



November 25, 2020

Demetrios Kouzoukas
Principal Deputy Administrator
Centers for Medicare & Medicaid Services
Director, Center for Medicare
200 Independence Avenue, S.W.
Washington, DC 20201

Jennifer Wuggazer Lazio, F.S.A., M.A.A.A.
Director, Parts C & D Actuarial Group
Office of the Actuary
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Principal Deputy Administrator Kouzoukas and Director Wuggazer:

The members of Kidney Care Partners (KCP) appreciate having the opportunity to provide comments on the “Advance Notice of Methodological Changes for Calendar Year (CY) 2022 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies – Part II.” (Advance Notice). KCP is an alliance of members of the kidney care community that serves as a forum for patient advocates, dialysis care professionals, providers, and manufacturers to advance policies that support the provision of high quality care for individuals with chronic kidney disease (CKD), including End-Stage Renal Disease (ESRD).

I. KCP Encourages CMS to Reinstate the Network Adequacy Standards for Outpatient Dialysis

In the Advance Notice, CMS reiterates its commitment to provide access to MA plans for dialysis patients who become eligible for Medicare because of their diagnosis of kidney failure.

As stated in the CY 2022 Final Rule, we note that MA organizations must maintain a network of contracted providers that is sufficient to provide adequate access to covered services to meet the needs of the population served and is consistent with the prevailing community pattern of health care delivery in the areas where the network is being offered. Importantly, the regulations at § 422.112(a) provide a critical beneficiary protection in that even if a provider or facility specialty type is not subject to specific quantitative network adequacy standards, that access to providers at in-network cost sharing must be provided by the MA organization. This critical beneficiary protection, in conjunction with the standard that MA plan networks provide access and availability of services consistent with prevailing community pattern of health care delivery, ensures that MA enrollees have similar reasonable access to providers and facilities as beneficiaries in FFS Medicare. Therefore, we expect that MA plans will

continue to provide adequate access to outpatient dialysis providers. Section 1852(b) of the Act prohibits MA plans from denying, limiting, or conditioning the coverage or provision of benefits under this part, for individuals permitted to be enrolled with the organization under this part, based on any health status-related factor and prohibits use of a plan design that discourages enrollment by certain beneficiaries, such as those with diagnoses of ESRD.

If beneficiaries believe that an MA organization is not providing adequate access to services, complaints may be submitted by calling 1-800-MEDICARE. CMS monitors and investigates complaints related to plan coverage and CMS caseworkers assist in the resolution of any issues with the MA organizations. CMS may take compliance or enforcement actions against an MA organization for failing to meet any contract requirements, such as providing adequate access to medically necessary services, as warranted.

While our members are pleased that CMS recognizes the importance of providing access to MA plans for dialysis patients, we reiterate our concern that an attestation alone will not provide adequate protection to beneficiaries to ensure their access to these plans. Therefore, we urge CMS to reinstate the time and distance standards and the minimum number of provider requirements of the Network Adequacy Standards for outpatient dialysis services.

The Medicare Payment Advisory Commission (Commission) has raised similar concerns that the changes to the Network Adequacy Standards could diminish access to MA plans for beneficiaries with ESRD. They have agreed that the loosening of these requirements could result in beneficiaries' facilities and providers being removed from a plan's network. If a patient does not see his/her facility or provider listed as in network, they are less likely to select the plan, rather than go through the process of getting the services covered after enrollment.

The Commission has also raised concerns about the negative impact that the absence of time and distance standards could have on beneficiaries' health and well-being. Research supports their concerns that longer distances and times between a patient's home and their health care provider can harm patients. Patients have better compliance with their treatment and better outcomes when their facilities are closer to where they live or work, as several studies have shown. Travel time can affect adherence to treatment protocols, hospitalization, and transplantation. Missed treatments (for other than hospitalizations) are associated with inadequate fluid removal, higher levels of depression, and increased negative outcomes, including all-cause mortality, cardiovascular mortality, sudden death/cardiac arrest, hospitalization, higher serum phosphorus levels, higher parathyroid hormone levels, lower hemoglobin levels, higher kidney disease burden, and

worse general and mental health.¹ Longer travel times can be especially problematic for dialysis patients living in rural areas.²

Thus, KCP continues to support the network adequacy time and distance requirements for outpatient dialysis. To provide meaningful access to MA plans as the Congress intended, KCP believes that CMS needs to maintain outpatient dialysis on the list of time and distance standards and also to provide direct oversight of plan compliance with these requirements.

We also reiterate our recommendations that the Network Adequacy Standards also include the specialists that dialysis patients need. Not only should there be nephrologists, vascular access surgeons, and other similar professionals, but the number of such specialists included in the network needs to be sufficient to ensure that patients have practical access to them. A network would not be adequate if there is a vascular surgeon, for example, but a patient is unable to schedule an appointment with him/her because all of the appointment slots are filled for months. Not having access to vascular surgery in a timely manner thwarts the quality indicator of a permanent rather than a temporary access and negatively impacts the patient health as well as increases long term costs. An attestation process or other policy that would remove direct CMS oversight would only make this problem worse. It would eliminate access to these plans for all practical purposes or drive up costs of care by not having the most efficacious intervention available.

II. Ensuring Payment for Innovative Drugs, Biologicals, and Devices Are Incorporated into the MA Program in a Timely Manner

The ESRD PPS serves as the basis for the MA payments. As the Administration has recognized through the KidneyX initiative and Advancing American Kidney Health, there is a substantial need to support and expand innovation for dialysis patients. Payment policy needs to support the research and approval processes as well. To that end, CMS has finalized two policies in the ESRD PPS to support innovation – the Transitional Drug Add on Payment Adjustment (TDAPA) and the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES). We ask that CMS coordinate these policies with the MA program, so that the additional funding for these products is also incorporated into the MA reimbursement program. It is critically important that these steps are taken to ensure that there is adequate funding for innovative products in the MA program as well.³

¹Salmi, A.; Larkina, M; Wang, *et al* “Missed Hemodialysis Treatments: International Variation, Predictors, and Outcomes in the Dialysis Outcomes and Practice Patterns Study (DOPPS).” *72 Am J Kidney Dis.* 634-43 (Nov. 2018).

²Stephens, JM; Brotherton, S; Dunning, SC; *et al.*, “Geographic Disparities in Patient Travel for Dialysis in the United States” *29 J. Rural Health* 339-48 (2013).

³*See*, 42 C.F.R. §422.109.

III. KCP Recommends Re-Examining the Methodology Used to Calculate MA ESRD Rates

As CMS expands MA plan access to dialysis patients, it is important that the MA rates paid to plans are set in a manner that covers the cost of providing care to dialysis patients. In addition to addressing problems with the MA rates, CMS should also account for the fact that the ESRD PPS itself does not cover the cost of providing services. Addressing both of these issues is critically important to make sure that plans have the resources to incentivize enrolling dialysis patients.

Inadequate rates create a significant disincentive (or in some instances make it impossible) for MA plans to provide coverage to dialysis patients and thwart the will of the Congress. Therefore, KCP strongly urges CMS to use its existing authority to address the underlying problems within the ESRD PPS and to use its discretionary authority to make sure that the rates for 2022 do not disincentivize plans from enrolling dialysis patients.

IV. Conclusion

Thank you again for providing us with the opportunity to comment. KCP continues to support dialysis patients who want to enroll in MA plans and encourages CMS to remove barriers to that access. It is important for the payment rates to MA plans to support the cost of providing outpatient dialysis services. The additional services and reduced cost sharing aspects of many MA plans can provide great value to patients with kidney disease. Additionally, MA plans have shown how effective they can be in improving health status for patients with chronic diseases through care coordination and management activities. We welcome the chance to continue to work with CMS to help patients understand their options and ensure that they are able to exercise their right to enroll in MA plans that the Congress provided to them.

Please do not hesitate to reach out to our counsel in Washington, Kathy Lester at 202-534-1773 or klester@lesterhealthlaw.com, if you have questions or would like to discuss our comments.

Sincerely,

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

John Butler
Chairman

Appendix: KCP Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Pediatric Nephrology
Amgen
Ardelyx
American Society of Nephrology
AstraZeneca
Atlantic Dialysis
Baxter
BBraun
Cara Therapeutics
Centers for Dialysis Care
CorMedix
DaVita
DialyzeDirect
Dialysis Patient Citizens
Dialysis Vascular Access Coalition
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
Otsuka
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Vertex
Vifor Pharma