April 6, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-4190-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

RE: CMS-4190-P: Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

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 Proposed Rule for the Medicare Advantage (MA) program for contract years (CY) 2021 and 2022. 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.

Home dialysis—peritoneal dialysis (PD) and home hemodialysis (HHD)—is an important treatment option that offers patients significant quality of life advantages, including clinically meaningful improvements in physical and mental health. Approximately 11.6 percent of prevalent dialysis patients receive treatment at home.[1] Those patients who are able to elect home dialysis modalities have shown improved clinical outcomes, including reduced cardiovascular death and hospitalization,[2][3] lower blood pressure,[4] reduced use of antihypertensive agents,[5] and reduced serum phosphorus.[6] Studies have also

[1] United States Renal Data System (USRDS), 2017 Annual Data Report: Epidemiology of Kidney Disease in the United States.
[2] Weinhandl ED, Liu J, Gilbertson DT, Arneson TJ, Collins AJ: Survival in daily home hemodialysis and matched thrice-weekly in-center hemodialysis patients. J. Am. Soc. Nephrol JASN 23: 895-904, 2012.
[3] Weindhandl ED, Nieman KM, Gilbertston DT, Collins AJ: Hospitalization in daily home hemodialysis and matched thrice-weekly in-center hemodialysis patients. Am. J. Kidney Dis. Office. J, Natl Kidney Found. 65: 98-108, 2015.
[4] Kotanko P, Garg AX, Depner T, et al. Effects of frequent hemodialysis on blood pressure: Results from the randomized frequent hemodialysis network trials. Hemodial Int. Int. Symp. Home Hemodial. 19: 386-401, 2015.
[5] Jaber BL, Collins AJ, Finkelstein FO, Glickman JD, Hull AR, Kraus MA, McCarthy J, Miller BW, Spry LA.; FREEDOM Study Group: Daily hemodialysis (DHD) reduces the need for anti-hypertensive medications [Abstract] J Am Soc Nephrol 20: SA-PO2461, 2009.
[6] FHN Trial Group, et al: In-center hemodialysis six times per week versus three times per week. N. Engl J Med, 363: 2287-2300, 2010.

shown that patients using home dialysis experience better mental health outcomes, including social function, which is vitally important for overall well-being.[7]

The 21st Century Cures Act (the Cures Act), enacted on December 13, 2016 (Pub. L. 1 14-255), created a new option for individuals diagnosed with End-Stage Renal Disease (ESRD) to enroll in MA plans beginning January 1, 2021. The Alliance hopes that this change will help to increase home dialysis uptake. Currently, a limited number of individuals with ESRD are eligible for Medicare Advantage (e.g., individuals already enrolled in an MA plan who subsequently develop ESRD).[8] In a recent analysis of the potential impact of section 17006 of the Cures Act, the Moran Company estimated that without the Cures Act provisions, MA enrollees with ESRD would rise from 107,000 in 2019 to 130,000 in 2028, but taking the Cures Act into account, a projected additional 61,000 beneficiaries with ESRD would enroll in MA initially, rising to an additional 71,000 beneficiaries in 2028.[9]

The Alliance is eager to serve as a resource to CMS as the ESRD-related provisions of the 21st Century Cures Act become effective in 2021, specifically those related to Medicare Advantage.

We are pleased to offer the following specific comments related to the Proposed Rule:

The Alliance urges CMS to expand the proposed telehealth credit to include home dialysis services.

The Alliance appreciates the opportunity to provide comments on the benefits of telehealth services for home dialysis patients. As written, the Proposed Rule would allow MA plans to receive a 10 percent credit for beneficiaries contracting with telehealth providers for dermatology, psychiatry, cardiology, otolaryngology, and neurology. Home dialysis has been at the forefront of telehealth technology and the Alliance believes this 10 percent credit should be expanded to included nephrologists and their patients dialyzing at-home.

We believe that the use of telehealth better aligns payment with patient care needs, and better ensures that clinically complex and ill beneficiaries have appropriate access to home therapies. Telehealth also improves interdisciplinary team processes, allowing for better coordination of care and reduces the burden on patients by eliminating the need to travel to and from office visits.

The Alliance has long advocated for expansion of telehealth services for home and in-center dialysis patients. The Alliance championed a provision of the CHRONIC Care Act, signed into law and implemented by regulation in 2018, which enabled home dialysis patients and their providers to conduct the monthly clinical visit via telehealth in the patient's home. Specifically, the law created the opportunity for the in-person visit for home dialysis to be completed via telehealth, after the patient has been home for three months, and as long as the physician completes an in-person visit with the patient once every three months.

Given our longtime support of telemedicine and its positive impact on patient care in nephrology, we respectfully urge CMS to expand the proposed 10 percent credit to include home dialysis.

---

[7] Finkelstein FO, Schiller B, Daoui R et al: At-home short daily hemodialysis improves the long-term health-related quality of life. Kidney Int. 82: 561-569, 2012.

[8] Kaiser Family Foundation, Medicare Advantage 2017 Spotlight (June 6, 2017), available at https:www.kff.org/medicare/issue-brief/medicare-advantage-2017-spotlight-enrollment-market-update/.

[9] The Moran Company, Analysis "Peritoneal Dialysis Patient Projections in Medicare Advantage Post-Cures Act" (Dec. 2017).

The Alliance urges that CMS address certain unintended barriers to expanding telehealth utilization.

Although CMS has taken great strides to expand the use of telehealth, we would like to call attention to two issues that currently present barriers to the expanded use of telehealth:

- First, we are concerned that state-by-state licensure requirements remain a barrier to physicians providing remote care to patients who reside in other states. We urge CMS to work to work with states to find solutions to restrictive licensing practices.

- Second, we are concerned that the regulatory restriction on asynchronous images has created significant limitations to the adoption of telemedicine for ESRD beneficiaries. For example, situations where a provider, patient, or other healthcare worker wishes to send an image of a catheter insertion site for review by a physician may not qualify. In general, Medicare beneficiaries are eligible for telehealth services only if they are presented from an originating site located in either a rural health professional shortage area (HPSA) as defined in section 332(a)(1) (A) of the Public Health Services Act, or in a county outside of an MSA as defined in section 1886(d)(2)(D) of the Social Security Act. The "originating site" means the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. For asynchronous, store and forward telecommunications technologies (as a substitute for interactive telecommunications system), an originating site is limited to demonstrations conducted in Alaska or Hawaii. To encourage broader adoption, we recommend that CMS create an exception to the normal telehealth requirements for asynchronous images. Specifically, CMS should allow asynchronous images to be one of the services included in the Monthly Capitation Payment (MCP) made for patients on dialysis.

The Alliance urges CMS to consider an incentive payment for MA plans to offer home dialysis.

The Alliance for Home Dialysis believes that all MA plans offering home dialysis as a covered service should be eligible to receive a one-time, five percent upward payment adjustment in the first year of participation. In the three subsequent performance years ("PYs"), MA plans would only be eligible for the five percent payment adjustment if the plan reaches discrete coverage benchmarks for home dialysis: 12, 15, and 20 percent, respectively. In subsequent performance years, MA plans may continue to be eligible for an upward payment adjustment only upon reaching additional coverage benchmarks for home dialysis: PY5, MA Plan eligible to receive four or five percent payment adjustment upon achieving 25 or 30 percent coverage benchmark, respectively; PY6, MA Plan eligible to receive three or four percent payment adjustment upon achieving 40 or 50 percent coverage benchmark, respectively. Beginning with PY7 and beyond, we recommend maintaining some level of upward payment adjustments for MA plans, conditioned upon reaching certain performance benchmarks, in order to reach the Administration's goal to transition 80 percent of ESRD patients to the home dialysis setting.

Maintaining an ongoing incentive structure for increased payment amounts that MA plans may receive from CMS, coupled with the one-time payment adjustment in the initial base year, will further incentivize both the increased coverage of home dialysis and the increased utilization of home dialysis overall. Moreover, because the 21st Century Cures Act gives all Medicare beneficiaries with ESRD the option to enroll in an MA plan starting in 2021, this structured payment incentive would further support MA plans interested in expanding opportunities for home dialysis in rural areas, increase competition

between plans, and allow providers in a given network to take advantage of the latest healthcare technologies and innovations for their ESRD patients, many of whom may otherwise lack access to home dialysis. Finally, we believe such an approach to the MA community is consistent with the Administration's goals to transition 80 percent of ESRD patients to the home dialysis setting, and within a defined period of time.

###

We hope that you will consider these issues as CMS finalizes the Medicare Advantage 2021 and 2022 Contract Year Proposed Rule, and we appreciate the opportunity to share our views here. Please do not hesitate to reach out to Alliance members or staff to discuss how we may be a resource and support the implementation of these important policies for ESRD patients in MA. Please contact Michelle Seger at Michelle@homedialysisalliance.org or 202-466-8700 if you have any questions.

Sincerely,

Stephanie Silverman
Executive Director
Alliance for Home Dialysis

Alliance for Home Dialysis 2020 Members

American Association of Kidney Patients
American Kidney Fund
American Nephrology Nurses Association
American Society of Nephrology*
American Society of Pediatric Nephrology
Baxter*
Cleveland Clinic
DEKA*
Dialysis Clinic, Inc.*
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*