



August 17, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

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

Re: CMS-4203-NC: Medicare Program; Request for Information on Medicare

Dear Secretary Becerra and Administrator Brooks-LaSure,

On behalf of Kidney Care Partners (KCP), I want to convey our appreciation for the Administration's efforts to seek input on various aspects of the Medicare Advantage program through the "Request for Information on Medicare"¹ (RFI). KCP led the effort to expand access to the MA Program for individuals who are diagnosed with kidney failure (End Stage Renal Disease (ESRD)), are under 65 years old, and choose to enroll in Medicare. Having this option has been critically important for those patients who require benefits not available in traditional Medicare or who do not have access in their states to Medigap policies. Even though the option to enroll opened only in January 2021, Medicare ESRD beneficiaries immediately embraced the program. Avalere reports that just over 40,000 Fee-for-Service (FFS) patients with ESRD (or about 30 percent) selected to enroll in MA during the 2021 open enrollment period.² Given the increasing number of individuals with kidney disease enrolled in MA plans, KCP is working closely with our members to ensure these plans are providing access to the health care services these individuals require to maintain a high quality of life.

Kidney Care Partners is a non-profit, non-partisan coalition of more than 30 organizations comprising patients, physicians, nurses, dialysis professionals, researchers, therapeutic innovators, transplant coordinators, and manufacturers dedicated to working together to improve the quality of care for individuals living with kidney disease.

KCP supports CMS's strategic vision "to serve the public as a trusted partner and steward, dedicated to advancing health equity, expanding access to affordable coverage and care, and improving health outcomes." We are pleased that the Administration is focusing on advancing health equity and expanding access to quality, affordable coverage

¹CMS. "Request for Information on Medicare." 87 *Fed. Reg.* 46918 (Aug. 1, 2022).

²Avalere. "ESRD Enrollment in MA Now Exceeds 30 Percent of all Dialysis Patients."

<https://avalere.com/insights/esrd-enrollment-in-ma-now-exceeds-30-percent-of-all-dialysis-patients>. (Dec. 16, 2021).

and care for all Medicare beneficiaries, but it is particularly important for the Medicare ESRD beneficiaries.

We appreciate the opportunity to offer suggestions and comments on selected questions set forth in the RFI related to advancing health equity and expanding access to health coverage and care.

I. Advance Health Equity

CMS's strategic vision is particularly appropriate given the factors defining the ESRD population. In the CY 2023 ESRD Prospective Payment System (PPS) proposed rule, CMS describes in detail how the ESRD population differs from other FFS beneficiaries. "When compared with all FFS beneficiaries, FFS beneficiaries receiving dialysis are disproportionately young, male, disabled, and African-American, have low income as measured by dual status, and reside in an urban setting."³ In addition, CMS provides the following snapshot of ESRD beneficiaries.

- The ESRD PPS population was 58.7 percent male compared to 46.9 percent male in the non-ESRD Medicare population.
- Approximately 40 percent of the ESRD beneficiary population was younger than 60 years old, compared to 10 percent in the non-ESRD beneficiary population.
- Forty-seven percent of the ESRD population was originally eligible for Medicare due to disability (with or without ESRD), compared to 21 percent for the non-ESRD Medicare population.
- Members of racial or ethnic minority groups comprised a larger proportion of the ESRD Medicare population compared to the non-ESRD Medicare population. This was especially true among Blacks/ African-Americans who comprised 34.5 percent of the ESRD population, compared to 8.9 percent of the non-ESRD Medicare population.
- Approximately 84 percent of ESRD beneficiaries lived in urban areas, while approximately 79.6 percent of the non-ESRD Medicare population lived in urban areas.
- Forty-two-and-a-half percent of the ESRD Medicare population was dually eligible for Medicare and Medicaid as compared to 15.4 percent of the non-ESRD Medicare population. As compared to the non- ESRD Medicare population, ESRD Medicare beneficiaries were more likely to be enrolled in Medicare Part D (73 percent ESRD PPS as compared to 61 percent of non-ESRD Medicare beneficiaries).
- ESRD Medicare beneficiaries were more likely to be living in socioeconomically disadvantaged neighborhoods compared to non-ESRD Medicare beneficiaries; approximately 29 percent of the ESRD PPS population resided in the most

³87 Fed. Reg. 38464, 38500 (June 28, 2022).

disadvantaged ADI percentiles (76th to 100th percentile) compared to 19.2 percent of non-ESRD Medicare beneficiaries.⁴

As KCP has noted in previous letters to CMS, the Medicare ESRD beneficiary population is disproportionately impacted by socio-economic status factors (SES) and social determinants of health (SDOH). These factors affect access to treatment at all stages in the progression of kidney disease and the comorbidities these individuals experience. These factors often lead to inequities in the health care they receive.

There is no question that Medicare ESRD beneficiaries have experienced significant inequities in the delivery of health care even before enrolling in the Medicare program. Based on the CMS definition of health equity as “the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes,” the kidney care community recognizes that there is much work to be done to achieve the goal of health equity for individuals living with kidney disease and kidney failure.

Q1: What steps should CMS take to better ensure that all MA enrollees receive the care they need, including but not limited to the following:

- ***Enrollees from racial and ethnic minority groups...***
- ***Enrollees with disabilities, frailty, other serious health conditions, or who are nearing end of life...***
- ***Enrollees of disadvantaged socioeconomic status...***
- ***Enrollees who live in rural or other underserved communities.***

Q2: What are examples of policies, programs, and innovations that can advance health equity in MA? How could CMS support the development and/or expansion of these efforts and what data could better inform this work?

As noted in the introduction, individuals who require dialysis in the MA program experience inequities in the delivery of their care for a variety of reasons. While the MA plans often offer important supplemental benefits that can be important to drive toward greater health equity for individuals receiving dialysis services, a disconnect has arisen that limits access to innovative treatment options for MA enrollees and to which FFS beneficiaries have access. This situation has led to an inequity that we believe CMS can address under its existing authority.

The Medicare ESRD PPS provides an add-on available for two to three years for innovative drugs, biologicals, and devices. Known as The Transitional Drug Add-on

⁴*Id.* at 38525.

Payment Adjustment (TDAPA) and the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES), these add-ons provide reimbursement for new products. In the case of drugs or biologicals the Food and Drug Administration (FDA) has classified as being within certain categories. If the drug is approved by the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or the new drug application (NDA) for the drug is classified by FDA as Type 3, 5, 7, or 8; Type 3 in combination with Type 2 or Type 4; Type 5 in combination with Type 2; or Type 9 when the parent NDA is a Type 3, 5, 7 or 8, the product is excluded from the add-on payment;⁵ otherwise, the new product will qualify for an add-on payment for two years. For TPNIES, a manufacturer must complete an application, which includes a substantial clinical improvement analysis, to be awarded the add-on.

Currently, two drugs have been awarded TDAPA and one device is receiving TPNIES. In each of these cases, we understand from our members that MA plans have not provided the TDAPA or TPNIES add-ons to contracted facilities. This decision is problematic for two reasons. First, the base rate does not include funding for these products. CMS acknowledged that there were no dollars in the ESRD base rate for the calcimimetics. Based on CMS data, there is less than \$1 in the base rate for antipruritics. If the MA plans do not provide the add-on, facilities will not have the resources to provide the products to patients. Second, the contracting process cannot account for the innovative products. The bid cycles and PDUFA or TPNIES applications approval dates rarely align. This timing lag means that the contracts cannot anticipate the additional resources needed to protect patient access to the products.

MA plans are required to provide at least the same items and services available in the Medicare FFS program. By not providing TDAPA or TPNIES, the MA plans are not providing the same level of access to these innovative products to which FFS beneficiaries have access. We believe that CMS can address this inequity by taking steps to ensure that there is adequate funding for innovative products in the MA program as well. Specifically, we ask CMS to consider adopting a policy in line with new NCD/Legislative changes coverage policy at 42 C.F.R. § 422.109. CMS could accept the risk and pay the add-on during the transitional period by paying the add-ons directly to facilities that submit claims for the products. Once a product is folded into the ESRD PPS bundle, the reimbursement would become part of the negotiations with the plans. This policy would address inequities created under the current policy.

II. Expand Access: Coverage and Care

The expansion of access to MA plans for individuals who qualify for Medicare because of their disability – kidney failure – has been an important opportunity for individuals living with kidney failure. Strengthening access to these plans remains a

⁵42 C.F.R. § 413.234(e)(1) - (7).

priority for KCP, and we are pleased that CMS is seeking comments on how it can continue to strengthen beneficiary access to health services to support this goal in MA.

Q6. What factors do MA plans consider when determining whether to make changes to their networks? How could current network adequacy requirements be updated to further support enrollee access to primary care, behavioral health services, and a wide range of specialty services? Are there access requirements from other federal health insurance options, such as Medicaid or the Affordable Care Act Marketplaces, with which MA could better align?

We appreciate that CMS has repeatedly highlight its commitment to provide access to MA plans for dialysis patients who become eligible for Medicare because of their diagnosis of kidney failure. While many individuals with ESRD selected MA plans for 2021, KCP members remain concerned that without a specific requirement for plans to include outpatient dialysis services in-network, individuals who require dialysis will be discouraged from enrolling in MA plans. It is difficult to estimate the number of enrollees who might have been affected by the removal of outpatient dialysis services from the Network Adequacy Standards, but we also recognize that there are other factors that can be taken into account.

The vast majority of Medicare ESRD beneficiaries identify as belonging to groups that CMS has identified as experiencing health inequities. Kidney failure itself has been deemed as a disability. If a plan were to limit or exclude nephrologists, dialysis facilities, or other health care providers directly related to providing ESRD-related services, individuals requiring dialysis services would not have access to the core health care services they require. In essence, restricting networks in this way is a proxy for eliminating access to MA enrollees who require dialysis services and who are mostly Black/Brown, low-income, disabled, and living in underserved areas. The problem is also occurring in medically underserved areas or rural areas, which limits access to MA plans in a way that the Congress and CMS did not intend.

The Medicare Payment Advisory Commission (MedPAC or Commission) has raised similar concerns that eliminating dialysis outpatient services from the Network Adequacy Standards could diminish access to MA plans for individuals with ESRD. The Commission has argued that loosening these requirements could result in an individual's facilities and providers being removed from a plan's network. If an individual does not see his/her facility or provider listed as in-network, the individual is less likely to select the plan, rather than go through the onerous process of getting the services covered through an out-of-network exception after enrollment.

The Commission has also raised concerns about the negative impact that the absence of time and distance standards could have on enrollees' health and well-being. Research supports MedPAC's concerns that longer distances and times between a patient's

home and their health care provider can harm patients. 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.

Longer travel times can be especially problematic for dialysis patients living in rural and underserved areas. As several studies have shown, patients have better compliance with their treatment and better outcomes when their facilities are closer to where they live or work.

To avoid this inequity, we request that CMS reinstate the time and distance standards and the minimum number of provider requirements of the Network Adequacy Standards for outpatient dialysis services. Ensuring that these individuals have access to high quality care and the full range of treatment options they medically require is even more important now that more individuals living with ESRD are enrolling in MA plans.

We also reiterate our recommendations that the Network Adequacy Standards include the specialists that dialysis patients require. We appreciate that many of these specialists are included in the time and distance and minimum number requirements, but it is also important to ensure that enrollees 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 a timely appointment. 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. Similar situations could occur with other types of specialists.

Q10: How do MA plans use utilization management techniques, such as prior authorization? What approaches do MA plans use to exempt certain clinicians or items and services from prior authorization requirements? What steps could CMS take to ensure utilization management does not adversely affect enrollees' access to medically necessary care?

While KCP understands that prior authorization can be an important tool in managing care, we do not believe it is appropriate to apply to individuals whose lives depend upon receiving life-sustaining dialysis three to four times a week. Even the slightest delay in dialysis treatments can have a negative impact on individuals' outcomes and quality of life. It can also lead to death.

Insurers rely upon prior authorization to affirm that an individual covered by the plan truly meets the medical necessity requirements to obtain a specific service. Dialysis is

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not an optional service, nor is it one for which there is any question that an individual must have it. Without the dialysis treatments, individuals suffer significant adverse health events and incur otherwise unnecessary health care costs. A delay in receiving treatments can also lead to death. Adding additional paperwork for providers and potential delays in treatments for individuals with kidney failure is not fulfilling a meaningful utilization management purpose.

KCP is concerned that some MA plans have been requiring individuals with kidney failure to obtain a prior authorization before being able to dialyze. We ask CMS to exempt dialysis treatments from any prior authorization requirement.

III. Conclusion

KCP appreciates the opportunity to provide comments on the RFI. We look forward to working with CMS to address the recommendations highlight in this letter. Please do not hesitate to reach out to our counsel in Washington, Kathy Lester, if you have any questions. She can be reached at 202-534-1773 or klester@lesterhealthlaw.com. Again, thank you for the opportunity to provide comments.

Sincerely,



John Butler
Chairman

cc: Cheri Rice, Deputy Director, Parts C and D, Center for Medicare

Appendix: KCP Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Society of Nephrology
American Society of Pediatric Nephrology
Ardelyx
AstraZeneca
Atlantic Dialysis
Baxter
Cara Therapeutics
Centers for Dialysis Care
Cormedix
DaVita
Dialysis Patient Citizens
DialyzeDirect
Dialysis Vascular Access Coalition
Fresenius Medical Care
Greenfield Health Systems
Kidney Care Council
NATCO
Nephrology Nursing Certification Commission
Otsuka
ProKidney
Renal Healthcare Association
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
U.S. Renal Care
Satellite Healthcare
U.S. Renal Care
Vertex
Vifor Pharma