



Administrator Chiquita Brooks-LaSure
Center for Medicare and Medicaid Service
7500 Security Boulevard
Baltimore, MD 21244

June 2, 2023

Dear Administrator Brooks-LaSure:

The Alliance for Home Dialysis is a coalition of kidney dialysis stakeholders that brings together patients, clinicians, providers, and industry in order to advance policies that improve treatment choices for people who need dialysis. We work together to address systemic barriers that limit access to home dialysis, which can provide both clinical and quality-of-life benefits. For example, home hemodialysis is associated with a lower risk of death and better control of blood pressure,¹ while peritoneal dialysis has better preservation of residual kidney function and, in some kidney failure conditions, it can help to reduce hospitalization rates and duration.² Both home modalities allow for more flexibility in scheduling treatments as compared to traditional three-days per week in-center hemodialysis, and many patients are even able to continue working, traveling and caring for families.

We are reaching out today to make you aware of some concerns we have related to acute kidney injury (AKI) patients who require dialysis (AKI-D). We are asking CMS to include policy changes in a formal rulemaking process to allow home dialysis for AKI patients who prefer this as their choice of dialysis. This specifically applies to those patients who are no longer hospitalized and have decided along with their doctor that home dialysis is the right choice for them as they attempt to regain kidney function.

As you may know, an AKI episode is sudden kidney damage that causes a build-up of waste in the blood within a few hours to a few days. AKI can have many causes, including allergic reactions, low blood pressure or shock, heart attack, blood loss, injury. Recently, this issue around care for patients with AKI was in the news due to the high percentage of ICU patients with COVID-19 who developed AKI requiring dialysis. In fact, according to the New York Times, at the height of the pandemic, between 20-40% of COVID-19 ICU patients needed dialysis due to AKI.³

Treatment of AKI, whether developed due to COVID-19 or other reasons, typically requires a hospital stay, often in the ICU. Many people who experience AKI are already in the hospital for another reason, and sometimes the reason they are hospitalized is what caused the AKI in the first place. While hospitalized, AKI patients receive

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5317253/>

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4260684/>

³ <https://www.nytimes.com/2020/04/18/health/kidney-dialysis-coronavirus.html>

kidney replacement therapy to perform the functions of the kidney with the hope that, eventually, the kidneys will regain some or all their function. Currently, once an AKI patient is stable enough to leave the hospital, if they still need dialysis (and many do), they begin outpatient hemodialysis in a dialysis facility. For these patients, the hope is that, over time, the kidneys will recover, and the patient can cease dialysis therapy. According to the USRDS 2022 Annual Data Report, at 3 months after beginning outpatient dialysis among individuals with AKI, 30% recovered kidney function, 36% progressed to ESRD (meaning they would need dialysis permanently or a kidney transplant), and 16% died.⁴ The remainder were administratively maintained as AKI-D.

While Medicare has reimbursed for post-discharge outpatient dialysis in ESRD facilities for AKI patients since 2017,⁵ Medicare *neither* allows nor reimburses for home dialysis (either peritoneal dialysis or home hemodialysis) for AKI-D patients. In 2020 alone, 3,023 patients received outpatient dialysis for AKI.⁶ **Given the potential clinical and quality of life benefits of home dialysis, mentioned above, the Alliance strongly believes that home modalities should be allowed for AKI patients after hospital discharge if their nephrologist or managing clinician agrees that it is the best clinically appropriate treatment modality for their individual case.** While we understand that not every AKI-D patient will be an appropriate candidate for home dialysis therapy, we do believe that all patients deserve the opportunity to collaborate with their doctor to determine their optimal, individualized treatment path without being limited by coverage or payment limitations.

We understand that CMS has expressed concern that AKI-D patients need close clinical supervision throughout their dialysis treatment. We agree and know that this supervision is possible, whether they receive their dialysis at a facility or at home. Home dialysis patients receive ample training to ensure they can perform treatment and are monitored closely by their care teams, through informational reports to the clinic. In addition, technological advances like remote patient monitoring help to ensure that providers can respond to potential problems and advise home patients in real-time.

Based on these factors, we respectfully request that CMS evolve its AKI policy to reflect the consensus feedback provided by stakeholders to the RFI in the CY2022 ESRD PPS rule and on *CMS-3409-NC – Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities*. This change will ensure that AKI patients if determined to be clinically appropriate candidates, can access home dialysis therapy post-discharge.

Sincerely,



Michelle Seger
Managing Director
Alliance for Home Dialysis

Cc: Jonathan Blum

⁴ <https://usrds-adr.niddk.nih.gov/2022/chronic-kidney-disease/4-acute-kidney-injury>

⁵ See *id.*

⁶ See *id.*

Signed by:

American Association of Kidney Patients
American Kidney Fund
American Nephrology Nurses Association *
American Society of Nephrology*
American Society of Pediatric Nephrology
Baxter*
Cleveland Clinic
DaVita*
DEKA*
Dialysis Clinic, Inc.*
Dialysis Patient Citizens*
Fresenius Medical Care *
Home Dialyzors United
ISPD North America
Medical Education Institute
National Kidney Foundation*
National Renal Administrators Association
Northwest Kidney Centers
NxStage Medical*
Outset Medical*
Renal Physicians Association*
Satellite Healthcare*
The Rogosin Institute*
TNT Moborg International Ltd.

** denotes Steering Committee Member*