April 10, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1744 IFC
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: ***Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency***

Dear Administrator Verma:

The Alliance for Home Dialysis (Alliance) appreciates the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments on the Interim Final Rule with Comment (IFR) in response to the COVID-19 Public Health Emergency (PHE). We support CMS' work to provide needed flexibilities to healthcare providers and suppliers to expand capacity and mitigate the impact of the pandemic. In particular, End-Stage Renal Disease (ESRD) beneficiaries face unique challenges stemming from COVID-19 and may be more susceptible to the illness. These patients may need additional flexibility to ensure dialysis and other care is not disrupted.

The Alliance is a coalition of kidney dialysis stakeholders that includes patients, clinicians, providers, and industry members. Together, we work to support policies that improve treatment choices for individuals in need of dialysis, and to address systemic barriers that limit access to the many benefits of home dialysis.

First, we want to thank you for the rapid and necessary changes you have made to allow dialysis patients to stay in their homes as much as possible during the PHE. Specifically, we appreciate your work in implementing the Coronavirus Aid, Relief, and Economic Security (CARES)[1] provision that would remove the once a quarter in-person visit requirement under the Monthly Capitated Payment (MCP) for home dialysis patients during this time. In addition, we appreciate that CMS relaxed the barriers to providing telehealth services over rural state lines in the updated waivers on April 9, 2020.[2] Furthermore, we appreciate the HHS sent a letter to state governors seeking to remove other barriers to telemedicine, including state licensing requirements and scope of practice laws.[3] We strongly believe

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[1] Coronavirus Aid, Relief, and Economic Security Act" or the "CARES Act, Pub. L. No. 116-136 § 3705.
[2] https://www.cms.gov/newsroom/press-releases/trump-administration-acts-ensure-us-healthcare-facilities-can-maximize-frontline-workforces-confront
[3] See https://www.ncsbn.org/HHS_Secretary_Letter_to_States_Licensing_Waivers.pdf.

that seeing patients remotely can preserve resources, promote social-distancing, and provide more convenience for patients, and appreciate CMS's attention to these important issues.

The following outlines our comments and recommendations on the Interim Final Rule.

Eliminate Monthly Laboratory Billing Requirement for Home Dialysis Patients.

Patients who, in the judgment of their physician, are medically stable need not risk violating social distancing orders nor expose themselves to unnecessary infection risks in order to satisfy a billing requirement to include monthly laboratory work. In order to further improve telehealth flexibility for dialysis patients during this crisis, CMS should waive the billing requirement to include monthly laboratory claims if the following conditions are met: 1) During the billing month, a dialysis patient has been unable to visit a facility due to a state-imposed stay-at-home order, self-quarantine, or other legal authority invoked for social distancing purposes during a pandemic; or 2) During the billing month, a patient has been transferred to a COVID-19-dedicated dialysis facility designed to aggregate COVID-19 patients only.

Clarify that PD Catheter Placement is not an Elective Surgery

In March, CMS and the Centers for Disease Control (CDC) issued guidance to prioritize key healthcare resources by rescheduling non-urgent outpatient visits, elective surgeries, and non-essential medical procedures during the COVID-19 outbreak. While we fully support the conservation of critical resources for the COVID-19 response, we are concerned that this guidance could negatively impact Peritoneal Dialysis (PD) catheter placement and thus deter efforts for ESRD patients to stay at home and follow social distancing practices.

PD is the most common dialysis modality that permits patients to dialyze in their own homes. Home dialysis makes social distancing much easier as it allows patients to avoid multiple clinic visits per week and conserves vital healthcare resources. This benefit is especially important for ESRD patients given the high correlation between COVID-19 and kidney damage.[4]

While we do not believe that PD catheter placement clearly fits into any of the tiers outlined in the CMS recommendations, we are concerned that it could be interpreted to be a "elective" or "low acuity surgery," and therefore, be postponed. Accordingly, the Alliance urges CMS to clarify that PD catheter placement is not an elective procedure in order to ensure that dialysis patients will continue to have access to this important therapy.

Provide Additional Waivers and Flexibilities to Promote Care for Dialysis Patients

As we see a greater number of COVID-19 cases, patients and providers are encountering a number of existing CMS requirements that are impeding their ability to safely respond to the pandemic. The following outlines new waivers that we believe could improve patient care, preserve resources, and allow healthcare workers to be more effective. We believe that under its emergency authority, CMS could provide the following flexibilities:

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[4] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30558-4/fulltext.

1. Include home dialysis training codes for telemedicine reimbursement

The Alliance appreciates the work CMS has done to expand the offering and reimbursement for telehealth visits during the COVID-19 emergency. As previously mentioned, home dialysis ensures patients may stay at home, avoid trips to facilities, and promote social distancing efforts. To better equip providers and patients to initiate and sustain home dialysis, we ask that CMS also waive the training codes associated with home dialysis care. Specifically, the Alliance requests that home dialysis training codes 90989 and 90993 be included on the list of services allowed *via* telehealth during the public health emergency period. This change would allow physicians to initiate and conduct home dialysis training for patients from home, thereby also protecting front-line workers from unnecessary exposure risks during the pandemic period.

2. Remove the prohibition on home dialysis and the face-to-face requirement for patients with Acute Kidney Injury (AKI)

Under existing CMS guidance, the home dialysis benefit is not permitted for patients with AKI.[5] CMS reasoned that, during normal times, these patients require supervision by qualified staff during their dialysis and close monitoring through laboratory tests to ensure that they are receiving the necessary care to improve their condition and get off of dialysis. Hospitals in a number of COVID-19 hotspots, however, have experienced massive influxes of COVID-19-infected patients, many of whom go into renal failure. This phenomenon has strained resources and created limitations on staff in way that leaves PD as the only option for some AKI patients.

Typically, patients with acute kidney injury (AKI) are treated using a special type of dialysis in the hospital through a Continuous Renal Replacement Therapy (CRRT) machine, followed by outpatient in-center hemodialysis after discharge. Because so many COVID-19 patients have AKI, hospitals are running out of CRRT capacity, and must instead begin PD to replace these patients' renal function. The CPT codes as written do not contemplate a PD regimen for AKI patients.

Given the lack of alternatives then, we urge CMS to waive the prohibition on home dialysis for AKI patients during the public health emergency. In addition, we request that CMS add CPT codes 90935, 90937, 90945, and 90947, the codes assigned for inpatient or outpatient dialysis for AKI patients, to the approved telehealth list during the crisis in order to remove the face-to-face requirement for these services. This will allow nephrologists to more easily prescribe PD for ICU patients with COVID-19 who have experienced an AKI and remove the face-to-face requirement for outpatient dialysis for AKI patients.

Support Grants for Urgent State Home Dialysis Programs

Given the high correlation between COVID-19 and kidney damage, facilitating a safe dialysis modality that allows patients to self-isolate and/or avoid group settings has taken on a unique urgency.[6] Home dialysis—peritoneal dialysis and home hemodialysis —are vitally important treatment options that offer patients significant quality-of-life advantages, including clinically meaningful improvements in their

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[5] See https://www.cms.gov/media/125161 Section100.6 Applicability of Specific ESRD PPS Policies to AKI Dialysis.

[6] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30558-4/fulltext.

physical and mental health. However, only 11.5 percent of patients currently dialyze at home. Promoting home dialysis as an option for patients could both preserve key medical resources and ensure patients are protected from exposure during the epidemic. The Alliance therefore asks that you support the establishment of a grant program to hospitals for the adoption of urgent start home dialysis programs.

Hospitals play a crucial role in triaging renal failure patients and in coordinating the care and services necessary for the efficient and expedited placement of a dialysis catheter. A hospital grant program targeting the adoption of home dialysis would give hospitals the resources they need to efficiently triage and treat patients presenting with an immediate need for dialysis. These grants could include, among other services, urgent dialysis modality education, instruction for home catheter placement techniques, and enhanced home training at discharge. We would be happy to work with the Department to understand the need for such a program and how to effectively provide funding.

Conclusion

Thank you for your attention to these important matters. We support CMS' efforts to address the COVID-19 crisis and appreciate the rapid response by the Department to date. Please let us know if we can be of any additional assistance.

Sincerely,

Sincerely,

Stephanie Silverman
Executive Director

Alliance for Home Dialysis 2020 Members

American Association of Kidney Patients
American Kidney Fund
American Nephrology Nurses Association
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