The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1807-P
P.O. Box 8016
Baltimore, MD 21244-8010

September 9, 2024

RE: CMS-1807-P: Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure:

The Alliance for Home Dialysis (the Alliance) appreciates the opportunity to comment on the CY 2025 Physician Fee Schedule (PFS) 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 disproportionately suffer from End Stage Kidney Disease (ESKD) and are significantly less likely to receive home dialysis than white individuals with kidney failure.

Consistent with our mission, the Alliance's comments relate to CMS proposals regarding Kidney Disease Education, vascular access codes, telehealth, acute kidney injury services, and dental services.

1. Increasing uptake of Kidney Disease Education

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, and 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. Waiving the KDE coinsurance requirement

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. 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.

2. Supporting robust reimbursement for vascular access codes

Vascular access is required for both in-center and home hemodialysis patients; options include surgically or percutaneously creating fistulas (connecting an artery to a vein) or less preferred methods like inserting a central line catheter or arteriovenous grafts (AVGs). Simply stated, safe and effective hemodialysis depends on timely vascular access.

a. Office-based codes

Unfortunately, office-based interventionalists face significant barriers that hinder patient access due to substantial payment cuts stemming from policies including in the CY 2021 PFS final rule. The 2025 Medicare PFS proposed rule drops the conversion factor to over 10% less than the 2020 factor. Additionally, 2025 marks the fourth year of clinical labor cuts to office-based

intervention relative value units (RVUs), reducing payments for certain interventional codes by another 4%. Consequently, key dialysis vascular access services will face a further 5-7% reduction in 2025. These ongoing cuts disregard patient outcomes and actual provider resource needs.

Cuts to office-based clinicians have become so severe that in 2024, 195 procedures are reimbursed at rates below their direct costs, as calculated by CMS.[1] The 2025 PFS Proposed Rule would increase this number to 300, almost a 50% rise. For these 300 services (including multiple codes impacting dialysis access—36901, 36902, 36903, 36904, 36905, 36906, 36907, 36908 and 36909) CMS will not cover the direct expenses, let alone physician work and indirect costs. These services are performed in community-based settings, the most cost-effective option for Medicare beneficiaries, and often involve high-tech, high-cost supplies. Since 2007, the reimbursement for these supplies under the PFS has been eroded by the "direct cost adjustment," with the discount increasing from 33% to 56%. Including indirect costs and physician work, the number of underfunded services likely exceeds 300.

The Alliance urges CMS to address these shortfalls and rescind proposed cuts directly and systemically impacting dialysis vascular access.

b. PD catheter placement

Currently, PD catheter procedures are generally reimbursed at a much lower rate than fistula creation. CMS should consider equalizing the reimbursement between PD catheter placement procedures and other vascular access placement procedures. 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.

3. Supporting the use of audio-only telehealth services

The Alliance has consistently supported expanded access to telehealth and remote patient monitoring, which are crucial for individuals with ESKD. For home dialysis patients, CMS' efforts to waive frequency restrictions for ESKD-related telehealth assessments and allow phone-only visits during the recent public health emergency (PHE) were vital in maintaining treatment access. These initiatives demonstrated the importance of telehealth and remote monitoring beyond the PHE, both in normal times and during infectious disease threats to this vulnerable population. We appreciate CMS's ongoing focus on expanding telehealth and remote

[1] Data from 2025 Physician Fee Schedule Proposed Rule Total Non-Facility Reimbursement and Total Direct Costs. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9441303/.

monitoring and encourage continued efforts, including assessing changing practice patterns for home dialysis.

Specifically, the Alliance urges the agency to continue to allow audio-only telehealth services for codes 99441, 99442, and 99443. These services are vital for patients with ESKD or AKI. Audio-only consultations are crucial for home dialysis patients in areas with poor broadband or limited technology access. The Alliance believes that the continued coverage of these telephone consult codes will ultimately prove that these services should be permanently included in the Medicare telehealth list.

4. Clarifying codes for AKI patients dialyzing at home

The Alliance was pleased to see that CMS proposed to allow acute kidney injury (AKI) patients to dialyze at home for the first time in the proposed CY 2025 ESRD PPS rule. The Alliance has been a long-time advocate for this policy change and believes it will open up home dialysis therapy to many patients who can benefit from it. While not every AKI patient may be suited for home therapy, we are pleased that all patients can now collaborate with their doctors to choose the best treatment without Medicare coverage barriers.

In order to properly reimburse for home dialysis in this patient population, we request that CMS clarify that services related to codes 90935, 90937, 90945, and 90947 can be used for home dialysis patients. Currently, the home is not listed in the approved sites of service for these codes, but we understand from our clinician members that these codes are the most likely to be used for AKI patients at home. Therefore, we ask that CMS clarify that this is appropriate.

Again, we applaud CMS' decision to cover home dialysis for AKI patents given the significant clinical and quality of life advantages and look forward to further collaborating with the agency to implement this change.

5. Dental services inextricably linked to covered services

Oral diseases are a preventable cause of poor health outcomes in people with ESKD, as they contribute to infection, inflammation, and malnutrition. Adults with ESKD suffer from more severe oral diseases than the general population.[2] Further, dental care supports the success of dialysis treatment given the overall risk of oral infections on clinical outcomes. Therefore, we thank CMS for establishing that "dental services to diagnose and treat infection prior to dialysis services in the treatment of ESRD represent a clinically analogous scenario to dental services for which Medicare payment under Parts A and B is currently permitted when furnished in the

[2] Palmer S. C., Ruospo M., Wong G., et al. Oral-D study investigators. Dental health and mortality in people with end-stage kidney disease treated with hemodialysis: a multinational cohort study. American Journal of Kidney Diseases. 2015;66:666–676.

inpatient or outpatient setting, such as prior to organ transplant."[3] We support CMS' conclusion that certain dental services are inextricably linked to other covered medical services[4] for ESKD patients and should be covered by Medicare.

Specifically, we appreciate CMS clarifying that an exchange of information between the physician or other medical professional and dental professional is considered necessary to establish an inextricable link between the dental and covered medical service for purposes of Medicare payment for dental services. We support proposed modifiers to help to establish a more clear, transparent standard to help ensure coordination between the dental and clinical professionals and agree that it will help to demonstrate when dental services are inextricably linked to Medicare-covered services. We urge CMS to educate impacted clinicians and provide clear guidance, including a list of linked dental services and answers to key questions on how the new modifiers will affect claims processing.

We appreciate the opportunity to provide feedback to the CY 2025 Physician Fee Schedule proposed rule. Thank you again for taking our comments into consideration. Should you need more information or have any questions, please don't hesitate to reach out to Michelle Seger at mseger@vennstrategies.com.

Sincerely,

Michelle Seger
Managing Director
Alliance for Home Dialysis

[3] https://www.federalregister.gov/documents/2024/07/31/2024-14828/medicare-and-medicaid-programs-cy-2025-payment-policies-under-the-physician-fee-schedule-and-other

[4] In this case, we agree with commenters who proposed linkage between dental services and CPT codes 36901-06. 90935, 90937, 90940, 90961, 90989-99, and DRG code 872.

Alliance for Home Dialysis Members

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