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

March 18, 2024

Dear Administrator Brooks-LaSure:

The Alliance for Home Dialysis is a coalition of kidney dialysis stakeholders that brings together patients, clinicians, providers, and industry 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 is known to preserve 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 dialysis treatments as compared to traditional three-day per week in-center hemodialysis, and many patients are even able to continue working, traveling and caring for families.

As you are aware, the Alliance has a long track record of advocating for access to home dialysis for acute kidney injury (AKI) patients, including an official comment to last year's proposed ESRD Prospective Payment System (PPS) Rule. Given the clinical and quality of life benefits associated with home dialysis, mentioned above, the Alliance urges that home modalities be enabled for AKI patients after hospital discharge when a nephrologist or other managing clinician agrees that the modality is the best treatment option for the patient's case. While not every AKI patient is an appropriate candidate for home therapy, all patients deserve the opportunity to work with their doctor to determine a treatment path that is not limited by payment restrictions on certain modalities.

While we appreciate CMS' attention to this important issue, we are concerned that home dialysis for AKI patients is still not reimbursed, nor allowed at all under Medicare. We urge CMS to use this year's PPS rulemaking process to explicitly allow AKI patients to dialyze at home. What follows is a response to

[1] Walker, Rachael C et al. "Home hemodialysis: a comprehensive review of patient-centered and economic considerations." ClinicoEconomics and outcomes research : CEOR vol. 9 149-161. 16 Feb. 2017, doi:10.2147/CEOR.S69340. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5317253/

[2] François, Karlien, and Joanne M Bargman. "Evaluating the benefits of home-based peritoneal dialysis." International journal of nephrology and renovascular disease vol. 7 447-55. 4 Dec. 2014, doi:10.2147/IJNRD.S50527. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4260684/

some concerns that CMS has raised about this prospect, which we hope will facilitate action on CMS' part to provide coverage for home dialysis for appropriate AKI patients.

1. **When determined to be appropriate by clinician and patient, dialyzing at home is widely considered by clinicians to be safe for AKI patients.**

We understand that CMS has expressed concern that AKI patients need close clinical supervision throughout their dialysis treatment. This is not only possible with home dialysis; in some cases, it is actually preferred. Home dialysis patients receive training to ensure they are capable of performing treatment and are monitored closely by their treatment teams, often through informational reports from the dialysis machine to the clinic. In addition, technological advances like remote patient monitoring help to ensure that providers can respond to potential challenges with home dialysis – in the same way as they do for ESKD patients -- and guide home patients in real time.

Perhaps one of the most important aspects of patient safety deals with dialysis access type. Currently, most patients with AKI start on in-center hemodialysis with a central venous catheter. These catheters carry the risk of infection and are associated with higher risks of death and cardiovascular events over other access types, like a fistula or peritoneal dialysis catheter.[3] CMS recognized these risks when it established the Fistula First Initiative in 2004 and sought to reduce the number of central venous catheters being used in dialysis.[4] AKI patients likewise deserve the opportunity to elect home dialysis and thereby avoid many of the risks that a central venous catheter carries.

In addition, one home dialysis modality - peritoneal dialysis (PD) - is not only safe but is also strongly associated with the preservation of residual kidney function. In fact, it is believed that this benefit explains the slightly higher survival of patients on PD compared to those on hemodialysis in the first 1.5-

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[3]Fan PY, Schwab SJ. "Vascular access: concepts for the 1990s." J Am Soc Nephrol 1992. https://www.uptodate.com/contents/tunneled-hemodialysis-catheter-related-bloodstream-infection-crbsi-epidemiology-pathogenesis-clinical-manifestations-and-diagnosis/abstract/9

Taylor G, Gravel D, Johnston L, et al. "Incidence of bloodstream infection in multicenter inception cohorts of hemodialysis patients." Am J Infect Control 2004. https://www.uptodate.com/contents/tunneled-hemodialysis-catheter-related-bloodstream-infection-crbsi-epidemiology-pathogenesis-clinical-manifestations-and-diagnosis/abstract/10

Pastan S, Soucie JM, McClellan WM. "Vascular access and increased risk of death among hemodialysis patients." Kidney Int 2002. https://www.uptodate.com/contents/tunneled-hemodialysis-catheter-related-bloodstream-infection-crbsi-epidemiology-pathogenesis-clinical-manifestations-and-diagnosis/abstract/11

Allon, Michael et al. "Effect of change in vascular access on patient mortality in hemodialysis patients." American journal of kidney diseases : the official journal of the National Kidney Foundation vol. 47,3 (2006): 469-77. doi:10.1053/j.ajkd.2005.11.023. https://pubmed.ncbi.nlm.nih.gov/16490626/

Ravani, Pietro et al. "Associations between hemodialysis access type and clinical outcomes: a systematic review." Journal of the American Society of Nephrology : JASN vol. 24,3 (2013): 465-73. doi:10.1681/ASN.2012070643. https://pubmed.ncbi.nlm.nih.gov/23431075/

[4]CMS. (2004, April 14). CMS Launches "Fistula First" Initiative to Improve Care and Quality of Life for Hemodialysis Patients. CMS.Gov. https://www.cms.gov/newsroom/press-releases/cms-launches-fistula-first-initiative-improve-care-and-quality-life-hemodialysis-patients

2 years of treatment.[5] For those AKI patients who do not progress to ESKD, preserving as much residual renal function as possible during treatment is key; and for those who do progress to ESKD, if PD can slow down that progression by preserving residual kidney function for a longer period of time, that is a good outcome.

In-center hemodialysis thrice weekly- even in the setting of AKI- is associated with cardiac, central nervous system and renal stunning (ischemia). This does not occur in peritoneal dialysis due to the continuous nature of the therapy and may be reduced with lower ultrafiltration associated with more frequent hemodialysis, also typically done in the home setting. Both home therapies are associated with better blood pressure control (both hypertension and hypotension), which also should prevent further renal and cardiac damage during the time of AKI, hopefully enhancing chances of renal recovery. While these blood pressure benefits have not been studied in the setting of AKI, we think a strong physiologic case is reasonable.

Currently, home dialysis for AKI is provided when specifically requested by the nephrologist. Because Medicare does not reimburse for home dialysis for patients with AKI, home modalities can only be provided to patients who are covered by commercial insurance. We believe that treatment decisions should be driven by the prescribing nephrologist in coordination with the patient's treatment goals as opposed to Medicare reimbursement policy. But for the current Medicare reimbursement exclusion, prescribing nephrologists would make a patient-by-patient decision on the appropriateness of home modalities by considering medical stability, any physical, cognitive or visual impairments that would

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[5] Schaubel, D E et al. "Comparing mortality rates on CAPD/CCPD and hemodialysis. The Canadian experience: fact or fiction?" Peritoneal dialysis international: journal of the International Society for Peritoneal Dialysis vol. 18,5 (1998): 478-84. https://pubmed.ncbi.nlm.nih.gov/9848625/

Collins, A J et al. "Mortality risks of peritoneal dialysis and hemodialysis." American Journal of kidney diseases: the official journal of the National Kidney Foundation vol. 34,6 (1999): 1065-74. doi:10.1016/S0272-6386(99)70012-0. https://pubmed.ncbi.nlm.nih.gov/10585316/

Termorshuizen, Fabian et al. "Hemodialysis and peritoneal dialysis: comparison of adjusted mortality rates according to the duration of dialysis: analysis of The Netherlands Cooperative Study on the Adequacy of Dialysis 2." Journal of the American Society of Nephrology: JASN vol. 14,11 (2003): 2851-60. doi:10.1097/01.asn.0000091585.45723.9e. https://pubmed.ncbi.nlm.nih.gov/14569095/

James G. Heaf, Hans Løkkegaard, Melvin Madsen et al. "Initial survival advantage of peritoneal dialysis relative to haemodialysis." Nephrology Dialysis Transplantation, Volume 17, Issue 1, January 2002, Pages 112–117. https://doi.org/10.1093/ndt/17.1.112

Liem, Y S et al. "Comparison of hemodialysis and peritoneal dialysis survival in The Netherlands." Kidney International vol. 71,2 (2007): 153-8. doi:10.1038/sj.ki.5002014. https://pubmed.ncbi.nlm.nih.gov/17136031/ McDonald, Stephen P. et al. "Relationship between dialysis modality and mortality." Journal of the American Society of Nephrology : JASN vol. 20,1 (2009): 155-63. doi:10.1681/ASN.2007111188. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2615722/

Foley, R N et al. "Mode of dialysis therapy and mortality in end-stage renal disease." Journal of the American Society of Nephrology: JASN vol. 9,2 (1998): 267-76. doi:10.1681/ASN.V92267. https://pubmed.ncbi.nlm.nih.gov/9527403/

make home therapy more difficult, and in the case of PD, whether the patient had any existing abdominal problems that would limit the ability to place a PD catheter.

Finally, home dialysis as a modality empowers patients to become an integral and active participant in their treatment plan, rather than a passive recipient of care. This kind of patient empowerment is key to ensuring that patients have the best outcomes possible.

2. **Dialysis facilities will be able to easily integrate AKI patients on home dialysis into existing patient workflows.**

The current state of care for dialysis patients is well-positioned to facilitate access to home dialysis for AKI patients. AKI patients can easily be integrated into existing systems including home dialysis training programs and technology schema like remote patient monitoring and telehealth programs. Connected cyclers allow monitoring of patient treatments in near real-time, enabling the patient's care team to immediately intervene for any identified issues. An AKI patient would be very similar in intake and training needs as a new ESKD patient. As with any new patient, the choice of modality would be a collaborative decision between the patient and their nephrologist, based on appropriate clinical, lifestyle, and other factors.

Clinically, patients - whether in-center or dialyzing at home - have their remaining kidney function measured on a regular basis along with the necessary adequacy of a patient's dialysis. Facilities and clinical teams will be able to do the same for AKI patients, bearing in mind that the goal for many AKI patients is to get better and progress off of dialysis entirely. There is an existing system built to watch for kidney recovery, as much as it watches for effective dialysis.

For these reasons, we believe that operationalizing AKI care at home is readily available and easily accessible.

3. **While time on-therapy is a consideration, AKI patients nonetheless deserve the chance to dialyze at home.**

Whether AKI patients dialyze for a short time and recover, or they progress to ESKD and need a lifetime of dialysis (or transplant), they deserve access to home dialysis. According to the USRDS, in 2020, 64 percent of older Medicare beneficiaries who initiated outpatient dialysis for AKI remained on dialysis while approximately 11 percent progressed to ESKD.[6] By 6 months, 2.4 percent remained on dialysis with AKI and approximately 48 percent had progressed to ESKD.[7] In contrast, training for peritoneal dialysis, which would be the most likely home therapy for an AKI patient, takes 7-8 days before the patient or caregiver can perform the therapy. For most patients who initiate outpatient dialysis for AKI, this timeline would allow for months of dialyzing at home, rather than in-center, before they are declared ESKD or before they recover. In addition, if patients do recover from AKI, they often do not regain all kidney function, but instead recover to an earlier stage of CKD; this means that eventually they

[6] USRDS Report 2023, Figure 4.10, Clinical outcomes during 6 months after initiation of outpatient dialysis for treatment of acute kidney injury in older adults, 2020
[7] *Id.*

may progress to ESKD anyway, and the education they received during their AKI treatment will be useful down the road.

It is important to recognize that 48% of AKI patients do not recover, but progress to ESKD and either stay on dialysis long-term or are transplanted. We know that only a small percentage of patients transition from in-center dialysis to a home modality; this is due to many factors including everything from lack of education or awareness of the opportunity to dialyze at home to difficulties related to needing a new type of access placed to go home. If CMS' goal is to prioritize home dialysis, it is much easier to *start* with a home modality rather than attempt to switch down the line once a patient has progressed from AKI to ESKD. In addition, patients who progress from AKI to ESKD become less likely to get permanent vascular access when they remain on hemodialysis, increasing morbidity after the progression to ESKD.

In addition, in accordance with CMS' commitment to home, we want to raise the idea that commercial insurance decisions tend to broadly follow Medicare decisions. This is important in the AKI space, especially for patients who ultimately convert to ESKD; we believe that if CMS allows home dialysis for AKI patients many commercial plans will follow suit. This way, when patients automatically transition to Medicare as ESKD, they will have the opportunity to do so already as a home dialysis patient. This would align with CMS' stated goal of prioritizing and increasing home dialysis and increasing numbers of home patients on Medicare.

Finally, in addition to the clinical benefits of home dialysis, as addressed above, many patients would find home dialysis appealing for quality--of life reasons – even for a few weeks. We believe that these patients all deserve the opportunity to dialyze at home if that is what their care team decides is the appropriate path.

Thank you for your attention to this letter. We would very much appreciate a meeting to discuss these topics in further detail, and Michelle Seger will be reaching out in the hopes that that can be scheduled. In the meantime, should you need any more information, you can reach out to Michelle at mseger@vennstrategies.com.

Sincerely,

Michelle Seger

American Association of Kidney Patients
American Kidney Fund
American Nephrology Nurses Association*
American Society of Nephrology*
American Society of Pediatric Nephrology
Baxter*
Centers for Dialysis Care
DaVita*
Dialysis Clinic, Inc.*
Dialysis Patient Citizens*
Fresenius Medical Care*
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Medical Education Institute
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*Denotes Steering Committee Member