



August 31, 2021

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

Re: 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 [CMS-1749-P]

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, Quality Incentive Program, 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-saving 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 in lower income brackets, and the elderly; these are communities that also have been disproportionately affected by the COVID-19 pandemic, exacerbating existing disparities.

Providing direct care for patients with kidney diseases, ASN members are on the frontline to fight for better kidney health for all Americans and striving to eradicate these inequities. ASN greatly appreciated the opportunity in July 2021, to respond to the White House Office of Management and Budget's (OMB) Request for Information (RFI) regarding the *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*. ASN applauds the Biden-Harris Administration for this extremely important executive order directing OMB to identify effective methods for assessing whether agency policies and actions (e.g., programs,

services, processes, and operations) equitably serve all eligible individuals and communities, particularly those that are currently and historically underserved.

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. Further, Black, Indigenous, and Latinx Americans are less likely to initiate home dialysis when requiring dialysis for kidney failure or receive a kidney transplant. 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, are so vital for achieving health equity. ASN provides comments in this letter outlining support of these efforts as well as comments on other aspects of the ESRD PPS, QIP and ETC Model.

The following are highlights of what ASN is recommending in this comment letter:

- Ensuring the Substantial Clinical Improvement (SCI) criteria for the Transitional Payment for Innovative ESRD Equipment and Supplies (TPNIES) accounts for common sense solutions to at least three critical areas:
 - i. First, there are barriers related to the use of items during the first few years after introduction. ASN recommends extending TPNIES to three years.
 - ii. Second, there are no current policies to adjust the base bundle rate to account for new products.
 - iii. Third, and most notable, is the challenge raised by the definition and interpretation of substantial clinical improvement (SCI) criteria.

Then,

- Increasing 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
- Supporting modality longevity with a machine that helps more people dialyze at home with reduced drop out, including technologies that are:
 - i. Easier for patients and care partners to use
 - ii. More reliable than current machines
 - iii. Able to boost communication between patients and care teams; or
- Improving quality of dialysis delivered and/or reducing complications.
- Adjusting the Pediatric Cost Report so the costs of pediatric care are broken down into the following age groups: <6 years old, 6- <12 years old, and 12- <18 years old. Acknowledging that the treatment of the typical young child of small size dialysis patient requires more staff resources and specialized equipment than treating the typical older and larger pediatric dialysis patient.

- Supporting measure suppression and criteria for CY 2022 in the Quality Incentive Program (QIP).
- Implementing the stratification of quality measures in the ESRD QIP across two social risk factors: dual eligibility and race/ethnicity. ASN also encourages CMS to evaluate Zip Code level data as a source. In addition to reviewing the use of Z Codes for housing insecurities, ASN encourages CMS to examine measuring food insecurity.
- Creating a reporting metric, with conditions detailed later in this letter, for COVID vaccination for dialysis facility patients and employees if applied uniformly across all health care settings covered by Medicare.
- Adjusting the Performance Payment Adjustment (PPA) in the ETC Model except for barring the use of nocturnal dialysis numbers by large dialysis organizations (LDOs). Establishing a static benchmark within the model as well.
- Modifying the proposed Achievement Benchmark Stratification by Dual-Eligible and Low-Income Subsidy (LIS) by examining more nuanced approaches to this important approach such as establishing more than one cut point or even a sliding scale approach.
- Establishing the Status Health Equity Incentive (HEI).
- Supporting Peritoneal Dialysis (PD) Catheter Placement. When examining the most common vascular access codes (CPT 36818-26921) and the most common PD catheter insertion code equivalents (CPT 49418, 49421, and 49324), the weighted average difference in vascular access code and PD code reimbursement rates is \$360.62, in favor of vascular procedures. ASN believes that if CMS wants to increase PD uptake, the agency must increase PD catheter insertions, and one way would be through equalizing reimbursements for PD catheters and vascular access procedures in a model setting where impact could be measured. An ETC Model track focused on reimbursement incentives (of at least an additional \$360.62 per PD catheter procedure) could help.

ESRD Prospective Payment System

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.

ASN has made its own \$25,000,000 commitment to the Kidney Innovation Accelerator (KidneyX) – a public-private partnership between the US Department of Health and Human Services (HHS) and ASN to accelerate innovation in the prevention, diagnosis,

and treatment of kidney diseases. Since its launch in 2018, KidneyX has run five 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 the US Centers for Medicare & Medicaid Services (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 and that very few parties will consider investment in improving care of people with kidney failure if requirements continue to result in no devices receiving TPNIES payment status. 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 100% thereafter) 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 die. 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. 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 that helps more people dialyze at home with reduced drop out, including technologies that are:
 - o Easier for patients and care partners to use
 - o More reliable than current machines
 - o Able to boost communication between patients and care teams; or
- Improves quality of dialysis delivered and/or reduces complications.
- Modifying site of service provided to Medicare beneficiaries with Acute Kidney Injury (AKI) allowing the patient and clinician to designate home care when appropriate.

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 innovating 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.

Pediatric Dialysis Payment Adjustment

CMS solicited feedback on the pediatric dialysis payment asking the following questions:

- Does the magnitude of total costs and pediatric multipliers reflect ESRD facilities' actual incurred costs? If not, what specific costs are not being reported on claims and/or cost reports?
- Is there sufficient variation in composite rate costs among pediatric patients to justify use of a proxy to distribute facility-level composite rate costs to individual treatments?
- If duration of treatment is not a valid proxy for composite rate costs per treatment, what are alternative proxies to consider?
- What, if any, are the specific concerns about incorporating pediatric patients into the estimation of multipliers for both the adult and pediatric populations?
- What are the issues facing pediatric billing and accounting staff with regard to completion of claims and cost reports? How can these problems be remedied?
- Are there additional costs factors for pediatric patients that are not adequately captured on the 72X claim?

ASN wishes to align its comments with those of the American Society of Pediatric Nephrology (ASPN). The recommendations in response to the above questions in this section reflect the opinions of both societies.

ASN agrees that, historically, there has been recognition that dialysis payments calculated almost entirely based on costs incurred to provide dialysis to adults is insufficient to cover the costs of pediatric dialysis. CMS allowed pediatric dialysis facilities to apply for exceptions to obtain higher rates based on actual facility costs for more than two decades, and then applied a 1.62 multiplier for payments to all patients younger than 18 years under the period of basic case-mix adjustment methodology from 2005-2011. With the subsequent institution of the bundled prospective payment system, pediatric adjusters were significantly reduced despite the costs of pediatric dialysis remaining significantly higher than those incurred with adult dialysis.

While adult and pediatric centers employ many of the same categories of providers – nurses, social workers, dietitians, nurse managers, nurse practitioners, and nephrologists – those who treat children must have specialized training in pediatric care, reducing the potential pool of individuals qualified to provide care and increasing the

costs for personnel in pediatric dialysis units, an expense not captured by CMS. Moreover, the staffing models used in pediatric dialysis facilities need to reflect the increased individual effort often needed for the safe provision of dialysis or the increased time needed to educate and counsel the responsible adult caring for the child at home, resulting in staff to patient ratios that are often much larger than with adults. Child life specialists and teachers also play integral roles in the care delivered to pediatric dialysis patients, and the cost of retaining these resources is not captured by claims or cost reports.

Similar increased expenses in a pediatric dialysis unit setting applies to dialysis supplies included in the bundled payment. Although most supplies needed in pediatric ESRD care are also used in adult dialysis, pediatric facilities need to be stocked to care for patients who range in size from infants weighing a few kilograms to fully grown adolescents of large adult size. Accordingly, there often need to be accommodations in the stocking of more individualized equipment and supplies and less reliance on standard supplies applicable to almost any patient. This pediatric difference pertains to basic dialysis supplies such as lines and dialyzers as well as to equipment.

CMS asks if sufficient variation exist in composite rate costs among pediatric patients to justify use of a proxy to distribute facility-level composite rate costs to individual treatments? And follows with, if duration of treatment is not a valid proxy for composite rate costs per treatment, what are alternative proxies to consider?

Duration of treatment is not a valid proxy for composite rate costs per treatment for pediatric care. Instead, ASN and ASPN recommend that a combination of age, weight, and pediatric-specific comorbidities be used as a proxy for composite rate costs. The Societies have compiled the following list of pediatric comorbidities for CMS:

- Failure to thrive/feeding disorders – 80% of children under 2 years of age require a G-tube and feeding pump or supplemental nutrition and the adequacy of nutrition profoundly affects somatic growth and cognitive development.
- Congenital anomalies requiring subspecialty intervention (cardiac, orthopedic, colorectal).
- Congenital bladder/urinary tract anomalies.
- Solid organ or stem cell transplant.
- Neurocognitive impairment.
- Global developmental delay.
- Cerebral palsy.

- Seizure disorder.
- Chronic lung disease (and ensuing dependency on CPAP and ventilators).
- Inability to ambulate or transfer.

Although all these comorbidities significantly impact the provision of pediatric dialysis care, neurocognitive impairment and global developmental delay are often more longitudinally complex since they continue to pose significant management challenges even as the child ages and there are not treatments or procedures that can readily ameliorate the underlying condition. Adolescents or young adults with profound neurocognitive impairment or global developmental delay continue to be complex despite their age and size and often require long-term approaches requiring much more intense utilization of staff resources.

ASN calls on CMS to closely examine ASPN's repeated suggestion that the costs of pediatric care be broken down into the following age groups: <6 years old, 6- <12 years old, and 12- <18 years old. Treating the typical young child of small size dialysis patient requires more staff resources and specialized equipment than treating the typical older and larger pediatric dialysis patient. ASPN has made specific recommendations, which ASN fully supports, found in the appendix of this letter regarding CMS's RFI on refining the Pediatric Cost Report.

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

According to the proposed rule: 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.

ASN has shared its concerns with CMS 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.

Medicare payment for home dialysis for AKI patients when the nephrologists determines that an AKI patient can safely dialyze at home should be allowed. 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 needs to 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 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.

ESRD Quality Incentive Program

Measure Suppression Criteria and Measures

CMS proposes adopting a policy that will last for the duration of the COVID-19 public health emergency (PHE) that will enable CMS to suppress the use of ESRD QIP measure data for all facilities if CMS determines that circumstances caused by the COVID-19 PHE have affected those measures and the resulting total performance scores (TPS) significantly. CMS outlines the following factors for measure suppression:

- Factor 1: Significant deviation in national performance on the measure during the COVID-19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
- Factor 2: Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the COVID-19 PHE.
- Factor 3: Rapid or unprecedented changes in: Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or the generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.
- Factor 4: Significant national shortages or rapid or unprecedented changes in: Healthcare personnel; medical supplies, equipment, or diagnostic tools or materials; or patient case volumes or facility-level case mix.

Because of these four factors, CMS proposes to suppress the following measures for CY 2022:

- Standardized Hospitalization Rate (SHR).
- Standardized Readmission Ratio (SRR).
- In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS).
- Long-Term Catheter Rate.

COVID-19 greatly affected people on dialysis as CMS has acknowledged in this proposed rule and in previous rules and statements. The hospitalization rate for individuals on dialysis who were diagnosed with COVID was seven times the rate of those on dialysis not diagnosed with COVID during the same period of time. The data reported in these measures should not be used to negatively adjust or rate facilities during the PHE; therefore, ASN strongly supports this move.

RFI on Measures Stratification of Quality Measures

CMS requests comment on the potential stratification of quality measures in the ESRD QIP across two social risk factors: dual eligibility and race/ethnicity. CMS cites the disproportionately high prevalence of kidney failure among minorities. For example, in 2016 ESRD prevalence was approximately 9.5 times greater in Native Hawaiians and other Pacific Islanders, 3.7 times greater in Black Americans, 1.5 times greater in Indigenous Americans and Alaska Natives, and 1.3 times greater in Asians than with non-Hispanic whites. As a result, CMS requests feedback on:

- Stratification of Quality Measure Results—Dual Eligibility.
- Stratification of Quality Measure Results—Race and Ethnicity.
- Improving Demographic Data Collection.
- Potential Creation of an ESRD Facility Equity Score to Synthesize Results Across Multiple Social Risk Factors

CMS states specifically that it wishes to develop the facility equity score based on the equity summary score for Medicare Advantage contract/plans, the Health Equity Summary Score (HESS). CMS writes:

We envision that the ESRD Facility Equity Score would synthesize results for a range of measures and using multiple social risk factors, using measures and social risk factors which would be reported to facilities as part of the CMS Disparity Methods.ⁱ

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 *** 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 encourages CMS to proceed with this proposal as the society agrees that collecting data on quality measure performance based on socioeconomic factors can better illustrate health inequities and ideally offer opportunities to alleviate disparities. ASN also believes strongly that two conditions must be met:

- Ensuring the highest degree of transparency possible in the selection, identification, and definition of “social risk factors” as well as the “range of measures”; and
- Ensuring continued kidney community input to inform the process of data collection, measure development and application to mitigate potential unintended consequences.

COVID–19 Vaccination Measures

CMS is seeking comments on:

- Adding a new measure to the ESRD QIP measure set in the next rulemaking cycle: “COVID-19 Vaccination Coverage Among Health Care Providers (HCP).” This measure would assess the proportion of a facility’s health care workforce that has been vaccinated against COVID-19.
- Adding a new measure to the ESRD QIP measure set in future rulemaking: “COVID-19 Vaccination Coverage Among Patients.” The measure would assess the proportion of a facility’s patient population that has been vaccinated against COVID-19.

- Potentially adding the COVID-19 vaccination measure for HCPs and the COVID-19 vaccination measure for patients, to the ESRD QIP measure set. It also seeks public comment on data collection, submission, and reporting for the COVID-19 vaccination measure for HCP and the COVID-19 vaccination measure for patients.

ASN believes that there is no more important intervention in 2021 for patient safety than high vaccination rates among staff and patients. That stated, ASN favors a COVID-19 vaccine **reporting** measure (made publicly available) for dialysis patients and staff for the following reasons:

- Provides useful information for patients and families to consider when choosing a dialysis facility.
- Avoids marginalizing already vulnerable dialysis patients who question the safety of vaccines.

ASN is not in favor of a COVID-19 vaccine **performance** measure for dialysis facilities. To move in that direction, CMS would need to provide more precise feedback on the details of the measure, including precise definitions (numerators and denominators), inclusion, and exclusion criteria. This precision is exceptionally challenging in rulemaking given the rapid changes in knowledge. For example, would “adequate vaccination” require a booster or third dose? Are all vaccines sufficient? What is the duration of vaccination for the numerator? How is the denominator defined? Additionally, as a payment metric, policies differ regionally, potentially resulting in highly variable vaccination rates across states. For patients, ASN has reservations that, although the reporting metric would likely marginally increase and sustain vaccination rates, tying the measure to facility reimbursement may have unintended consequences, such as:

- Pressuring patients could undermine their sense of autonomy.
- Creating barriers to patients who could be dismissed from, or not admitted to, a dialysis facility due to a negative vaccine status.

The broader community of dialysis providers has raised concerns that requiring staff vaccination will have major impacts on the dialysis workforce, particularly in regions with low rates of HCP vaccination. As a member of the Council of Medical Specialty Societies, ASN has asserted publicly that all HCPs should be vaccinated in order to optimize safe care for vulnerable patients, both by reducing the risk of patient exposure to transmissible SARS-CoV-2 and by ensuring fewer gaps in staffing due to illness among HCPs.

However, unless a vaccination metric is implemented broadly among healthcare providers across all settings, ASN is concerned that staffing shortages will exacerbate care limitations, potentially causing greater risk to patients than incomplete rates of

vaccination among HCPs. Accordingly, ASN favors a reporting measure rather than payment measure at this time, until broader payment measures are present across the entire healthcare system for HCP vaccination.

CMS also seeks public comment on data collection, submission, and reporting for the COVID-19 vaccination measure for HCP and the COVID-19 vaccination measure for patients. ASN would like dialysis patients and the public to have access to facility-specific COVID-19 vaccine information (x% of patients and x% of staff of this unit have been vaccinated). The time period over which vaccination continues to count in the numerator needs to be established.

ESRD Treatment Choices (ETC) Model

ASN applauds the decision of CMS and its Innovation Center (CMMI) to incorporate ongoing rulemaking on the ETC model. This step increases transparency and community engagement. ASN has long advocated for kidney care models that: 1) promote coordinated kidney care across silos; 2) promote upstream identification of kidney disease to slow kidney disease progression; 3) support increased rates of home dialysis and kidney transplant; 4) encourage innovation in kidney care; and 5) provide more patient-centered choice and better clinical outcomes. ASN believes the ETC Model and the KCC Model represent significant progress to advance patient-centered care and overall supports the elements incorporated into this proposed rule.

Performance Payment Adjustment (PPA)

The proposed changes to the Performance Payment Adjustment (PPA) Beneficiary Attribution for Living Kidney Donor Transplants makes sense to ASN and the society supports this change. Regarding the PPA Home Dialysis Rate/ Nocturnal Dialysis, ASN strongly supports the calculation of nocturnal dialysis as half of the home dialysis rate similar to the self-dialysis calculation (already present in the ETC) given the potential ability of nocturnal in-center hemodialysis to allow for greater modality choice among patients with housing or care partner limitations – partially addressing some health equity concerns. ASN does not understand; however, the rationale for the following language: “for ETC Participants that are either ESRD facilities not owned in whole or in part by an LDO or Managing Clinicians, to include nocturnal in-center dialysis in the numerator beginning for MY3.”

This LDO exclusion may have unfortunate impacts on both patients and Managing Clinicians. Managing Clinicians often care for their panel of patients with multiple different dialysis organizations, with some patients in LDO facilities and some in non-LDO facilities. The Managing Clinician should not be incentivized to move a patient receiving nocturnal dialysis at an LDO to a nocturnal dialysis program at a non-LDO. More importantly, this exclusion is not patient-centered, as the ability to choose a modality and location rather than the organization providing the modality should be paramount in patient-centered care. Accordingly, ASN does not support the LDO exclusion.

The priority should be clearing the backlog in certifying home programs. It is imperative that patient choice for accessing home dialysis be available from all providers – large or small -- particularly if CMS' intent is to incentivize a home dialysis center of excellence model rather than a home dialysis availability in each individual facility model. If the incentives in the model effectively encourage the mid-sized providers to launch home programs, it is absolutely essential that CMS help these facilities be successful in offering home dialysis.

For the PPA Achievement Benchmarking, CMS proposes to modify the percentile-based achievement benchmarking methodology based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year as the basis for achievement benchmarks in measurement year 3 (MY3) through MY10. This modification appears to ASN to be a very generous expectation of the rise of home dialysis rates and kidney transplantation across hospital referral regions (HRRs), based on the assumption that transplant and home dialysis rates will remain relatively static in the comparison geographic areas.

Most dialysis patients receive care from providers that operate in HRRs that not only comprise those randomized to the ETC but also those comprising comparison geographic areas. Therefore, initiatives to increase home dialysis and transplantation likely will not be limited to the HRRs that are participating in the model but will extend to all HRRs. Given the moving comparison benchmark and the annually increasing percent improvement versus the benchmark (from 10% to 40% over the model), this modification could result in a level of increase, particularly for home dialysis, that will incentivize non-patient centered care and loss of individualized choice while potentially accentuating health disparities.

In favoring a static benchmark, ASN also believes that this approach will allow more valid statistical assessment of the model. With a static benchmark CMS will be able to compare the change in home dialysis and transplant rates in participating HRRs directly to change in rates in comparison geographic areas, thereby testing if the model design can achieve its stated goals.

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

CMS proposes to stratify achievement benchmarks in the ETC Model based on the proportion of ETC Participant's patient group that are dually eligible for Medicare and Medicaid or Low-Income Subsidy (LIS) status, based on rates in Comparison Geographic Areas. CMS would create two strata with the cut point set at 50 percent of attributed beneficiary years being for those patients who were dual-eligible or received the LIS. As such, there would be one stratum for ETC Participants whose aggregation groups had 50 percent or more of their attributed beneficiary years during the MY for beneficiaries who were dual- eligible or received the LIS. There would be a second stratum for ETC Participants whose aggregation groups had less than 50 percent of

their attributed beneficiary years during the MY for patients who were dual-eligible or received the LIS. These determinations will be made using Medicare administrative data.

As stated above, ASN supports this effort and encourages CMS to execute this move with a maximum amount of transparency. However, ASN has concerns about using a single cut point and believes that a single cut point becomes arbitrary. ASN finds it difficult to imagine groups at 48 percent being significantly different from ones at 52 percent. ASN encourages CMS to reconsider this approach and examine either multiple cut points, a sliding scale that provides more nuance, or an adjustment approach rather than a stratification approach that preserves the continuous nature of the data. Reducing a continuous variable to a dichotomous term sacrifices a lot of information and data meaning. For ease of reporting, CMS could consider two cut points creating three distinct groups possibly at approximately 40 percent and approximately 60, although the adjustment approach would be stronger statistically.

Health Equity Incentive (HEI)

To incentivize ETC Participants to decrease disparities in the home dialysis rate and transplant rate between beneficiaries who are dual-eligible or LIS recipients and those who are not, CMS proposes to add a HEI to the improvement scoring methodology. CMS proposes to add the HEI to the ETC Participant's improvement score if the ETC Participant's patient group demonstrated sufficient improvement on the home dialysis rate or transplant rate for those individuals who are dual-eligible or LIS recipients. CMS also proposes to set the threshold for earning the HEI Incentive at five-percentage points improvement from the Benchmark Year.

ASN strongly supports the creation of an HEI, which is the innovation center's first direct effort to incentivize improving health equity. As outlined in Reddy et al. "*Ensuring the Equitable Advancement of American Kidney Health—the Need to Account for Socioeconomic Disparities in the ESRD Treatment Choices Model*," ASN members have viewed the ETC as an opportunity to address health disparities for kidney care in a meaningful way through incentivization and upfront financial investment. ASN thinks the HEI should be considered for other value-based care models. However, modifications are needed, specifically as dual eligibility will not capture disparities separate from income (i.e., race, ethnicity, housing insecurity, food insecurity, etc.). ASN strongly encourages CMS to expand the HEI to include other social drivers of disparities, and we hope that we can partner with CMS in developing these mechanisms.

Data Sharing

ASN supports the CMS proposal to provide identifiable patient data pertaining to a PPA Period for the ETC Participant no later than one month prior to the start of the given PPA Period.

Requests for Information (RFIs) on Topics Relevant to the ETC Model

Peritoneal Dialysis (PD) Catheter Placement

CMS seeks feedback about how CMMI can test and use Medicare payment policy, under the ETC model, to promote placement of PD catheters. Specifically, CMS seeks feedback on the following questions:

- What are the key barriers to increased placement of PD catheters?
- How can CMS promote placement of PD catheters in a timelier manner?
- Should the Innovation Center use its authority to test alternative payment structures to address the barriers to PD catheter placement as a part of the ETC Model? If so, why and how?

ASN, in support of the ETC Model, agrees that better incentivizing PD catheter placement is imperative for the success of the ETC. Because PD remains the dominant home modality in the US, ASN believes that to truly move the needle on home dialysis access and uptake, removing existing barriers to PD catheter placement must be prioritized by CMS and CMMI. However, barriers remain in ensuring that PD catheters are placed in a timely manner for all patients who seek one. ASN discusses this issue below along with a potential solution encompassing a new “track” within the ETC Model. In these comments, ASN is aligning with the Alliance for Home Dialysis’ (AHD) remarks as a member of the AHD Steering Committee.

As CMS is aware, there are several key barriers that impact PD catheter placement:

- Lack of dedicated hospital-based catheter insertion teams for unplanned peritoneal dialysis starts; instead, these patients often receive a central venous catheter and to initiate hemodialysis followed by discharge to in-center hemodialysis, even if home dialysis would be a better option;
- Inadequate training of surgeons and interventional radiologists on PD catheter insertion methodology and follow up care for catheter malfunction; and
- Obstacles related to scheduling of operating room time.

Critically, one of the most striking barriers, and the one that CMS/CMMI has the most ability to correct for in the immediate term, is the low reimbursement for PD catheter placement. This difference in reimbursement is especially stark when compared to reimbursement for vascular access. When examining the most common vascular access codes (CPT 36818-26921) and the most common PD catheter insertion code equivalents (CPT 49418, 49421, and 49324), the weighted average difference in vascular access code and PD code reimbursement rates is \$360.62, in favor of vascular procedures. This difference in reimbursement helps explain a motivation to perform more vascular procedures as opposed to PD catheter insertions and raises the question

of whether, if the reimbursement were equalized, more PD catheter insertions would be performed.

As stated above, ASN believes that if CMS wants to increase PD uptake, the agency must increase PD catheter insertions, and one way would be through equalizing reimbursements for PD catheters and vascular access procedures in a model setting where impact could be measured. An ETC Model track focused on reimbursement incentives (of at least an additional \$360.62 per PD catheter procedure) could help address a reason for low numbers of PD catheter insertions and contribute to an overall increase in PD starts.

- Incentivizing Clinicians

ASN recommends financially incentivizing surgeons, and other access specialists, to partner with the ETC Model's nephrologists or managing clinicians, as CMS identifies them. The obvious step is to provide a payment increase per PD placement to equalize the reimbursement between PD catheter insertion and vascular placement within the model. This demonstration would compare rates of PD catheters placed within and outside the model, to evaluate whether the payment increase within the model increased the rate of PD catheter placement.

The ETC Model does not currently provide direct incentive for these specialists to participate with the nephrologists. Consequently, the ETC model, as currently structured, does not specifically address the providers involved in the placement of PD catheters and their role in encouraging the uptake of home dialysis. This factor limits the success of increasing home dialysis utilization, which is contingent on timely and high-quality PD catheter placement. ASN urges CMS to consider establishing an incentive payment of at least \$360.62 for surgeons and other access specialist in the ETC model to achieve this goal.

- Utilizing the Authority to Add This to the ETC Model via the Final Rule

The ETC Model has already undergone extensive notice and comment rulemaking and this RFI provided the additional opportunity for stakeholder feedback specific to PD catheters. Establishing this incentive as soon as possible makes the most sense for both beneficiaries and providers to complement the current efforts established by CMS. Furthermore, we propose that participation in this portion of the model would not be mandatory, rather it would be a voluntary track where participants could opt-in to further test broader and more comprehensive incentive payments. CMS has developed similar tracks within models in other cases, which allow variations in incentives tested but that share the same overall goal or has expanded the scope of existing models.

Beneficiary Experience Measure

CMS poses a series of questions surrounding the creation of a home CAHPS. ASN believes that it is extremely important for CMS to develop a survey device that captures

experience or quality of life data for home dialysis patients for use in the ETC Model and the overall expansion of home dialysis outside the model. The device should, at the least, measure:

- Ease of use of their modality/device.
- Patient/provider burden in self administration or helping support a loved one.
- Sense of support from the care team.
- Sense of respect and value from the care team.
- Communication with the care team.

ASN highlights that the response rate on the current ICH CAHPS is quite low, potentially reflecting the presence of 62 questions over nine pages with multiple skip questions. With prior data showing that non-responders to ICH CAHPS disproportionately are non-white, dual-eligible, less educated and non-English speaking, ASN highlights the critical need to develop and implement a patient experience tool that does not further health inequities.ⁱⁱⁱ ASN encourages CMS to use its contractors to develop a concise and valid home dialysis experience assessment with robust input from patients and providers.

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 such as the creation of an HEI and the stratification of quality metrics 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 <https://www.govinfo.gov/content/pkg/FR-2021-07-09/pdf/2021-14250.pdf>

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

ⁱⁱⁱ Dad T, Tighiouart H, Fenton JJ, Lacson E Jr, Meyer KB, Miskulin DC, Weiner DE, Richardson MM. Evaluation of non-response to the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH

CAHPS) survey. BMC Health Serv Res. 2018 Oct 19;18(1):790. doi: 10.1186/s12913-018-3618-4. PMID: 30340585; PMCID: PMC6194668.

Appendix: Request for Information on the Pediatric Cost Report

CMS has requested comments on these potential changes to cost reports as well as the following questions:

- What degree of specificity is needed in the reporting of pediatric dialysis costs?

ASPEN has suggested the following changes be made to the cost reports to better capture pediatric-specific costs.

Suggested Revisions to CMS Cost Report

Link [here](#) to FORM CMS-265-11

- Include Breakdown of Patient Age Groups (page 2, line 3):

3	Number of patients currently in dialysis program
a)	0-less than 6 years old
b)	6-11 years old
c)	12-18 years old
d)	19-25 years old (includes transition to adult care)
e)	26 years or older, if neuro-cognitive challenges/other medical challenges that require specialized care at pediatric center

- Pediatric-specific Supplies (page 4, line 9):

9	0900	Supplies*
10		Pediatric-specific supplies

- Pediatric-specific supplies includes pediatric dialyzer and special lines (pediatric, neonatal), Crit-Line for fluid removal monitoring, etc.
- Pediatric unit with percentage of patients over 15% would fill out pediatric line. (NOTE: This is to capture pediatric patients in adult units.)

- Facility Employees (page 2, lines 22-31): Add a sub-line for pediatric staff under the adult staff line

23	Registered Nurses
24	Registered Nurses with pediatric experience
25	Licensed Practical Nurses
26	Nurses' Aides
27	Technicians
28	Social Workers
29	Dieticians
30	Pediatric dietitians
31	Administrative
32	Management
33	Other (Specify)
34	Designated as a pediatric unit (>50% patients <18 yo)

- Are there dialysis supply costs associated with the treatment of pediatric patients that cannot be reported currently on the cost reports? If so, please specify?

Yes, there are supply costs associated with pediatric care not currently captured by the cost reports. While most supplies utilized in pediatric ESRD care are used in adult dialysis and are represented on cost reports and included in the bundle, there are specific supply costs for pediatric care not captured. For instance, pediatric units are required to have supplies of various sizes to treat children including the following: a wider array of dialysis lines and dialyzers, emergency supplies for patients ranging from infants to young adults, cardiorespiratory monitors appropriate for patients of all sizes, blood pressure devices and cuffs, and scales and other measurement tools.
