The Honorable Mehmet Oz
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 29, 2025

Re: CMS 1830-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 Oz:

The Alliance for Home Dialysis (the Alliance) appreciates the opportunity to comment on the CY 2026 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 manufacturers. We have come together to promote and advance policies to facilitate treatment choices in dialysis care while addressing barriers that limit access for individuals with kidney failure and their families to the many benefits of home dialysis.

We are grateful for President Trump's courageous leadership that prioritized kidney disease treatment in the 45th administration and are eager to work with the 47th administration to continue that principled commitment.

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 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.

Home modalities have clinical benefits. HHD allows for intensive customization of a patient's dialysis prescription, including the ability to increase the hours and frequency of treatment; sometimes referred to as more frequent dialysis, this option is gentler than in-center HD.[1] While a healthy individual's kidneys function 24/7, typically in-center patients only receive average of 9 to 15 hours per week of renal replacement therapy. Research has shown that more frequent home hemodialysis provides greater solute clearance, volume control, and improved nutrition, among other clinical benefits.[2] Studies have found that PD improves survival in the first year in nondiabetic individuals with comorbidities and within the first 24 months for nondiabetic individuals over 65 without comorbidities.[3] At 9 years of follow-up, a similar survival rate between PD and HHD/HD was seen.[4]

Home dialysis also has significant lifestyle and mental health benefits, including more time for friends, family, hobbies, and leisure, and the ability to work or care for dependents.[5] 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.[6] Many people who dialyze at home can resume traveling or take vacations with family bringing along their dialysis supplies.[7]

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

I. Capturing the home dialysis experience in patient survey(s)

The Alliance would like to thank CMS for its longstanding interest in developing a metric to capture the home dialysis patient experience, given that the current ICH CAHPS instrument does not include these patients. We were encouraged to see that the proposed rule includes the following language: "we are also working on a modified survey to include questions that

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[1] 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

[2] *See id.*

[3] 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

[4] *See id.*

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

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

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

address the experience of care for patients on home dialysis modalities." We are eager to continue to work with you on this project and appreciate CMS' commitment to advancing this survey addition.

Overall, CMS should prioritize home dialysis indicators that are 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 HDCE[8] to expeditiously evaluate the validity of the instrument as a potential first PREM for home dialysis. We have also previously shared the metrics applied by several Alliance members to measure home dialysis patient experience and would be happy to meet with you to discuss these efforts further.

II. The post-ETC Model future: incentivizing home dialysis

The Alliance understands that the ETC Model will end Dec. 31, 2025. We appreciate the tremendous effort that CMMI put into developing a model designed to increase access to home dialysis, as well as President Trump's visionary leadership in his first administration to improve care and quality of life for patients with kidney disease. While we understand that the data coming out of the model was not as strong as we all hoped, we want to thank CMMI for being willing to stand behind the promotion of home dialysis therapies. We look forward to continuing to work with the agency in the future and appreciate your continued commitment to bettering the lives of kidney disease patients.

In this comment, we would like to share a limited number of ideas that CMMI could implement to enhance access to home dialysis.

Expanding Access 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 broaden eligibility to beneficiaries with Stage 5 CKD. As you are aware, KDE uptake outside the model has remained low, and we believe that clinical and beneficiary eligibility limitations contribute to this outcome- specifically limitations on both who can provide it and who can receive it.

[8] 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

We have long advocated for applying the expanded KDE benefit outside the ETC model. We believe that KDE is a useful tool for individuals with kidney failure to learn about their disease state, options for treatment, and steps they can take to make sure that home treatment is a good option for them as they progress to ESKD. In addition, we know that kidney failure patients who receive early, comprehensive, and accurate modality education, such as the content provided through KDE, are more likely to choose a home modality.

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.

Incentivizing PD Catheter Placement

Several barriers impact timely PD catheter placement, many of which CMS has previously identified, including:

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, CMS currently reimburses vascular access procedures at a higher rate, which incentivizes the delivery of more vascular procedures as opposed to PD catheter insertions. It also raises the question of whether equalizing the reimbursement would increase the number of catheter insertions. 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]

While some patients who crash into dialysis are medically frail and not clinically suited for home dialysis, others who would prefer to elect home therapy cannot receive a timely PD catheter placement. Since 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.

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 most patients perform hemodialysis, oftentimes leaving the SNF setting to receive therapy at a dialysis facility three times per week.[12] 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

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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] 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

recovery.[13] 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 a SNF 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. It would also reduce the need for costly medical transport.

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.

III. Potential QIP measures on well-being, nutrition, and physical activity

The Alliance supports CMS's interest in developing new ESRD QIP measures focused on well-being, nutrition, and physical activity. These items can be helpful indicators of patient experience, and we believe home dialysis plays a central role in supporting each of these domains for patients with kidney failure. We urge you to consider the impact of home dialysis when designing any new quality measures.

Specifically, individuals on home dialysis often experience better mental health outcomes, including fewer depressive symptoms and higher emotional well-being[14] and medication adherence, compared to those undergoing in-center hemodialysis.[15] Studies have shown that the prevalence of depression among individuals with kidney failure is roughly double that of the general population, and suicide is significantly more common among dialysis patients.[16] Home modalities may help address this burden by giving patients more control over their schedule and treatment setting, which supports greater independence and social engagement. On a modality specific basis, patients on PD report more frequent social interactions and a better sense of social support and felt more emotional well-being as compared to patients undergoing in-center HD.[17]

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[13] Id.

[14] Desbiens, L.-C., Bargman, J. M., Chan, C. T., & Nadeau-Fredette, A.-C. (2024). Integrated home dialysis model: Facilitating home-to-home transition. *Clinical Kidney Journal, 17*(Supplement_1), i21–i33. https://doi.org/10.1093/ckj/sfae079

[15] Hermanns, C. L., Young, K., Parks, A., Brooks, W. M., Lepping, R. J., Montgomery, R. N., & Gupta, A. (2024). A prospective study of depression and quality of life after kidney transplantation. *Kidney360, 5*(9), 1350–1358. https://doi.org/10.34067/KID.0000000000000538

[16] Id.

[17] Id.

Home dialysis is also associated with improved nutritional status and fewer dietary restrictions. Because waste and fluid are cleared more frequently in home settings, patients can typically eat and drink with more flexibility, which has been tied to improved quality of life.[18] In addition, individuals on home dialysis are better able to engage in physical activity. Recovery times are shorter after home treatment, and patients can choose to exercise when they feel their best, rather than being limited by facility schedules. Home hemodialysis patients typically recover in over an hour, while in-center patients take more than three hours on average, on top of the extensive time spent traveling to and from dialysis centers.[19]

As CMS continues to evaluate new QIP measures in these areas, we encourage consideration of home dialysis uptake as a potential factor in helping to ease the burden on patients and as an option for exploring the correlation between home dialysis and improved quality of life indicators. In addition, it will be important for CMS to gather feedback from the kidney disease community, including patients, clinical providers, manufacturers, etc. before finalizing any new outcome measures on these topics in order to ensure that all measures are appropriate and work properly to reduce burden and streamline the process.

IV. Updated to the ESRD PPS Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)

The Alliance has steadfastly 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 can 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. We are hopeful that we will see increased applications in the coming years.

In the meantime, we urge CMS to continue to work with the regional Medicare Administrative Contractors (MACs) to ensure a smooth and efficient process for providers to bill for any approved technologies, devices, or supplies are able to be billed for smoothly and efficiently. Specifically, we request that CMS establish payment parameters applicable to all MACs, removing regional discretion, and increasing public transparency into the payment process. Without more defined payment parameters and public transparency, significant regional variation in payments would undermine the program's intent. To resolve these ambiguities and

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[18] National Kidney Foundation. (2024). *Hemodialysis and your diet*. https://www.kidney.org/kidney-topics/hemodialysis-and-your-diet

[19] Jayanti, A., Foden, P., Morris, J., Brenchley, P., Mitra, S., & BASIC-HHD study group (2016). Time to recovery from haemodialysis: location, intensity and beyond. *Nephrology (Carlton, Vic.)*, *21*(12), 1017–1026. https://doi.org/10.1111/nep.12692

increase patient access, we recommend that CMS more clearly define the payment parameters and instruct the MACs to publish an online database.

V. The importance of decision aids in patient modality choice

The Alliance has long advocated for increased patient autonomy and empowerment in decision-making about dialysis modality. While partnership with the care team is of the utmost importance, patients should also have access to the tools that will help them successfully choose the best modality for their specific needs, whether that is ultimately a home or in-center dialysis experience. We have included comments supporting patient decision-aids in the past, including ones developed by members of our coalition.[20] These types of decision-aids can meet patients where they are in their journey and increase their involvement in treatment decision-making, understanding of treatment options, and prioritizing what is truly important to them. We believe that use of these evidence-based decision-aids can improve patient outcomes, including rates of patients comfortable with choosing home dialysis.

Thank you again for the opportunity to provide the Alliance's perspective on this proposed rule. Please feel free to reach out to Michelle Seger at mseger@vennstrategies.com with any questions or to discuss further,

Sincerely,

Michelle Seger
Managing Director

[20] One example is the Medical Education Institute's My Kidney Life Plan: https://mykidneylifeplan.org/

Alliance for Home Dialysis Members

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