



February 28, 2023

On behalf of The Alliance for Home Dialysis (Alliance), welcome to the 118th Congress. We look forward to working with you to improve the lives of your constituents who are living with kidney failure.

Today more than 780,000¹ Americans are living with kidney failure, otherwise known as end-stage renal disease or ESRD. Of these patients, 71 percent receive dialysis and only 29 percent receive a kidney transplant. These numbers show a ten-fold increase in ESRD patients since 1980.² In fact, the census of ESRD patients has increased every year it has been measured – with one exception: excess COVID deaths among this population resulted in the first decline in the number of U.S. dialysis patients in the 50-year history of the Medicare ESRD Program³.

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 ESRD patients of all ages, Congress has a key role in ensuring choice and quality care for the more than 780,000 Americans who are living with kidney failure. As more than 1 in 10 Americans are at risk from kidney failure, this role will only become more important in the coming years. As such, we are excited to share our legislative priorities and hope to work together with you to advance them.

Home dialysis—there are two modalities known as 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 effects⁴; improved cardiac status⁵ survival rates⁶; and increased rehabilitation opportunities.⁷ PD patients often experience fewer negative side effects, such as nausea and dietary restrictions, than in-center patients.⁸ Additionally, home dialysis offers significant quality-of-life advantages,

¹ U.S. Department of Health and Human Services. (2021, September). *Kidney Disease Statistics for the United States*. National Institute of Diabetes and Digestive and Kidney Diseases. Retrieved January 9, 2023, from <https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease>

² United States Renal Data System. 2020 *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, 2020.

³ <https://www.kidney.org/news/covid-19-and-its-impact-kidney-patients-utilizing-u-s-dialysis-centers>

⁴ 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.

⁵ Culleton, B et al. Effect of Frequent NHD vs. CHD on Left Ventricular Mass and Quality of Life. *JAMA* 2007;11

⁶ 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

⁷ 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. http://www.aami.org/publications/HH/Home_Blagg.pdf.

⁸ "A Brief Overview of Peritoneal Dialysis." DaVita, Inc., Web. 16 Jul 2012. <http://www.davita.com/treatment-options/home-peritoneal-dialysis/what-is-peritoneal-disease-a-brief-overview-of-peritoneal-dialysis/t/5483>.

including flexibility in the timing of dialysis treatments, the ability to work⁹, and reduced dependence on transportation.

Allowing patients to dialyze at home has never been more important than during the COVID-19 pandemic. Patients with ESRD had consistently higher COVID-19 testing rates, were twice as likely to be hospitalized from COVID-19, and had a 4 in 10 chance of dying within 90 days of being diagnosed.¹⁰ Additionally, COVID-19 is associated with a significant risk of acute kidney injury (AKI), even with individuals with healthy kidneys, resulting in serious illness and even death, often requiring dialysis. As hospitalization rates continued to rise with the different surges, hospitals struggled to provide life-saving treatment to patients because of shortages of both trained staff and supplies. Dialysis patients are immuno-compromised and allowing them to dialyze in the safety of their homes has never been so important to preserve the lives of this vulnerable community.

Today, however, only 13.7 percent¹¹ of U.S. dialysis patients receive treatment at home, with approximately 9 percent of patients receiving peritoneal dialysis and less than 2 percent of patients receiving HHD.¹² Congress' stated intent in the creation of the 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."¹³ 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.

ALLIANCE LEGISLATIVE PRIORITIES

We look forward to continuing to work with the 118th Congress to advance legislation beneficial to home dialysis patients including the following priorities:

Reimbursing Home Dialysis Treatments for AKI Patients

Acute Kidney Injury is an acute condition that, in many cases, does not have to progress to ESRD. For these AKI patients, the treatment goal is to recover kidney function. Under the PHE, waivers have been issued to hospitals to allow for acute hospital care to be delivered at home, and providers are offering home therapy to patients with acute care needs. Specifically, home dialysis for AKI patients is eligible for such a waiver only if the patient is admitted to the hospital as an in-patient. However, when an AKI patient is stable enough to be discharged from the hospital, they are no longer able to receive home dialysis. They are instead required to go to an in-center dialysis facility three or more times per week to receive their dialysis treatment. The Alliance believes that home dialysis should be available for an AKI patient if their managing clinician determines that the patient can safely dialyze at home.

⁹ 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)

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 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.

¹² U S Renal Data System, *USRDS 2016 Annual Data Report*.

¹³ Section 1881(c)(6) of the Social Security Act.

Prioritize Catheter and Vascular Access Placement

Patients who dialyze at home can receive either peritoneal dialysis or home hemodialysis. Peritoneal dialysis is a more common home modality and requires the insertion of a PD catheter.¹⁴ Home hemodialysis patients often prefer a fistula for their permanent access, given the lower risk of bloodstream infections, although a catheter is also an option for HHD patients.¹⁵ To prepare an individual for PD or HHD, the provider sends the ESRD patient home to train on the home modality and to schedule surgery for a permanent access placement of a fistula, graft, or PD catheter.

Systemic barriers have long existed to the timely placement of PD catheters, and we learned that the pandemic only exacerbated them. At the onset of the pandemic, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare and Medicaid Services (CMS) issued guidance to urge the rescheduling of non-urgent elective surgeries. Though catheter placement and fistula surgery are necessary steps to ensuring many patients can get dialysis at home, the guidance did not designate these procedures as non-elective in the guidance, leaving them open to interpretation as an “elective” or “low acuity” surgery. As a result, hospitals postponed PD catheter and fistula procedures indefinitely, which undermined ESRD patients’ ability to get permanent access placed and put many of them at risk. It is estimated that approximately 40 percent of access to health care in the United States was either delayed or canceled during the pandemic.¹⁶ Other barriers to PD catheter access include a shortage of trained staff, inadequate access to operating room space, and low reimbursement rate for PD catheter placement. The Alliance believes that these barriers need to be addressed, so ESRD patients that want to dialyze at home have ample opportunity to do so.

Continued Access to Telehealth Services Post-Pandemic

During the public health emergency (PHE), telehealth has proven to be very effective throughout the medical community. While the PHE granted new flexibilities for ESRD patients, virtual care is not new for this community. For example, the 2018 CHRONIC Care Act increased telehealth access by designating a patient’s home dialysis facility as an originating site for home dialysis services without geographic restrictions and allowing some monthly visits. Throughout the PHE, physicians were allowed to be reimbursed for visits delivered by phone. In addition to audio-only visits, digital tools can remotely monitor patients, enable providers to track the progress of disease, and can empower dialysis patients with the option to have their physiologic and therapeutic information monitored remotely, reducing the need for in-person visits.

Instead of continuously extending the telehealth services every 90 days, Congress passed a two-year extension for Medicare telehealth flexibilities in the end-of-year spending package. The U.S. Government Accountability Office (GAO) found that due to telehealth flexibility, 53 million virtual services have been provided in 2020, which is a drastic increase from 5 million.¹⁷ The Alliance applauds the two-year extension but would urge Congress to act and make some PHE waivers, such as the audio-only permissions, permanent.

¹⁴ *Annual Data Report*. (n.d.). USRDS. <https://usrds-adr.niddk.nih.gov/2022>, See Figure 1.13

¹⁵ Charmaine E. Lok, Thomas S. Huber, Timmy Lee, Surendra Shenoy, Alexander S. Yevzlin, Kenneth Abreo, Michael Allon, Arif Asif, Brad C. Astor, Marc H. Glickman, Janet Graham, Louise M. Moist, Dheeraj K. Rajan, Cynthia Roberts, Tushar J. Vachharajani, Rudolph P. Valentini, KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update, *American Journal of Kidney Diseases*, Volume 75, Issue 4, Supplement 2, 2020

¹⁶ Agarwal AK, Sequeira A, Oza-Gajera BP, et al. Lessons learnt and future directions in managing dialysis access during the COVID 19 pandemic: Patient and provider experience in the United States. *The Journal of Vascular Access*. June 2021. doi:10.1177/11297298211027014

¹⁷Office, U. S. G. A. (2022, September 15). *Telehealth in the pandemic-how has it changed health care delivery in Medicaid and Medicare?* U.S. GAO. Retrieved January 9, 2023, from <https://www.gao.gov/blog/telehealth-pandemic-how-has-it-changed-health-care-delivery-medicaid-and-medicare#:~:text=We%20found%20that%20the%20number,GAO's%20Medicaid%20expert%2C%20Carolyn%20Yocom>.

Addressing Dialysis and Nephrology Staffing Shortage

Every industry has been impacted by supply chain issues and staffing shortages due to the pandemic, and the nephrology community is no different. These challenges have been particularly difficult for manufacturers of ESRD-related supplies, who have faced upstream supply challenges in securing raw materials and component parts. Unlike other sectors, delays in treatment are the difference between life and death. Healthcare stakeholders have struggled to compete with larger industries for access to dialysis equipment. Even though they were able to fix the short-term problems, a more thoughtful policy approach for sourcing life-saving medical equipment needs to be developed for future pandemics. Alliance believes that policymakers must prioritize the needs of medical equipment manufacturers, who are integral to America's vulnerable population, and create ample supply to ensure consistent access even when global markets are disrupted.

Additionally, the Alliance believes Congress should work with the Department of Health and Human Services (HHS) to replenish dialysis supplies at the Strategic National Stockpile within the Office of the Assistant Secretary for Preparedness and Response to reduce staff burden and mitigate the chances of future shortages.

Even before the COVID-19 pandemic, the nursing shortage was projected to continue through 2030 for multiple reasons, including the retirement of an entire generation of nurses, persistent insufficient staffing, and unsupportive work environments that contributed to job stress, reduced job dissatisfaction burnout, and job exit.¹⁸ Due to the industry-wide nursing shortage, patients new to dialysis have been delayed in being discharged from the hospital. Not only are hospitals not equipped to help dialysis patients adjust to dialysis and help regain some sense of “normalcy”, but they are also exposing immuno-compromised individuals to other illnesses. The Alliance believes in efforts to reduce industry barriers that prevent a stable ESRD patient from being safely discharged, allowing them to dialyze at home safely.

Expand the Kidney Disease Education Benefit

Medicare covers up to 6 sessions of Kidney Disease Education (KDE) services provided by doctors, nurses, physician assistants, and clinical nurse specialists for individuals with stage IV 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.

We believe that Congress should permit reimbursement for KDE services for Stage V Chronic Kidney Disease patients and for all KDE services provided at dialysis facilities. Furthermore, we would like to add to the current list of providers eligible to provide KDE be expanded to include nurses at any level with over five years of home dialysis experience. We also believe it would be beneficial to allow physician assistants, nurse practitioners, and clinical nurse specialists to prescribe KDE services.

Once again, congratulations and we look forward to working with you on these and other important initiatives. For any questions you may have please contact Kelly Ferguson at kferguson@vennstrategies.com or Michelle Seger at mseger@vennstrategies.com.

Sincerely,

¹⁸ Thomas-Hawkins, C., Payne, G. M., & Bednarski, D. (2022). The growing demand for home dialysis therapies: Challenges and potential solutions. *Nephrology Nursing Journal*, 49(2), 109. <https://doi.org/10.37526/1526-744x.2022.49.2.109>

Stephanie Silverman
Executive Director