



The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1784-P  
7500 Security Boulevard  
Baltimore, MD 21244

September 11, 2023

**RE: CMS-1784-P Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program**

Dear Administrator Brooks-LaSure:

The Alliance for Home Dialysis (Alliance) appreciates the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments on the proposed rule to establish the CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program.

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 to the many benefits that home dialysis can offer for individuals with kidney failure and their families.

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.<sup>1,2</sup>

For example, HHD allows for intensive customization of an individual’s dialysis prescription, including the ability to increase the hours and frequency of treatment; sometimes this is called more frequent dialysis

---

<sup>1</sup> 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

<sup>2</sup> “The Benefits of More Frequent Home Dialysis.” *NxStage Medical Inc.*, 2021,  
[www.nxstage.com/patients/benefits-of-home-hemodialysis](http://www.nxstage.com/patients/benefits-of-home-hemodialysis).

and is known as a gentler option than in-center HD.<sup>3</sup> More frequent dialysis has been shown to provide greater solute clearance, volume control, and improved nutrition, among other clinical benefits.<sup>4</sup> 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.<sup>5</sup> At 9 years of follow-up, a similar survival between PD and HHD/HD was seen.<sup>6</sup>

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.<sup>7</sup> 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.<sup>8</sup> Many people who dialyze at home are even able to resume traveling or take vacations with family bringing along their dialysis supplies.<sup>9</sup>

Recent data show that in 2020, 13.7% of prevalent patients performed dialysis in the home, an increase from 9.1% ten years prior.<sup>10</sup> 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 among 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.<sup>11</sup> We commend CMS for the proposed rule’s focus on social determinants of health (SDOH) and underserved populations.

We appreciate the opportunity to present the following comments:

1. The Alliance supports CMS’ proposals to cover certain health equity and social determinants of health (SDOH) related services.

CMS proposes to cover services related to Community Health Integration, Social Determinants of Health Risk Assessment and Primary Illness navigation services. The Alliance is in favor of this proposal, as well as CMS’ goal to promote the utilization of community health workers, care navigators, and support specialists. These services are especially important in underserved communities, where kidney failure is

---

<sup>3</sup> 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

<sup>4</sup> See *id.*

<sup>5</sup> 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

<sup>6</sup> See *id.*

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

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

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

<sup>10</sup> 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>.

<sup>11</sup> 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](http://www.healio.com/news/nephrology/20211118/racial-disparities-persist-in-home-dialysis-use-across-the-us).

often seen at high rates. They are also key to reach individuals with low-incomes and communities of color for the following reasons:

- Relatively low utilization of home dialysis in the U.S. is partially attributable to the disproportionate lack of home dialysis access for low-income communities and communities of color, which make up a significant portion of dialysis patients. Yet, at the same time, home dialysis is critical for underserved patients and can make dialysis easier for patients to access and maintain over time due to the reduced need to travel and customizability of treatment.
- Data make clear that, in the United States, people of color have less access to home dialysis therapy.<sup>12</sup> Nationally, as of 2018, Black patients were 30.1% less likely, and Hispanic patients 7.6% less likely, than white patients to start on peritoneal dialysis (PD). Similarly, for home hemodialysis (HHD), Hispanic patients were on average 42.1% less likely, and Black patients were 9.8% less likely, to receive HHD.<sup>13</sup> In 2018-2019, when minority patients did initiate home dialysis, they had higher rates of conversion back in in-center HD. Specifically, Black patients had high rates of conversion from PD and Black and Hispanic patients had higher rates of conversion from HHD than any other ethnic or racial group.<sup>14</sup> In addition, Black patients had higher rates of hospitalization than other ethnic groups.<sup>15</sup>

The Alliance believes that if factors related to SDOH are addressed and adequate supports are given, more individuals will be able to access important treatment modalities like home dialysis, and support this proposal.

2. The Alliance supports increased access to dental services for people with kidney failure, but does not believe these services are inextricably linked with hemodialysis stent or graft placement.

We appreciate CMS' interest in determining whether dental services are inextricably linked to the clinical success of placing a stent or vascular access graft for hemodialysis, including home hemodialysis. As a threshold matter, receiving regular dental care is very important for individuals with kidney failure, especially if their goal is to get a kidney transplant. Post-kidney transplant, dental work is not recommended for a number of months due to risk of infection, bleeding risk, and medication interaction.<sup>16</sup> The Alliance is supportive of policy changes that will increase access to dental care for people with kidney failure.

However, we do not believe that dental evaluation and treatment are absolutely necessary prior to performing the procedures listed in the rule: stents and vascular access grafts for hemodialysis. Our clinician members report that while completing dental care before such a procedure is a laudable goal, they would proceed with placing the stent or graft without having this completed and do not believe dental services are inextricably linked to the procedures.

---

<sup>12</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4926974/>

<sup>13</sup> Distribution of Dialysis Patients Utilizing Home Modalities in 2018 by State, the Moran Company

<sup>14</sup> *See id.*

<sup>15</sup> <https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/2-home-dialysis>

<sup>16</sup> <https://www.kidney.org/content/it-time-visit-dentist#:~:text=After%20an%20organ%20transplant%2C%20routine,antibiotics%20prior%20to%20your%20appointment.>

3. The Alliance supports efforts to expand telehealth and remote patient monitoring.

The Alliance has long supported expanded access to telehealth and remote patient monitoring. The COVID-19 pandemic has only increased our conviction that access to these innovations is key for patients, especially those dialyzing at home. As CMS has noted, the COVID-19 public health emergency (PHE) deeply impacted how medical care is delivered, as evidenced by the significant increase in telehealth utilization. For individuals with ESKD, this has been especially important. For example, for home dialysis patients, CMS waived the frequency restrictions for ESKD related clinical assessments furnished via telehealth and allowed phone-only visits in some circumstances. These efforts have led to learnings that telehealth and remote patient monitoring are exceedingly important even after the end of the PHE- both during times of relatively normal risk as well as if other infectious diseases pose a danger to this vulnerable population. We appreciate CMS' continued attention to expanding telehealth and remote patient monitoring and encourage you to continue doing so, including assessing changing practice patterns specific to home dialysis regarding the use of telehealth during the PHE.

4. The Alliance urges CMS to clarify that home dialysis training is a covered service.

Before individuals with kidney failure can dialyze at home, they must undergo a training program through their dialysis center; training ensures that people are capable and confident in doing their own dialysis procedures before initiating home therapy. For home hemodialysis, Medicare pays for up to 25 training sessions, for intermittent PD, Medicare pays for training 3 times a week for up to 3 months, and for continuous ambulatory PD and continuous cyclic PD, Medicare pays for up to 15 sessions.<sup>17</sup> Importantly, according to the End-Stage Renal Disease Treatment Choices (ETC) Model 1<sup>st</sup> Annual Evaluation and Report Appendices, gains in home dialysis training rates could indicate a first step in increased home dialysis.<sup>18</sup> We strongly believe that ready access to training is crucial to achieving CMS' overall goal of increasing and the availability and uptake of home dialysis.

While the ESRD Prospective Payment System (PPS) covers some training and supplies, and provides for a home dialysis training add-on payment, physicians can also bill for home dialysis training. According to the Medicare Claims Manual, physicians may bill a fee of \$500 for each individual under their supervision who completes home dialysis training; for individuals who do not complete training, the physician can prorate the visits based upon a \$20 per treatment amount. This payment is in excess of any monthly capitated payment visits.<sup>19</sup>

We are concerned that there may be an unintended barrier to home dialysis training within the Physician Fee Schedule. As explained above, the Medicare Claims Manual lists home dialysis training as a covered service for physician payment. However, the claims status indicator for home dialysis training in the Physician Fee Schedule is listed as "X," which is described as "codes represent[ing] an item or service that is not in the statutory definition of 'physician services' for fee schedule payment purposes. No RVUs pr payment amounts are shown for these codes, and no payment may be made under the physician fee schedule."

During a time when CMS is encouraging and incentivizing home dialysis, this conflicting information may inadvertently cause physicians to believe that home dialysis training is not a covered service and therefore elect not to perform it. We strongly encourage CMS to clarify that home dialysis training is a

---

<sup>17</sup><https://homedialysis.org/professional-tools/billing>

<sup>18</sup><https://innovation.cms.gov/data-and-reports/2023/etc-1st-eval-report-app>

<sup>19</sup><https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c08.pdf>

covered service and does have a corresponding payment amount with payment to be made under the fee schedule.

5. The Alliance urges CMS to make changes to increase access to the Kidney Disease Education (KDE) benefit.

The Alliance has advocated for changes to the KDE benefit that we believe would increase uptake; we appreciate CMS's attention to this issue, particularly through finalizing expansions of KDE within the ESRD Treatment Choices (ETC) Model. We believe that there are additional steps, described below, that CMS can take to make KDE more accessible to patients.

- a. CMS should waive 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. We recommend that CMS waive the coinsurance requirement that would otherwise be applicable under section 1833(a)(1) of the Social Security Act concerning KDE services for beneficiaries.

- b. CMS should designate KDE as a preventive service.

As stated above, the Alliance is concerned that the coinsurance associated with KDE disincentivizes both providers and patients from taking advantage of this education. Providers are reluctant to bill patients for a service that was provided for free in the past, and patients may not have the resources to pay the coinsurance.

However, 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.

6. The Alliance urges CMS to enact policies to increase PD catheter placement, which is necessary to begin PD at home.

Beginning on PD, the most commonly utilized home dialysis modality in the US, requires insertion of a PD catheter, as opposed to a fistula, which is placed in hemodialysis patients. PD catheters are typically placed by general surgeons, interventional radiologists, and interventional nephrologists.<sup>20</sup>

The Alliance has identified systemic barriers associated with the timely placement of PD catheters to CMS, such as lack of adequate physician training and lack of sufficient operating room time in hospital.

In addition, we continue to believe that PD catheter placement should be incentivized even more including through reimbursement. When examining the most common vascular access codes (CPT 36818-26921) and the most common PD catheter insertion code equivalents (CPT 49418, 49421, and 49324), as of 2020, the weighted average difference in vascular access code and PD code reimbursement rates is \$360.62, in favor of vascular procedures. This difference in reimbursement

---

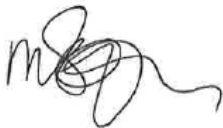
<sup>20</sup><https://www.davita.com/treatment-services/peritoneal-dialysis/preparing-for-peritoneal-dialysis-catheter-surgery#:~:text=Surgery%20is%20typically%20performed%20by,two%20weeks%20before%20beginning%20PD>

helps explain a motivation to perform more vascular procedures as opposed to PD catheter insertions and raises the question of whether, should the reimbursement be equalized, more PD catheter insertions would be performed.

As stated above, we believe that if CMS wants to increase PD uptake, the agency must increase PD catheter insertions, and one way would be through equalizing reimbursements for PD catheters and vascular access procedures. We urge CMS to consider this change, including through model creation and testing.

Thank you for your attention to these comments. We look forward to continuing to work with CMS to increase access to and uptake of home dialysis. For any questions, please reach out to Michelle Seger at [mseger@vennstrategies.com](mailto:mseger@vennstrategies.com).

Sincerely,

A handwritten signature in black ink, appearing to read 'MS', with a stylized flourish extending to the right.

Michelle Seger  
Managing Director



American Association of Kidney Patients  
American Kidney Fund  
American Nephrology Nurses Association\*  
American Society of Nephrology\*  
American Society of Pediatric Nephrology  
Baxter\*  
Centers for Dialysis Care  
DaVita\*  
Dialysis Clinic, Inc.\*  
Dialysis Patient Citizens\*  
Fresenius Medical Care\*  
Home Dialyzors United  
Medical Education Institute  
National Kidney Foundation\*  
National Renal Administrators Association  
Northwest Kidney Centers\*  
Outset Medical\*  
Renal Healthcare Association  
Renal Physicians Association\*  
Satellite Healthcare\*  
The Rogosin Institute\*  
TNT Moborg International Ltd.

\*Denotes Steering Committee Member