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NATIONAL KIDNEY FOUNDATION®

August 22, 2022

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
Room 314G-01
200 Independence Avenue SW
Washington, DC 20201

Re: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

Dear Administrator Brooks-LaSure,

The National Kidney Foundation (NKF) appreciates the opportunity to provide our perspective on the proposed CY2023 ESRD rule. The annual ESRD rule is an important policy vehicle for improving the patient experience of kidney disease. In this letter, we highlight major trends that affect kidney patients and, in that context, offer recommendations for how CMS can use public policy and specifically the ESRD rule to improve kidney care on behalf of patients.

Kidney Care Trends

1. COVID-19 and its sequalae have had a devastating impact on dialysis facilities causing staff and supply shortages and facility closures. Staffing continues to be a pervasive problem, especially impacting patients who wish to use home modalities but who are unable to be trained due to a lack of nurses who are familiar with home dialysis. Inflation presents a significant challenge to both consumers and suppliers.
2. The 7-2 Supreme Court ruling in *Marietta Memorial Hospital v. DaVita* that allows employer group health plans (EGHPs) to limit coverage for maintenance dialysis under Medicare Secondary Payer law is likely to influence the ability of patients to remain on an EGHP during the 30-month Coordination of Benefits (COB) period, is a potential threat to patient choice, and may impact the stability of the dialysis market. Though the implications of the ruling have yet to play out, we have preliminary concerns that the potential loss of income from the COB period may disproportionally impact rural facilities meeting a critical patient access need, which already have negative Medicare margins and have struggled to maintain operations through the COVID-19 pandemic.
3. Kidney transplantation and home dialysis remain underutilized treatments for irreversible kidney failure. Ideally, nephrologists would take the lead role in providing empowering education and support for patients who wish to pursue these modalities. Many nephrologists do take on this primary role *and* the majority of patients still spend much more time in the dialysis facility than they do with their nephrologist. For practical purposes, dialysis facilities

have a critical role in enhancing choice of the modality that aligns with patients' values and preferences. Further, earlier diagnosis in the primary care setting can better prepare patients for optimal dialysis starts, access home dialysis, and prepare for transplantation (including pre-emptive transplant).

4. Novel financial arrangements are changing kidney care incentives. The transition of end-stage renal disease (ESRD) patients to Medicare Advantage (MA) is bringing care management companies to the table. ESRD subsequent to crash starts (e.g., when a patient learns their kidneys have failed in the hospital and begin dialysis in that capacity), is extremely expensive for health plans. Care management companies share in the savings when crash starts can be more effectively managed or prevented. Traditional dialysis companies are partnering and incorporating with care management companies, changing the kidney business model. The approximately eighty participants in the Innovation Center's Kidney Care Choices (KCC) model and the 30% of nephrologists and dialysis facilities aligned to the ESRD Treatment Choices (ETC) model have novel incentives to invest in ESRD prevention, optimal starts, home dialysis and transplant.
5. Consolidation within the dialysis industry continues to present a challenge to patient choice. Though improvements have been made (for example, the percentage of patients initiating with peritoneal dialysis (PD) has doubled over a decade), in 2019, 85% of incident ESRD patients initiated with in-center hemodialysis (ICHD). Horizontal integration threatens the independent dialysis market, anti-competitive behaviors are a barrier to new market entrants and vertical integration may one day create new barriers to patient choice of dialysis machine. At the same time, narrow networks in Medicare Advantage plans have the potential to inhibit patient choice.

<u>NKF's Priorities</u>

In general, patients tell us that status quo kidney care is not working for them. Patients want to avoid dialysis whenever possible; they want access to meaningful innovations that improve their quality of life, offer greater choice, and significantly enhance patient-centricity. Though addressing the range of these challenges is not entirely in scope for the ESRD rule, CMS can act through the regulatory process to make improvements that are aligned with patient goals. In the final rule, NKF recommends that CMS:

- Ensure the Substantial Clinical Improvement (SCI) criteria for the Transitional Payment for Innovative ESRD Equipment and Supplies (TPNIES) account 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 measures 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 to improve its patient-centricity
- Modify Kt/V Dialysis Adequacy Measure to allow for greater flexibility to prescribe individualized dialysis prescriptions.

Comments on End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

Proposed Rebasing and Revising of the ESRD Market Basket & Update to the ESRD PPS Base Rate

NKF supports the proposed rebasing of the ESRD market basket based on CY2020 Medicare Cost Report (MCR) data. We acknowledge that CMS is constrained by the need for a complete year of cost report data though we would note that while patients are, for the moment, insulated from the impact of inflation, dialysis companies are not. Increased costs associated with supply chain and staffing challenges are straining providers and resulting in scaling back of shifts, thus limiting options for patients and their families. NKF encourages CMS to carefully review recent data regarding the costs of delivering care to ensure that the final rate is adequate to support delivery of high-quality patient care.

Outlier Payment Refinement and Annual Update to the Outlier Policy

NKF continues to support the outlier payment adjuster as an appropriate protection for patients who utilize significantly more services than the average patient and applauds CMS' proposal to adjust its methodology for calculating the fixed dollar loss (FDL) amounts.

Proposed Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for CY 2023 Payment

NKF enthusiastically supported the creation of TPNIES and appreciate that CMS has created a pathway and approved a new technology for home dialysis. We continue to hope that the payment adjustment will incentivize additional innovation in dialysis equipment and supplies and home dialysis machines From its inception, we have supported the substantial clinical improvement (SCI) criteria as the basis for approval. However, we remain concerned with the evidence needed to meet the SCI criteria. In the three years following FDA approval during which a product can qualify for TPNIES, clinical trial evidence beyond what was needed for FDA clearance is an unrealistic expectation.

While it would be preferable to prioritize innovation with robust evidence from a randomized control trial (RCT) of improved clinical outcomes (such as technology that could reduce hospitalizations related to cardiovascular conditions, eliminate infections, or dramatically improve Health Related Quality of Life), it 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 patientIn 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."[1] Per the authors, technologies that simplify the process of home dialysis, generate smaller and quieter machines, aid with self-cannulation, provide on-demand dialysate, and allow for remote adjustment of the dialysis prescription are all crucial for improving the initiation and support of home dialysis.[2]

We urge CMS to keep in mind the needs of current and potential home dialysis patients 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 to Patient Success**	**Innovation to Facilitate Patient Success**
Peritoneal Dialysis (PD)	Lack of storage space for PD supplies Inability to lift heavy boxes/bags	On-line generation of dialysate which eliminates the need for large bags of dialysate
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

[1] https://linkinghub.elsevier.com/retrieve/pii/S0272-6386(18)31060-6
[2] Ibid.

		-On-line generation of dialysate which eliminates the 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

While NKF does not comment on any specific product seeking TPNIES, we do offer the following general comments. Patients want the ability to access therapies that enhance their quality of life. Different technologies offer different benefits with regard to ease-of-use, impact on recovery time, and reduction in side effects such as pruritis or restless leg syndrome.

Patients also 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. Technologies that promote early detection of peritonitis and BSI could transform the patient experience and increase the likelihood of success on home dialysis modalities.

We reiterate that evidence in support of these outcomes is not likely to come from RCTs, but that CMS should exercise appropriate flexibility in deliberating the kinds of evidence it will accept in assessing SCI.

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

NKF reiterates its concerns about 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. While the percentage of patients with AKI who are appropriate candidates for home dialysis is not large, there are patients for whom this is a safe and effective option. We encourage CMS to allow a treatment pathway and reimbursement for the treatment of an AKI patient with home dialysis if deemed medically appropriate.

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Request for Information About Addressing Issues of Payment for New Renal Dialysis Drugs and Biological Products After Transitional Drug Add-On Payment Adjustment (TDAPA) Period Ends

The Transitional Drug Add-on Payment Adjustment allows patients to access novel and innovative therapies that ease their experience with dialysis. We share concerns raised by others in the kidney community, however, that the current methodology creates potential access barriers following the transitional period. We applaud CMS for considering solutions to this challenge.

Request for Information on Advancing Health Equity Under the ESRD PPS

NKF is strongly committed to reducing myriad barriers that racially and ethnically diverse communities face in achieving kidney health. These barriers span the spectrum of kidney risk factors and kidney disease therapies, beginning with societal factors that put people at risk for kidney disease and extending through accessing a kidney transplant.

We appreciate CMS' desire to address, define and collect accurate and standardized, self-identified demographic information as a component of a larger strategy to advance health equity under the ESRD PPPS. However, equity will only be achieved when dialysis facilities serving structurally disadvantaged patients have the incentives, resources, and support needed to close gaps in care - both those gaps identified by the QIP and those which patients report but are not described by empirical data.

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.

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. Ideally, stratifying the QIP would allow for targeted incentives and interventions to close the gaps identified by the stratification. Race, ethnicity, and dual eligibility may be data points that are too blunt to decipher the underlying cause of identified disparity. Nonetheless, 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 continental United States, for example people from Puerto Rico.

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 National Kidney Foundation's 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, assessing and addressing Social Determinants of Health effectively also requires adequate social worker staffing ratios. Finally, CMS should strongly encourage use of the ICD-10 CMS Z codes by dialysis facilities to report on dialysis patients' social needs. Resources can then be allocated to those facilities to address these disparities.

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.

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Comments on the ESRD QIP

Updates for the PY 2025 ESRD QIP

NKF recognizes that mortality, hospitalization, and other rates were impossible to interpret in the face of the public health emergency prompted by SARS-CV-19. In the initial years of the pandemic, it was appropriate to suppress these measures. However, as SARS-CV-19 becomes endemic, it is important that providers report and that CMS share information with patients and the public about dialysis provider performance. NKF's comments and recommendations related to those measures is outlined in more detail below.

Patient & Family Engagement			
	NKF Supports (Y/N)	*Comments*	*Recommendations*
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.**

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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.	Even the highest quality dialysis facilities struggle with their obligation to reduce readmissions, in part because hospitals do not always meet their shared obligation to reduce readmissions. 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. **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.** **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	**NKF recommends that the measure should be stratified for causes that are actionable by the nephrology care team**. As a tradeoff for giving the

		preventing hospitalizations is appropriate.	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**	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. Dialysis facilities, nephrologists, and transplant facility staff share the responsibility of ensuring patients are waitlisted and maintain their health for transplant. We 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	**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. NKF does acknowledge that rural dialysis facilities tend to fare poorly on the measure. Dialysis patients in rural 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. **We recommend that CMS undertake an assessment of rural versus urban disparities in the measure.** Given the important of rural facilities for patient access, a risk adjusted PPPW

		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. NKF supports ETC model. Its implementation allows 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.	measure could 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.
Clinical Depression Screening and Follow-Up	**N**	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.	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 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.
Clinical			

Standardized Transfusion Ratio (STrR)	**N**	NKF is extremely concerned that the STrR 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.	We do not believe it is appropriate to use the STrR measure 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. Further, a transfusion avoidance measure does not consider a patient's quality of life, or the cardiovascular risks associated with low hemoglobin levels. We are sensitive to the fact that CMS has a statutory obligation per the 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. 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. 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.**[3]
Kt/V Dialysis Adequacy Comprehensive	**N**	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 pooled measurement is distorted and no longer aligns with the KDOQI Guidelines, which recommend separate adequacy targets for hemodialysis and peritoneal dialysis.[4] 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.	**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.** **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 significant residual kidney function**. With regard to hemodialysis, the strict single target of spKt/V ≥ 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**.** For hemodialysis patients, a consensus on targets that account for residual kidney function and lead to optimal outcomes has not been well defined

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

[4] 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

		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.	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.** Further, we urge CMS to use the measure suppression period to assess the impact of reduced reliance on Kt/V.
Hemodialysis Vascular Access: Standardized Fistula Rate	**N**	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.	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 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. These recommendations align with the updated KDOQI Vascular Access Guideline, which emphasizes that a patient's access needs stem from the creation of an individualized ESKD life-plan.[5] 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. The exclusions we recommend could be captured by modifying EQRS 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. We do believe that, in conjunction, facilities should be required to continue

[5] https://www.kidney.org/professionals/guidelines/current-KDOQI-projects

			to attempt education on the risks of catheters and the benefits of AVF or AVG at least annually.
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 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. However, the long-term catheter rate measure 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.
Hypercalcemia	**Y**	NKF supports hypercalcemia as a reporting measure only as the hypercalcemia measure is topped out.	**NKF thanks CMS for removing hypercalcemia as a clinical measure and replacing it as a reporting measure.**
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.[6] 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 reporting 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.**
NHSN Dialysis Event Reporting Measure	**N**	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	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. **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.**

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

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 on Home Dialysis Quality

NKF strongly supports the development of home dialysis quality measures. Quality domains relevant to patients as they relate to home dialysis are:

1. Home dialysis access
2. Clinical care
3. Safety
4. Retention
5. Quality of Life (QoL)

Home Dialysis Access

A home dialysis access measure 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

Safety

The current safety domain need only include a measure of peritonitis to evaluate safety across dialysis settings. The Centers for Disease Control and Prevention (CDC) should expand the National Healthcare Safety Network (NHSN) to surveil bloodstream infections in home hemodialysis (HHD) patients. Novel approaches to infection surveillance among PD and HHD patients should be implemented concurrently so as to not unfairly penalize any one modality.

Retention

A retention measure helps assess the quality of home training, one of the most important factors in a person's ability to be successful on home dialysis. It also incentivizes facilities to take steps 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 measure of home dialysis satisfaction, perhaps based on the Home Dialysis Care Experience (Home-DCE) instrument developed by the University of Washington. While the Home-DCE is a good starting point, it currently does not capture outcomes or the patient experience. The goal of a home satisfaction measure 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 encourage CMS to 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

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affected by processes outside of dialysis, and does not necessarily correlate with quality of care; 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.

Thank you, again, for the opportunity to comment on the proposed CY 2023 proposed rule, and for CMS' efforts to ensure high-quality care for dialysis patients. We look forward to working with CMS to continue to improve the PPS and the QIP. Please contact Sharon Pearce at Sharon.Pearce@kidney.org to further discuss any of NKF's positions or recommendations.

Sincerely,

Kevin Longino
CEO and Transplant Patient

Paul M. Palevsky, MD
President