



February 9, 2024

Dear Members of Congress:

On behalf of the Alliance for Home Dialysis (the Alliance), thank you for your work in the first session of the 118th Congress to empower patients and expand access to healthcare. As lawmakers return to Washington for the second session, we respectfully request your attention to the following matters that directly and substantially impact the over 800,000 people in the United States who are living with end-stage kidney disease (ESKD).

Background

The Alliance is a coalition of kidney disease stakeholders representing patients, clinicians, providers, and industry that works to promote policies to facilitate treatment choices—with an emphasis on home dialysis—for individuals in need of dialysis and to address systemic barriers that limit access to the many benefits of home dialysis. Because Medicare covers ESKD patients of all ages, Congress has a key role in ensuring choice and quality care. Our coalition members represent a large share of the health care continuum and work to build consensus around key priorities to improve the utilization of home dialysis. We are grateful and fortunate to share that goal with both the Centers for Medicare and Medicaid Services (CMS) and lawmakers in Congress.

Concerningly, the existing Medicare payment system, coupled with insufficient beneficiary education, may inadvertently promote in-center hemodialysis as the default choice for patients initiating dialysis. Home dialysis growth has been slow over time, with current rates sitting at 13.7 percent across the U.S. The Alliance’s goal is to help create policy change to increase that percentage, ensuring patients have every opportunity to choose the best modality for their specific situation.

Home dialysis, peritoneal dialysis (PD) and home hemodialysis (HHD), is an important treatment option that offers patients significant quality of life advantages, including clinically meaningful improvements in physical and mental health. HHD, for example, allows for more frequent and/or longer-lasting dialysis sessions. Studies have demonstrated that more frequent hemodialysis results in faster recovery after treatment

and fewer side effects¹; improved cardiac status² survival rates;³ and increased rehabilitation opportunities.⁴ PD patients often experience fewer negative side effects, such as nausea and dietary restrictions, than in-center patients.⁵ Additionally, home dialysis offers significant quality-of-life advantages, including flexibility in the timing of dialysis treatments, the ability to work,⁶ and reduced dependence on transportation to and from the clinic.

Congress' stated intent in the creation of the end-stage renal disease (ESRD) benefit was that "the maximum practicable number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated."⁷ However, data suggests that barriers remain for optimizing home dialysis's availability and utilization. In the Government Accountability Office's (GAO) October 2015 report, "Medicare Payment Refinements Could Promote Increased Use of Home Dialysis," they estimate that up to 25 percent of dialysis patients could realistically dialyze at home.⁸

We strongly encourage Congress to collaborate with CMS, emphasizing patient choice as the focal point of care, to improve kidney care options for patients. Working alongside their healthcare providers, patients should have access to treatment options that enhance both their overall health outcomes and quality of life. This choice is especially significant among the ESKD community.

Legislative Priorities

AKI to Home Dialysis Pathway

Acute kidney injury (AKI) is a temporary condition that, in many cases, can be prevented from progressing to ESKD. During the COVID-19 pandemic, hospitals, under a waiver, used home dialysis modalities in the intensive care unit (ICU) to treat patients with AKI. Those experiences reinforced the conclusion that home modalities are safe for AKI patients. Unfortunately, once an AKI patient reaches stability and is eligible for discharge from the hospital, the option for home dialysis is no longer permitted by Medicare regulations, which prohibit home therapy for these patients. Instead, they are required to visit an in-center dialysis facility three or more times per week for their dialysis treatment. The availability of home dialysis for AKI patients should be determined by their managing clinician, assessing the patient's ability to safely dialyze at home. Ensuring increased access and better outcomes for AKI patients is crucial, given the potential for these

¹ Heidenheim AP, Muirhead N, Moist L, et al. Patient Quality of Life on Quotidian Hemodialysis. *Am J Kidney Dis.* 2003 Jul; 42(1 Suppl):36-41.

² Culleton, B et al. Effect of Frequent NHD vs. CHD on Left Ventricular Mass and Quality of Life. *JAMA* 2007;11

³ Foley, R.N, D.T. Gilbertson et al. Long interdialytic interval and mortality among patients receiving hemodialysis. *New England Journal of Medicine.* 2011 365, no.12:1099-1107

⁴ Blagg, Christopher. "It's Time to Look at Home Hemodialysis in a New Light." Hemodialysis Horizons: Patient Safety & Approaches to Reducing Errors. (2006): 22- 28. Web. 12 Apr 2012. <https://www.aami.org/docs/default-source/uploadedfiles/filedownloads/horizons/home-blagg.pdf>

⁵ "A Brief Overview of Peritoneal Dialysis." DaVita, Inc., Web. 16 Jul 2012. <https://www.davita.com/treatment-services/peritoneal-dialysis/living-well-on-pd>

⁶ Rebecca J. Muehrer, Dori Schatell, Beth Witten, Ronald Gangnon, Bryan N. Becker, and R. Michael Hofmann, "Factors Affecting Employment at Initiation of Dialysis," *Clinical Journal of the American Society of Nephrology* 6, no. 3 (March 2011)

⁷ Section 1881(c)(6) of the Social Security Act.

⁸ Government Accountability Office. (2015). End-Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis. (GAO Publication No. 16-125). Washington, D.C.: U.S. Government Printing Office.

patients to recover kidney function and avoid permanent kidney failure, which would otherwise necessitate years of dialysis or transplantation.

Primary Care Interventions Upstream

Primary care providers play a significant role in a chronic kidney disease (CKD) or ESKD patient's journey. It is vital that patients have access to the information and education they need to make informed decisions about their modality of care. This is especially the case when considering ESKD patients, who often have comorbidities that primary care providers treat. Therefore, it is critical that Congress works with CMS to ensure patients are appropriately screened for CKD and ESKD and offered access to information about their disease, its progress, and opportunities for treatment at the right time, by the right provider. We urge lawmakers to increase CKD and ESKD screening and direct CMS to incentivize CKD and ESKD screenings in the primary care setting. Kidney screening supports a proactive, cost-effective health care strategy, aligns with value-based care principles, and empowers patients to proactively plan their care strategy in consultation with their doctor and health care team.

Expand Access to Kidney Disease Education

Currently, Medicare covers up to six sessions of kidney disease education (KDE) services provided by doctors, nurses, physician assistants, and clinical nurse specialists for individuals with stage 4 chronic kidney disease that require dialysis. However, it is extremely underutilized. It was reported in the 2015 GAO report that less than 2 percent of eligible patients used the KDE benefit and noted that its expansion could encourage an uptake of home dialysis.⁹ Congress should permit reimbursement for KDE services for Stage 3b and 5 CKD patients. Moreover, we urge the expansion of the current list of providers eligible to provide KDE to include nurses at any level with over five years of home dialysis experience. It would also be beneficial to allow physician assistants, nurse practitioners, and clinical nurse specialists to prescribe KDE services, which could help integrate primary care providers into this important educational benefit.

Collect and Analyze Medicare Advantage ESKD Data

Prior to 2021, individuals with ESKD covered under Medicare's fee-for-service (FFS) program were restricted from transitioning to Medicare Advantage (MA) plans (however, those who already had existing MA coverage were allowed to maintain it). The landscape changed with the implementation of the 21st Century Cures Act, which made all Medicare beneficiaries with ESKD eligible to enroll in MA plans starting from the 2021 open enrollment period. This shift led to a significant growth of about one-third in MA enrollment among the prevalent ESKD population in 2021, rising from 18.3 percent in 2020 to 24.5 percent in 2021.¹⁰ The Congressional Research Service expects the number of MA enrollees with ESKD to increase by 83,000 (more than 60 percent) by 2027.¹¹ The surge in MA enrollment resulted in a substantial increase of ESKD spending among MA plans of 46.4 percent within a single year and, correspondingly, Medicare FFS spending

⁹ Ibid.

¹⁰ 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, Bethesda, MD, 2022.

¹¹ U.S. Congressional Research Service. Medicare Advantage (MA) Coverage of End Stage Renal Disease (ESRD) and Network Requirement Changes. R46655. January 11, 2021

experienced a decrease.

This massive transition from FFS to MA could have unintended consequences for ESKD patients and their providers. It is critical that patients maintain access to the care they need and deserve, and aren't hindered by network adequacy, a lack of quality metrics, or a lack of other guardrails to ensure positive patient outcomes and experience. Lawmakers should consider directing a study to undertake a landscape assessment to not only compare quality and outcomes in FFS and MA, but also measure the patient experience. Importantly, there is no data readily available that measures home dialysis uptake among MA ESKD beneficiaries. Collecting and analyzing this information now will allow policymakers to nimbly adapt to this seismic shift in patient population and ensure patients are not falling through the cracks. This data will also assist lawmakers in future policymaking and better align incentives across the health care continuum.

Thank you and we look forward to working with you on these and other important initiatives aimed at improving the lives of ESKD patients in America, including expanding access to home dialysis. For any questions you may have please contact me at mfrench@vennstrategies.com or Michelle Seger at mseger@vennstartegies.com.

Sincerely,

Margaret French
Managing Director, Legislative Affairs
Alliance for Home Dialysis