



July 16, 2021

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20005

Dear Representative DeGette and Representative Upton:

The Alliance for Home Dialysis (Alliance) is pleased to offer comments in response to the 21st Century CURES 2.0 discussion draft issued on June 22. We thank you for your work to modernize and improve care delivery to patients through this legislation, including those who utilize home dialysis.

The Alliance is a coalition of kidney community stakeholders representing patients, clinicians, providers, and industry. Alliance members have come together to identify policy opportunities and regulatory actions that can increase and improve utilization of home dialysis for Americans with End Stage Renal Disease (ESRD), because we believe that all patients deserve the opportunity to dialyze at home. Through our efforts, the Alliance promotes and advances policies to facilitate treatment choice in dialysis care, while addressing systemic barriers that limit access for patients and their families to the many benefits of home dialysis.

As you may know, there are two types of home dialysis: peritoneal dialysis (PD) and home hemodialysis (HHD). PD treatment uses a special solution injected into the individual's abdominal cavity to filter blood and remove waste. This process occurs several times during a 24-hour period and can be done at home, in the workplace, or in other non-medical settings. Individuals treated with PD can also use a machine, known as a cyclor, to perform these exchanges while they are sleeping.¹ Hemodialysis (HD) is a treatment in which an artificial membrane, known as a hemodialyzer, filters the blood. This is the most common type of treatment used in dialysis facilities, but it can also be done at home.² At the end of 2018, there were nearly 69,000 patients performing dialysis in the home, or 12.5% of all dialysis patients. Nearly 85% of patients on home dialysis performed peritoneal dialysis.³ While the portion of dialysis patients performing home dialysis in the United States is slowly increasing, the U.S. lags many other industrialized countries.⁴

¹ <https://www.mayoclinic.org/tests-procedures/peritoneal-dialysis/about/pac-20384725>

² <https://www.healthline.com/health/dialysis#types-of-dialysis>

³ <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>

⁴ <https://adr.usrds.org/2020/end-stage-renal-disease/11-international-comparisons>

Although the burden of kidney disease is felt in all communities across the country, the degree of burden differs significantly depending on socioeconomic, racial, cultural, and geographic factors. Research shows that communities of color and low-income communities are disproportionately affected by chronic kidney disease (CKD) and possess a much higher risk of developing kidney failure. Unequal access to home dialysis therapy, pre-dialysis nephrology care, insurance, health care technologies, education about CKD and treatment options, and health education more generally all contribute to these disparate outcomes. Tragically, these barriers and the ensuing inequity for low-income patients and communities of color have been both revealed and exacerbated by the COVID-19 pandemic.

The Alliance believes that Congress can play an integral role in ensuring that all patients have equitable access to the home dialysis modalities. Therefore, outlined below are comments to targeted sections of the discussion draft that identify opportunities for this legislation to ensure that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis can access these modalities.

Sec. 201. Educational Programs and Training for Caregivers

Patients who do choose home dialysis need, and often lack, assistance and moral support when beginning dialysis. Dialysis care partners are trusted friends or family members who play a critical role, assisting patients with important tasks such as setting up the home dialysis equipment, cooking meals, and running errands. Care partners also provide patients with support and encouragement. Unfortunately, all too many patients, especially those in underserved communities, lack care partners entirely. Furthermore, where these caregivers do exist, they are highly vulnerable to burnout. When support is lacking, particularly in the beginning of a home dialysis journey, adverse health outcomes may occur, and patients may be forced to revert to in-center treatment.

We are encouraged to see the recognition of the importance of caregivers in this discussion draft and appreciate your commitment to augmenting the at-home care team by including grants for caregiver education and training. In recognition of the further need for robust caregiver support, particularly in underserved communities, we ask you to consider more broadly applicable funding, such as grants for childcare, replacement of lost income, or compensation. Doing so may help alleviate the economic burden currently shouldered by caregivers and provide more flexibility for these individuals.

Sec. 403. Extending Medicare Telehealth Flexibilities

Telehealth access can be a struggle for underserved patients living in both urban and rural communities. Many of our member organizations are investing in new telehealth and remote patient monitoring (RPM) capabilities because we know that patients can benefit from the option to receive some of their dialysis care remotely. However, lack of access to high-speed internet or appropriate communication devices keeps some of our member organizations' patients from leveraging the benefits of telehealth and RPM technology. We were encouraged to see Congress' recognition of these challenges when it appropriated \$200 million in the CARES Act for the Federal Communications Commission (FCC) to support the efforts of health care providers to enable the provision of telehealth. Beyond this initial effort, we urge Congressional leadership to provide further funding for broadband access in underserved communities to ensure that patients living or working in these communities can receive needed care through telehealth or RPM.

The Alliance for Home Dialysis has long supported the designation of both a patient's home and dialysis facility as originating sites for home dialysis services, without geographic restrictions. We were pleased to see Congress grant this request in the 2018 Balanced Budget Act, which included the CHRONIC Care

Act and its provisions to waive these requirements for home dialysis patients. Since the Centers for Medicare and Medicaid Services (CMS) has temporarily allowed both these venues to serve as originating sites for all dialysis patients regardless of modality during the COVID-19 public health emergency, our members report that the benefits have redounded to the benefit of the broader kidney patient community:

- Chronic kidney disease (CKD) patients need regular care to properly manage their disease, including education on their modality options if and when they enter kidney failure. Many of the challenges that CKD patients face in receiving that care can be ameliorated by allowing them to receive some care through telehealth or RPM.
- Kidney transplant patients require extensive evaluation and education before and after their transplant surgery, as well as continued monitoring post-surgery to evaluate organ function, medication adherence, and so on. Accessing this care requires regular visits with medical staff located at kidney transplant centers, which are often urban institutions that require patients to travel a long way to seek care. Many of these visits can be conducted by telehealth, saving patients time and expense.
- Providers who may be called upon to serve in an acute care setting can use telehealth or RPM capabilities to provide dialysis care to patients in a dialysis center or at home.

We therefore continue to call on Congress to permanently remove Medicare's geographic and originating site restrictions, to open these opportunities to ESRD patients across the country, regardless of modality.

Sec. 405. Secretary of Health and Human Services Report on Coverage for Innovative Technologies

Increased use of digital platforms and online applications often empower patients to take a more active role in their healthcare decisions, alongside their care provider. The Alliance believes that as the standard of care for patients evolves towards more patient-centered modalities, RPM will be an important tool for providers to track the progress of disease and empower dialysis patients with the option to have their physiologic and therapeutic information monitored remotely, reducing the need for in-person visits. We encourage Congress to recognize that dialysis patients are likely to use digital technologies across the course of their day, not simply in conjunction with a particular dialysis session. As standards of care evolve, payment for digital technologies should reflect that reality.

Conclusion

The Alliance values the opportunity to provide comments to the 21st Century CURES 2.0 discussion draft. We appreciate your efforts to improve healthcare delivery and look forward to working with you on this critical issue. Should you need any further information or wish to contact Alliance staff, please contact Kelly Ferguson at kferguson@homedialysisalliance.org or 202-280-1965.

Respectfully,



Michelle Seger
Managing Director



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American Nephrology Nurses Association*
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