

Submitted electronically via www.regulations.gov

January 16, 2018

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Attention: CMS-4182-P
Baltimore, MD 21244-8013

RE: CMS, Medicare Program, Contract Year 2019 Policy and Technical Changes to the Medicare Advantage and Part D, Proposed Rule

Dear Administrator Verma,

On behalf of the Alliance for Home Dialysis (the “Alliance”), we appreciate this opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Contract Year 2019 Policy and Technical Changes to the Medicare Advantage and Part D Proposed Rule, published in the Federal Register on November 28, 2017.¹ In our comments, we urge CMS to consider the impact that provisions of the 21st Century Cures Act concerning end-stage renal disease (ESRD) and the Medicare Advantage (MA) program will have on Medicare beneficiaries, MA organizations, and the MA program. In particular, we urge CMS to put in place policies and regulations that support and incentivize high quality care for the ESRD beneficiaries who will enroll in MA plans once the 21st Century Cures Act provisions are implemented.

The Alliance is a coalition of kidney dialysis stakeholders, representing patients, clinicians, providers, and industry that works to promote policies that facilitate treatment choice for individuals in need of dialysis, and to address systemic barriers that limit access to the many benefits of home dialysis. These issues are particularly important given how many Americans are currently living with ESRD and depend on dialysis for survival.

Medicare Advantage and ESRD Beneficiaries

The 21st Century Cures Act, enacted on December 13, 2016 (Pub. L. 114-255), created a new option for individuals who are diagnosed with ESRD to enroll in MA plans beginning Jan. 1, 2021. Currently, a limited number of individuals with ESRD are eligible for Medicare Advantage (e.g. individuals who are already enrolled in an MA plan and subsequently develop ESRD).² According to MedPAC’s March 2016 Report to the Congress, in 2014, about 15

¹ CMS, Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, Proposed Rule, 82 Fed. Reg. 56336, 56336 (Nov. 28, 2017).

² See 42 CFR § 422.50(a)(2)(i)-(iii).

percent of ESRD beneficiaries were enrolled in MA plans; by comparison, about 30 percent of all Medicare beneficiaries were enrolled in MA plans. The Kaiser Family Foundation states that from 2004 to 2017, enrollment in MA plans has steadily increased. As of 2017, one in three people with Medicare (33% or 19 million beneficiaries) was enrolled in a MA plan.³ 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 2028.⁴

The MA program has historically been successful in allowing for innovative approaches to providing benefits to beneficiaries. With implementation of the Cures Act provisions, CMS has an important opportunity to ensure that Medicare ESRD beneficiaries not only have the additional choice of enrolling in private plans, but that the private plans offer high quality options. The Alliance believes CMS should begin now – if the Agency has not already – developing policies in anticipation of the additional ESRD beneficiaries who will enroll in MA plans so that such policies can be finalized in time for MA plans to develop their bids and submit applications in 2020 for the 2021 year.

Benefits of Home Hemodialysis and Peritoneal Dialysis

It is well documented in peer reviewed medical literature that home dialysis, which includes peritoneal dialysis (PD) and home hemodialysis (HHD), offers unique benefits over in-center dialysis, including improvements in the physical, mental health, and nutritional status of patients. In addition, Congress and CMS have long recognized the importance of home dialysis and of having in place incentives – not barriers – for increased use of home dialysis.⁵ Home dialysis offers improved individualized care and the opportunity for the patient to retain employment as the patient has greater autonomy and flexibility over when he or she dialyzes. PD treatment, which involves a special solution injected into the individual’s abdominal cavity to filter blood and remove waste, occurs several times during a 24-hour period and can be done at home or in the workplace. Individuals treated with PD can also use a machine, known as a cycler, at night to perform exchanges while the patient is sleeping. PD patients often experience fewer negative side effects, such as nausea and dietary restrictions, than in-center patients. Both PD and HHD have been shown to make a significant tangible clinical difference for patients, and have been cited in clinical evidence as the cause for many health-related quality of life improvements.

³ 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/>.

⁴ The Moran Company, Analysis “Peritoneal Dialysis Patient Projections in Medicare Advantage Post-Cures Act” (Dec. 2017).

⁵ See, e.g. CMS, Medicare Program, End-Stage Renal Disease Prospective Payment System, Final Rule, 75 Fed. Reg. 49030, 49032 (Aug. 12, 2010) (discussing the Omnibus Budget Reconciliation Act of 1981, Public Law 97–35, which changed the ESRD payment system, noting a need for providing greater incentives for increased use of home dialysis). See also *id.* at 49058 (stating “We appreciate the comments from individual home dialysis patients who support our recognition of the importance of home dialysis which we believe results in a better quality of life for the patient.”)

Studies have demonstrated that more frequent hemodialysis results in faster recovery time after treatment and fewer side effects⁶; improved cardiac status⁷ and survival rates⁸; and increased opportunity for rehabilitation.⁹

Home hemodialysis uses similar technology to in-center hemodialysis, but is generally done more frequently and/or for longer hours than in-center dialysis, which allows the treatment to be administered in a much more gentle, gradual, and healthy fashion. In addition, some patients on home hemodialysis can dialyze overnight while sleeping, which provides more comprehensive cleaning of the blood, more gentle fluid removal than conventional dialysis, and also allows a more normal lifestyle and improved quality of life for patients and their loved ones.

Despite the advantages of home dialysis, and estimates that up to a quarter of ESRD patients could benefit from home dialysis, only approximately 12 percent take advantage of the modality.¹⁰ This suggests that there are systemic barriers hampering optimal utilization of home dialysis.

We believe that a key to the successful implementation of the Cures Act ESRD MA provisions will be the ability of MA plans to incorporate home dialysis into their plan benefits thereby allowing MA plans to offer high quality care to ESRD beneficiaries via the most cost effective means.

CMS Should Develop Policies that Ensure MA Plans Have the Flexibility They Need to Maximize and Incentivize Utilization of Home Dialysis

Under the Cures Act, HHS is required to conduct an evaluation of whether the 5-star rating system based on data collected under the MA Quality Improvement Program should include a quality measure specifically related to care for ESRD enrollees in MA plans, and the results of the evaluation must be posted by Apr. 1, 2020.¹¹ In advance of this mandatory evaluation and report, the Alliance recommends CMS put in place a method for tracking the quality of care for ESRD beneficiaries enrolled in MA plans in part by tracking how many beneficiaries are offered (and enrolled in) home dialysis, and how many are provided education on the option of home

⁶ Heidenheim AP, Muirhead N, Moist L, et al. Patient Quality of Life on Quotidian Hemodialysis. *Am J Kidney Dis.* 2003 Jul; 42(1 Suppl):36-41.

⁷ Culleton, B et al. Effect of Frequent NHD vs. CHD on Left Ventricular Mass and Quality of Life. *JAMA* 2007; 11

⁸ Foley, R.N, D.T. Gilbertson et al. Long interdialytic interval and mortality among patients receiving hemodialysis. *New England Journal of Medicine.* 2011 365, no.12:1099-1107

⁹ Blagg, Christopher. "It's Time to Look at Home Hemodialysis in a New Light." Hemodialysis Horizons: Patient Safety & Approaches to Reducing Errors. (2006): 22- 28. Web. 12 Apr 2012. <http://www.aami.org/publications/HH/Home.Blagg.pdf>.

¹⁰ See GAO, End-Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis, GAO-16-125: Published: Oct 15, 2015. Publicly Released: Nov 16, 2015, available at <http://www.gao.gov/products/GAO-16-125>.

¹¹ § 17006(d)(1) of the 21st Century Cures Act, Pub. L. 114-255, 130 STAT. 1335 (Dec. 13, 2016).

dialysis. It is critical for CMS to be able to monitor the care that MA enrollees with ESRD are receiving, especially in the first years of integrating this medically complex population into MA plans.

In addition, CMS is proposing to make changes to the MA Quality Rating System, including delineating the rules for adding, updating, and removing measures via the rulemaking process, as opposed to going through the subregulatory process, beginning with the 2019 measurement period. Under this proposal, if finalized, changes to quality measures will take longer to implement. CMS states in the Proposed Rule that it believes this “will provide plans with more stability to plan multi-year initiatives, because they will know the measures several years in advance.”¹² Given the longer process for implementing future quality measures that may be specific to ESRD, the Alliance encourages CMS to begin considering how to incorporate one or more quality measures specific to ESRD beneficiaries, home dialysis, and/or education about home dialysis. CMS must begin this process early to ensure appropriate policies are in place for ESRD beneficiaries to receive high quality care once they enroll in MA plans.

In sum, the Alliance urges CMS to work toward removing any regulatory barriers to home dialysis and to develop policies that ensure the MA structure allows and incentivizes, where possible, MA plans to utilize the most cost effective settings and modality to achieve the highest quality care possible for MA enrollees with ESRD. Given the significant changes to the MA program that are on the horizon with implementation of section 17006 of the Cures Act, the Alliance strongly urges CMS to begin planning now to ensure not only that payments to MA plans are adequate for the new ESRD enrollees, but also that MA plans will have the tools necessary to offer high quality care to these medically complex patients.

We look forward to working with the Agency as it prepares for implementation of the Cures Act ESRD MA provisions.

Thank you for your time and consideration.

Sincerely,

A handwritten signature in black ink that reads "Stephanie Silverman". The signature is written in a cursive style and is positioned above the printed name.

Stephanie Silverman

Executive Director

The Alliance for Home Dialysis

¹² 82 Fed. Reg. at 56378 (Nov. 28, 2017). See Table 2, Proposed Measures for Performance Period beginning 2019.