



The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1782-P
P.O. Box 8016
Baltimore, MD 21244-8010

August 25, 2023

Re: CMS-1782-P; 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 Alliance for Home Dialysis (Alliance) appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on the proposed rule that updates and revises the End Stage Renal Disease (ESRD) prospective payment system (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI); the ESRD Quality Incentive Program (QIP); and the End-Stage Renal Disease Treatment Choices (ETC) Model for calendar year (CY) 2024.

The Alliance is a coalition of kidney dialysis stakeholders representing individuals with kidney failure, clinicians, providers, and industry. We have come together to promote and advance policies to facilitate treatment choices in dialysis care while addressing systemic barriers that limit access for individuals with kidney failure and their families to the many benefits of home dialysis.

We appreciate that CMS has long recognized home dialysis – peritoneal dialysis (PD) and home hemodialysis (HHD) – as important treatment options that offer individuals with kidney failure

significant quality of life advantages, including clinically meaningful improvements in physical and mental health.^{1,2}

For example, HHD allows for intensive customization of patient dialysis prescription, including the ability to increase the hours and frequency of treatment; sometimes this is called more frequent dialysis and is known as a gentler option than in-center HD.³ More frequent dialysis has been shown to provide greater solute clearance, volume control, and improved nutrition, among other clinical benefits.⁴ PD has been shown to improve survival in the first year in nondiabetic individuals with comorbidities and within the first 24 months for nondiabetic individuals over 65 without comorbidities.⁵ At 9 years of follow-up, a similar survival between PD and HHD/HD was seen.⁶

Home dialysis also has lifestyle benefits, including more time for friends, family, hobbies, and leisure due to not having to travel to the clinic three times per week and the ability to work or care for dependents.⁷ Individuals with kidney failure are also often able to take fewer medications while dialyzing at home, experience improvements in neuropathy, sleep better, and feel more energetic.⁸ Many people who dialyze at home are even able to resume traveling or take vacations with family bringing along their dialysis supplies.⁹

When CMS implemented a bundled payment in 2011, the agency indicated that the new bundled payment would “encourage patient access to home dialysis,” and “make home dialysis economically feasible and available to the End Stage Renal Disease (ESRD)¹⁰ population.”^{11,12} Recent data show that in 2020, 13.7% of prevalent patients performed dialysis in the home, an

¹ Pravoverov, Leonid V et al. “Trends Associated With Large-scale Expansion of Peritoneal Dialysis Within an Integrated Care Delivery Model.” *JAMA internal medicine* vol. 179,11 (2019): 1537-1542. doi:10.1001/jamainternmed.2019.3155

² “The Benefits of More Frequent Home Dialysis.” *NxStage Medical Inc.*, 2021, www.nxstage.com/patients/benefits-of-home-hemodialysis.

³ Walker, Rachael C et al. “Home Hemodialysis: A Comprehensive Review of Patient-Centered and Economic Considerations.” *ClinicoEconomics and outcomes research: CEOR* vol. 9 149-161. 16 Feb. 2017, doi:10.2147/CEOR.S69340

⁴ See *id.*

⁵ François, Karlien, and Joanne M Bargman. “Evaluating the Benefits of Home-Based Peritoneal Dialysis.” *International journal of nephrology and renovascular disease* vol. 7 447-55. 4 Dec. 2014, doi:10.2147/IJNRD.S50527

⁶ See *id.*

⁷ Shivakumar, Oshini. “Home Dialysis the Advantages.” *National Kidney Federation*, 2023, www.kidney.org.uk/home-dialysis-the-advantages.

⁸ “Home Hemodialysis.” *National Kidney Foundation*, 31 July 2023, www.kidney.org/atoz/content/homehemo.

⁹ “Health Equity: Home Dialysis.” *American Kidney Fund*, 8 Aug. 2023, www.kidneyfund.org/kidney-health-for-all/home-dialysis.

¹⁰ For purposes of this letter, we will use End Stage Renal Disease (ESRD) and End Stage Kidney Disease (ESKD) interchangeably.

¹¹ 75 Fed. Reg. 49,030, 49,058 (Aug. 12, 2010)

¹² 75 Fed. Reg. 49,060 (Aug. 12, 2010)

increase from 9.1% ten years prior.¹³ We acknowledge that all individuals with kidney failure must have good access to the treatment option that best meets their clinical needs, whether that is PD, HHD, or in-center dialysis, but specifically thank CMS for its support of home modalities and urge continued growth in this area – specifically with respect to people of color, who suffer from End Stage Kidney Disease (ESKD) disproportionately and are significantly less likely to be treated with home dialysis than white individuals with kidney failure.¹⁴

As a preliminary matter, we wish to address the ESRD PPS base rate, which we are concerned has not adequately kept pace with the rapidly changing economic landscape in the US, particularly related to the workforce and inflation. According to our members, the base rate does not always cover the cost of a dialysis session and is part of the reason clinics across the country- especially small and rural clinics- are closing. While we have not yet seen reports of widespread closure of home dialysis programs, we are concerned that any ensuing threat to the stability of dialysis could undermine access to home therapy. We urge CMS to consider the base rate's impact on home dialysis as you finalize this year's PPS rule.

We are committed to continuing to work with CMS so that even more individuals with kidney failure can experience the benefits of a home dialysis modality. We are pleased to offer the following specific comments related to this year's proposed rule.

1. Acute Kidney Injury: Pathway to Home Dialysis

Under current CMS policy, home dialysis is not allowed for people with acute kidney injury (AKI) after hospital discharge. While this has always been a concern of the Alliance, it became even clearer that these individuals must have access to home dialysis during the early days of the COVID-19 pandemic. During this time, our members reported a lack of appropriate locations, like skilled nursing facilities and rehab centers, to discharge individuals who had been admitted to the ICU for COVID-19 and experienced kidney failure. In fact, according to the New York Times, at the height of the pandemic, between 20-40% of COVID-19 ICU patients needed immediate dialysis due to AKI.¹⁵ Many of these individuals had also been started on a home dialysis modality in the hospital, most often peritoneal dialysis, and needed to continue that therapy post-discharge. Providers experienced problems getting these individuals appropriately placed.

Outside of the pandemic, our providers also believe that many people with AKI can successfully dialyze at home after hospital discharge. Historically, the predominant treatment pathway for AKI outside the hospital once an individual is stable enough to leave, and if they still need

¹³ United States Renal Data System. "2022 USRDS Annual Data Report: Epidemiology of kidney disease in the United States." *National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases*, 2022, <https://usrds-adr.niddk.nih.gov/2022>.

¹⁴ Keenan, Julie. "Racial Disparities Persist in Home Dialysis Use across the US." *Healio*, 18 Nov. 2021, www.healio.com/news/nephrology/20211118/racial-disparities-persist-in-home-dialysis-use-across-the-us.

¹⁵ Abelson, Reed, et al. "An Overlooked, Possibly Fatal Coronavirus Crisis: A Dire Need for Kidney Dialysis." *The New York Times*, 18 Apr. 2020, www.nytimes.com/2020/04/18/health/kidney-dialysis-coronavirus.html.

dialysis, is in-center hemodialysis. Over the past several years, it has become more popular to treat AKI using peritoneal dialysis- with similar outcomes as other therapies.¹⁶ The International Society for Peritoneal Dialysis (ISPD) guidelines also state that choice of dialysis modality for individuals with AKI should be “made according to the patient’s clinical symptoms, laboratory examination indexes, and local resources,” and that those choices should include PD.¹⁷ Hemodialysis can also be done at home, and in fact, it is an Administration goal to move more chronic dialysis patients to a home modality- either peritoneal dialysis or home hemodialysis.

An AKI is sudden kidney damage that causes a build-up of waste in the blood within a few hours to a few days. AKI can have many causes, including allergic reactions, low blood pressure or shock, heart attack, blood loss, injury, and more. Treatment of AKI, whether developed due to COVID-19 or other reasons, typically requires a hospital stay, usually in the ICU; many people who experience AKI are already in the hospital for another reason- sometimes the initial reason for admission is the same injury or illness that causes the AKI in the first place. While hospitalized, people with AKI usually receive renal replacement therapy to replace kidney function with the hope that eventually, the kidneys will regain some or all their function. Once a person is stable enough to leave the hospital, if they still need dialysis (and most do), they will begin outpatient hemodialysis in a freestanding dialysis facility. For these people, the hope is that over time, the kidneys will recover, and they can cease dialysis therapy. According to the USRDS 2022 Annual Data Report, at 3 months after beginning outpatient dialysis among individuals with AKI, 29.7% had recovered kidney function, 18.8% continued with dialysis for their AKI, 35.7% progressed to ESKD (meaning they would need dialysis permanently or a kidney transplant), and 15.8% died.¹⁸

While Medicare has paid for post-discharge outpatient dialysis for people with AKI since 2017,¹⁹ unfortunately it does *not* allow or pay for home dialysis (both peritoneal and home hemodialysis) for these individuals. In 2020 alone, 3,023 individuals received outpatient dialysis for AKI.²⁰ Given the clinical and quality of life benefits to home dialysis, mentioned above, the Alliance strongly believes that home modalities should be allowed for individuals with AKI after hospital discharge if their nephrologist or managing clinician agrees that it is the best treatment modality for their individual case. While we understand that not every AKI patient will be an appropriate candidate for home therapy, we do believe that everyone deserves the opportunity

¹⁶ Cullis, Brett et al. “ISPD Guidelines for Peritoneal Dialysis in Acute Kidney Injury: 2020 Update (Adults).” *Peritoneal dialysis international : journal of the International Society for Peritoneal Dialysis* vol. 41,1 (2021): 15-31. doi:10.1177/0896860820970834

¹⁷ See id at page 17

¹⁸ United States Renal Data System. “2022 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States.” National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2022, <https://usrds-adr.niddk.nih.gov/2022>.

¹⁹ See id.

²⁰ See id.

to collaborate with their doctor to determine their treatment path without payment limitations.

We understand that CMS has expressed concern that individuals with AKI need close clinical supervision throughout their dialysis treatment; we agree and know that this supervision is possible. Individuals on home dialysis receive training to ensure they can perform treatment and close monitoring by their treatment teams, through informational reports to the clinic. Many safety protocols are already in place for individuals on home dialysis and would equally apply to people with AKI dialyzing at home. In addition, technological advances like remote patient monitoring help to ensure that providers can respond to potential problems and advise these individuals in real time.

In a recent meeting with CMS officials, the Alliance was asked how quickly coverage for individuals with AKI to dialyze at home could make an impact in behavior, thereby increasing the number of individuals dialyzing at home overall- in accordance with overall CMS goals. In response, we stated that we believe the impact would be fairly immediate. There are many nephrologists, including our members, who would be ready and willing to make the required changes, as they have been asking for this update for some time. In addition, in facilities, the care pathways for AKI are in many places already developed; turning them into pathways to home therapy would be relatively straightforward as PD and HHD training materials already exist.

To provide an illustration, we conducted research into a comparable situation from 2017. Beginning January 2017, ESKD facilities were able to furnish dialysis services to individuals with AKI. Adoption of outpatient dialysis procedures for these people increased rapidly following implementation of this policy.

Specifically, outpatient dialysis claims among individuals with AKI increased by 49% from 820 in January 2017 to 1,222 in February 2017, and approximately 34% to 1,633 in March 2017. The growth rate levelled off by May of 2017, with 1,945 people with AKI receiving dialysis in the outpatient setting. Over time, more individuals with AKI continue to receive dialysis in ESRD facilities, with 3,207 receiving dialysis through an ESRD facility in December of 2019.

Therefore, based on our clinical experts' opinions and this analogous situation, we believe that the impact of covering home dialysis for people with AKI would be rapid. CMS should permanently allow for reimbursement of home dialysis treatments for these individuals.

2. ESRD PPS Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)

The Alliance has strongly supported the TPNIES program since its inception as we strongly believe that more innovation is needed in the kidney disease and dialysis space. We believe

that TPNIES has the ability to help facilitate the adoption of innovative equipment and supplies and can partially cover the implementation costs of providing these technologies to individuals with kidney failure. As the number of individuals with kidney failure continues to increase over time, this will only become more important.

While we are pleased to see one application for the 2024 TPNIES, we believe that certain changes to the program could make it even more appealing for innovators pursuing substantial clinical improvements and the providers who, with the benefit of facilitation from CMS, will adopt the equipment and supplies.

- a) The Alliance recommends that CMS extend the TPNIES eligibility period to at least three years- preferably five.

We recommend that CMS extend the TPNIES adjustment period from two years to at least three years- preferably 5 years - to equalize the program's effective period with that of TDAPA and CMS' proposed post-TDAPA payment adjustment. While we of course understand the programs are different, they are both aimed at increasing innovation in the kidney disease space and ensuring patient access to either new drugs or new products/devices.

CMS has expressly stated that the basis for the TPNIES payment adjustment is to enable and support the adoption of recent technologies in the ESKD continuum of care, and we wholeheartedly agree. In its current form, the ESRD PPS requires providers to cover the incremental cost of using recent technologies under the existing bundled rate at the conclusion of the two-year TPNIES period. However, two years is an inadequate amount of time after considering the scale of resources and time necessary to build a responsible support and distribution infrastructure nationwide. This is especially true for companies in their earlier stages. Two years is also not a long enough time period for providers to go through strategic planning and budgeting for new technology, particularly capital assets. Furthermore, a longer adjustment period will provide companies with more time to collect data on a technology's safety and efficacy, and allow for greater cooperation between CMS, manufacturers, and other third parties in standing up potential data infrastructure. Therefore, we urge CMS to extend eligibility.

- b) The Alliance requests that CMS implement a post-TPNIES payment adjustment to ensure appropriate reimbursement upon the expiration of TPNIES.

We have long expressed our concerns about CMS's intentions not to adjust the ESRD PPS payment rate to account for the expiration of drugs and devices' short-term add-on payments, at which time those products enter the ESRD PPS bundle. The availability of a short-term add-on payment like TPNIES is one crucial factor an innovator will consider when making decisions to invest in developing recent technology. However, we are concerned that without the assurance of sustained and adequate reimbursement outside of the TPNIES period, an

opportunity to ensure optimal clinical gains for individuals with kidney failure and better value for the Medicare program could be missed. Specifically, we are worried that the lack of continuity in payment after the TPNIES period ends will impact facility behavior with regard to uptake of new products and technologies; providers must compare the acquisition cost of new products against not only the price of others on the market, but also against the depreciation rate of what they currently use. For example, if a provider currently has dialysis machines that will work for another 5 years, they will be unlikely to switch to a different machine until that period is over unless there are stronger guarantees of not necessarily savings, but at least stability. We strongly urge CMS to make sustained, adequate funds available for TPNIES-approved products beyond the TPNIES period.

- c) CMS should instruct Medicare Administrative Contractors (MACs) to provide public, timely, and consistent payment determinations.

We recognize that in the CY24 proposed rule, CMS is proposing clarifications to the TPNIES program. We recommend additional clarifications to ensure good governance and smooth operation of the program. More specifically, clarification is needed as to how the A/B Medicare Administrative Contractors (MACs) will determine payment rates and process claims in order to support uptake, facilitate beneficiary access, and uphold the program's intent. We also continue to recommend that CMS clarify the regulatory language on MAC invoice pricing determinations to exclude language that gives MACs flexibility to determine the pricing based on "charges and payment amounts required for equipment and supplies that may be comparable or otherwise relevant." Current policy confers discretion to the MACs to establish TPNIES payment rates based upon invoices received. Without more defined payment parameters and public transparency, there could be significant variation in regional payments which would undermine the program's intent. To resolve these ambiguities and increase patient access, we recommend that CMS more clearly define the payment parameters and instruct the MACs to publish an online database that provides a discrete TPNIES payment amount, no later than March 31 of the first year of TPNIES eligibility.

3. Kidney Disease Education (KDE)

The Alliance is a staunch supporter of kidney disease education (KDE) and policies that incentivize utilization of this benefit, which is currently underutilized. We believe that KDE is a useful tool for individuals with kidney failure to learn about their disease state and options for treatment, among other things.

The Alliance has previously advocated for policies that will reduce barriers and improve access to this important education, including the elimination of patient cost-sharing and expanding eligibility for the KDE benefit. We have also advocated in the Physician Fee Schedule for an elimination of the 20% coinsurance cost for KDE for individuals with kidney failure for whom it is prohibitive to accessing care, especially given the prevalence of CKD in underserved communities. We were pleased to see some of these issues addressed through the ETC Model in last year's ESRD PPS rule.

To expand KDE even further, both inside and outside the ETC Model, we urge CMS to allow dialysis facilities to provide and bill for KDE through CKD stage 5 with appropriate guardrails. CKD and ESKD individuals who need KDE should have access to the best clinical experts possible to deliver that education, regardless of where that expert is employed. To avoid “patient steering” and “marketing” in such instances, we recommend that CMS implement balanced guardrails. For example, the substance of the education should only be clinical information- not information specific to a certain provider or advertising information. And when facilities participate in conducting KDE sessions, facilities should conduct the education sessions in a provider neutral manner. We also recommend that CMS play a role in approving educational materials or modules before they are deployed.

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

a. Home Dialysis Patient Experience Metric

The Alliance strongly believes that individuals on home dialysis’s experiences should be measured in patient surveying; unfortunately, the current ICH-CAHPS survey does not adequately take their perspectives into account. The Alliance believes such exclusion significantly limits the ability to assess and improve the quality of care provided to individuals dialyzing at home, and to compare care across modalities and settings. We understand that there is considerable effort required by CMS to validate new survey questions, however we also believe that many the already validated questions related to in-center dialysis could be revised to reflect home dialysis and reduce the workload of creating an entirely new survey.

Overall, we believe the priority for home dialysis indicators should be outcome measures, patient-reported outcome measures (PROMs), and patient-reported experience measures (PREMs). Work in the PREMs area has been significant, and we urge CMS to examine the Home Dialysis Care Experience instrument developed by Rivara, et al. The Home Dialysis Care Experience instrument is a 26-item patient-reported experience measure that assesses the patient experience of care for individuals on both PD and HHD. Utilizing this already completed instrument, or portions of it, could also help CMS alleviate some of the burden of creating a new measurement tool. CMS should collaborate with the authors of HDCE²¹ to expeditiously evaluate the validity of the instrument as a potential first PREM for home dialysis.

²¹ Rivara, Matthew B et al. “Development and Content Validity of a Patient-Reported Experience Measure for Home Dialysis.” *Clinical journal of the American Society of Nephrology : CJASN* vol. 16,4 (2021): 588-598. doi:10.2215/CJN.15570920

b. Social Determinants of Health and Equity Metrics

We are committed to addressing systemic inequities to CKD and ESKD care and believe that metrics related to social determinants of health are helpful to measure and act on factors that can make it difficult for individuals with kidney failure to access care.

The burden of kidney disease is felt across the country in all communities, but the degree of this burden depends significantly on socioeconomic, racial, cultural, and geographic factors. Research shows that communities of color are disproportionately affected by chronic kidney disease (CKD) and possess a much higher risk of developing kidney failure due in part to this population's increased propensity to experience dialysis risk factors, such as hypertension and diabetes.²² In addition, there is also a lower rate of home dialysis among non-White patients as compared to White patients.^{23,24}

i. Facility Commitment to Health Equity Reporting Measure

The Alliance supports the goals behind the creation of the Facility Commitment to Health Equity Reporting Measure. We agree that incentivizing facilities to collect and utilize data to identify critical equity gaps, implement plans to address said gaps, and ensure that resources are dedicated to addressing those gaps will go far in bettering patient outcomes.

However, we recommend that the proposed measure be tailored to dialysis facilities. We urge CMS to consider the unique nature of dialysis facilities and individuals with kidney failure as the measure is finalized. For example, in order to tailor the measure directly to facilities- and home dialysis- we would urge CMS to focus facility attention on home dialysis consistent with CMS' priority on increasing home dialysis utilization. We recommend that in CMS' education to facilities on this measure, the Agency include education and best practices on how addressing disparities in home dialysis can be part of facility strategic planning, data collection, data analysis, and quality improvement efforts.

ii. Screening for Social Determinants of Health and Screen Positive Rate for Social Drivers of Health Reporting Measurement

Overall, the Alliance supports adding the Screening for Social Determinants of Health (SDOH) reporting measure and the Screen Positive Rate for Social Drivers of Health reporting measurement to the QIP measure set beginning in 2027. However, we also request that CMS clarify the technical specifications related to these measures, particularly the ability of the

²² "Race, Ethnicity, & Kidney Disease." *National Institute of Diabetes and Digestive and Kidney Diseases*, www.niddk.nih.gov/health-information/kidney-disease/race-ethnicity. Accessed 9 Aug. 2023.

²³ Wang, Virginia and Zepel, Lindsay, "Have Racial Disparities in Home Dialysis Utilization Changed Over Time?", *Am J. Manag Care*. 2023; 29(3): 152-1582-158.

²⁴ Mehrotra R, Soohoo M, Rivara MB, Himmelfarb J, Cheung AK, Arah OA, Nissenson AR, Ravel V, Streja E, Kuttykrishnan S, Katz R, Molnar MZ, Kalantar-Zadeh K. Racial and Ethnic Disparities in Use of and Outcomes with Home Dialysis in the United States. *J Am Soc Nephrol*. 2016 Jul;27(7):2123-34. doi: 10.1681/ASN.2015050472.

Electronic Data Interchange to be used between systems and the use of existing SDOH tools already in use by many providers. We also request clarification that CMS plans to collect the data for these measures through the End Stage Renal Disease Quality Reporting System (EQRS). Finally, we request that CMS consider how to align these new measures with the requirements of the Comprehensive Kidney Care Contracting Model (CKCC).

Thank you for the opportunity to provide these comments. For any questions you may have, please do not hesitate to contact Michelle Seger at mseger@vennstrategies.com or 202-466-8700.

Sincerely,



Michelle Seger
Managing Director



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