March 4, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies

Dear Ms. Brooks-LaSure:

The Alliance for Home Dialysis (Alliance) is a coalition of kidney community stakeholders representing patients, clinicians, providers, and industry. Through the Alliance, we promote policies and programs to facilitate treatment choice in dialysis care, while addressing systemic barriers that limit access for patients and their families to the many benefits of home dialysis. We have long supported the important work that the Department of Health and Human Services (HHS) has done in the interests of patients with kidney disease. In particular, we appreciate the efforts to increase access to home dialysis, including in the Medicare Advantage (MA) space once the 21st Century Cures Act (Cures) became law in 2016, which, as you know, created an option for individuals with end-stage renal disease (ESRD) to enroll in MA plans beginning in 2021.[1]

Overall, the Alliance has been hopeful that allowing a new pathway for ESRD patients to access MA plans would help to increase home dialysis uptake and retention. We therefore appreciate all that the Centers for Medicare and Medicaid Services (CMS) has done thus far to better support patients as they and their care teams choose the appropriate therapy.

In December 2021, Avalere issued an analysis showing that over 40,000 Medicare ESRD patients moved from fee-for-service to MA during the 2021 open enrollment period, which increased the proportion of ESRD patients enrolled in MA from 23% to 30%.[2] At this time, some of our members report that up to 40% of their dialysis patients have already enrolled in MA,

[1] Pub. L. 1 14-255
[2] https://avalere.com/insights/esrd-enrollment-in-ma-now-exceeds-30-percent-of-all-dialysis-patients

suggesting that many patients with kidney disease have already begun accessing MA plan benefits.

Further, in its 2020 report, the United States Renal Data System (USRDS) reported that expenditures for beneficiaries with ESRD increased to $49.2 billion in 2018.[3] But perhaps the most striking piece of data is that while expenditures for beneficiaries with Medicare as the primary payer rose slightly between 2009 and 2018, "expenditures for beneficiaries with Medicare Advantage (MA) more than doubled, in adjusted terms, from $4.8B to 10.5B."[4] Importantly, USRDS also reported that when considering ESRD expenditures by treatment modality, in-center hemodialysis remains the most expensive treatment option per person annually, over both home peritoneal dialysis (PD) and home hemodialysis (HHD), as well as transplant.[5] Therefore, when looking at the full picture of an increase in MA spending coupled with a decrease in spending for home modalities, it makes sense for CMS to support increased utilization of home dialysis under those plans.

In addition, home dialysis has been shown to offer unique benefits, including improvements in physical health, mental health, and nutritional status of patients. While of course not every patient will be eligible for home dialysis, this important therapy offers improved options for individualized care and the opportunity for patients to retain employment, given that patients often have greater autonomy and flexibility of dialysis scheduling. PD patients have reported fewer negative side effects, such as nausea and dietary restrictions, than in-center patients. Both PD and HHD have been shown to make significant clinical outcomes differences as well, and have been cited as the cause for many quality-of-life improvements.

We have seen over time that the MA program has been successful in allowing for innovative approaches to providing benefits to patients. We believe that now is the time for CMS to implement changes that will ensure that ESRD beneficiaries not only can access the MA plans on the market today, but that these plans offer high quality options geared towards the needs of dialysis patients. Further, we believe that there are things CMS can do to incentivize the uptake of home dialysis amongst patients enrolled or enrolling in MA plans. Specific populations that should be considered include patients in rural areas and patients of color, who have traditionally been underrepresented in home dialysis, but can benefit from this important treatment option.

The Alliance appreciates the opportunity to share our views on these important topics through our response to the Advance Notice of Methodological Changes for Calendar Year 2023 for Medicare Advantage Capitation Rates and Part C and Part D Payment Policies (Advance Notice).

[3] https://adr.usrds.org/2020/end-stage-renal-disease/9-healthcare-expenditures-for-persons-with-esrd
[4] Id.
[5] Id.

CMS should encourage MA plans to maximize policies that lead to patient choice, including facilitating access to home dialysis and increasing uptake of this important therapy.

In order to align with CMS's broad goal of increasing utilization of home dialysis, the Alliance urges CMS to think creatively about how MA plans can work to facilitate increased home therapy uptake, which could include items like removing regulatory barriers to home dialysis and ensuring that innovative approaches are taken advantage of during rate setting and structuring of MA plans. While the Alliance understands that home dialysis will not be the clinically appropriate therapy for every single patient, we also believe that many more patients than are currently utilizing home dialysis can do so, but face barriers. For example, within the rate-setting landscape, we encourage MA plans to consider innovative approaches, such the ESRD Treatment Choices Model's (ETC) Home Dialysis Payment Adjustment (HDPA), which includes only an upward adjustment on home dialysis and home dialysis-related claims for the first three years of the model in an effort to incentivize home dialysis uptake during the beginning of the ETC period. The Alliance believes that a similar tactic, in MA plans, could help to increase home dialysis uptake here as well.

Quality ratings and experience measures should be inclusive of home dialysis patient experiences.

The Alliance has long advocated for patient experience metrics, including ICH-CAHPS, to reflect the experiences not only of in-center dialysis patients, but also home dialysis patients, especially given CMS's goal of increasing home dialysis rates. As a baseline, the Alliance recommends that CMS put into place a method for tracking the quality of care provided to ESRD beneficiaries in MA plans in part by tracking how many beneficiaries are offered (and subsequently begin) home dialysis and how many are provided education on the option of home dialysis. Ideally, CMS would create a validated quality of life survey that could be used for insight into the home dialysis experience, but we understand that creation of such a measure takes time. We would be pleased to work with CMS on such a project.

It is critical that CMS is able to monitor the quality-of-care MA enrollees are receiving, especially during the first few years of integrating this population into new plans.

Specifically, data that could be monitored by modality could include:

- Residual renal function
- Frequency of hospitalization
- Receipt of transplant
- Mortality
- Need for antihypertensive drugs
- Need for phosphate binders
- Recovery time post-dialysis
- Flexibility for work, life activities, and travel
- Dietary requirements or lack thereof

- Sleep quality
- Physical and emotional wellbeing, including depressive symptoms

Studies reflect that home dialysis (both HHD and PD) provides advantages in many if not all of these areas. Specific data reflecting such within the MA population could be very helpful to CMS as you work to increase uptake of these therapies.[6]

Star Ratings and Socio-Economic Data

The Alliance appreciates the attention that CMS has paid to Star Ratings in the Advance Notice, in particular the focus on a potential quality measure to assess how often plans are screening for common social needs like food insecurity, housing instability, and transportation challenges. The Alliance believes that there are many patients who are medically good candidates for home dialysis who simply cannot access the therapy due to issues like these. We urge CMS to consider these social needs in the context of health equity, as they truly do impact access to care, including access to all dialysis modalities. We support the gathering of this kind of data from patients as it is an important part of the full picture that informs their options. Further, we would offer our support to the proposal in the Advance Notice that would allow MA organizations to better connect patients to covered social services and public organizations who can help address these socio-economic barriers to care – and urge you to include all dialysis patients in this program.

As stated above, socio-economic barriers can often keep patients who would benefit from home dialysis from accessing this treatment option. We understand that current policy allows

[6] Mayo Clinic Staff. Peritoneal dialysis overview. Mayo Clinic. July 4 2021. https://www.mayoclinic.org/testsprocedures/peritoneal-dialysis/about/pac-20384725; Auguste BL, Agarwal A, Ibrahim AZ, et al. A Single-Center Retrospective Study on the Initiation of Peritoneal Dialysis in Patients With Cardiorenal Syndrome and Subsequent Hospitalizations. Can J Kidney Health Dis. 2020;7:2054358120979239. Published 2020 Dec 8. doi:10.1177/205435-8120979239; Tang S, Lai KN. Peritoneal dialysis: the ideal bridge from conservative therapy to kidney transplant. Journal of Nephrology. (2020) 33:1189–1194. https://doi.org/10.1007/s40620-020-00787-0; Marshall MR, Walker RC, Polkinghorne KR, Lynn KL. Survival on Home Dialysis in New Zealand. Plos One. 2014 May 7. https://doi.org/10.1371/journal.pone.0096847; 1 Marshall, Mark R, Home Versus Facility Dialysis and Mortality in Australia and New Zealand. Article in Press; 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. 2015;19(3):386-401. doi:10.1111/hdi.12255; 3 Daugirdas JT, Chertow GM, Larive B, et al. Effects of frequent hemodialysis on measures of CKD mineral and bone disorder. J Am Soc Nephrol. 2012;23(4):727-738. doi:10.1681/ASN.2011070688; Jaber BL, Lee Y, Collins AJ, et al. Effect of daily hemodialysis on depressive symptoms and postdialysis recovery time: interim report from the FREEDOM (Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements) Study. Am J Kidney Dis. 2010;56(3):531-539. doi:10.1053/j.ajkd.2010.04.019; 5 Chertow, G. M., Alvarez, L., Plumb, T. J., Prichard, S. S., & Aragon, M. (2020). Patient-reported outcomes from the investigational device exemption study of the Tablo hemodialysis system. Hemodialysis International, 24(4), 480-486. doi:10.1111/hdi.12869; Jaber BL, Lee Y, Collins AJ, et al. Effect of daily hemodialysis on depressive symptoms and postdialysis recovery time: interim report from the FREEDOM (Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements) Study. Am J Kidney Dis. 2010;56(3):531-539. doi:10.1053/j.ajkd.2010.04.019.

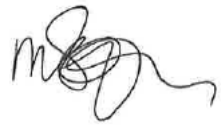
plans to cover a range of non-traditional benefits and services that could be particularly impactful to patients who want to transition to home dialysis, but face barriers in the home, or patients who are currently home, but are considering a return to in-center dialysis.

Specific issues related to home dialysis include lack of or sporadic electricity (home dialysis cyclers typically require electricity to run, though some PD can be done without), challenges related to clean water, the need for caregiver support, adequate space to store supplies, and lack of access to internet services.[7] The Alliance urges CMS to encourage MA plans to utilize their flexibility under current CMS policies in offering non-traditional benefits and services that could help address these issues and increase uptake of and retention on the home therapy. Further, the Alliance believes it could be helpful if, over the next few years as more ESRD patients begin to take advantage of being able to elect an MA plan, CMS begin to collect data on what innovative tactics plans have used to increase home dialysis. This data collection could also include information about what barriers to home dialysis plans are seeing within their patient populations, which could be different than traditional Medicare, and how these have been addressed.

The Alliance appreciates the attention CMS has given to beneficiaries who are eligible for both Medicare and Medicaid ("dual eligible") benefits. We particularly appreciate your focus on the challenges these patients face in navigating both programs, which as noted in the Advance Notice, often have overlapping benefits. However, we would like to point out that in addition to overlapping benefits, many of these patients, especially kidney disease patients, also face conflicting rules between the two programs.

Thank you for your consideration of our comments. Should you have any questions or want more information, please feel free to reach out to Michelle Seger at mseger@vennstrategies.com.

Sincerely,



Michelle Seger
Managing Director
Alliance for Home Dialysis

[7] While many home dialysis machines can transmit data to clinicians and facilities without needing an internet connection, home dialysis patients are able to utilize telehealth for many of their monthly doctor visits, which does often require an internet connection.

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
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Dialysis Clinic, Inc.*
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