NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

The Honorable Seema Verma
200 Independence Ave SW
Room 314G-01
Washington, DC 20201

September 4, 2020

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

Dear Administrator Verma:

Each year, the End-Stage Renal Disease (ESRD) prospective payment system (PPS) offers dialysis patients and the professionals who care for them the opportunity to provide their feedback on the issues that matter most to patients. As we are each year, the National Kidney Foundation (NKF) is grateful for the opportunity to share our comments on the proposed calendar year (CY) 2021 ESRD Prospective Payment System.

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).

Dialysis is a lifesaving but often arduous treatment for the over 500,000 U.S. patients who rely on it. We offer the following comments in the spirit of improving patient access to the kidney replacement therapy (KRT) of their choice, whether that be home dialysis, in-center dialysis, a kidney transplant, or conservative management, as well as ensuring that all dialysis is less burdensome, safer, and more patient centered.

Our comments this year are focused on the continued drive towards home dialysis. In the following sections, we elaborate on our hope that CMS will cogitate on the meaning of innovation to home dialysis patients and interpret TPNIES eligibility with the specific needs of these patients in mind, as well as recommendations for future efforts achieve parity between home and facility-centered quality measures in the Quality Incentive Program (QIP). A priority for NKF over the next year is to initiate a discussion with CMS and other patient, professional, and industry organizations on policy solutions and incentives that enable dialysis facilities to provide staff assistance to patients using home dialysis.

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

Patients' lives should not have to begin and end with dialysis, but this is the reality for too many Americans who have to give up their jobs, hobbies, travel, and other contributors to their quality of life to travel back and forth to a 4 hour dialysis treatment 13 times a month. We strenuously support policy solutions that enable more patients to access home dialysis and be successful on the modality and prescription of their choice so they can live the lives of their choice. We believe that dramatically more patients could and would want to do dialysis home if provided with the right empowerment, education, and support. Staff-assisted home dialysis is the single most impactful and patient-centered change we can make to provide more support to many more patients so they can benefit from the advantages that home dialysis provides. This is especially true because 40 percent of the dialysis population is elderly and at least 30 percent of the dialysis population is single or widowed. These are patients who may prefer home dialysis but who are limited by the lack of a care partner to support them.

We ask for CMS' assistance with the first step of this endeavor, which is to provide clarity to the provider community on the circumstances under which dialysis facility staff can aid patients in their homes. We believe that this kind of arrangement poses *some* risk under the beneficiary inducement statute because staff-assisted home dialysis is specifically excluded from coverage in the PPS by the Medicare Benefit Policy Manual, but also that CMS view staff assistance as permissible under some circumstances. We would greatly appreciate CMS' clarification on what these circumstances are so that we can move forward identifying other barriers. In the future, we envision state-by-state changes to scope of practice laws to allow professionals other than an RN to provide this kind of assistance and an add-on payment to the PPS to fund it. In the interim, we hope to come to a better understanding of costs and benefits and to learn from arrangements where a staff-assisted home dialysis model is already being utilized, for example in Skilled Nursing Facilities (SNFs).

Summary Recommendations

Inclusion of Calcimimetics into the ESRD PPS Bundled Payment

The National Kidney Foundation (NKF) appreciates the care with which CMS is transitioning calcimimetics into the bundle. Approximately 30 percent of hemodialysis patients use calcimimetics; this is true of in-center and home hemodialysis (HHD) alike, as the HHD population despite its relative youthfulness, is enriched with people who have accumulated multiple years on in-center hemodialysis beforehand and developed more advanced secondary hyperparathyroidism.. In the extremely complex and evolving environment of mineral and bone disorder (MBD), patient access to these products may be important, despite the current lack of evidence beyond short-term assessment on a surrogate endpoint for the benefits of calcimimetics therapy. Etelcalcitide has had significantly greater penetration into the non-profit over the for-profit environment. We urge CMS to proceed with the greatest caution to limit the financial pressures on non-profit and home facilities and to honor patient preference for the IV product. In subsequent comments on the Quality Incentive Program (QIP), we note that the hypercalcemia measure has topped out and should be retired. An additional advantage of doing so is that etelcacitide is more effective at dropping serum calcium than cinacalcet, which may

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

be driving its use. By retiring the measure, CMS can relieve the possible incentive favoring the IV product and thus some of the financial pressures that facilities may experience as the TDAPA period concludes. Doing so would allow facilities to proceed with what is truly in the best interest of the patient.

In establishing the utilization rate, we recommend that CMS use the most recently available 12 months of claims data rather than the proposed data from CYs 2018 and 2019 as our understanding is that these data do not reflect current utilization. Doing so would have the additional advantage of aligning with CMS's proposal to use the most recently available ASP data for establishing price as well as CMS' rationale for providing a three-year TDAPA period. We believe it is important to derive utilization data based on the most recent trends because for any new product, the patterns of physician and patient uptake take time to grow and then stabilize. We encourage CMS to use the most recent publicly available 12 months of data when assessing utilization for all innovative products and in this specific case, calcimimetics.

Finally, and most importantly, any increase to the bundle impacts patient finances. Calcimimetics are not prescribed to every dialysis patient, but every dialysis patient will see their cost sharing increase as a result. This despite the lack of clinically important benefit and the potential to take money from other aspects of care that might be of greater benefit to patients. While the increase may amount to just a few dollars, many dialysis patients will notice and be affected by the additional financial burden. Much attention over many years has been paid to the methodology for calculating utilization and price of calcimimetics as they are transitioned into the bundle. We ask that CMS not lose sight of the impact of these changes on our most important stakeholders: patients and their families.

Proposed Changes to the TPNIES Eligibility Criteria

NKF ardently supports the Transitional Payment for New and Innovative Equipment and Supplies (TPNIES). Like any other patient population, patients with kidney failure deserve the opportunity to benefit from innovations in science and technology that have the potential to improve their lives. We are extremely grateful to CMS for proposing thoughtful approaches to the design and implementation of the pass-through payment.

NKF supports the specific proposed changes to the eligibility criteria for TPNIES including alignment with the changes to the HCPCS Level II coding guidance. We also have no philosophical objection to CMS' proposed definition of "new" as within 3 years of the date of FDA marketing authorization. NKF continues to support Substantial Clinical Improvement as described at 42 CFR 413.236(b)(5) and 412.87(b)(1)) as the basis of TPNIES eligibility.

It is, however, of the utmost importance that the eligibility criteria for TPNIES are interpreted and applied in a manner that strikes the balance between creating a pathway for payment that encourages innovation in dialysis and incentivizing the kind of innovation that genuinely makes a difference in patients' everyday lives.

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

NKF is sympathetic to the challenges of developing a policy that achieves both these goals. In a post on the Home Dialysis Central KidneyViews blog, Dr. Eric Weinhandl notes that "TPNIES will be effective if and only if devices qualify."[1] NKF agrees with this position. If the bar for TPNIES eligibility is too high, most dialysis patients will not benefit from new and innovative equipment and supplies, both because dialysis facilities will lack an incentive to invest in existing marketed technology, and because the lack of an achievable pathway for payment will act as a disincentive to venture firms and companies that might otherwise see an opportunity in the ESKD space. This approach is neither in the best interest of patients, nor the success of the TPNIES policy. Conversely, if the bar for TPNIES eligibility is too low, innovators lack an incentive to pursue and substantiate with evidence the kind of advances that make a meaningful difference to patients. Innovation is a laudable goal in healthcare, but not all innovation is created equal. What NKF seeks are new technologies that allows dialysis patients to live their lives with as few limitations as possible, ideally while improving ESKD patient outcomes over time and generating cost savings to CMS and commercial payors.

We believe the solution to this conundrum lies in how CMS interprets the Substantial Clinical Improvement (SCI) criteria and how CMS works with companies to achieve it. Our understanding is that companies can meet TPNIES eligibility if CMS views the product as having met one of four criteria: (1) the product provides a new treatment option for patients who do not benefit from existing treatments, (2) the product diagnoses patients sooner, (3) the product results in improved clinical outcomes, or (4) the totality of the evidence suggests that the product substantially improves the diagnosis or treatment of Medicare beneficiaries. We do not believe that criteria 1 or 2 are likely to be relevant to most products that would be paid for through a pass-through payment associated with the ESRD bundle. Leaving criteria 3 and 4, **we urge CMS not to focus on criteria 3 at the exclusion of criteria 4, especially for home dialysis devices.** Certainly, in an ideal world, NKF would ask CMS to prioritize innovation with robust evidence of improved clinical outcomes. For all dialysis patients, regardless of modality or prescription, technology that could reduce hospitalizations related to cardiovascular conditions or infections 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.

We hope that the availability of TPNIES will become one piece of a more modern kidney care paradigm in which new and innovative dialysis technologies are deployed in a context where kidney failure is prevented more often, chronic kidney disease (CKD) and its complications and comorbidities are better managed, more patients benefit from preemptive transplant, transitions to dialysis are more patient-centered, dialysis is offered in different settings, and as many patients as possible are supported in their home dialysis journeys. It may be a more reasonable proposition for a company to demonstrate improvements in clinical outcomes as part of a multipronged approach to higher value

[1] https://homedialysis.org/news-and-research/blog/374-tell-cms-what-home-dialysis-machine-innovation-means-to-you

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

ESKD care. For example, a product that contributes to lower rates of technique failure among PD patients and is used in an environment where paid staff are able to assist patients in their homes might shower greater evidence of improvement in peritonitis than if the product is evaluated in an environment where PD is still relatively uncommon compared to facility-based dialysis.

As we work towards a future where higher value dialysis care is the norm, we urge CMS to carefully evaluate a potential TPNIES-eligible product holistically, understanding the many factors that contribute to clinical challenges of dialysis as it is delivered in 2021, the unique complexity of home dialysis, the rapidly changing environment, and the barriers of evidence collection. In this vein, we ask CMS to recognize that most applicants will not come to the TPNIES application process with large, long-term randomized control trials (RCTs). Smaller patient preference studies or evidence of improvements in patient reported outcomes (PROs) should also suffice. Additionally, it would not be appropriate for CMS to use the 3-year "newness" window as a reason to require companies to produce these data, which would run counter to the intent of the policy to provide patients with access to innovative products on a more rapid timeline. As resources allow, we recommend that CMS open a two-way dialogue with product manufacturers who are interested in pursuing TPNIES such that manufacturers understand the types of evidence CMS wants to see. These meetings could be structured like FDA meetings with drug and device companies or alternatively as the Medicare Administrative Contractors (MACs) have done in the past when developing LCDs. FDA supports the company throughout the development process and thus the company is more likely to meet FDA's standards for evidence of safety and efficacy. We do acknowledge that CMS may face barriers to implementing such a program, as FDA's capacity is funded by user fees. No such mechanism exists at CMS, as far as we are aware.

In simple terms, our request is that CMS work with organizations like ours to inform CMS' understanding of the dialysis landscape and the types of innovation that are important to dialysis patients and evaluate the SCI criteria in that context. CMS' interpretation of the SCI criteria can and should evolve with time to meet the changing needs of dialysis patients and to continue to "raise the bar" for manufacturers of ESRD equipment and supplies in a manner that matches pace with the innovator community's appetite for risk and investment in dialysis. We believe that this is the right approach to holding companies accountable for impactful innovation while creating a stable reimbursement pathway that encourages investment in dialysis and uptake of new and innovative equipment and supplies.

<u>Proposed Expansion of the TPNIES for New and Innovative Capital-Related Assets That Are Home Dialysis Machines When Used in the Home for a Single Patient</u>

NKF strongly supports the proposed expansion of TPNIES to encompass capital-related assets that are home dialysis machines. Since TPNIES was first proposed, NKF has advocated for home dialysis machines to qualify for it because of the potential for improvements to dialysis machines that could make home dialysis specifically more feasible and less burdensome for patients. We thank CMS for responding to the community's desire to see capital assets included in TPNIES. CMS' change to the

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

eligibility criteria for TPNIES to allow home dialysis machines to qualify is a significant step in incentivizing impactful innovation that matters to patients.

In line with our comments in the previous section, we believe it is especially critical that CMS interpret the SCI criteria with special flexibility when the product under consideration is a home dialysis machine. The SCI criteria may place the manufacturers of home dialysis machines under duress to demonstrate clinical improvement when impactful innovation in home dialysis often has little to do with outcomes and more to do with access and feasibility. This point harkens back to a point made previously that CMS should benchmark its interpretation of the SCI criteria to the needs of patients in today's home dialysis landscape. As CMS knows, home dialysis is grossly underutilized compared to facility-based dialysis. There are many well-documented barriers to home dialysis, including most significantly, the economic incentives that favor in-center dialysis, but also lack of exposure to home dialysis among patients and professionals, lack of patient and caregiver empowerment and support, unstable or inadequate housing situations that do not allow for storage of supplies, fear of cannulation, and many others. These may not be the barriers to home dialysis in ten years, but they are the barriers of today. We recommend that home dialysis machines that can overcome current barriers to home dialysis qualify as substantial clinical improvements for the time being. An unbiased patient organization could assist CMS with identifying the most important of these barriers for use in CMS' evaluation of the types of technologies that are truly impactful to patients' lives on home dialysis versus those that are not.

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 identifies some 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
Peritoneal Dialysis (PD)	Connection of PD catheter can contribute to infections	Automating the connection process which reduces infection risk
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 -Monitoring technology that provides assessment of

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

		biochemical parameters and volume status -Automatic adjustment of ultrafiltration to optimize fluid removal
Home Hemodialysis (HHS)	Portability	HHD machine with a weight of 10-20 kg

Regarding subsection 2 on pricing of new and innovative capital-related assets that are home dialysis machines, we are concerned that the invoice-based approach gives too much discretion to the MACs to set difference prices and that those inconsistences may undermine the success of the policy. Public transparency may help ensure that the payment rates do not differ too widely across MACs. Accordingly, we recommend that CMS instruct the MACs to publish a database online that provides a discrete TPNIES payment amount, no later than March 31 of the first year of TPNIES eligibility. We further encourage CMS to modify the language that allows MACs to set prices based on "charges and payment amounts for other equipment and supplies that may be comparable or otherwise relevant." We believe that this runs counter to the intent of TPNIES to pay for equipment and supplies that represent a substantial clinical improvement over existing technology.

Finally, we recommend that CMS adopt a three year rather than two-year TPNIES period. We want to encourage small companies with novel ideas about how to improve quality of care to enter the dialysis space. Our understanding from smaller companies is two years is not sufficient time to implement a nationwide distribution infrastructure. This may act as a disincentive for a facility to acquire the technology, since the facility will only receive a portion of the two-year TPNIES coverage by the time the manufacturer is able to make the product available. Extending the coverage period would help level the playing field between small innovators and large, global manufacturers with an existing support and distribution footprint.

Proposed CY2021 ESRD PPS Update

Wage Index

NKF appreciates CMS' careful efforts to implement OMB Bulletin No. 18-04. We agree with CMS that allowing for a transition that cushions the impact of the change in wage index for the 34 facilities impacted by it is appropriate. It is understandable why CMS is proposing a less administratively complex methodology of managing the transition given the relatively small proportion of dialysis facilities that will be impacted. If the total change in payment is ten percent or less for all facilities, a methodology that caps the decrease in a facility's wage index at 5 percent in the first year makes sense. However, by CMS' own accounting, at least one facility will see a 17 percent decrease in the wage index, which simply defers the burden of the transition to the second year. While providing an extra year for the facility to adjust to the change is helpful, we do note that facilities that see a drop in wage index payments in the second year and that are located in states without staffing requirements, the negative implications for hiring and retention of staff will be significant. We would prefer CMS apply the blended rate methodology to manage the transition, but could support the 5 percent cap

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

approach if the staff time saved by using a less complex methodology is redirected to addressing higher priority issues for NKF, such as securing staff assistance for home dialysis patients or developing a flexible approach to interpretation of the SCI criteria for TPNIES.

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. 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. We believe this issue will be exacerbated by the significant increases to the FDL and MAP thresholds that have been proposed by CMS. An analysis by Kidney Care Partners (KCP) found that patients whose treatments have in the past qualified for outlier payments would no longer quality because of the increased thresholds. We also expect that, as proposed, the outlier pool will be consumed by IV calcimimetics. This effect is concerning not only because the outlier payment is intended to cover all the needs of a higher cost patient, but also because it diverts resources from facilities that have not historically used IV calcimimetics. The outlier pool is a protection for all patients, not just for patients using IV calcimimetics and not just for patients using high cost pharmaceuticals. As a preliminary step for the purposes of the CY2021 final rule, we recommend that CMS consider much lower thresholds than have been proposed. This will not prevent IV calcimimetics from consuming the outlier payments but would at minimum allow other high cost patients due to other causes to also qualify. A larger discussion of a solution to the outlier pool being dominated by a single product is warranted, perhaps through a TEP or in another forum.

Proposed Changes to the Low-Volume Payment Adjustment (LVPA)

Low-Volume Payment Adjustment (LVPA)

NKF supports the proposed flexibilities for facilities without three years of cost reports to attest to their low-volume status. 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."[2]

[2] http://www.medpac.gov/docs/default-source/default-document-library/dialysis-april-2019-public.pdf?sfvrsn=0

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

Case-Mix Adjusters

NKF has longstanding concerns that the case-mix adjusters are not serving their intended policy purposes. We do not believe that the comorbid case-mix adjusters for gastrointestinal tract bleeding with hemorrhage, hereditary hemolytic or sickle cell anemia, pericarditis, or myelodysplastic syndrome are adding any value for patients or the facility. We recommend that the comorbid case-mix adjusters be removed. Further, it appears that the cost reports as the data source for the age, BSA, and BMI case mix adjusters are neither reliable nor reflective of the patient characteristics that clinicians believe are drivers of high costs. These adult case-mix adjusters should similarly be suspended. When a facility treats a patient associated with greater spending, these costs can be paid from the outlier pool. We note that this strategy would not be possible with the FDL and MAP thresholds proposed for CY2021.

<u>CY 2021 Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)</u>

NKF supports the proposed CY2021 per treatment payment rate of $255.59 for patients with AKI. AKI patients are higher cost patients, so these additional dollars will allow facilities provide the more frequent labs and intensive nursing AKI patients require. We remain concerned that the proposed payment could act as a disincentive to allowing patients to recover kidney function, especially as AKI patients are not generally prescribed calcimimetics. This may have special implications for COVID-19 patients who are discharged to outpatient dialysis. Much remains unknown in this space, from the post-hospitalization course of AKI to the burden of COVID-19 on outpatient dialysis. We believe it would be prudent for CMS to pay close attention to how AKI is managed in dialysis facilities in 2021.

For the purposes of the COVID-19 pandemic, NKF continues to support payment through the PPS for AKI patients using home dialysis, specifically PD. As CMS is aware, many hospitals have had to turn to PD when they supersede their capacity to handle AKI cases. We share CMS' concern regarding the frailty of these patients and the risks of performing dialysis in the home, however are equally if not more so concerned about putting patients recovering from COVID-19 through a second procedure to place a hemodialysis access prior to discharge, solely so these patients can dialyze in a facility. Under the extenuating circumstances of the PHE, we recommend that CMS temporarily allow for AKI patients to pursue PD in the home if the patient and nephrologist agree it is safe to do so and the home setting is the patient's choice.

IV. End-Stage Renal Disease Quality Incentive Program

NKF strongly supports value-based purchasing (VBP) programs such as the Quality Incentive Program (QIP) that tie a portion of a provider's Medicare reimbursement to indicators of quality. NKF enthusiastically embraced the proposed ESRD Treatment Choices (ETC) payment model because of its understanding that achieving high value and high-quality kidney care is tied closely to overcoming the incentives that favor in-center dialysis over transplantation and home dialysis. In a broad sense, the QIP is designed for in-center patients. While that may be appropriate now, when most dialysis

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

patients dialyze in facilities, elements of the QIP will increasingly become obsolete as more patients select home dialysis.

We are extremely grateful to CMS for its efforts to administer the QIP over the past 8 years. Moving forward, we hope to work with CMS to improve the program such that it is more closely tied to patient choice and to quality measures that reflect the patients' values and preferences for care. The QIP must evolve with greater utilization of home dialysis, so that it does not inadvertently incentivize facility-based dialysis over other treatment modalities**.** NKF is eager to work with CMS to ensure that all dialysis patients, regardless of the setting in which they dialyze, are receiving the highest quality of care.

Elements of Quality Care for Home Patients

In the process of developing these comments, NKF's Public Policy Committee discussed aspects of high-quality home dialysis that differ from in-center dialysis and what concepts could, in the future, form the basis of home dialysis-centered quality measures. A common tension in quality measurement is seeking the balance between individual patient preferences and measures that reflect standardized elements of high-quality care. This is a challenge that is amplified when developing measures specifically for home dialysis because a key element of patient-centered home dialysis is the flexibility afforded to the patient.

We acknowledge that the inclusion of a home dialysis QIP measure that assesses the rate of patients on home dialysis in a facility or in facilities under common ownership would be the most straightforward mechanism for implementing a home dialysis quality measure. In a landscape where economic incentives favor in-center dialysis, access to high-quality home dialysis is an important metric of patient-centered dialysis care. NKF's comments on the ETC payment model reflect our belief that while a home dialysis measure can be a valuable preliminary step in improving patient choice, access cannot be the exclusive measure of home dialysis quality. Home dialysis is much more flexible and complicated than in-center dialysis. We have identified elements of home dialysis below that we believe are common to home patients, regardless of home modality or home prescription, and that are also important contributors to patient outcomes on home dialysis. Recognizing the challenges inherent in developing these measures, NKF would welcome the opportunity to assist CMS with this endeavor.

- Assessment of the percentage of patients who declare a preference for home dialysis who are successfully trained in a timely manner.
- Patient and caregiver access to standardized elements of high-quality home training
- Assessment of the adequacy of home dialysis training, including:
    - Patient's perception of whether the training was sufficient
- Patient's comfort performing dialysis independently. Very few patients are completely comfortable with home dialysis after training so a discussion regarding when this assessment should be conducted would be necessary.

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

- Evaluation of the facility's responsibility to address attrition and patient and caregiver burnout
- Technique failure during the patient's first year at home.
- Infection: bloodstream infections (BSIs) for home hemodialysis (HHD) and peritonitis in peritoneal dialysis (PD) patients
    - Tracking of peritonitis on a national scale is a critical element of understanding and improving home dialysis quality. Peritonitis should be tracked and reported by the National Healthcare Safety Network (NHSN)
- Incentives to promote the application of intensive hemodialysis such as an ultrafiltration rate reporting and/or performance metric

Proposed Updates to PY 2023 and 2024 ESRD QIP

Patient & Family Engagement			
	NKF Supports (Y/N)	*Comments*	*Improvements Needed*
ICH CAHPS	**Y**	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 administered too frequently. The frequency of administration does not allow a facility sufficient time to implement an action plan nor does it allow patients to see results, which discourages patient participation. **NKF recommends the survey be administered no more frequently than annually.** Some patients feel the survey does not reflect elements of care that are meaningful. ICH CAHPS was developed in 2004 and endorsed by NQF in 2005 and so is out of date. As CMS is aware, ICH CAHPS is not suitable for home dialysis patients. This is an especially important consideration as the Administration seeks to improve uptake of home dialysis. We appreciate

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

			the TEP convened earlier in the year to evaluate the measure and hope that CMS will continue its efforts to develop a new NQF-endorsed measure. **NKF recommends an updated patient-reported measure that is designed to report the views and preferences of a more modern cohort of dialysis patients, including home, in-center patients and dialysis patients waitlisted for a transplant.**
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 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 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. **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**

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

			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 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**	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	**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.

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

		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 not 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. 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.	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. **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 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	**Y**	A measure of clinical depression is of the utmost importance. Depression is the most common psychiatric condition among patients with ESKD and may exacerbate the complications of ESKD, treatment adherence, hospitalizations, and mortality.	NKF is concerned that the current reporting measure is not adequately incentivizing appropriate follow-up within the facility. We understand that patients with persistent or severe depression may need to be referred to a mental health practitioner outside the facility and note that it would not be appropriate to hold the dialysis facility or nephrologist accountable for

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

			counseling or prescribing anti-depressant medications to these patients. For many patients, however, behavioral health interventions can successfully be provided by dialysis facility social workers. We believe that a clinical measure is more appropriate, given the high proportion of depressive symptoms reported in the dialysis population and the potential for care to be provided within the facility. **We recommend that CMS work with NKF, the Council of Nephrology Social Workers (CNSW), and the broader nephrology and dialysis communities to develop a more adequate measure of clinical depression screening and follow-up.** At the 2015 Quality Conference, CMS clarified that the potential clinical measure would score facilities on the quality of its screening practices. Facilities would not be measured or penalized on their patients' mental health, but instead on the quality (not outcome) of the steps taken to assist patients.
Clinical			
Standardized Transfusion Ratio (STrR)	**N**	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.	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

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

			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 and avoidance of transfusion is not a more important measure of quality in home programs compared to in-center. A transfusion avoidance measure does not consider a patient's quality of life or the cardiovascular risks associated with low hemoglobin levels. **NKF recommends that CMS include 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 problematic. 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,	If CMS intends to retain this measure, despite it being unclear there is a performance gap, **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.**

[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

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

		which may be inappropriate given the anticipated increase in the number of patients using this modality. 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.	NKF would welcome a discussion with CMS to discuss the purpose of this measure in the QIP.
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 well as patients that**

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

			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. This recommendation aligns 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 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. 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.
	Y		

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

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

Hemodialysis Vascular Access: Long-Term Catheter Rate		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. 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.
Hypercalcemia	**N**	NKF does not believe the hypercalcemia measure is driving improvements in patient outcomes.	**NKF recommends either retiring the hypercalcemia measure, or, at minimum, removing hypercalcemia as a clinical measure and replacing it as a reporting measure.** NQF has retired the measure because it is topped out and believe CMS should do the same. 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

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

			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.
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.

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

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

			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.
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.**
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.	

NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

Nutritional Status

NKF urges CMS to review the recently published Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guideline on Nutrition in Chronic Kidney Disease, which offers recommendations that could inform future guideline-concordant quality efforts in dialysis facilities.

Due to its capacity to be influenced by fluid, chronic inflammation, and oxidative stress, serum albumin is often inappropriately used as a diagnostic criterion for malnutrition. The dialysis team, however, looks to RDNs to develop and implement nutrition care plans aimed to resolve malnutrition assessed by low serum albumin. The new guideline notes the limitations of serum albumin as a marker of nutritional status, though does affirm that low serum albumin is associated with increased risk of mortality and hospitalization for dialysis patients, and supports the Subjective Global Assessment (SGA) as a valid and reliable tool for assessing nutritional status in the ESKD population:

- **CKD: Single Biomarker Measurements**
  "In adults with CKD stages 1-5D or post-transplantation, biomarkers such as normalized protein catabolic rate (nPCR), serum albumin and/or serum prealbumin (if available) may be considered complementary tools to assess nutritional status. However, they should not be interpreted in isolation to assess nutritional status as they are influenced by non-nutritional factors (OPINION)."

- **CKD: 7-Point Subjective Global Assessment (SGA)**
  "In adults with CKD 5D, we recommend the use of the 7-point Subjective Global Assessment as a valid and reliable tool for assessing nutritional status (1B)."

It is vital that dialysis centers to staff up allow RDNs to follow evidence-based practice guidelines to achieve improved outcomes in this vulnerable population. We further encourage CMS to allow qualified RDNs, upon delegation of the authority by the attending physician, to independently:

- Order all patient diets, including therapeutic diets
- Order both standard house and disease-specific nutrition supplements
- Order enteral nutrition or parenteral nutrition
- Order nutrition-related laboratory tests needed to inform nutrition decisions and orders; and
- Order therapeutic diets in states that do not license RDNs if delegated ordering privileges by the attending physician and consistent with state law

We believe allowing RDNs greater independence to meet the needs of the patient is in the best interest of the physician, the interdisciplinary team (IDT), and achieving the goal of improved patient outcomes.

***

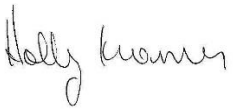
NATIONAL KIDNEY FOUNDATION®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
www.kidney.org

NKF once again expresses our gratitude to CMS for the opportunity to comment on the proposed CY 2021 proposed rule, and for everything CMS does 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 Miriam Godwin, Director of Health Policy, at miriam.godwin@kidney.org to further discuss any of NKF's positions or recommendations.

Sincerely,



Kevin Longino
CEO and transplant patient

Holly Mattix Kramer, MD, MPH
President