

Dear Kidney Care Advocate,

Below is a draft letter that can be sent to Chiquita Brooks-LaSure, Administrator for the Centers for Medicare & Medicaid Services (CMS). It is our hope that your outreach will further move CMS to take action on modernizing the Medicare Conditions for Coverage, giving more people with end-stage renal disease (ESRD) access to the flexibility, quality, and choice that home dialysis modalities provide. We hope you will lend your name to this effort by sending this letter and request to Administrator Brooks-LaSure.

Urgent action is needed as CMS is currently drafting the ESRD proposed rule this spring and we would like to see separate regulations and guidance for home dialysis in association with the upcoming release of this rule. Please let us know if you have any questions and thank you for your support on this essential advocacy for the ESRD community.

Sincerely,

Innovate Kidney Care

EMAIL ADDRESS: chiquita.brooks-lasure@cms.hhs.gov

SUBJECT LINE: Action Needed – Modernizing the ESRD Conditions for Coverage Cannot Wait

April 28, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Brooks-LaSure:

I write to you today, on behalf of the more than 700,000 Americans affected by end-stage renal disease (ESRD). As an ESRD **patient, provider, or advocate**, I know firsthand how the burden of kidney disease can impact the lives and communities of those living with this disease. ESRD patients, living with total and permanent kidney failure, are among the most vulnerable patient populations, requiring either kidney transplantation and/or living dependent on consistent dialysis. ESRD accounts for approximately \$37 billion in Medicare and Medicaid spending annually, or the equivalent of \$67,000 a year for each beneficiary¹. **I am writing today to ask**

¹ USRDS, [Healthcare Expenditures for Persons with ESRD](#), 2020.

CMS to modernize the Medicare ESRD CfCs through separate regulations for home dialysis to be included with the FY 2022 ESRD rule.

It is also important to note that the disease burden falls disproportionately on minority populations, particularly Black and Brown communities. According to the US Renal Data System (USRDS) 2020 Annual Data Report, for every white person who develops ESRD, three Black people develop the condition, and for every three non-Hispanic people who develop ESRD, four Hispanic people develop it.² While African Americans comprise 13% of the U.S. population, they represent 30% of the ESRD population.

More than half a million Americans depend on dialysis treatments three or more times per week to live. And, while there are few physical limitations on who can receive home dialysis treatment, only 13% of people who dialyze currently do, despite data indicating more favorable outcomes with home compared to in-center hemodialysis. Receiving in-center dialysis can create a significant burden on patients, impacting their quality of life, ability to maintain employment and adherence to their dialysis treatment regimen.

Home dialysis offers people autonomy, which in turn allows them to pursue economic opportunities and a better quality of life. It also allows for more flexible and personalized care, including personalized ultrafiltration rates, dialysis duration and treatment frequencies, which impact both patient clinical outcomes, symptom burden and quality-of-life outcomes. In addition, studies indicate that in the initial five years of therapy, hemodialysis conducted more frequently at home is associated with similar survival rates as transplantation, suggesting that when preemptive and living donor transplantation is not an immediately available option, home dialysis can serve as a bridge to transplantation.³

I write to you today to ask for your support in addressing a significant challenge to patients accessing home dialysis services. In 2008, CMS ESRD Conditions for Coverage (CfCs) Final Rule, setting the minimum health and safety standards and requirements that all Medicare and Medicaid participating dialysis facilities must meet. While there have been groundbreaking improvements and innovations in the kidney care space since that time, the CfCs have remained unchanged. Currently, these outdated requirements present many barriers to patients looking to access home dialysis modalities and clinicians looking offer this treatment option to their patients. We need to modernize the Medicare ESRD CfCs to bring current regulations into alignment with current and future kidney care delivery models and treatment modalities.

I would kindly ask CMS to modernize the Medicare ESRD CfCs through separate regulations for home dialysis to be included with the FY 2022 ESRD rule. It is essential that we address this substantial barrier to ESRD patients and providers to improve patients' lives and reduce the disease burden of ESRD for Americans today. Specific recommendations on my requested updates can be viewed in the [Innovate Kidney Care response to the CMS Request for Information](#) on kidney disease.

² USRDS, [Annual Data Report: ESRD](#), 2020.

³ Axelrod DA, Schnitzler MA, Xiao H, et al. An economic assessment of contemporary kidney transplant practice. *Am J Transplant.* 2018;18(5):1168-1176. doi:10.1111/ajt.14702.

Thank you for your consideration of this urgent request.

Sincerely,