



July 10, 2023

Honorable Bernie Sanders
Chairman
U.S. Senate Health, Education, Labor, and
Pension Committee
428 Senate Dirksen Office Building
Washington, D.C., 20510

Honorable Bill Cassidy, M.D.
Ranking Member
U.S. Senate Health, Education, Labor, and
Pension Committee
428 Senate Dirksen Office Building
Washington, D.C., 20510

Chairman Sanders and Ranking Member Cassidy,

On behalf of the Alliance for Home Dialysis – a coalition of providers, patients, and innovators focused on policies that facilitate treatment choices in dialysis care – thank you for your bipartisan efforts to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA). We appreciate the opportunity to offer comments on the July 3rd discussion draft and ask you to work with us and our member organizations to bolster the proposed bill with measures to safeguard the lives and well-being of ESRD patients.

The COVID-19 pandemic was a life-altering experience for all Americans, but those living with end-stage kidney disease (ESKD) have borne a uniquely heavy burden felt by a smaller fragment of our country. The pandemic reality is illustrated by data that show unusually high mortality rates for ESRD patients. The impact of COVID-19 on people with kidney failure resulted in the first-ever decline in the number of patients receiving dialysis in the United States in the 50-year history of the Medicare End-Stage Renal Disease Program¹. Dialysis patients often live with multiple comorbidities and have far higher risks of severe illness or death from COVID-19 than the rest of the population^{2,3}. Moreover, ESKD occurs disproportionately among racial minorities who have likewise been in the crosshairs of COVID-19, particularly in more disadvantaged metropolitan statistical areas⁴. These trends created a perfect storm of mortality and made ESRD an acutely dangerous condition to live with during the pandemic.

The risks to this population bore out in tragic COVID statistics: In just the first 7 months of the pandemic, the Centers for Disease Control and Prevention (CDC) estimated that there were 7,000-10,500 excess deaths in the ESKD population⁵. As the emergency phase of COVID-19 ends⁶, and your committee

¹ https://www.asn-online.org/policy/webdocs/22.1.16JointNephrologyLettertoHHS_.pdf

² <https://jasn.asnjournals.org/content/31/7/1409>

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7314621/>

⁴ <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html>

⁵ <https://www.cdc.gov/mmwr/volumes/70/wr/mm7022e2.htm>

⁶ <https://health.clevelandclinic.org/is-the-pandemic-over/>

advances key legislation in preparation for a future pandemic, we submit to you that there has never been a more critical time to address systemic barriers limiting access to home dialysis in the United States. Home dialysis, both peritoneal dialysis (PD) and home hemodialysis (HHD), not only offers patients significant quality of life advantages, including clinically meaningful physical and mental health improvements, but also allows these highly vulnerable patients to socially distance themselves, avoid potential exposure, and recuperate from illness if they do fall ill with COVID-19⁷. As Congress, regulators, and stakeholders work to bolster our national pandemic preparedness for future health emergencies, the Alliance offers for consideration the perspectives below on learnings from home dialysis patients and their clinicians' experiences from COVID-19.

Supply Chain Challenges

During the height of the pandemic, the healthcare industry experienced wide-ranging supply chain challenges alongside many other sectors. That said, patients' and providers' access to medical products can make the difference between life and death. These challenges have been particularly difficult for manufacturers of ESRD-related supplies, who faced upstream supply challenges in securing raw materials and component parts, e.g., microchips, resins, polymers, and plastic derivatives. Healthcare stakeholders struggled to compete with larger industries for access to these component parts, which added to an already challenging environment. Dialysis providers did collaborate with CMS on efforts such as the Dialysis Community Response Network (DCRN); several stakeholders pointed to this public-private effort as a key to mitigating some of the worst supply constraints. A more planful, dynamic policy approach to sourcing the component parts necessary for lifesaving and life-sustaining treatments should be developed for future pandemics. A widespread breakdown of the supply chain requires a whole-of-system approach to fix – an approach that accounts appropriately for life-sustaining devices and modernizes our national stockpiling strategy to incorporate real-time vendor input. In this way, Congress can prioritize the needs of medical equipment manufacturers, who are integral to vulnerable patients like those with ESRD while creating ample supply to ensure consistent access even when global markets are disrupted.

Catheter and Vascular Access Placement

Patients who dialyze at home can receive either peritoneal dialysis or home hemodialysis. Peritoneal dialysis is a more common method of home dialysis and requires the surgical insertion of a PD catheter⁸. Some home hemodialysis patients also get a catheter placed surgically. To prepare an individual for home dialysis, the provider sends the ESRD patient home to train on the home modality and to schedule surgery for a permanent access placement fistula, graft, or PD catheter⁹. Systemic barriers – such as lack of trained staff, inadequate operating room space access, and the low reimbursement rate for PD catheter placement - have long existed to the timely placement of PD catheters, and the pandemic exacerbated these barriers. Perhaps most challenging was that, at the onset of the pandemic, the CDC

⁷ NX Stage. The Benefits of More Frequent Home Dialysis. NX Stage. 2021.

<https://www.nxstage.com/patients/benefits-of-home-hemodialysis>

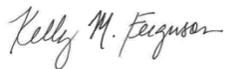
⁸ <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>, See Figure 1.13 10 KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update - American Journal of Kidney Diseases (ajkd.org)

⁹ KDOQI Clinical Practice Guideline for Vascular Access: 2019 Update - American Journal of Kidney Diseases (ajkd.org)

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 – a lifesaving procedure -- at home, where they would be free from potential COVID exposure, the guidance did not designate these procedures as non-elective, leaving them open to interpretation surgery. Some alternative surgical theaters, such as ambulatory surgical centers, closed entirely to preserve personal protective equipment (PPE) and mitigate labor shortages. The result was that 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% of access care in the United States was either delayed or canceled during the pandemic¹⁰. In 2020, the Alliance wrote to CMS urging them to clarify that PD catheter placement is not an elective procedure, and CMS addressed this issue in later guidance. However, the delay in issuing the clarification resulted in widespread delays in PD catheter placements. Furthermore, some states were slow to align with the federal guidance, continuing confusion and adding an extra barrier to access. We encourage CMS and its state counterparts to provide more precise and earlier guidance on these issues in future healthcare emergencies so that patients who begin dialysis under adverse circumstances do not face unnecessary barriers to the access procedure and the modality of their choice.

In conclusion, the ESRD community's experience over the last 3+ years has provided us with profound learnings that can be acted upon to create positive change for ESRD patients. We appreciate your attention to these issues and would appreciate the opportunity to discuss these issues in more detail with your staff as they work to advance this legislation. Please contact kferguson@homedialysisalliance.org with any questions or to arrange a further discussion.

Sincerely,



Kelly Ferguson
Policy Director
Alliance for Home Dialysis

¹⁰ 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