



September 21, 2021

The Honorable Chiquita Brooks-LaSure
Hubert H. Humphrey Building
Room 314G-01
200 Independence Avenue SW
Washington, DC 20201

Re: Administrator's Listening Sessions

Dear Administrator Brooks-LaSure,

The National Kidney Foundation (NKF) appreciated the opportunity to share our perspective on challenges in and opportunities to improve kidney care during the July 23rd Listening Session. NKF's Senior Vice President of Government Relations, Sharon Pearce, spoke briefly during the Listening Session. This letter follows up and expands upon her remarks.

CMS has the authority to do much to improve kidney care in the U.S. Many of the recommendations herein require no new spending and could be implemented through regulatory means. Our policy recommendations also run parallel to NKF's [call](#) to the Biden-Harris Administration to prioritize kidney patients in its first 100 days. NKF's requests to the Administration include:

1. Prioritize kidney patients in the Administration's COVID-19 response
2. Invest in kidney health
3. Implement plans to create an HHS-level Office of Organ Transplantation
4. Expand and build upon the [Advancing American Kidney Health \(AAKH\) initiative](#) and its goals to (1) reduce the incidence of kidney failure, or end-stage renal disease (ESRD), (2) increase the number of ESRD patients being treated with a kidney transplant or home dialysis, and (3) Increase the number of kidneys available for transplant (see note).¹

Kidney disease is a public health emergency. Chronic kidney disease (CKD) affects 15 percent of adults living in the United States. The vast majority are unaware. Left unmanaged, CKD can progress to end-stage renal disease (ESRD), also known as end-stage kidney disease (ESKD), at which an individual is reliant on a kidney transplant or dialysis to survive. *kidney disease is a disease of poverty and one of the preeminent examples of the impact of structural inequalities on health care.* The policy recommendations outlined in this letter would have a dramatic impact on the health and quality of

¹ End-Stage Kidney Disease (ESKD) is the preferred terminology, however in this letter we will use the term End-Stage Renal Disease (ESRD) to align with CMS' usage of ESRD in the context of the ESRD benefit.



life of Black/African American, Hispanic, American Indian or Alaska Native and Asian individuals, all of whom bear a disproportionate risk for kidney disease.

The Centers for Medicare and Medicaid Services (CMS) Role in Kidney Care

In 1972, Congress amended the Social Security Act (SSA) to provide Medicare coverage for all people with irreversible kidney failure who also meet Medicare's work requirements. Since then, the ESRD Benefit has paid the largest share of costs for kidney failure. At the time the benefit was authorized, Congress anticipated it would only serve a small population of patients. In reality, by the end of 2018, there were 554,038 patients undergoing dialysis and 229,887 patients with a functioning kidney transplant at a cost to CMS of 42.9 billion dollars, or 7.2 percent of all fee-for-service (FFS) expenditures in 2018 alone. When combined with Medicare expenditures on CKD, approximately 1 in 4 FFS dollars are spent on kidney disease.

ESRD is a uniquely expensive condition. People with kidney failure are very sick. 80 percent of people on hemodialysis have some form of cardiovascular disease.¹ Diabetes, dyslipidemia, anemia, malnutrition, depression, and mineral and bone disease are pervasive. At 11.9 billion dollars in FFS expenditures, CMS spends almost as much on inpatient care as for the dialysis itself (\$12.9 billion).² Due to the low awareness and poor management of CKD, approximately 30 percent of incident ESRD patients receive little to no nephrology care prior to dialysis meaning they learn their kidneys have failed in the Emergency Room (ER). These "unplanned starts" are associated with higher costs and greater morbidity and mortality. As a result, Medicare spends approximately \$90,000 per-patient-per-year (PPPY) on hemodialysis. This is, however, not the full story.

The vast majority of individuals with kidney failure, nearly 90 percent, do dialysis in a center, where they must travel three times a week for four hours at a time. Astonishingly, despite its prevalence, in-center dialysis is not the optimal treatment for kidney failure. A kidney transplant, preferably one an individual receives before ever beginning dialysis, is the closest thing to a cure for irreversible kidney failure. **Kidney transplants are cost saving and life prolonging when compared to dialysis and clearly the best use of Medicare dollars, yet, under 30 percent of prevalent ESRD patients have received one.**³ Even if a kidney transplant is unrealistic, people can do dialysis in their homes, allowing them to live and work on their own terms and providing substantial improvements in quality of life as well as the potential for improved dialysis outcomes and cost savings.

CMS' liability for kidney failure need not be an inevitability. ESRD can be prevented if detected earlier. In 2018, 13.5 percent of Medicare beneficiaries aged 66 and older had CKD. CKD costs to Medicare

² <https://adr.usrds.org/2020/end-stage-renal-disease/9-healthcare-expenditures-for-persons-with-esrd>

Note: Dialysis expenditures include other outpatient services.

³ <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>

increase at every stage and dramatically so with comorbid conditions like diabetes and heart failure.⁴ Medicare is responsible for patients throughout their kidney care trajectories as well as many younger patients who become Medicare eligible at the point of kidney failure. Simple interventions deployed earlier on in the progression of CKD and improvements in access to kidney transplantation and home dialysis will improve public health, patient's lives, health equity, and health expenditures.

Recommendations for CMS

I. Improve CKD Detection by Rapidly Adopting the Quality Measure Kidney Health Evaluation

Despite its pervasiveness and the severity of its consequences, CKD awareness is exceptionally low. Up to 90 percent of people affected don't know they have CKD. Even when CKD is severe, up to 40 percent of people affected remain unaware.⁵ Diabetes is the leading cause of CKD, responsible for over 40 percent of new cases. Even diabetic patients are often not screened for CKD despite recommendations to do from the National Kidney Foundation (NKF) Kidney Disease Outcome Quality Initiative (KDOQI), Kidney Disease Improving Global Outcomes (KDIGO), the American Diabetes Association (ADA) and the American Association of Family Physicians (AAFP), among other groups. Two tests are required to screen for CKD. Estimated glomerular filtration rate (eGFR) measures kidney function. Urine albumin-to-creatinine ratio (uACR) measures kidney damage. Both are needed to detect and risk stratify CKD.

In collaboration with an expert Technical Expert Panel (TEP), NKF developed a physician- and plan-level measure of annual eGFR and uACR testing for adults with diabetes. We thank CCSQ for adopting the measure onto the CY2021 Measures Under Consideration (MUC) list and look forward to working with CMS and NQF to shepherd the measure through the pre-rulemaking process. Pending the results of that process, we request that CMS:

- Adopt the measure into the Merit-Based Incentive Payment System (MIPS) beginning in CY2023.
- Ensure the measure is implemented in other relevant CMS programs as soon as possible, including the Medicare Shared Savings Program (MSSP), the Next Generation ACO Model, the Comprehensive Primary Care Plus Model and the Primary Care First Model.
- Expediently adopt the National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS)-endorsed plan-level measure, Kidney Health Evaluation, into the Medicare Advantage (MA) Star Ratings. This is especially important because the Star Ratings inform the quality program for Federally Qualified Health Centers (FQHCs). FQHCs have no measures associated with the detection and management of CKD. It is of the utmost importance for improving health equity to ensure that the people, typically already underserved, who use FQHCs have CKD detected as soon as possible.

⁴ <https://adr.usrds.org/2020/chronic-kidney-disease/2-identification-and-care-of-patients-with-ckd>

⁵ <https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html>



II. Improve Kidney Disease Education

Education has a unique role in improving the quality of care that kidney patients receive. Even people with high levels of health literacy are unfamiliar with the kidney, the myriad roles it has in maintaining health, and the consequences associated with the loss of kidney function. From the patient perspective, managing kidney disease is complex, involving lifestyle, nutritional, and pharmacologic interventions deployed by a range of providers. As individuals approach kidney failure, they need education on the modalities available to them. This education should align with shared decision-making regarding the modality that best aligns with the patient's preferences and values for how to live his or her life. Rather than simply a choice between dialysis and transplant, patients' choices include two types of transplants and numerous ways to facilitate each, three types of dialysis, each with its own specifications, schedules, and sets of pros and cons, and conservative management.

Section 152(b) of the Medicare Improvement for Patients and Providers Act (MIPPA) established Kidney Disease Education (KDE) as a Medicare covered benefit. Part B reimburses for up to six hours of KDE provided to CKD Stage 4 patients less the 20 percent coinsurance covered by the patient. The education can cover a range of topics and be provided by a physician, physician assistants, nurse practitioner, or clinical nurse specialist. KDE is underutilized with a few thousand patients, approximately 2 percent of eligible beneficiaries, receiving it annually. Several barriers prevent the KDE benefit from being more highly utilized and meaningful:

1. Architecture of the KDE Benefit

Reasons why KDE is infrequently utilized are hypothesized to include the 20 percent coinsurance, the limitation to just CKD stage 4 patients, the relatively narrow categories of providers who can bill for it, and the requirement that an outcome assessment be performed. The Center for Medicare and Medicaid Innovation (CMMI) included KDE waivers in its kidney models, the ESRD Treatment Choices (ETC) Model and Kidney Care Choices (KCC) Model, to provide more flexibility around to whom the benefit can be provided (i.e., other stages of CKD beyond CKD Stage 4), by whom the benefit can be provided (i.e., providers other than those specified by MIPPA and codified at 42 CFR § 410.48) and most recently, to waive the coinsurance on it. **The co-pay waiver should be adopted as permanent Part B policy as soon as possible.** NKF is pleased to support legislation that would expand the KDE benefit per the CMMI waivers described above.

By nature of being available to CKD 4 patients only, KDE is a de-facto ESKD modality education benefit for individuals with CKD approaching kidney failure. **In conjunction with a legislative fix to expand KDE to people with other stages of CKD, we recommend that CMS work with NKF and the Coalition for Kidney Health (C4KH) to design an early-stage CKD education benefit focused specifically on delaying CKD progression.** Such a benefit could be modeled on Diabetes Self-Management Training, leveraging community

resources rather than relying on primary care physicians to detect, manage and educate patients on early kidney disease.

2. Quality of Kidney Disease Education

A recent study by Koch-Weser et al. found dramatic gaps in the quality, accessibility, and accuracy of kidney disease education.⁶ Notably, nephrologists, primary care physicians, nurses and other providers educate patients on CKD outside of the specific KDE benefit. Across settings, the CKD education that is being provided to patients is not meeting their needs. Expanding KDE through CMMI waivers and statute, are laudable goals that are unlikely to improve the quality of education provided. NKF recommends that CMS adopt an accreditation model for materials used to educate people about kidney disease. An independent third-party would provide oversight over educational materials, ensuring they meet standards for accuracy, health literacy and numeracy, and are appropriately targeted to the patient population. The accrediting body could certify educational materials used by primary care physicians, community health organizations, FQHCs, nephrologists, dialysis facilities and transplant centers to educate patients across the spectrum of kidney disease, from people at risk for CKD to those seeking kidney transplants.

III. Improve Access to Preemptive Kidney Transplant

For most people, a kidney transplant is the optimal treatment for kidney failure. Yet, the prevalence of kidney transplants is not commensurate with their value to individuals and the health system. Approximately 30 percent of the U.S. ESRD population is living with a functioning kidney transplant. The remaining 70 percent is dependent on dialysis to survive.⁷ A preemptive transplant, one a patient receives from a living donor before dialysis is ever initiated, provides the best outcomes and the lowest costs to CMS and other payers. Yet, of the 131,636 incident ESRD patients in 2018, fewer than 4000 individuals, less than three percent, received a preemptive transplant.

Medicare coverage is associated with a lower likelihood of preemptive transplant.⁸ This finding is attributable not to age but rather to Medicare policy. Preemptive transplant is nearly impossible without pre-ESKD nephrology care. Thirty percent of incident ESKD patients with Medicare as the primary payer had between zero and six months of nephrology care prior to kidney failure. Another 20 percent had between six months and year of pre-kidney failure nephrology care.⁹ In addition, Medicare coverage for an ESRD beneficiary seeking a transplant begins the month the patient is

⁶ [https://www.ajkd.org/article/S0272-6386\(21\)00561-8/fulltext](https://www.ajkd.org/article/S0272-6386(21)00561-8/fulltext)

⁷ <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>

⁸ <https://cjasn.asnjournals.org/content/13/8/1280>

⁹ <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>

admitted to the hospital for the transplant. This creates considerable uncertainty for the transplant center with regards to reimbursement for the evaluation and workup, should the individual not meet the eligibility criteria for Medicare.

Though silos across payers do limit the levers available to CMS to improve access to preemptive transplant, **we recommend that CMS create a mechanism to provide transplant centers with assurance of coverage for people approaching kidney failure who wish to receive a preemptive transplant and who will be Medicare eligible in the month they are admitted to the hospital for the transplant.**

IV. Align Reimbursement for Kidney Transplant with its Value

It is worth restating that many kidney transplants are cost saving when compared to dialysis, all kidney transplants provide a survival advantage over dialysis and all kidney transplants are cost effective (<\$100,000/QALY).¹⁰ Historically, CMS reimbursed all kidney transplants at the same rate. This approach created a disincentive for the use of less than perfect kidneys (e.g., from an older donor) that result in more expensive procedures, interventions and hospital stays *but that still provide a survival advantage when compared to dialysis*. In the FY 2021 IPPS, CMS created a differential payment for transplant cases where the patient received dialysis during the inpatient stay and after the date of the transplant. While we greatly appreciate this change, the Acute Inpatient PPS is a budget neutral system meaning that refining the payment system does not increase CMS spending on kidney transplant overall. **CMS must implement novel approaches to drive Medicare dollars towards kidney transplantation.** While we understand the reticence to incentive any single procedure over others, CMS has unique liability for kidney failure due to the ESRD benefit. Increasing reimbursement for kidney transplantation has a direct impact on Medicare expenditures in Parts A, B, and D.

V. Increase Accountability for Kidney Transplant

Nephrologists and dialysis facilities are gatekeepers to transplant. CMS has acknowledged their role by incorporating elements of accessing a kidney transplant into its value-based purchasing programs and Center for Medicare and Medicaid Innovation (CMMI) payment models. The Quality Incentive Program (QIP), which ties a percentage of a dialysis facility's Medicare reimbursement, includes the measure, Percent of Prevalent Patients Waitlisted. The ESRD Treatment Choices (ETC) model was initially designed to include an outcome measure of transplantation for nephrologists and dialysis facilities, but, after much opposition, was scaled back to the rate of waitlisting plus the rate of living donor transplants.

1. ESRD Treatment Choices (ETC) Model

¹⁰ <https://pubmed.ncbi.nlm.nih.gov/29451350/>

The ETC model is a mandatory CMMI model that took effect on January 1, 2021. The model was designed to overcome the economic and operational barriers that lead most patients to in-center dialysis, precluding patients from accessing their preferred treatment modality for kidney failure. The model proposed tying payment bonuses and penalties to nephrologist and facility rates of transplant and home dialysis. Rather than a portion of the transplant process, the proposed model sought to test the hypothesis that patient access to a kidney transplant will improve when physicians and dialysis providers are accountable for the outcome of transplantation. As stated, the proposed transplant rate measure was removed due to stakeholder pressure. We do not believe this is in the best interest of patients. Nephrologists, dialysis facilities, and transplant centers all have responsibilities to patients throughout the transplant process. It is crucial that each entity have an incentive to co-manage patients during this time. **NKF urges CMMI to incorporate a full transplant measure into the ETC model as soon as is feasible.**

2. Transplant Referral

ESRD care is marked by silos. Transitioning from the nephrologist, dialysis facility, and transplant center is treacherous for patients, particularly in the early steps to transplant. Consider that people seeking a kidney transplant are very ill, increasing the difficulty of navigating this especially complex part of the health care infrastructure. Few patients have the privileges of health literacy, empowerment, and knowledge of the intricacies of the transplant system needed to self-refer to a transplant center. Under the Conditions for Coverage for End-Stage Renal Disease (ESRD) Facilities at 42 CFR § 494.90, dialysis facilities are required to assess individuals for suitability for transplant referral, document the plan for transplantation, the reasons for non-referral if the patient declines, and the results of each kidney transplant referral. A study of transplant referral from 690 dialysis facilities in Georgia, North Carolina and South Carolina found a median within-facility cumulative percentage of patients referred for kidney transplant within 1 year of dialysis of 33.7%.¹¹ Patient advocates and nephrologists agree the true percentage of dialysis patients suitable for referral is closer to 60%. Nephrologists have no measure of transplant referral under the Merit-Based Incentive Payment System (MIPS). There is a clear need for greater accountability for transplant referral. As a threshold matter, dialysis facility regulations refer to transplant referral but neglect to define one. This is a matter of great consequence to patients, who at one center may be handed a piece of paper with a phone number on it and at another, may have the appointment made for them by dialysis facility staff. NKF recommends that CMS:

- Convene a Technical Expert Panel (TEP) to define transplant referral for the purposes of the Conditions for Coverage and additional oversight of and accountability for the patient journey to kidney transplant.

¹¹ <https://pubmed.ncbi.nlm.nih.gov/31981441/>



- Report transplant referrals in the End-Stage Renal Disease Quality Reporting System (EQRS)
- Continue the development and adoption of a nephrologist-level measure of transplant referral for use in MIPS.

3. Oversight of Kidney Transplant

On August 26, 2021, the Center for Clinical Standards and Quality (CCSQ) launched a transplant learning collaborative, the Technical Assistance Quality Improvement Learning (TAQIL) contract, intended to identify and disseminate best practices from the nation's highest performing Organ Procurement Organizations (OPOs) and transplant centers. The learning collaborative is an important step in identifying and sharing behaviors in the transplant system that increase the number of transplants and improve the patient-centricity of the transplant experience. The TAQIL contract does not, however, address the need to adopt and incentivize improvement on these best practices among the 260 kidney transplant programs currently operating in the U.S.

Beyond the Conditions of Participation for organ transplant programs, most oversight of the transplant system lies in the hands of the Health Resources and Services Administration (HRSA). HRSA manages the Organ Procurement and Transplant Network (OPTN), the system of OPOs and transplant centers that facilitate transplants from deceased donors. The OPTN has been operated by the United Network for Organ Sharing (UNOS) since 1986. Concurrently with the TAQIL contract, UNOS, HRSA, and the Scientific Registry of Transplant Recipients (SRTR) are engaged in an effort to develop new metrics for transplant centers to supplant the outcome measure, one year patient-and-graft survival, historically used by both CMS and UNOS to assess transplant center performance. **We recommend that CMS closely monitor the outcome of TAQIL contract and the metrics workstream and consider how CMS can provide more patient-centered and performance improvement driven oversight of transplant centers and the entire organ donation and transplantation system.**

VI. Increase Access to Home Dialysis

Dialysis is one of the most challenging treatments in medicine. Many people who find themselves with kidney failure give up their lives, hobbies, and jobs to commute to and from a dialysis facility and recover from the arduous treatments. Nearly 90 percent of dialysis patients do dialysis in a center despite the availability of home dialysis options that allow the individual to spend more time living on their own terms. Many studies suggest that home dialysis modalities are associated with improved clinical outcomes and decreased spending. Per person per-year (PPPY) spending on hemodialysis,

which is almost exclusively performed in dialysis centers is \$93,191 compared to a PPPY expenditure of \$78,741 on peritoneal dialysis (PD), performed exclusively at home.¹²

1. Staff Assistance for Home Dialysis

The most impactful policy for growing home dialysis is to provide for paid care partners. Home dialysis patients receive between 20 and 25 days of home training, after which the individual must perform their own treatments without any support. Becoming comfortable with home dialysis can take time, during which paid assistance from a nurse, technician, or other member of the dialysis facility staff can serve as a bridge. Home hemodialysis requires the patient to cannulate himself or herself, i.e., place a needle inside a vein. PD patients must learn to connect a PD catheter to a PD bag. Over time, home dialysis patients learn to respond to alarms, monitor blood pressure, care for catheters, and cannulate themselves. The empowerment that home patients gain from taking charge of their treatments serves them in all aspects of their care. Still, the adjustment to home dialysis can be difficult and patients are comforted in choosing home dialysis knowing that assistance will be available in the home if they need it. Most home patients need only a short period of assistance but some, for example the blind or individuals without a care partner at home, may require assistance on an ongoing basis. Staff assistance in the home is also a key component of ensuring equitable access to home therapies. NKF is supporting introduction of a home dialysis bill that would create an add-on payment to the ESRD bundle to support paid care partners. In the interim, we ask CMS to support staff assisted home dialysis in the following ways:

- Provide clarification of the circumstances under which dialysis facility staff are able to assist patients in the home.
- Include a safe harbor specifically for the provision of staff assisted home dialysis in the CMMI kidney models.
- Support an Office of the Inspector General (OIG) safe harbor for the provision of staff assisted home dialysis in fee-for-service (FFS) Medicare.

NKF recently submitted comments to CMS in response to the proposed CY2022 ESRD PPS. These comments, included as Appendix I, provide a comprehensive overview of NKF's dialysis and home dialysis policy recommendations.

The National Kidney Foundation (NKF) highly values the work CMS is doing to improve health care across the nation. Taking specific steps to address kidney disease is closely aligned with CMS' pledge to use "innovative approaches to improving quality, accessibility, and affordability" for patients and intersects with HHS' response to the COVID-19 pandemic and desire to improve health equity. We

¹² <https://adr.usrds.org/2020/reference-tables>



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would welcome the opportunity to collaborate with CMS to further discuss these policy recommendations. Please contact Miriam Godwin (miriam.godwin@kidney.org).

Sincerely,

Kevin Longino
CEO and transplant patient



Appendix I.

August 30, 2021

The Honorable Chiquita Brooks-LaSure
Hubert H. Humphrey Building
Room 314G-01
200 Independence Avenue SW
Washington, DC 20201

Re: CY 2022 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System and Quality Incentive Program

Dear Administrator Brooks-LaSure,

The National Kidney Foundation (NKF) appreciates the opportunity to comment on the proposed CY2022 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Quality Incentive Program (QIP). The National Kidney Foundation (NKF) is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention, and treatment of kidney disease in the U.S. In addition, the National Kidney Foundation has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI).

NKF heartily applauds the Centers for Medicare and Medicaid Services (CMS) for the focus of this year's proposed rule on the many social injustices that manifest in kidney care. Kidney disease is one of the most dramatic examples of the impact that poverty and structural racism have on health outcomes. In this letter, we respond to CMS' proposals and offer feedback to improve the rule from the patient perspective. Broadly speaking, NKF supports the proposed rule and thanks CMS for its work in putting it forward. Our summary recommendations are as follows:

Summary Recommendations

- Ensure the Substantial Clinical Improvement (SCI) criteria for the Transitional Payment for Innovative ESRD Equipment and Supplies (TPNIES) accounts for the views and preferences of home dialysis patients.
- Allow machines that mitigate barriers to home dialysis to qualify as Substantial Clinical Improvements (SCIs).
- Exercise appropriate flexibility in assessing the evidence to support SCI for TPNIES.
- Develop a home dialysis quality roadmap based on key domains of home dialysis quality: Home dialysis access, clinical care, safety, retention, and quality of Life (QoL).



- Institute claims based adjustments to the Standardized Fistula Rate Quality Incentive Program (QIP) measure in order to improve its patient-centricity
- Modify Kt/V Dialysis Adequacy Measure to allow for greater flexibility to prescribe individualized dialysis prescriptions.
- Look beyond stratification of QIP measures by race, ethnicity, and dual status to consider what CMS can do to close known health equity gaps.
- Publicly report dialysis facility staff vaccination rates rather than implement a measure for the QIP.
- Clear backlog in certifying home dialysis programs instead of providing ½ credit for nocturnal home hemodialysis in the ESRD Treatment Choices (ETC) model.
- Implement a transplant rate measure in the ETC model as soon as is feasible.
- NKF supports raising the achievement benchmarks above Comparison Geographic Areas by 10 percent every two measurement years (MYs) beginning in MY3 in the ETC model.
- NKF does not support the proposal for the ETC model to create achievement benchmarks for model participants serving a greater proportion of dual-eligibles and beneficiaries receiving the LIS.
- NKF supports the Health Equity Incentive in the ETC model.
- Waive the 20 percent coinsurance for beneficiaries receiving 1:1 KDE and KDE in groups.
- Institute an accreditation model for Kidney Disease Education (KDE) content in order to improve quality of education provided through the benefit.
- For the purposes of the ETC model and the QIP, acknowledge that the Home Dialysis Care Experience (Home-DCE) instrument or other beneficiary experience measures do not capture domains of quality of life that are vital for home patients.
- Remove the rural payment adjuster and instead combine the funds from the rural and LVPA adjusters to fund a tiered Low Volume Payment Adjustment (LVPA) that applies the most dollars to facilities that are serving a critical patient need, but also likely operating at a loss.
- Refine the case-mix adjusters used in the PPS to focus on those that are true drivers of high costs and for which data can be collected and reported on for practical purposes by the facility.
- Lower the outlier threshold percentage.

Proposed CY 2022 ESRD PPS Update

Proposed Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for CY 2022 Payment

NKF enthusiastically supported the creation of TPNIES. We continue to hope that the payment adjustment will be successful in incentivizing innovation in dialysis equipment and supplies and home dialysis machines. **However, the program, as structured currently, is not yielding results.** It appears that the evidentiary “bar” for demonstrating TPNIES eligibility may be too high. From its inception, we have supported the substantial clinical improvement (SCI) criteria as the basis for

approval. Though we acknowledge it is challenging, CMS must find a way to achieve a balance between bringing innovative dialysis technologies to patients and incentivizing innovation that is not marginal, but truly meaningful to the end-user. If it appears that no technologies are able to qualify for TPNIES, that is a disincentive for innovation. Our concern lies with the evidence needed to meet the SCI criteria. In the three years from FDA approval during which a product can qualify for TPNIES, clinical trial evidence beyond what was needed for FDA clearance is an unrealistic expectation.

In an ideal world, NKF would ask CMS to prioritize innovation with robust evidence from a randomized control trial (RCT) of improved clinical outcomes. For all dialysis patients, regardless of modality or prescription, technology that could reduce hospitalizations related to cardiovascular conditions, eliminate infections, or dramatically improve Health Related Quality of Life (HRQoL) would provide enormous value to patients and payors. However, we fear this is not a reasonable expectation for every emerging dialysis technology. As a long history of incentives, quality programs, and value-based models demonstrate, improving clinical outcomes for the medically complex, frail, and vulnerable dialysis population requires a multifactorial strategy and remains a challenge under the best of circumstances. Nevertheless, there is great value to patients in innovations that improve the ability of people to be successful on home modalities. In 2018, the NKF Kidney Disease Outcomes Quality Initiative (KDOQI) sponsored a home dialysis conference to identify barriers to starting and retaining patients on home dialysis. Several papers resulted from the conference highlighting clinical, operational, social, and policy barriers to improved access to and success with home dialysis. For the purposes of TPNIES, *Exploring Barriers and Potential Solutions in Home Dialysis: An NKF-KDOQI Conference Outcomes Report* notes that “we view technological solutions as enablers that maximize patient potential while ensuring the safety and high quality of the therapy.”¹³ Per the authors, technologies that simplify the process of home dialysis, generate smaller and quieter machines, aid with self-cannulation, provide on-demand dialysate, allow for remote adjustment of the dialysis prescription are all crucial for improving the initiation and support of home dialysis.¹⁴ **Home dialysis machines that can overcome these and other barriers to home dialysis should qualify as SCIs.**

We urge CMS to keep the needs of current and potential home dialysis patients in mind as it applies the SCI criteria to a home dialysis machines under consideration. The following table summarizes common barriers to home dialysis and examples of innovations that should qualify as substantial clinical improvements.

Dialysis Modality	Barrier for Implementation	Innovation to Increase Implementation
Peritoneal Dialysis (PD)	Lack of storage space for PD supplies Inability to lift heavy boxes/bags	On-line generation of dialysate which eliminates need for large bags of dialysate

¹³ [https://linkinghub.elsevier.com/retrieve/pii/S0272-6386\(18\)31060-6](https://linkinghub.elsevier.com/retrieve/pii/S0272-6386(18)31060-6)

¹⁴ Ibid.

Peritoneal Dialysis (PD)	Connection of PD catheter can contribute to infections	-Automating the connection process which reduces infection risk -Sensors to detect early signs of infections at connection site
Home Hemodialysis (HHD)	Fear of cannulation	Improved mechanism of cannulation to decrease risk of needle dislodgement
Home Hemodialysis (HHD)	Burden on patient/family/caregivers	-Simpler equipment/interface On-line generation of dialysate which eliminates need for large bags of dialysate -Monitoring technology that provides assessment of biochemical parameters and volume status -Automatic adjustment of ultrafiltration to optimize fluid removal -More options for dialyzers and dialysates.
Home Hemodialysis (HHS)	Portability	HHD machine with a weight of 10-20 kg

We reiterate that this evidence is not likely to come from RCTs. CMS must exercise appropriate flexibility in deliberating the kinds of evidence it will accept in assessing SCL.

NKF does not comment on any specific product seeking TPNIES, however we are responding to the questions posted by CMS in the rule:

1. NKF firmly believes that greater flexibility is of the utmost importance to home dialysis patients. In-center dialysis, performed three times a week for four hours at a time, can easily take over a patient's life, ending the patient's ability to live on his or her terms. Flexibility means that the individual has more choices about how to live with the need for dialysis. Flexibility is the core of patient-centeredness and one of the most significant reasons NKF advocates for more home dialysis. Home dialysis is time and patient-intensive and options that increase its feasibility, making it easier for dialysis patients to live the lives of their choosing is essential. As we note in the table above, innovations that increase the feasibility of home dialysis are of great value to patients. This means that, for example, smaller sized,

easier to use home dialysis machines can represent an improvement over existing technologies because the barriers to entry and retention on home dialysis are lower.

2. Patients express the desire for earlier detection of peritonitis and blood stream infections (BSIs), which can lead to death, hospitalizations, and/or a return to in-center dialysis. Nephrologists agreed that data from a validated, sensitive and specific diagnostic test could be acted upon sooner. Nephrologists were very interested in the possibility of detecting early signs of infection, even earlier than solid particles in dialysis effluent, however reported that they would not use the test without more peer-reviewed evidence on the technical specifications and clinical experience.

End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

In this proposed rule, the Centers for Medicare and Medicaid Services (CMMI) propose developing a beneficiary satisfaction with home dialysis measure for use in the ESRD Treatment Choices (ETC) model. The QIP as currently designed favors in-center dialysis, focusing on biochemical parameters that in many cases are fundamentally misaligned with the goal of home dialysis to provide individualized prescriptions that emphasize how patients feel and function and that are aligned with patients' values and goals. CMMI's effort aligns with a broader objective of NKF to guide the development of a quality program that is credible for use in a changing, home dialysis-focused policy environment. In the following section we outline our perspective on how the QIP can be expanded to better incorporate measures of home dialysis. In a larger sense, we continue to consider whether the QIP can be a successful tool to achieve high quality, equitable, person-centered dialysis care. Several recent publications highlight two possible problems with the QIP. Sheetz et al. found that penalties levelled under the QIP disproportionately impact facilities in zip codes with a higher proportion of non-White and lower income residents and further that the penalties fail to incentivize improvement regardless.¹⁵ These data raised several issues. At baseline, NKF has concerns that many of the QIP measures are not sufficiently patient-centered. The Sheetz et al. data point to the need to discern what elements of care are actionable in a facility in a structurally racist and inequitable society. While we do not support suspending QIP penalties in racially segregated neighborhoods, as has been suggested, it is possible that the QIP should be redesigned with an eye towards health equity. The most significant matter is simply that the QIP appears not to be driving improvement at all.

While our community debates larger problems with the QIP, we urge CMS to expand the program to better incorporate home dialysis. Quality domains relevant to home dialysis are:

1. Home dialysis access
2. Clinical care
3. Safety
4. Retention

¹⁵ <https://www.acpjournals.org/doi/pdf/10.7326/M20-6662>

5. Quality of Life (QoL)

We strongly encourage CMS to develop a quality roadmap for home dialysis based on these domains. A home dialysis quality roadmap should constitute one pillar of a holistic home dialysis strategy to ensure that the Agency's efforts to encourage home dialysis (e.g., TPNIES, equity in home dialysis access, the CMMI models, the growing interest in staff assisted home dialysis, and our shared goal to ensure that patients are educated on and empowered to select home dialysis well before dialysis is ever necessary), are aligned. An aligned cross-CMS home dialysis strategy must address home dialysis education. We are unsure that home dialysis education can or should be incentivized by use of traditional process measures. However, CMS can use tools of payment, regulations, guidance, and the ESRD Networks to standardize and improve the quality of home dialysis education. Home dialysis education underpins access to home modalities and every aspect of patients' ability to be successful. The ESRD facility Conditions for Coverage require that patients be informed about all treatment modalities and settings and specify the educational domains that must be covered in home training. Nevertheless, the quality of home dialysis education and training is extremely inconsistent.¹⁶

Home Dialysis Access

A home dialysis access measure for practical purposes, can be modified for use in the QIP from the ETC model. The home dialysis access domain should also include patient-reported assessments of whether the individual was given a choice of modality, meaningful education on those choices and whether they are being treated with the modality they prefer. A home dialysis access domain could also include an assessment of the percentage of eligible patients who declare a preference for home dialysis who are successfully trained in a timely manner. Backlogs in home training are themselves a barrier to access.

Clinical Care

Measures in the clinical care domain should account for residual kidney function (RKF), incentivizing nephrologists and providers to incorporate RKF into the dialysis prescription and dosing. Current practice is better in PD than in HHD, where overtreatment and loss of residual function are common. We appreciate CMS' adjustments to Kt/V for home patients and ask CMS to continue to decrease reliance on this measure for home patients in favor of a complete spectrum of lab values and assessment of how the patient feels and functions. Even with adjustment, Kt/V can still be punitive for home patients whose facilities will not exercise the flexibility they are allowed under the QIP.

Other concepts that should be captured in the clinical domain are:

- Intensive hemodialysis
- Volume status
- Blood pressure control

¹⁶ https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_h_esrdpdf



Safety

The current safety domain need only include a measure of peritonitis to evaluate safety across dialysis settings.

Retention

Measures in the retention domain will by definition get at the quality of home training, one of the most important factors in a person's ability to be successful on home dialysis. Retention measures will also elucidate the steps the facility is taking to anticipate and manage patient and care partner burnout. A measure of short-term retention on home dialysis is not useful and may be actively harmful. The goal should be to support patients through their first year on home dialysis, which can be very challenging, but after which many patients will experience substantial improvements in their quality of life.

Home Satisfaction

Our understanding is that CMS is considering a QIP A measure of home dialysis satisfaction, perhaps based on the Home Dialysis Care Experience (Home-DCE) instrument developed by the University of Washington. The Home-DCE instrument measures the patient experience of home dialysis with a focus on the processes associated with home dialysis. We are concerned that the subtle effect of such a measure would be to suggest that, while important, a facility's responsibility to home patients ends with how the facility interacts with home patients. Home-DCE does not capture outcomes and cannot be the only tool used to incentivize individualized home dialysis that is aligned with a person's goals and values and allows them to feel their best. We also note that many elements of quality dialysis care, regardless of modality, can be captured by the questions:

1. "Do you feel respected by your care team?"
2. "Do you feel safe?"

The goal of an instrument like Home-DCE should be to incentivize improved communication between the home patient and the care team. If the Home-DCE instrument is adopted by CMS the QIP, we strenuously encourage CMS to avoid the pitfalls that have made it difficult for dialysis patients and providers to find ICH-CAHPS meaningful, i.e., ensure the survey is provided on a timeline that allows the facility to make improvements and for patients to see that their feedback has been taken into account, thus encouraging patients to continue to want to engage in improving their care.

Quality of Life (QoL)

The patient-centered outcome that matters to home dialysis patients, in fact, all dialysis patients, is quality of life (QoL). Nephrologists and dialysis facilities can and should be responsible for some elements of a patient's QoL. We acknowledge that quality of life is

unique to each individual, is affected by processes outside of dialysis, and does not necessarily correlate with quality of care and therefore that developing accountabilities associated with QoL may be challenging. As a preliminary step, facilities could report an individual's Activities of Daily Living (ADLs), which are much more closely related to an individual's quality of life. There are also existing mechanisms that could be deployed to encourage nephrologists and providers to focus on QoL, for example better leveraging the Kidney Disease Quality of Life (KDQOL) tool that dialysis facilities must already administer to dialysis patients under the existing Conditions for Coverage, the development of the Plan of Care and the ESKD Life Plan. As a note, NKF's home dialysis legislation, the CARE for Home Dialysis Act, directs the Secretary to develop a QoL measure for dialysis patients that is agnostic to modality. A QoL measure need not be specific to home dialysis.

Proposed Updates to Requirements Beginning with the PY 2024 ESRD QIP

We thank CMS for clarifying the PY 2024 and PY 2025 ESRD QIP Measure Sets. Our comments on the measures in the QIP Measure Set are as follows:

Patient & Family Engagement			
	<i>NKF Supports (Y/N)</i>	<i>Comments</i>	<i>Recommendations</i>
ICH CAHPS	N	The measure reflects an important premise that dialysis patients, many of whom spend a considerable amount of time in the dialysis facility, are satisfied with the attention they receive from facility staff and feel safe and comfortable in their surroundings.	ICH CAHPS is focused on the wrong concepts. The survey tool solicits feedback on some important questions like whether the dialysis facility staff respect what the patient has to say, but overall does not capture the outcome of the patient's experience with the nephrologist, facility, facility staff and treatment, namely whether the patient is satisfied with the care he or she is receiving. In terms of operationalizing the survey tool, the reporting measure in the QIP combined with the extremely low response rates on the tool render ICH CAHPS purposeless. NKF recommends the measure be suspended until CMS can develop a



			survey instrument that is meaningful to patients, produces data that are generalizable and actionable, and is delivered in a manner that allows facilities to process and improve upon the feedback.
Care Coordination			
Standardized Readmission Ratio (SRR)	Y	The SRR measure must strike the appropriate balance between ensuring that dialysis facilities meet their responsibility to reduce 30-day dialysis related readmissions and not creating a barrier to patient access to care when necessary.	<p>Even the highest quality dialysis facilities struggle with their obligation to reduce readmissions, in part because hospitals do not always meet their obligations in the shared accountability to elimination unnecessary utilization. For example, hospitals may discharge the patient before the reason for the admission has been resolved, all but resulting in a readmission. Facilities also report challenges in accessing hospital discharge data on medication changes and plans of care post-discharge. Though we understand that these transitions of care are challenging for both dialysis facilities and hospitals, both entities must recognize their responsibility to collaborate. NKF will follow up on this point with the Division of Acute Care at CMS.</p> <p>In order for the SRR measure to be actionable by facilities, NKF recommends that CMS require hospitals to share discharge information directly with dialysis facilities and stratify the measure for causes of readmission for which it is reasonable to hold the dialysis facility accountable.</p>

			We additionally recommend that CMS evaluate the growing role of outpatient observation stays during the 30-day follow up period for readmission
Standardized Hospitalization Ratio (SHR)	Y	NKF supports the SHR measure. We agree that a measure that holds dialysis facilities accountable for preventing hospitalizations is appropriate.	NKF recommends that the measure should be stratified for causes that are actionable by the nephrology care team. As a tradeoff for giving the dialysis facility more latitude in its responsibility for all hospitalizations, CMS could initiate a discussion of which causes of hospitalizations may be actionable by the facility in the first 90 days of dialysis, a period where patients are especially vulnerable and at high risk for poor outcomes.
Percentage of Prevalent Patients Waitlisted (PPPW)	Y	<p>It is far too common for patients who are interested in a kidney transplant to fall through the gaps across silos of care. Every provider involved in the care of patients with ESKD is obligated to work towards providing patients with the highest quality of care, which for many patients is a kidney transplant. The PPPW measure is a step in the right direction, acknowledging the responsibility of the dialysis facility in providing patients with access to transplant.</p> <p>Dialysis facilities, nephrologists, and transplant facility staff share the responsibility of ensuring patients are waitlisted and maintain their health for transplant. We</p>	<p>In the future, we suggest that the PPPW measure might also be applied to a nephrologist participating in the Merit Based Incentive Payment System (MIPS) or in other physician-level quality programs. The nephrologist shares accountability for managing ESRD patients and coordinating care and has a leading role in evaluating patients for referral to a transplant center and assisting patients in getting on the waitlist. We do note, however, that exclusions would need to account for circumstances affecting a patient's ability to be waitlisted that are beyond the nephrologist's control.</p> <p>NKF does acknowledge that rural dialysis facilities tend to fare poorly on the measure. Dialysis patients in rural</p>



		<p>acknowledge the view of dialysis facilities that they should not be held accountable for waitlisting patients when transplant centers are the final decision-maker regarding whether a patient is waitlisted. The solution to this is <u>not</u> to standardize waitlist criteria, as is often suggested, but rather to make sure dialysis facilities and patients have visibility into the waitlist criteria at their local transplant centers. Many transplant centers have guidelines in place that obligate them to provide their waitlist criteria to a dialysis facility that requests it.</p> <p>NKF is eager to see the ETC model implemented. Doing so will allow us to learn how nephrologists and dialysis facilities collaborate when both are held accountable for the outcome of transplantation. This information will help our community develop better quality measures that incentivize access to transplant across multiple care settings.</p>	<p>areas deserve the same access to transplantation as any other patients, however, we understand that the barriers to transplant in a rural area may be greater for example, accessing the needed dental assessment.</p> <p>We recommend that CMS undertake an assessment of rural versus urban disparities in the measure.</p> <p>Given the important of rural facilities for patient access, a risk adjusted PPPW measure <u>could</u> be appropriate. We also understand, however, that dialysis facilities and transplant centers in rural areas are implementing creative solutions that support coordination of care such as contracting with a local nephrologist to perform the transplant evaluation. An evaluation of urban versus rural disparities will help us understand the barriers to transplant in rural areas as well as possible solutions to overcoming them.</p>
Clinical Depression Screening and Follow-Up	N	<p>It is vitally important to improve the mental health of dialysis patients. Depression is the most common psychiatric condition among patients with ESKD and may exacerbate the complications of ESKD, treatment adherence, hospitalizations, and mortality.</p>	<p>It is imperative that CMS address the high rates of depression in the dialysis population, however we are unsure that the reporting measure is making a meaningful difference in depression treatment. In theory, CMS could deploy a clinical measure of depression treatment, a solution that NKF has supported in the past, but we have come to understand that staffing limitations preclude leveraging the social workers to provide behavioral</p>



			<p>health interventions in the facility. We reiterate the importance of screening and treatment of depression. We would be interested in working with CMS to determine how to use the levers of quality, payment, transparency, and regulation to ensure that facilities are meeting patients' mental health needs. We do not, however, believe the current QIP measure is achieving this goal.</p>
Clinical			
Standardized Transfusion Ratio (STrR)	N	<p>NKF is extremely concerned that the STrT measure may be leading to the undertreatment of anemia, a condition that is increasing among dialysis patients and that has an enormous impact on a patient's quality of life.</p>	<p>We do not believe it is appropriate to use the STrR measure as a means to target anemia. Avoidance of transfusion is an important goal in and of itself, particularly among patients waiting for a kidney transplant. Even in this context, aspects of transfusions are out of the control of the facility. Transfusions can happen incidentally when a patient is hospitalized for infection. Home programs tend to perform poorly on the measure because infection represents a larger share of morbidity with home versus in-center hemodialysis, and infection tends to cause ESA hyporesponsiveness and depress hemoglobin. This concerns us when our shared aim is to encourage greater uptake of home dialysis.</p> <p>A transfusion avoidance measure does not consider a patient's quality of life, or the cardiovascular risks associated with low hemoglobin levels.</p> <p>We are sensitive to the fact that CMS has a statutory obligation per the</p>

			<p>Medicare Improvements for Patients and Providers Act (MIPPA) to include measures that reflect labeling approved by the Food and Drug Administration (FDA) and that FDA has endorsed no such hemoglobin targets due to the black box warning on ESAs.</p> <p>That being said, anemia management is of the utmost importance to dialysis patient quality of life. The subset of patients with whom NKF speaks are willing to accept the risk of death and serious cardiovascular events if it means that anemia is properly managed, allowing them to do simple things like get off the couch.</p> <p>Accordingly, NKF supports a measure in the QIP that incentivizes facilities to adequately manage anemia. The KDOQI Anemia Management guidelines recommend a low hemoglobin range of 9.0g/dL-10.0g/dL.¹⁷</p>
Kt/V Dialysis Adequacy Comprehensive	N	<p>The Kt/V measure is not patient centered. There is very limited evidence that outcomes are improved by achieving a Kt/V ≥ 1.2 for hemodialysis or > 1.7 for peritoneal dialysis. Importantly, many patients and nephrologists do not favor the concept of “adequacy” in the form of these metrics, noting that a specific adequacy target has little bearing on patients’ ability to live safely and well and longer on dialysis. In its current iteration, the</p>	<p>NKF recommends that CMS assess individual adequacy measures or to construct a composite measure where each individual measure is evaluated and then rolled up into a single score.</p> <p>For PD patients, we recommend that CMS accept Kt/V ≥ 1.7, <u>or</u> alternatively Kt/V as low as 1.3 when accompanied by a statement that the patient has acceptable biochemical parameters and no uremic symptoms or if patient is deemed to have</p>

¹⁷ [https://www.ajkd.org/article/S0272-6386\(13\)00978-5/fulltext](https://www.ajkd.org/article/S0272-6386(13)00978-5/fulltext)



		<p>pooled measurement is distorted and no longer aligns with the KDOQI Guidelines, which recommend separate adequacy targets for hemodialysis and peritoneal dialysis.¹⁸ In addition, the measure excludes dialysis adequacy for HHD, which may be inappropriate given the anticipated increase in the number of patients using this modality.</p> <p>In a larger sense, we are unsure what the measure is intended to incentivize. The percentage of patients with low Kt/V is very low. In addition, performance on the measure can adversely impact patients if they have some form of residual kidney function.</p>	<p>significant residual kidney function. With regard to hemodialysis, the strict single target of $spKt/V \geq 1.2$ does not account for the important contribution of patient's native kidneys in the form of the residual renal function. The target disadvantages patients who wish to preserve their residual kidney function longer and may lead to the acceleration of the loss of residual renal function.</p> <p>For hemodialysis patients, a consensus on targets that account for residual kidney function and lead to optimal outcomes has not been well defined compared to PD. We recommend that CMS establish a technical expert panel (TEP) that includes patient input to explore the current evidence and make specific recommendations that recognize that incident dialysis patients, patients with a recently failed kidney transplants, and prevalent patients with significant residual native renal function might benefit from different $spKt/V$ corrected for residual function thresholds or other appropriate measure of dialysis adequacy.</p>
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¹⁸ http://www.kidney.org/sites/default/files/docs/12-50-0210_jag_dcp_guidelines-pd_oct06_sectionb_ofc.pdf
[https://www.ajkd.org/article/S0272-6386\(15\)01019-7/pdf](https://www.ajkd.org/article/S0272-6386(15)01019-7/pdf)



<p>Hemodialysis Vascular Access: Standardized Fistula Rate</p>	<p>N</p>	<p>NKF is concerned that a measure based on autogenous arteriovenous fistula (AVF) as the sole means of vascular access is not sufficiently patient-centered. There are numerous reasons, some clinical and some based on patient preferences, that lead to patients choosing not to go through the process of evaluation or maturation of an AV fistula. We note that further vascular surgery may not align with patients' preferences for care, for example for patients who have been on dialysis for many years and have had multiple vascular access surgeries.</p>	<p>Given that this measure is not adequately patient-centered, as well as that it causes cherry picking of patients, we do not see any additional value to this measure beyond what is provided by Hemodialysis Vascular Access: Long-Term Catheter Rate</p> <p>Should CMS choose to retain the measure, we recommend that CMS exclude patients from the measure who have severe steal syndrome affecting the partial or complete use of a limb, severe congestive heart failure, severe psychiatric illness, limited life expectancy, or other conditions in which the risk of surgery to place AV access, or use of AV access on dialysis, is deemed to be unacceptable by their physician. It would also be appropriate to exclude patients who have exhausted all potential sites for AVF or AVG placement, or in whom there are no viable vessels for AVF or AVG placement, as patients that refuse consideration of AVF or AVG placement or use, despite greater than two attempts at education on the risks of catheters and benefits of AVF or AVG by their provider, patients for whom a living donor transplant is imminent, patients with malignancies, and patients with heart disease.</p> <p>These recommendations align with the updated KDOQI Vascular Access Guideline, which emphasizes that a patient's access needs stem from the</p>
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			<p>creation of an individualized ESKD life-plan.¹⁹ Rather than a “fistula-first, catheter-last” approach, the guideline reflects that the “right” vascular access is different for every patient. NKF would welcome the opportunity to discuss incorporation of the ESKD life-plan in the ESRD QIP.</p> <p>The exclusions we recommend could be captured by modifying CROWNWeb to add checkboxes for facility reporting of patients who are not suitable for AVF or AVG placement, or who have declined to pursue it. Successful implementation of these exclusions will require CMS to adjust the measure threshold, as it currently allows little room to account for the preferences of patients who choose not to pursue an AV fistula.</p> <p>We do believe that, in conjunction, facilities should be required to continue to attempt education on the risks of catheters and the benefits of AVF or AVG at least annually.</p>
Hemodialysis Vascular Access: Long-Term Catheter Rate	Y	NKF supports the long-term catheter rate measure, which successfully reduces catheter rates in a patient’s first year on dialysis.	The long-term catheter rate measure better achieves the goal of incentivizing high-quality vascular access than the long-term catheter rate measure and the standardized fistula rate in combination. The long-term catheter rate measure encourages the facility to pursue a permanent vascular access for most patients, while allowing some flexibility for patients for whom it is appropriate to continue on dialysis with

¹⁹ <https://www.kidney.org/professionals/guidelines/current-KDOQI-projects>



			<p>a catheter. This approach is more closely aligned with updated KDOQI Vascular Access Guideline, which places the patient at the center of access planning and decision-making.</p> <p>The long-term catheter rate measure is an improved vascular access measure but has its own limitations. A certain number of patients will always have catheters for patient-centered reasons. We ask CMS to acknowledge this reality to the extent feasible.</p>
Hypercalcemia	N	NKF does not believe the hypercalcemia measure is driving improvements in patient outcomes.	<p>NKF recommends either retiring the hypercalcemia measure, or, at minimum, removing hypercalcemia as a clinical measure and replacing it as a reporting measure.</p> <p>NKF has retired the measure because it is topped out and believe CMS should do the same.</p> <p>An alternative path forward would be to remove hypercalcemia as a clinical measure and replace it as a reporting measure. We are unclear of CMS' statutory obligation to include this measure in the QIP, as an oral and IV product will be included in the bundle in 2021. If this obligation remains, changing the measure to a reporting measure would balance the requirement to include quality measures related to conditions treated with oral-only medications with the need for the QIP to more highly value measures that drive improvements in patient outcomes.</p>

Ultrafiltration Rate	N	NKF does not support the Ultrafiltration Reporting Measure.	There is limited evidence for a specific ultrafiltration target. The KDOQI Hemodialysis Adequacy Guideline does not include a target for UFR, recommending instead the minimization of UFR as best possible to maximize hemodynamic stability and tolerability of the hemodialysis procedure. ²⁰ We are also concerned that conventional UFR targets fail to incentivize the use of more frequent and/or longer HD to drive UFR down. Because UFR targets remain an active area of debate, NKF recommends that CMS suspend the measure.
Patient Safety			
NHSN Bloodstream Infections in Hemodialysis Patients	Y	NKF supports the NHSN BSI clinical measure. Decreasing BSIs among dialysis patients is a critical element of improving the quality and safety of dialysis.	Given the importance of a BSI measure in the QIP, we do not believe that including a BSI <u>reporting</u> measure in this domain is an adequate solution to the problem of underreporting of BSIs by hospitals to dialysis facilities. We recommend that CMS institute a system where hospitals are required to report BSIs either to NHSN or directly to dialysis facilities so that they can appropriately report on the measure. We further recommend the measure exclude infections that are unrelated to dialysis.
	N		

²⁰ [https://www.ajkd.org/article/S0272-6386\(15\)01019-7/pdf](https://www.ajkd.org/article/S0272-6386(15)01019-7/pdf)

NHSN Dialysis Event Reporting Measure		NKF does not support the inclusion of a dialysis event reporting measure in the QIP. The reporting measure serves to dilute the value of the clinical measure	<p>The underlying problem with the clinical measure is the failure of hospitals to report BSIs to dialysis facilities. We do not believe that including the reporting measure in the patient safety domain will address this problem.</p> <p>We recommend that CMS institute a system where hospitals are required to report BSIs either to NHSN or directly to dialysis facilities so that they can appropriately report on the measure.</p>
Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec)	Y	NKF continues to support the addition of the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) reporting measure to the QIP. Ensuring that dialysis facilities have the most accurate record of a patient’s medications, including prescription, over the counter, and herbal supplementals, is critical for assuring patient safety and outcomes. We believe the MedRec measure is adequate to achieve these goals.	

Requests for Information (RFIs) on Topics Relevant to ESRD QIP

Closing the Health Equity Gap in CMS Quality Programs Request for Information

As CMS seeks information on mechanisms to achieve equity for ESRD beneficiaries, we wish to emphasize that practical steps taken to close gaps in access to high quality, patient-centered dialysis are of the utmost importance to patients, especially those who have had suboptimal experiences with dialysis related to structural factors like neighborhood segregation. We agree that data collection is important to understand the scope of the problem, but patients by and large don’t need data to validate their experiences. Black/African American, Hispanic, Native American patients and patients

from other structurally disadvantaged groups see that dialysis facilities are nicer and better staffed in predominantly White areas. They know that dialysis facilities located in lower income, majority non-White neighborhoods are less likely to offer the guidance people need to get on a successful path to home dialysis or transplant, engage patients in discussions about their plan of care, and support patients with their mental health. These patients know they are singled out as troublesome or as the only patient in the facility asked to change their dialysis schedule. Potent acts of discrimination, conscious and unconscious on the part of dialysis staff, persist. None of these experiences are captured by a tool like the QIP yet are fundamental to many patients' experiences of care. We agree with the statement that "improving data collection to allow for better measurement and reporting on equity" is an important step in improving health disparities.²¹ However, equity will only be achieved when dialysis facilities located in structurally disadvantaged areas serving structurally disadvantaged patients have the incentives, resources, and support needed to close gaps in care, those identified by the QIP and those which patients report but are not described by empirical data. While doing so is an extremely preliminary step towards health equity, NKF supports CMS' proposal to expand the CMS Disparity Methods to the ESRD Quality Incentive Program (QIP), stratifying the QIP by race, ethnicity, and dual eligibility, both within and across facilities. Most of the QIP measures would be important to stratify, but Percent of Prevalent Patients Waitlisted (PPPW) is of the utmost importance. For all CMS' data collection efforts around equity, transparency is fundamental. It is imperative that patients understand why CMS is collecting data on their identities and lives and how CMS intends to use those data to improve their care and the care of others. Patients must also be able to opt-out of reporting.

We appreciate that CMS is limited in the tools available to it with regards to data collection and that the imputation of race and ethnicity and the use of dual status are perhaps the best CMS can do under its current circumstances. As CMS is aware, disparities in kidney disease stem from a wide range of social factors including the unequal allocation of wealth, employment, housing, education, access to health care, access to nutrition and exposure to toxic environments, psychosocial stress (i.e., racism) and mass incarceration. In an ideal world, the goal of stratifying the QIP would be to apply targeted incentives and interventions to close the gaps elucidated by the stratification. Race, ethnicity, and dual eligibility may be data points that are too blunt to decipher the underlying cause of identified disparity. That being said, NKF supports this data collection effort and the imputation method of identifying race and ethnicity as a preliminary step while more precise methods are developed. We note that much of the information CMS wishes to collect are reported on the 2728 form. While the data are imprecise, so is the imputation method, particularly for American Indians, Alaskan Natives, and those who are multiracial. This is a concern since American Indian/Alaskan Native populations still have the highest prevalence of diabetes in the United States and though incidence of ESKD has fallen among AI/AN populations, these individuals are still at very high risk. In addition, patients who are dialyzed in dialysis facilities on Native American reservations report the experience is extremely poor. As an immediate next step, CMS must determine how to collect self-reported race and ethnicity data, as this is the gold standard. We note that some people may not understand the concept of race as it is commonly used in the United States, for example people from Puerto Rico.

²¹ CMS-2021-0114-0001 pg. 123



CMS notes that “stratified facility-level reporting using indirectly estimated race and ethnicity and dual eligibility would represent an important advance in our ability to provide equity reports to facilities.” We believe that making these reports available to facilities would encourage thinking about health equity, which in and of itself is positive. It is essential that CMS report these data to patients through Dialysis Facility Compare (DFC) or another mechanism. Part of patient-centered decision-making is the opportunity to understand whether and how effectively a facility is caring for patients who are like them.

NKF supports future efforts to collect and share a standardized set of social, psychological, and behavioral data by facility. We understand that collecting data on social determinants of health is challenging. In general, most clinicians are not trained to assess social determinants of health. Identifying a person’s social risk factors, however, is part of a standard social work assessment. We strenuously recommend that CMS work closely with the Council of Nephrology Social Workers and other nephrology social worker groups to discuss how social workers already embedded in dialysis facilities can contribute to data collection on and intervention in the determinants of health and other social, psychological, and behavioral factors that impact dialysis patient outcomes. In addition, CMS should strongly encourage use of the ICD-10 CMS Z codes by dialysis facilities to report on dialysis patients’ social needs.

In theory, NKF supports the creation of an ESRD Facility Equity Score (HESS). For practical purposes, we are unsure of whether the score would be meaningful for patients. Ultimately, what CMS does with the data it collects and the score it generates is what matters most, i.e., what happens if a facility is providing inequitable care. Facilities should be accountable for closing gaps in equity; however, HHS should also provide support for to facilities in doing so. An example that is especially important to NKF is that CMS could make staff assistance available to facilities with disparities in home dialysis access and retention.

COVID-19 Vaccination Measures Request for Information

Accountabilities for dialysis providers to ensure their staff and patients have been vaccinated against COVID-19 are of the utmost importance. It is possible that dialysis patients will need to receive a third dose of the vaccine, in which case an incentive, either public reporting or a traditional quality measure may be appropriate. Rates of full vaccination, not only for COVID-19 but also flu and pneumonia for staff and patients should be reported to CMS and the public so patients have the opportunity to “vote with their feet” and select the dialysis facility at which they feel safest. These data should be available on Dialysis Facility Compare (DFC) rather than only in Dialysis Facility Reports, which would not be interpretable by the average person. However, we are unsure that measures of full COVID-19 vaccination should be added to the QIP. A single QIP measure is already only worth 14 percent of the 2% maximum payment reduction, meaning that any new QIP measure dilutes the importance of all the others. COVID-19 vaccination is extraordinarily important, but a QIP measure may not serve to



change behavior to increase the rates of vaccination, especially because vaccination rates among dialysis patients are already high (anecdotally, over 90%, meaning the measure would already be topped out) and the staff who have not already been vaccinated are highly resistant. Dialysis providers are very motivated to vaccinate their staff and patients. Even in a scenario where dialysis patients require a third dose of vaccine, the experience vaccinating the dialysis population thus far suggests there will be little resistance. Public reporting of full vaccination rates is likely to incentivize pro-vaccination behavior as far as it is possible to change it. If CMS wishes to include COVID-19 vaccination measures in the QIP, a measure of COVID-19 vaccination for dialysis healthcare providers should be prioritized over a measure of COVID-19 vaccination for patients.

End-Stage Renal Disease Treatment Choices (ETC) Model

PPA Home Dialysis Rate – Proposed Inclusion of Nocturnal In-Center Dialysis in Home Dialysis Rate

NKF is an ardent support of the End-Stage Renal Disease Treatment Choices (ETC) model. We are committed to improving patient access to kidney transplantation and home dialysis. Payment incentives, such as those being tested in are essential to overcoming longstanding barriers to patient choice. We are eager for the model to be successful and also for it to represent a transformative change in patients' ability to be treated with the modality of their choice, whether that is a kidney transplant, a home modality, or dialysis provided in a center.

In the first rulemaking on the ETC model, we expressed our thoughts about CMMI's proposal to count self-care dialysis as $\frac{1}{2}$ of a home treatment in the numerator of the home dialysis rate. Self-care dialysis is not home dialysis. While individuals take greater charge of their care, the prescription is still fundamentally a 3x in-center prescription. We did support the proposal because self-care dialysis can be a bridge to home and because self-care dialysis is another option for patients. We have a similar position on the proposal to count in-center nocturnal hemodialysis as $\frac{1}{2}$ of a home treatment. Nocturnal in-center HD is not home dialysis, but it can present an important additional option for patients.

As the community approached the first year of the model, our understanding was that many facilities expanded their capacity for self-care dialysis under the assumption that it would be easier to transition two in-center patients to self-care than to transition one in-center patient to home. Self-care claims were extremely low in 2020, so it would be important to validate this trend using claims data. We have also heard that small and mid-sized facilities are struggling to open home programs. **The priority should be clearing the backlog in certifying home programs.** It is imperative for patient choice that the two largest dialysis providers are not the only options for accessing home dialysis, 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 have effectively encouraged the mid-sized providers to launch home programs, it is absolutely essential that CMS help these facilities to be successful in offering home dialysis rather than incentivizing

another in-center option. In addition, we do not think that counting nocturnal in-center HD in the model will necessarily help small and mid-sized facilities to succeed because nocturnal in-center HD is extremely difficult to staff, perhaps even more so during the ongoing COVID_19 pandemic. Thus, while we don't believe the same trends of facilities possibly emphasizing nocturnal in-center HD at the expense of home would emerge, because nocturnal in-center HD is not home dialysis, counting as ½ of a home claim likely would not achieve the aim of helping small and mid-sized facilities succeed in the model and because we have preexisting concerns about the growth of self-care at the expense of home, we instead recommend the following:

1. Work with CMS to ensure that facilities seeking to open home facilities are able to do so expeditiously
2. CMMI should closely track the growth in self-care dialysis relative to home dialysis in the context of provider size.
3. Depending on trends, CMMI might consider phasing out the ½ credit for self-care dialysis over the course of the model for mid-sized and large facilities.
4. Given the structure of the dialysis market, it is reasonable to create specific provisions in the model for small (<50 facilities) dialysis providers. ½ credit for self-care and nocturnal in-center HD should be available to small facilities throughout the model.

NKF does support in-center nocturnal hemodialysis and would like to see the modality grow beyond .03% of claims in 2020. Nocturnal in-center HD is an important option for patients. We would be more inclined to support ½ credit for nocturnal **self-care** hemodialysis in the ETC model but understand this is limited by current regulations that require an RN to be on site when patients are dialyzing. NKF is a member of the Innovate Kidney Care campaign that is encouraging CMS to modernize the Conditions for Coverage. Revising the Conditions for Coverage may represent an opportunity to open the door to more nocturnal hemodialysis, both self-care and supported by staff.

Performance Payment Adjustment Transplant Rate

The gap between dialysis facilities, nephrologists, and transplant centers through which patients fall is one of the most pernicious problems in renal policy. Incentivizing transplant education, referrals, waitlisting, remaining active on the waitlist, education about living donation, time to evaluation for candidate and donor and many other aspects of accessing transplant and patient experience are important but none will as effectively incentivize transplantation as simply making dialysis facilities and nephrologists accountable for it. This being said, access to the waitlist, i.e., bringing individuals into the system, is and of itself an issue of equity. We appreciate the difficulties of implementing accountabilities for transplantation when the organ supply remains limited. For the time being, we continue to support the transplant rate measure that is the sum of waitlisted patients and living donor transplants. We strongly encourage CMMI to implement a transplant rate measure that holds facilities and Managing Clinicians accountable for the outcome of transplantation as soon as possible.



PPA Achievement Benchmarking

NKF supports raising the achievement benchmarks above Comparison Geographic Areas by 10 percent every two measurement years (MYs) beginning in MY3.

We struggled greatly with the proposal to create two separate achievement benchmarks, one for participants whose aggregation group has more than 50 percent of attributed beneficiary years from beneficiaries who are dual eligible for both Medicare and Medicaid or who receive the Low-Income Subsidy (LIS). **Ultimately, we cannot support this proposal.** We understand the arguments that it is appropriate to risk adjust the model for nephrologists and facilities who serve a greater proportion of individuals who are structurally disadvantaged. We believe that CMS should support independent clinician and providers who serve dialysis patients in order to protect against further consolidation of the dialysis market, however it seems hyperbolic to suggest that facilities in segregated areas will close because of the payment penalties in the ETC model. The risk adjustment that is being proposed is a very blunt and somewhat arbitrary instrument that doesn't account for the SDoH that might be in a provider's ability to change versus those that are not. For example, health literacy barriers that might preclude effective education about home dialysis and transplant can certainly be overcome. Stratified benchmarks, though having a practical purpose, reflect an acceptance of an unjust reality, both within and outside the facility. Notably, not every barrier to home dialysis and transplant is structural. Patients report discriminatory treatment by providers, for example being excluded from education because they don't look like an optimal candidate. Stratifying the achievement benchmarks fully accepts that clinicians and providers are doing everything in their power to reach their low-income and structurally disadvantaged patients. This is unequivocally not the case. Finally, stratifying the achievement benchmarks pulls focus from what CMMI and CMS can do to better serve structurally disadvantaged patients. We believe that reimbursing for staff assistance for home dialysis patients is one way to overcome barriers that may be disproportionately affecting these especially socially vulnerable patients. Targeted safe harbors to provide nutritional services, counseling services, and transportation may also be appropriate to address the root causes of health disparities. However, it is difficult to conceive of a robust policy discussion about how CMS/CMMI can best serve the structurally disadvantaged when the model is risk adjusting these differences away. In conclusion, we do not support the proposal to create achievement benchmarks for model participants serving a greater proportion of dual eligibles and beneficiaries receiving the LIS. We simply believe this proposal is unfair to patients, especially those who have been left behind in so many other ways. As we note in the section on the QIP, CMMI and CMS should engage the community in discussion of what facilities and clinicians can reasonably held accountable for with regards to health equity and bring in other Agencies and government stakeholders to develop a set of incentives to close the gaps that leave patients behind.

PPA Improvement Benchmarking – Health Equity Incentive



As we understand it, the health equity incentive is intended to close within aggregation group gaps group in access to home dialysis and the transplant waitlist among dual-eligibles and those receiving the LIS. NKF supports the proposed health equity incentive. Like the ETC model itself, a combination of “carrots” and “sticks” will likely be needed to change behaviors standing in the way of health equity.

Proposed Kidney Disease Patient Education Services Telehealth Waiver and Additional Flexibilities

NKF appreciates CMMI’s efforts to increase usage of the Kidney Disease Education (KDE) benefit in the context of the ETC model. The steps that CMMI has already taken, waiving the requirement that KDE can only be provided for Stage IV CKD, allowing for other types of professionals such as dietitians and social workers to provide the benefit, and waiving the requirements that KDE cover management of comorbidities and that an assessment of knowledge be provided, are important and will be impactful. We strongly support continued waivers of telehealth restrictions such that qualified staff can provide KDE via telehealth regardless of the beneficiary’s location or the site of service and the proposed waiver on the 20 percent coinsurance. We recommend waiving the 20 percent coinsurance for beneficiaries receiving 1:1 KDE and KDE in groups.

Increasing the billing of KDE will not address the poor quality of and lack of consistency in the education provided through the benefit. NKF supports an accreditation model for kidney disease education whereby educational curriculums, developed by any entity, must be approved by an independent third-party that ensures minimum standards.

NKF does not support billing of KDE by dialysis facilities. We do understand the practical benefits of such a model but, to the point above, are concerned that such an allowance would increase billing of KDE without increasing the quality of the education and further entrench the existing dialysis market structure. Overall, NKF favors an entirely new approach to kidney disease education that is more similar to diabetes education, leveraging group education and trained kidney disease educators. Requests for Information (RFIs) on Topics Relevant to the ETC Model – Beneficiary Experience Measure

NKF strongly supports the inclusion of a home dialysis satisfaction measure in the ETC model. We thank CMS for acknowledging that ICH CAHPS is not appropriate for use with home dialysis patients. The CMMI effort for purposes of the ETC model should complement and not replicate potential efforts to leverage the Home Dialysis Care Experience (Home-DCE) instrument developed by the University of Washington into a home dialysis quality measure for use in the QIP. As we describe in the section on the Quality Improvement Program (QIP) above, the purpose of home dialysis is to allow people whose kidneys have failed the opportunity to live life on their own terms. A beneficiary experience measure is important and can capture important elements of care, but it doesn’t capture other extremely and arguably more important domains of home dialysis quality such as retention, safety, and quality of life (QoL).



Informing Payment Reform under the ESRD PPS

NKF greatly appreciates CMS' effort to explore possible improvements to the ESRD payment model. Our comments follow below.

Calculation of the Low-Volume Payment Adjustment (LVPA)

We share the concerns of MedPAC and others in our community that the low-volume payment adjustment (LVPA) is failing to target low-volume clinics in geographically isolated areas. We fear that these clinics, that serve predominantly Medicare and Medicaid beneficiaries, will be the first to be targeted for closure, a concern that even the rural payment adjuster cannot overcome. We reiterate a request that we have made in previous years to remove the rural payment adjuster, which is not required by statute, and instead combine the funds from the rural and LVPA adjusters to fund a tiered LVPA that applies the most dollars to facilities that are serving a critical patient need, but also likely operating at a loss. Though we remain concerned that a combined adjuster that is targeted to number of treatments is gameable and would have to be closely monitored by CMS, we are encouraged by data from MedPAC that suggest a combined adjuster that targets facilities more than 5 miles from the nearest facility regardless of ownership would redistribute LVPA payments to isolated facilities and mitigate the "cliff effect."²²

Calculation of the Case-Mix Adjustments

NKF has longstanding concerns that the case-mix adjusters are not serving their intended policy purposes. In addition to adding very little value for patients, is extremely time consuming for facility staff to obtain the information needed to report on the adjusters meaning that they are rarely documented. While we believe it would be too preliminary to eliminate the case-mix adjusters wholesale, we do believe that CMS should initiate a discussion of the adjusters that are true drivers of high costs included in which is a conversation about how the use adjusters can be operationalized for practical purposes. We do continue to believe that the outlier pool is an important tool for supporting the treatment of high-cost patients and that questioning the extent to which the outlier pool and case-mix adjusters are redundant is reasonable.

Calculation of the Outlier Payment Adjustment

NKF continues to support the outlier payment adjuster as an appropriate protection for patients who utilize significantly more services than the average patient. We share the concern of the larger nephrology community that the outlier threshold is too high, resulting in the underpayment of the outlier pool and the withhold of dollars that could otherwise go towards improving patient care.

NKF thanks CMS for its work on the ESRD Prospective Payment System and for the care CMS takes in making sure the needs of ESRD patients are met. We always welcome the opportunity to collaborate

²² <http://www.medpac.gov/docs/default-source/default-document-library/dialysis-april-2019-public.pdf?sfvrsn=0>



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and would be glad to discuss any of the issues raised in this letter further. Please contact Miriam Godwin, Health Policy Director, at miriam.godwin@kidney.org.

Sincerely,

Kevin Longino
NKF CEO and Transplant Patient