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 26, 2024

Re: CMS 1805-P; Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

Dear Administrator Brooks-LaSure:

The Alliance for Home Dialysis (the Alliance) appreciates the opportunity to comment on CY 2025's End Stage Renal Disease (ESRD) Prospective Payment System (PPS) proposed rule. 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.

Home dialysis, both peritoneal (PD) and home hemodialysis (HHD), offers important clinical and quality of life advantages, and we appreciate CMS' commitment to increasing access to this important therapy. We recognize that individuals with kidney failure need good access to the treatment option that best meets their clinical needs, whether that is PD, HHD, or in-center dialysis. We thank CMS for supporting home modalities and urge continued growth in this area, especially for people of color who suffer from End Stage Kidney Disease (ESKD) disproportionately and are significantly less likely to receive home dialysis than white individuals

with kidney failure.[1] We were particularly encouraged to see that this year's proposed rule includes important policy changes that will increase access to and uptake of home dialysis for Acute Kidney Injury (AKI) patients – a change the Alliance has advocated strongly for.

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.[2] More frequent dialysis has been shown to provide greater solute clearance, volume control, and improved nutrition, among other clinical benefits.[3] 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.[4] At 9 years of follow-up, a similar survival between PD and HHD/HD was seen.[5]

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.[6] 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.[7] Many people who dialyze at home are even able to resume traveling or take vacations with family bringing along their dialysis supplies.[8]

We are committed to working with CMS to increase access to and uptake of home dialysis and are pleased to offer the following comments to this year's proposed rule.

Home Dialysis Access for AKI Patients

The Alliance applauds CMS' decision to cover home dialysis for Acute Kidney Injury (AKI) patients for the first time, which is a policy change we have strongly advocated for over the years. The Alliance looks forward to AKI patients having the opportunity to realize the clinical and quality of life benefits of both peritoneal and home hemodialysis. While we understand

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[1] Keenan, Julie. (2021). Racial Disparities Persist in Home Dialysis Use across the US. *Healio*. www.healio.com/news/nephrology/20211118/racial-disparities-persist-in-home-dialysis-use-across-the-us

[2] Walker, R. C., Howard, K., & Morton, R. L. (2017). Home hemodialysis: a comprehensive review of patient-centered and economic considerations. *ClinicoEconomics and Outcomes Research*: CEOR, 9, 149–161. https://doi.org/10.2147/CEOR.S69340

[3] *See id*.

[4] François, Karlien & Bargman, Joanne. (2014). Evaluating the benefits of home-based peritoneal dialysis. *International Journal of Nephrology and Renovascular Disease*, 7, 447-455. https://doi.org/10.2147/IJNRD.S50527

[5] *See id*.

[6] Shivakumar, Oshini. (2023). Home Dialysis the Advantages. *National Kidney Federation*. www.kidney.org.uk/home-dialysis-the-advantages

[7] Home Hemodialysis. (2023). *National Kidney Foundation.* https://www.kidney.org/atoz/content/homehemo

[8] Health Equity: Home Dialysis. (2023). *American Kidney Fund*. www.kidneyfund.org/kidney-health-for-all/home-dialysis

that not every AKI patient will be an appropriate candidate for home therapy, we are pleased that everyone with AKI will have all treatment options available to them and can collaborate with their doctor to determine their best treatment path without having to worry about Medicare coverage. We urge CMS to finalize the proposal to allow home dialysis for AKI patients.

Budget Neutrality

We appreciate that CMS is also poised to allow home dialysis training for AKI patients; training is absolutely vital to success on a home dialysis therapy. However, we are concerned that CMS' efforts to make the training add-on payment budget neutral, which ultimately reduces the AKI dialysis payment rate, could be detrimental to CMS' stated goal of increasing access to home dialysis for this population. As a threshold matter, we urge CMS to consider whether budget neutrality is necessary in this instance. Specifically, we understand that the AKI base rate is based on the ESRD base rate, to which CMS has already applied a budget neutrality adjustment for the training add-on. Therefore, the proposed budget neutrality adjustment for AKI patient training would result in an unnecessary double adjustment. We are concerned that this proposed cut to the base rate will strip resources from important activities, like modality education, during the course of AKI. These resources are important for all AKI patients, but especially to those who ultimately go on to transition to ESKD. We urge CMS to allow billing for home training for AKI patients without subjecting it to budget neutrality.

However, if CMS determines that budget neutrality is required, we would like to offer some considerations related to the assumptions made when estimating utilization of home dialysis in the AKI patient population.

1) Patient Population

First, we want to point out that it will likely take time to implement new policies allowing for AKI patients to dialyze at home. Instead of an instant influx of new patients into home programs, we expect a steady ramp up over time. We believe that CMS' calculations should reflect this growth over time, and that CMS should even consider collecting data on actual utilization among beneficiaries with AKI.

Second, we think that it is likely that the number of AKI patients dialyzing at home will be lower in practice than the projected 15.4% CMS has identified. Some of our members have reported that they foresee the rates being closer to 6-7%, but actual utilization data is needed in order to know for sure. The main reason for this difference is assumptions related to the denominator used; we understand that around 50% of AKI-d patients will be good candidates for home dialysis, so the underlying body of patients is actually smaller than CMS assumes. We also believe that if CMS does not want to wait for actual utilization data here, it will likely be more

accurate to compare home dialysis rates for AKI patients to urgent start PD rates. We think this comparison will be more comparable to what we would expect to see.

2) Retraining

While the ultimate clinical goal is to help patients recover, the Alliance understands that despite the best care and efforts, some patients will progress to ESKD. It is important to mention that AKI patients who convert to ESKD will not be trained twice, and therefore, there will likely be some cost savings related to ESRD payment. This is significant as our members report that up to 50% of AKI patients progress to ESKD. Specifically, we mean that an AKI patient who elects home dialysis and is trained at that time, but later moves into ESKD, will not be retrained at that point, but rather will rely on the original training they received when they were an AKI patient. While we understand that the AKI payment and ESRD payments are different funding streams, we still think it relevant to mention.

3) Other Options for Home Dialysis Training

We appreciate CMS' consideration of other locations where an AKI patient could be trained on home dialysis, and thus, Medicare would not incur the training add-on payment. We believe that it is likely that some patients could be trained in the hospital setting and that this should be considered when thinking through how budget neutrality should be applied. If a patient is trained on a home modality in the hospital they would not be retrained as a dialysis outpatient once discharged.

The Conditions for Coverage

The Alliance agrees with CMS that including AKI patients under "ESRD patients" and defining "kidney failure" to include anyone needing temporary or permanent dialysis in the Conditions for Coverage are adequate changes to ensure access to home modalities for patients with AKI.

The ESRD Treatment Choices Model

The Alliance has long supported the goals of the ESRD Treatment Choices Model (ETC Model), especially its focus on increasing access to and uptake of home dialysis. We appreciate CMMI's commitment to transforming kidney disease treatment and increasing the quality of life for kidney disease patients. We also agree with CMS that there are still barriers to access to home dialysis and that more must be done to incentivize home modalities. We appreciate CMS' focus at this time on how to address this issue as well as how to determine what comes next as a successor to the ETC Model. We are pleased to provide feedback to the questions posed in the proposed rule.

1. How should any future Innovation Center model that incorporates home dialysis incorporate what the community has learned from the ETC Model?

Kidney Disease Education

The Alliance strongly supports the ETC Model's Kidney Disease Education (KDE) provisions, which allow for additional clinical practitioners to provide KDE services under the model and for Stage 5 CKD patients to be eligible for KDE. As you are aware, KDE uptake outside the model has remained low, and we believe that limitations on both who can provide it and who can receive it are partly responsible.

We have long advocated for expanding KDE outside the ETC. 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. In addition, we know that patients who receive early and accurate modality education, such as what is provided through KDE, are more likely to choose a home modality should their disease progress to ESKD.

Therefore, we urge CMS to maintain the ETC's changes to the KDE program in any future models related to increasing home dialysis. One other potential changes CMS could consider in a model environment could be waiving the 20% coinsurance related to KDE, which we understand can be a barrier to patients electing to participate.

2. What barriers to home dialysis could be addressed through the ESRD Prospective Payment System (PPS)?

Incentivizing PD Catheter Placement

There are several barriers impacting timely PD catheter placement, many of which have been identified in the past by CMS. These include 1) challenges scheduling operating room time in the hospital setting for PD catheter placement, 2) the need for additional training on PD catheter placement for both surgeons and interventional nephrologists, and 3) the lack of dedicated PD catheter insertion teams in the hospital setting who can immediately place catheters for patients who "crash" into dialysis and would benefit from urgent start PD. But perhaps the biggest barrier is the low reimbursement for PD catheter placement compared to vascular access procedures. Taken together, these barriers often result in patients who would be good candidates for PD receiving in-center hemodialysis due to factors outside their control.

We encourage CMS to develop a demonstration to test the impact of policy changes on mitigating these barriers. Specifically, the demonstration's design could equalize the reimbursement between PD catheter placement procedures and vascular access placement procedures. As stated above, vascular access procedures are currently paid at a higher rate. This difference in reimbursement helps to explain a motivation to perform more vascular procedures as opposed to PD catheter insertions. It also raises the question of whether, should the reimbursement be equalized, more PD catheter insertions would be performed. Equalizing the reimbursement in a demonstration model setting would allow CMS to study how doing so

impacts rates of PD catheter placements as compared to vascular access procedures. CMS could also compare rates inside and outside of the model to evaluate whether the payment increase within the model increased the rate of PD catheter placement.

As mentioned briefly above, too many patients in the US are crashing into dialysis, or unexpectedly start dialysis with a visit to an emergency department with little or no preparative nephrology care. According to one report, as many as 60%[9] of patients crash into dialysis in the hospital, which usually results in poorer outcomes and more expense[10] than a planned start. The Alliance suggests that CMS consider a model with a focus on this patient population, including incentives geared toward hospitals who are willing to prioritize PD catheter placements through urgent start PD programs. Urgent start programs can provide an opportunity for patients who crash to get a PD catheter and start dialyzing almost immediately, or at least within 14 days of placement.[11] Since we know that the majority of patients who begin dialysis in the hospital continue on the same therapy as outpatients, currently mostly in-center hemodialysis, incentivizing immediate PD catheter placement through urgent start PD programs means it's likely that these patients will continue on PD post-discharge. Not only could a program like this incentivize PD catheter placement, but it could also increase home dialysis uptake overall.

Finally, we urge CMS to consider the role of outpatient or stand-alone ambulatory surgery centers in PD catheter placement. Placing PD catheters in this setting can avoid some of the common barriers found in the hospital setting, like issues reserving operating room time. We ask you to be careful not to inadvertently disincentivize PD catheter placement through policies created to impact these outpatient surgical centers.

Kidney Disease Education

As stated above, the Alliance strongly believes that expanded KDE will be key to increasing uptake of KDE and ultimately home dialysis. Further, there is strong patient demand for education. One study found that 46% of CKD patients were willing to attend a class on CKD and that 73% of those patients wanted "more than basic CKD information," with 20% of respondents reporting that they would like to know "everything a doctor knows."[12]

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[9] Fresenius Case Study. (2020). *CMS*. https://www.cms.gov/priorities/innovation/media/document/aco-casestudy-fresenius

[10] Azar, A (2024, March 4). US kidney care is broken. But we have the means to fix it. *The Hill*. https://thehill.com/opinion/4507306-us-kidney-care-is-broken-but-we-have-the-means-to-fix-it/

[11] Vogt, Braden, and Ankur D. Shah. (2024). Urgent-Start Peritoneal Dialysis: Current State and Future Directions. *Kidney and Dialysis 4*, no. 1: 15-26. https://doi.org/10.3390/kidneydial4010002

[12] Allen, R. J., Nakonechnyi, A., Phan, T., Moore, C., Drury, E., Grewal, R., Liebman, S. E., Levy, D., & Saeed, F. (2024). Exploring Patient Needs and Preferences in Chronic Kidney Disease Education: A Cross-Sectional Survey Study. *Kidney360*, *5*(3), 344–351. https://doi.org/10.34067/kid.0000000000000369

In addition to the solutions explained above, we urge CMS to also consider waiving the coinsurance requirement for KDE. Currently, Medicare beneficiaries are responsible for the 20% copay associated with KDE as a Part B benefit. For some beneficiaries, the 20% coinsurance is prohibitive to accessing these important educational services. In addition, we believe that CMS has the authority to designate KDE as a preventive service—and should do so. CMS has the authority to add full coverage for preventive services in Medicare through the National Coverage Determination process if the new service meets certain criteria. We believe that KDE meets these criteria and encourage CMS to support the inclusion of KDE as a preventive service.

Finally, we believe that dialysis facilities should be allowed to provide and bill for KDE for CKD stages 3b to 5 with appropriate guardrails to prevent patient steering and marketing.

Social Determinants of Health

There is a disproportionate lack of home dialysis access for low-income communities and communities of color, which make up a significant portion of dialysis patients overall. Research shows that communities of color are disproportionately impacted by CKD and possess a much higher risk of kidney failure due in part to increased incidence and prevalence of dialysis risk factors such as hypertension and diabetes among this population. Data make clear that, in the United States, people of color have less access to home dialysis therapy. Nationally, Black patients are 30.1% less likely, and Hispanic patients are 7.6% less likely than white patients to start PD. Similarly, for HHD, Hispanic patients are on average 42.1% less likely, and Black patients are 9.8% less likely, to receive HHD.[13] Non-white patients are also more likely to start dialysis urgently and most patients who start dialysis in a hospital are immediately referred for in-center dialysis upon discharge making urgent start solutions for patients who crash into dialysis to access PD and HHD critical to achieving near-term equity in home dialysis access.

Addressing barriers to home dialysis is critical for underserved patients given its benefits in helping patients to maintain their prescribed treatments over time due to the reduced need to travel and its customizability. Many of these barriers are also experienced by patients living in rural areas. The Alliance suggests that CMS consider innovative approaches in a model setting to address some of the factors that our members have identified as barriers contributing to the lower uptake of home dialysis in communities of color and underserved communities. These could include encouraging MA plans to apply the Special Supplemental Benefits for the Chronically Ill (SSBCI) to offer benefits to reduce barriers to home dialysis, copay assistance programs for necessary dialysis related medications, stipends for utility costs and necessary

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[13] Shen, J. (2020, February 19). Home dialysis use varies by race, largely due to socioeconomic factors. *Nephrology News & Issues*. https://www.healio.com/news/nephrology/20200219/home-dialysis-use-varies-by-race-largely-due-to-socioeconomic-factors

home modifications, assistance for care partners or respite when needed, and assistance in installing and paying for broadband internet.

Incentivizing Skilled Nursing Facilities to offer PD

The Alliance understands that all dialysis performed in a skilled nursing facility (SNF) is considered home dialysis, but the vast majority of patients perform hemodialysis, oftentimes leaving the SNF setting to receive therapy at a dialysis facility three times per week.[14] These patients typically continue to receive in-center treatments post-discharge. We believe there is an opportunity for CMS to incentivize SNFs to work with patients to perform PD when clinically appropriate. PD is advantageous in the SNF setting for a number of reasons, including the fact that PD is often performed overnight, leaving the entire day for patients to spend participating in rehabilitation programs, attending physical therapy, and other activities beneficial to their health and recovery.[15] Further, patients performing PD in a SNF setting would be likely to continue doing so post-discharge, contributing positively to CMS' goal of increasing home dialysis across the board. Finally, incentivizing PD in the SNF setting could also alleviate some of the workforce burden felt by nurses and other health care professionals in this setting, as we anticipate that PD patients would dialyze mostly independently.

Staff Assisted Home Dialysis

While the Alliance is supportive of potential congressional action to allow for reimbursement for staff assisted home dialysis, we believe all stakeholders, including CMS, should consider its role in advancing home dialysis as a whole. Staff assisted home dialysis offers patients the same clinical and quality of life benefits as traditional home dialysis. It can also provide a way for patients with "physical, mental and psychosocial limitations that make self-care difficult" or those who want to do home hemodialysis but lack a care partner to dialyze at home.[16] Moreover, staff assisted home dialysis can serve as a "bridge" to fully independent home dialysis; help from a nurse at home for a period of time can increase confidence in the patient and help them get more comfortable performing their treatment so that they can ultimately perform it on their own. Technological advances, like remote patient monitoring and other

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[14] Palace, Z., & Bologa, R. (2015). Development of a Peritoneal Dialysis Program in the Skilled Nursing Facility. *HMP Global Learning Network*. https://www.hmpgloballearningnetwork.com/site/altc/articles/development-peritoneal-dialysis-program-skilled-nursing-facility
[15] Id.
[16] Hussein, W. (2022, February 21). Opinion: Patients can benefit from staff-assisted peritoneal dialysis. *Nephrology News & Issues*. https://www.healio.com/news/nephrology/20220221/opinion-patients-can-benefit-from-staffassisted-peritoneal-dialysis?utm_source=selligent&utm_medium=email&utm_campaign=topicalert&M_BT=5508642237049

digital tools, can also couple with staff assisted home dialysis to connect patients to their in-office providers and increase safety and confidence.

3. What approaches could CMS consider to increase beneficiary access to home dialysis modalities in Medicare Advantage?

Data Considerations

We strongly believe that publicly accessible data is needed for lawmakers and CMS to conduct appropriate oversight into Medicare Advantage (MA) and ensure that beneficiaries with kidney failure who elect an MA plan maintain access to the care they need. The Alliance urges CMS to update MA data collection and reporting efforts to match other Medicare programs. Currently, there is a lack of clarity around the availability of data that measure home dialysis uptake among MA ESKD beneficiaries, which is a key piece of information for our community. There is also inconsistency in whether data is available on MA plan offerings of home dialysis training. Collecting and analyzing this information now will allow policymakers to nimbly adapt to this seismic shift in the MA enrollee population resulting from beneficiaries with ESKD electing MA plans and ensure beneficiaries are not falling through the cracks. This data will also assist lawmakers in future policymaking and provide information needed to better align incentives across the health care continuum.

More specifically, the current data that the community does have access to is known as encounter data, which is intended to use "encounters" with clinicians to collect detailed records of a patient's health care treatment. Unfortunately, our members have reported that this encounter data is not comprehensive and therefore, it keeps the MA program opaque, as opposed to FFS, where more types of datasets are available for analysis. We urge CMS to ensure that encounter data is as comprehensive and reliable as possible.

Home Dialysis as a Quality Measure in MA

All MA plans are subject to standards that measure their performance against a set of quality measures determined by CMS. The Alliance believes that it would incentivize MA plans to prioritize home dialysis uptake if home dialysis penetration was included as a new quality marker for all MA plans to be measured against. Such a change would align with CMS' stated goal of increasing access to home dialysis as it would encourage MA plans to offer home dialysis to more patients.

Time and Distance Standards

The Alliance urges CMS to reconsider requiring time and distance standards in MA for dialysis facilities. In 2020, CMS removed outpatient dialysis facilities from the list of facilities subject to time and distance standards; instead, plans are now required to self-attest that they have an

adequate network for patients to access. While we understand that the change was made in part to increase focus on home dialysis, we are concerned about unintended consequences on patients-including home dialysis patients. Home dialysis patients still need regular access to a dialysis facility. For example, home dialysis patients are often seen in the dialysis facility if they are ill or have a problem that needs medical attention or if they dialyze with a care partner who is seeking respite care for a period of time. MA plans should have to ensure that there are adequate facilities available for these patients through compliance with time and distance standards.

4. How should nephrologist payment from traditional, fee-for-service Medicare and from MAOs account for clinician-level barriers to prescribing and retaining patients on home modalities?

Physician Training

Our members have reported barriers to physician training in home dialysis modalities, which lead to a reluctance to prescribe these therapies in practice. While certain physicians have embraced home dialysis and become its so-called "champions," it is important to realize that not every region has access to such a clinician. While developing the skills of more champions will continue to be important, we also believe that a "wholesale shift in clinical culture" is necessary to move from prioritizing in-center treatment over home dialysis.[17] Education for all clinicians will be key in accomplishing this goal.

Incentive Payments for Home Dialysis

There are two areas where the Alliance believes an incentive payment could help to incentivize clinicians to prescribe home dialysis. First, the current payment structure does not adequately account for all of the upstream work that is required to prepare a patient for home dialysis- most of this is education beginning in mid to late-stage CKD, but before a dialysis modality is chosen. We believe that upstream incentive payments could serve as a benefit for those physicians already doing the upstream work and serve as encouragement for those who are not. Second, we urge CMS to consider providing a one-time incentive payment per referral to home dialysis- either PD or HHD. Such a payment could alter prescribing behavior for the better.

Payment for KDE

The Alliance urges CMS to consider increasing the payment for HCPCS codes G0420 and G0421, which are used for individual face-to-face education services and group face-to-face education

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[17] Mendu, M. L., Divino-Filho, J. C., Vanholder, R., Mitra, S., Davies, S. J., Jha, V., Damron, K. C., Gallego, D., & Seger, M. (2021). Expanding utilization of home dialysis: An action agenda from the first International Home Dialysis Roundtable. *Kidney Medicine*, *3*(4), 635–643. https://doi.org/10.1016/j.xkme.2021.04.004

services related to CKD. We understand from our members that by inflationary standards (note that the codes have not been meaningfully updated in about a decade), the codes are not current and should be updated. Further, we believe that the current payment level is not reflective of CMS' commitment to home dialysis. As you are aware, studies have shown that when patients receive education, they are more likely to choose a home modality. A code update could therefore incentivize more KDE, which aligns with CMS' ultimate goal of increasing home dialysis uptake.

Dialysis Training Payment

The Alliance understands that HCPCS code 90989 for dialysis training has not been updated since the mid-1990s. We urge CMS to consider adjusting this code for inflation. We believe that an increase to this code's payment will result in increased home dialysis.

Thank you again for the opportunity to provide comments to the proposed ESRD PPS rule for 2025. We hope these comments have been helpful and are happy to answer any questions you may have or provide more information. Please feel free to reach out to Michelle Seger at mseger@vennstrategies.com.

Sincerely,

Michelle Seger
Managing Director
Alliance for Home Dialysis

Alliance for Home Dialysis Members

American Association of Kidney Patients
American Kidney Fund
American Nephrology Nurses Association*
American Society of Nephrology*
American Society of Pediatric Nephrology
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Centers for Dialysis Care
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