reduce that risk, the disease is particularly impactful for individuals living with kidney disease. The experience of the last two years of the pandemic affirm that these individuals are more likely than other Americans to contract COVID in their communities and experience far higher morbidity and mortality rates. Critically, as individuals dependent on multiple aspects of the healthcare system, ESRD beneficiaries have been markedly impacted by surges in the pandemic, losing opportunities for vascular access placement and other life changing elements of kidney care.

Even though it is helpful to suppress specific measures once again this year, ASN also believes it is important to suspend the penalties for PY 2023 as CMS did for PY 2022. Once again, the pandemic has negatively impacted the ability of facilities to submit data through the EQRS system. The CMS EQRS group has reported a significant decrease in data submitted in the last year. This decrease means that the data will be skewed.

In addition, suppressing nearly half of the QIP measures as proposed will skew the scores and not present a meaningful picture of the quality performance of facilities. ASN supports suppressing the measures CMS has proposed and recommends also suppressing the AV fistula measure (discussed below). CMS correctly recognizes that the pandemic has had a significant impact on these measures. Suppressing these measures has an enormous impact on the calculation of the minimum total performance score (mTPS) and ASN supports not scoring the facilities on the remaining measures and not implementing penalties for PY 2023. For example, the weight of the Clinical Depression reporting measure shifts from 2 percent to 35 percent, making it the most weighted measure in the ESRD QIP for PY 2023. The next highest weighted measure would be the STTrR at nearly 14 percent. While CMS indicates that the validity concerns with this measure have been addressed, there are not publicly available data demonstrating that this measure is actually assessing facility performance as opposed to hospital's utilization of transfusions. Additionally, the list of remaining measures is very high stake and includes hypercalcemia. Appropriately, the hypercalcemia measure is being eliminated as a performance measure in subsequent years because of multiple issues including a lack of importance. ASN does not believe this juxtaposition is consistent with a meaningful quality program.

The examples above are only three examples of how trying to score facilities on the remaining measures will skew the results in a way that is inconsistent with CMS' goals

for the ESRD QIP. Applying the penalties based upon the skewed results will not drive quality as the Congress intended the QIP to do. Therefore, ASN asks that CMS not score facilities for PY 2023 and not apply penalties.

Not applying the penalties for PY 2023 would parallel the proposal in the Hospital Inpatient Prospective Payment System proposed rule for the hospital value-based purchasing program. In that program, CMS proposes to suppress several measures and not to score the hospitals and not to penalize them. CMS states in this proposed rule that *“Awarding negative or positive incentive payment adjustment percentages using TPSs calculated using the current scoring methodology would not provide a representative score of a hospitals’ overall performance in providing quality of care during a pandemic.”* ASN believes the same is true for dialysis facilities.

ASN also specifically supports suppressing the AV Fistula measure along with the long-term catheter rate (LTCR) measure due to significant deviation in national performance during the pandemic. However, it is unclear to ASN why CMS chose not to suppress both measures given how intertwined the fistula and catheter measures are. CMS notes that a steep increase in catheter rates during CY 2021 indicates that the COVID-19 PHE continued to impact the ability and/or desire of ESRD patients to seek permanent vascular access placement. Because the two measures are directly linked, it follows that the same PHE-related factors that are increasing catheter rates will also necessarily and materially decrease fistula rates. Thus, ASN urges CMS to suppress both VAT measures in PY 2023.

Updating the PY 2023 Performance Standards Using CY 2019 Data

While the approach outlined by CMS may seem reasonable from an ease standpoint, conceptually the use of pre-COVID data as a baseline for COVID-era data seems like an “apples to oranges” comparison and is problematic given the ongoing challenges faced by dialysis providers that may impact quality metrics (e.g., staffing shortages) and are likely to persist for some time.

CMS should consider alternative approaches such as suspending use of a baseline comparison this year and re-establish a new “post-COVID” baseline next year using the CY 2021 data. An alternative approach could incorporate simulating early COVID 19 PHE using 2019 data and then using this data as the baseline for PY 2023 (an “adjusted” CY 2019 baseline).

ASN is also concerned that these ‘deficits’ related to the COVID public health emergency have accumulated over the past few years (i.e., more catheters) and stresses that this will take time to resolve. Comparing data in 2021 to that from 2019 while discarding 2020 ignores the fact that time is continuous and that COVID remained tremendously impactful during this time as well (and is very impactful moving forward still). The usual minimal time between surgery and AV fistula utilization is 4 months, and a high proportion of patients will require more than one attempt to construct an AV fistula. These timeframes emphasize the lack of validity that would result from ignoring

the impacts of 2020 on key measures, such as vascular access type. Again, ASN encourages CMS to suspend penalties in the QIP for PY2023.

Technical changes to some rates and clinical measures for 2024, 2025, and 2026 and creating a new domain for reporting measures and reweighting of measures for 2025

ASN believes creating a new Reporting Measure Domain is reasonable. It would include the four current reporting measures (Clinical Depression Screening and Follow-up, UF rate, MedRec, NHSN Dialysis Event) plus hypercalcemia and the new measure for HCP COVID-19 vaccination coverage. These changes and the associated reweighting of the measure domains and weights also seem reasonable. It appears that the measures that contribute most significantly to the TPS (ICH CAHPS, SHR, SRR, Kt/V, STrR, BSI) are largely unchanged in terms of their weights with respect to the TPS.

As for the adoption of COVID-19 vaccination coverage among healthcare personnel reporting measure, ASN asks CMS to clarify one issue. The potentially confusing issue is that vaccination coverage is defined as the complete vaccination course. How will that be defined? What time period will HCPs be given to get boosters or new vaccines? ASN supports the measure being proposed as a reporting measure as it is currently proposed and weighted to 1.67 percent of the TPS.

CMS' proposed conversion of hypercalcemia measure from clinical to reporting aligns with the QIP given concerns that the measure is topped out. The proposed rule mentions potentially replacing this with another mineral and bone disorder (MBD) measure at some point (e.g., serum phosphorus) given that MIPPA states that the QIP should include "to the extent feasible" measures for iron management, MBD, and vascular access. ASN cautions CMS to consider feasible measures as those with a performance gap that is clinically meaningful and modifiable. Including an alternate MBD clinical measure in the future is not feasible on the basis that this measure, like serum calcium, might not reflect clinically meaningful differences across facilities (e.g., if one facility is drawing a serum phosphorus post-HD while another is drawing it pre-HD) and lacks the evidence base to show that changing the analyte value is associated with improved clinical outcomes. ASN encourages CMS to keep any MBD measures as reporting measures only and highlights that two large trials evaluating serum phosphorus will be completed in 2025, potentially allowing for a serum phosphorus clinical measure thereafter.

ETC Model Payment Adjustments

CMS is also proposing several changes in the ETC model.

- *We propose to further modify the achievement scoring methodology for the ETC Model. Specifically, we propose to add a requirement, to be codified in a new provision at § 512.370(b)(3), to specify that, beginning MY5, an ETC Participant's*

aggregation group must have a home dialysis rate or a transplant rate greater than zero to receive an achievement score for that rate.

- *Specifically, we are proposing to add a sentence to § 512.397(b)(1) stating that, for purposes of the waiver under § 512.397(b)(1) of our regulations, beginning for MY5, “clinical staff” may not be leased from or otherwise provided to the ETC Participant by an ESRD facility or related entity. Applying this prohibition on “clinical staff” could also protect beneficiaries and their care choices and limit the likelihood that the “clinical staff” furnished to the ETC Participant from an ESRD facility or related entity would result in steering a beneficiary to a specific ESRD facility or chain of ESRD facilities.*

ASN agrees with CMS's proposal that an aggregation group must have a non-zero home dialysis rate or transplant rate to receive a positive achievement score. The 30th percentile benchmark is currently 0% home dialysis for the Dual/LIS >50% strata. This is in part because all aggregation groups are given equal weighting regardless of their size. ASN believes there are flaws in the aggregation methodology i.e., not weighting by patient volume, and the aggregation methodology needs to be corrected as the root cause before applying this requirement. ASN stands ready to assist in that effort. ASN urges CMS to revisit weighting strategies to account for the number of patients in each aggregation group, while still avoiding undue penalties to smaller providers.

ASN also strongly supports broadening the availability of kidney disease education as CMS “*waived the requirement that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish kidney disease patient education services to allow kidney disease patient education services to be provided by clinical staff under the direction of and incident to the services of the Managing Clinician who is an ETC Participant.*” CMS then continues “*To further ensure that beneficiaries are not unduly influenced to choose a particular ESRD facility, we are also considering whether the final rule should include a requirement that, for purposes of the waiver under § 512.397(b)(1), the content of the kidney disease patient education furnished by clinical staff cannot market a specific ESRD facility or chain of ESRD facilities to beneficiaries.*” ASN supports the prohibition of marketing a specific ESRD facility or chain of ESRD facilities.

Conclusion

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 ASN members thank the Biden-Harris Administration for its commitment to improving the Medicare ESRD program and the ETC Model while addressing inequities and disparities in kidney care for all patients. ASN is committed to ensuring that efforts contribute to those essential goals. To discuss this letter further, please contact David White, ASN Regulatory and Quality Officer, at dwhite@asn-online.org or (202) 640-4635.

Sincerely,



Susan E. Quaggin, MD, FASN

President

ⁱ “Development and Content Validity of a Patient-Reported Experience Measure for Home Dialysis” CJASN ePress. Published on March 30, 2021 as doi: 10.2215/CJN.15570920

ⁱⁱ <https://jasn.asnjournals.org/content/jnephrol/early/2021/07/10/ASN.2021020189.full.pdf?with-ds=yes>

ⁱⁱⁱ <https://cjasn.asnjournals.org/content/16/5/809>

^{iv} <https://bmcnephrol.biomedcentral.com/articles/10.1186/s12882-019-1673-7>

^v The Coverage Gap: Uninsured Poor Adults in States that Do Not Expand Medicaid

<https://www.kff.org/medicaid/issue-brief/the-coverage-gap-uninsured-poor-adults-in-states-that-do-not-expand-medicaid/>

^{vi} <https://jasn.asnjournals.org/content/32/12/2994>

^{vii} Laster M, Soohoo M, Hall C, et al. Racial–ethnic disparities in mortality and kidney transplant outcomes among pediatric dialysis patients. *Pediatr Nephrol*. 2017;32(4):685-695. doi:10.1007/s00467-016-3530-2; Leonard MB, Donaldson LA, Ho M, Geary DF. A prospective cohort study of incident maintenance dialysis in children: An NAPRTC study. *Kidney Int*. 2003;63(2):744-755. doi:10.1046/j.1523-1755.2003.00788.x; Moxey-Mims M. Kidney Disease in African American Children: Biological and Nonbiological Disparities. *Am. J. Kidney Disease*, 2018;72(5):S17-S21. doi.org/10.1053/j.ajkd.2018.06.025.

^{viii} <https://adr.usrds.org/2021/end-stage-renal-disease/8-esrd-among-children-and-adolescents>

^{ix} Mehotra R, et al. Racial and Ethnic Disparities in Use of and Outcomes with Home Dialysis in the United States.

^x <https://adr.usrds.org/2021/end-stage-renal-disease/8-esrd-among-children-and-adolescents>

^{xi} *Ibid.*

^{xii} <https://www.abp.org/content/estimated-driving-distance-visit-pediatric-subspecialist>

^{xiii} <https://www.abp.org/sites/public/files/pdf/workforcedata2020-2021.pdf>