



June 17, 2020

The Honorable Alex M. Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program Final Rule

Dear Secretary Azar and Administrator Verma:

I am writing on behalf of members of Kidney Care Partners in support of the expansion of the Medicare Advantage (MA) program to allow beneficiaries who qualify for Medicare because of kidney failure. However, we are concerned about the decision to remove outpatient dialysis facilities from the list of facility specialty types to whom the network adequacy standards apply. While this policy may provide flexibility to insurers, the practical consequence of the policy is that it could create a substantial barrier for dialysis patients seeking to enroll in an MA plan and could undercut Congressional intent.

All Medicare beneficiaries should be allowed to select the Medicare coverage option that best meets their needs. For some beneficiaries, traditional/original Medicare (fee-for-service) may be the right option, while for others an MA plan may better align with their needs. The Congress extended access to the MA program beginning in Calendar Year (CY) 2021 to patients who qualify for Medicare not just because of age or disability, but also when they qualify because of kidney failure. For many of these patients, selecting an MA plan means that they will have access to care coordination programs, transportation to appointments, expanded mental health care, and dental coverage (which is essential for patients seeking to be accepted on a transplant waitlist), as well as other services. Traditional Medicare rules do not allow such services to be provided or restrict them so that they are not as effective. Patients recognize, as we know this Administration does, that care coordination services for patients living with chronic conditions can lead to better patient outcomes and improved quality of life. It is important that patients, regardless of their disease status, have the ability to select the plan that will support them in meeting their health care goals.

In October 2019, the President issued an Executive Order that sought to ensure that Medicare payment rules would not create a barrier to patients exercising this choice. At the time of its release, Secretary Azar noted:

[T]he executive order commissions us to examine all practices, regulations, guidance to just make sure that we're not steering people into Fee-for-Service, as opposed to giving them a genuine choice of Medicare Advantage or Fee-for-Service.... So we'll be looking at all of those issues: how does the enrollment process work when new people come in; how the annual enrollment process works; are we providing adequate information through the various plan-finder tools to ensure people can make informed choices, make sure there's no financial disincentive to being in MA versus Fee-for-Service.¹

KCP was pleased with the commitment of the Administration to ensure that Medicare rules not create barriers to real patient choice. Yet, the rules finalized June 2 in the *Federal Register*, could create such a barrier, even if unintentionally.

Under the finalized policy, MA plans have to attest to having adequate providers to meet the needs of dialysis patients, but outpatient dialysis facilities are not subject to network adequacy regulation,² which means they do not have to meet the minimum facility number requirement or the longstanding time and distance standards.³ Under the policies in the final rule, plans could attest to having an adequate dialysis provider network by relying upon home dialysis only (which would not be clinically appropriate as described below) or hospital-based facilities (which might not have the capacity). By removing the minimum facility number requirement, CMS could create an opportunity for MA plans not to include any outpatient dialysis facilities.

In such instances, if a patient requires outpatient dialysis services, he/she could face difficult choices: forgo enrollment in an MA plan, try to get the plan to approve care at an out-of-network facility within a reasonable time/distance, or agree to go out-of-network and experience higher cost sharing obligations. In some instances, a patient might try to enforce the requirement that a plan arrange for out-of-network services. Even if the plan were to agree that it must provide access to the out-of-network outpatient dialysis facility, beneficiaries may not know this information at the time of enrollment. They would know only that the facilities are not in-network and that they would be required to fight their plan to gain access. It is unlikely many patients who acknowledge the clinical reality that they will need in-center dialysis services at some time(s) during their treatment, even if they are home dialysis patients, would enter into such a plan. It is a practical, real-world deterrent.

¹Excerpted from the Center for Medicare Advocacy's press release "The President's Medicare Executive Order Expands Towards Private Medicare Advantage Over Traditional Medicare" (October 3, 2019), available at: <https://www.medicareadvocacy.org/the-presidents-medicare-executive-order-expands-towards-private-medicare-advantage-over-traditional-medicare/>.

² Display Copy at 261.

³*Id.*

Below are five examples of how the decision to remove outpatient dialysis facilities from the network adequacy requirement could create potential financial and administrative disincentives for dialysis patients to being in MA versus fee-for-service.

- **Increases costs for home dialysis patients.** A plan may seek to attest to access to dialysis services by offering a home-only provider option in-network. While home dialysis patients may be able to dialyze at home, clinicians agree that the standard of care requires periodic access to outpatient dialysis facilities. Some patients may require in-center respite dialysis care, which may be planned or due to an emergency. Other patients who may begin as home dialysis patients may experience clinical complications (known as technique failure) that require them to shift to in-center hemodialysis treatments during the middle of a plan year. When a beneficiary is considering joining an MA plan, he/she may focus on whether or not his/her providers are in the network and the costs associated with out-of-network services. A Medicare beneficiary on dialysis may be unwilling to select an MA plan and remain in traditional Medicare, if faced with unclear provider information, modality options and out-of-pocket obligations.
- **Reduces access to care coordination services that could promote kidney transplants.** While transplant services remain in traditional Medicare, beneficiaries with kidney failure often find themselves on multi-year waiting lists before they receive a matching organ. During these intervening years, it is clinically important for these patients to receive high quality care, including dental benefits, to meet the transplant waitlist eligibility criteria. For example, something as minor as an infected tooth can result in a dialysis patient no longer qualifying. Traditional Medicare does not offer routine dental coverage or care coordination services that have been shown to improve a patients' ability to access a transplant. The lack of assurance of network adequacy and financial obligations could discourage the very patients who can most benefit from the additional MA services offered by MA plans from accessing them. CMS's decision could be particularly harmful for African American and Hispanic patients, who are disproportionately affected by ESRD and face significant disparities in care access and outcomes.
- **Increases costs for in-center dialysis patients.** Some dialysis patients already have access to MA plans, because they developed kidney failure while already enrolled in an MA plan. For these beneficiaries, the new policy may result in their facility no longer being in-network, which could lead them to abandon the MA program and return to traditional Medicare.
- **Limiting access for in-center hemodialysis patients.** Not all patients can or want to rely upon home dialysis. Even the most optimistic models suggest that a substantial number of patients will require in-center hemodialysis. Any such

patient looking at an MA plan that has no, or a limited number of, outpatient dialysis facilities listed as in-network may be disincentivized from joining. Once again, the very patients who could benefit from the care coordination services would be steered toward traditional Medicare instead.

- **Restricts access to those who can afford out of network rates.** We recognize that some dialysis patients may have the resources to pay the out-of-network rates and remain in MA plans. Yet, the Administration should avoid policies that limit patient choice, as the Secretary's comments in October noted, by halting regulations or policies that establish burdens to enrolling in MA plans. According to the Medicare Payment Advisory Commission (MedPAC), 48 percent of dialysis patients are dually eligible for Medicaid and Medicare.⁴ The finalized policy could negatively impact the ability of dual eligibles to join MA plans, especially if the plan limits dialysis modality choice. Many dual eligible patients, unfortunately, do not have the ability to select home dialysis because they may lack stable housing or have other socio-economic barriers.

In each of these examples, the finalized policy eliminating outpatient dialysis organizations from the network adequacy requirements could limit a beneficiary's ability to make a "genuine choice" of enrolling in an MA plan. It is not enough to have a plan attest to having access to an outpatient dialysis facility; there must be credible enforcement mechanisms that beneficiaries can trust to protect their access to necessary care. Additionally, we ask that CMS review plan networks to ensure they accommodate existing patients' choices.

Perhaps this result is unintentional, but we believe this decision creates significant impediments to patient choice and ask that CMS reverse its policy. CMS should be mindful of implementing policies that could create higher cost sharing obligations, administrative burdens, limitations on providers, and access barriers to coordinated care which could reduce overall Medicare costs and improve beneficiary outcomes.

We understand that CMS may believe the MA Star Rating program (which includes patient satisfaction measures) and beneficiary complaint processes would be sufficient to alert the agency to patient access problems that may arise. Even if one were to assume these mechanisms had a similar effect as a regulatory standard, a patient must be enrolled in a plan for these mechanisms to even be triggered. If a patient requires dialysis and wants to ensure that there is an in-center option available, but few or no outpatient dialysis facilities are listed in plan documents as being in-network, the patient would likely not enroll. The patient would have been "steered" to traditional Medicare before there was a chance to determine the adequacy of the potential arrangement.

⁴MedPAC. *Report to the Congress*. 173 (March 2020).

For those patients who do enroll, MA Star Rating data lag behind the plan year and the issue of adequate treatment options would be lost among the myriad of other metrics used to assign stars. Similarly, complaint mechanisms involve substantial time and effort, which patients who require life-sustaining services may not have the time or ability to pursue. Maintaining outpatient dialysis facilities on the list of specialty providers for network adequacy standards would provide patients with a prospective understanding of the care they could access. Patients make choices based on what is being offered, not on the hope they could win the care they need through a lengthy appeals process.

The preamble also suggests the elimination of outpatient dialysis facilities from network adequacy standards is patient-centered because it promotes innovative treatment options. That reasoning is unclear. Innovation in treatment is spurred by offering multiple treatment options, not by limiting access to the prevalent modality utilized by the majority of patients with kidney failure – hemodialysis. A plan that seeks to promote innovative treatment options to patients should offer a robust network that allows genuine choice. Just because a network includes outpatient dialysis, it does not mean that patients must select to receive only that modality. Patients can and should be trusted to select the treatment modality that best meets their health care goals, whether it is in-center or home dialysis or transplant.

We appreciate that CMS may be concerned that singling out outpatient dialysis facilities for network adequacy standards might seem to disadvantage certain provider models, but that concern is misplaced. The focus should be on making sure that dialysis patients have access to all modalities. Data from Dialysis Facility Compare suggests that dialysis patients have access to home dialysis training facilities, even in states with certificate of need rules. Overall, approximately 98 to 100 percent of patients receiving care from KCP member facilities currently have access to a home facility with 30 miles of their own home.

KCP sincerely appreciates the increased focus and desire to improve treatment options for dialysis patients. We believe that making sure dialysis patients understand the right provided by the Congress to enroll in MA plans is a priority that aligns with the President's intent as expressed through multiple Executive Orders last year. A key component to achieving that goal is to ensure that kidney patients have access within MA plan networks to the providers they need to meet their health care goals.

As KCP has noted in previous letters to CMS, clinical studies have shown that longer travel times to dialysis facilities result in serious negative health outcomes for patients. For example, one study analyzing DOPPS data found that patients who travelled longer than 60 minutes to in-center hemodialysis had a 20 percent higher risk of mortality when compared to patients who travelled 15 minutes or less. The same study found that patients who travel longer than 15 minutes reported significantly diminished health-related quality

The Honorable Alex Azar
The Honorable Seema Verma
June 17, 2020
Page 6 of 7

of life.⁵ Another study, again relying upon DOPPS data, found that patients who missed one or more dialysis sessions in a 4-month period because of having longer travel times have a 57 percent higher all-cause mortality risk compared to patients who did not miss a treatment.⁶ Researchers have also found that a dialysis patient is more likely to miss an appointment if his/her travel time is longer than 17 minutes by car or transportation van (an increased risk of 1.10 and 1.21 respectively).⁷ Therefore, we ask that CMS correct its decision so that outpatient dialysis facilities are reinstated on the list of specialty providers as part of the network adequacy requirements.

On behalf of KCP, we appreciate the ongoing dialogue with CMS and welcome the opportunity to share the perspective of patients, physicians, nurses, and facilities about the benefits that MA enrollment can have for dialysis care, and its optimal implementation. Please do not hesitate to reach out to Kathy Lester, our counsel in Washington, DC, if you have any questions or would like to further discuss these concerns. She can be reached at klester@lesterhealthlaw.com or (202) 534-1773.

Sincerely,

A handwritten signature in black ink, appearing to be 'John Butler', with a long, sweeping flourish extending to the right.

John Butler
Chairman

⁵Moist L, Bragg-Gresham J, *et al.* "Travel time to dialysis as a predictor of health-related quality of life, adherence, and mortality: The Dialysis Outcomes and Practice Patterns Study (DOPPS)." *51 Am J Kidney Dis.* 641-50, (2008).

⁶Salmi, A [Larkina M](#), [Wang M](#), *et al.* "Missed Hemodialysis Treatments: International Variation, Predictors, and Outcomes in the Dialysis Outcomes and Practice Patterns Study (DOPPS)." *72 Am J of Kidney Dis.* 634-43 (2018).

⁷Chan K, Thadhani R, Maadux F. "Adherence barriers to chronic dialysis in the United States." *25 J Am Soc Nephrol* 2642-48 (2014).

Appendix: Kidney Care Partner Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Pediatric Nephrology
Amgen
Ardelyx
AstraZeneca
Atlantic Dialysis
Baxter
Board of Nephrology Examiners and Technology
BBraun
Cara Therapeutics
Centers for Dialysis Care
DaVita
DialyzeDirect
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Kidney Care Council
Nephrology Nursing Certification Commission
National Renal Administrators Association
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Vertex
Vifor Pharma