KIDNEY CARE PARTNERS

February 28, 2024

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Deputy Administrator
Center for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

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

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2025 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies

Dear Deputy Administrator Seshamani and Director Lazio,

Kidney Care Partners (KCP) appreciates having the opportunity to provide comments on the "Advance Notice of Methodological Changes for Calendar Year (CY) 2025 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies" (Advance Notice). KCP is an alliance of members of the kidney care community that includes patient advocates, dialysis care professionals, providers, and manufacturers organized to advance policies that improve the quality of care for individuals with both Chronic Kidney Disease (CKD) and irreversible kidney failure, known as End Stage Renal Disease (ESRD).

KCP remains pleased that individuals who decide to enroll in Medicare after being diagnosed with ESRD are permitted to also enroll in an MA plan. As more individuals requiring dialysis select this option, we encourage CMS to recognize the unique aspects of this patient population to protect the long-term stability of the program. We would like to work closely with CMS in the coming months to address the challenges that individuals who rely upon dialysis and are enrolled in MA plans are experiencing to ensure equitable access to these life-sustaining services.

I. Section D: MA Rates

A. KCP requests that CMS provide more oversight of MA plans to ensure that payment policies do not result in a lack of access, which amounts to a *de facto* lack of coverage, for services provided under Traditional Medicare.

KCP supports the efforts to ensure that the Medicare Advantage (MA) ESRD rate adequately covers the cost of providing services for enrollees. As we noted in previous comment letters, MA enrollees who rely on dialysis treatments continue to experience a *de facto* lack of access to innovative treatments. Because CMS does not require MA plans to reimburse dialysis facilities for the Transitional Drug Add-on Payment Adjustment (TDAPA) or the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Suppliers (TPNIES), facilities do not have the financial resources to provide these products even when prescribed by the physician. Without the requirement, many MA plans are not recognizing these payment adjustments. Our patient and patient advocate members report not having been able to access the two drugs that have received TDAPA during the past few years, as well as a lack of access to the home dialysis machine that received TPNIES. While MA plans do not release data publicly, we encourage CMS to carefully review the data and evaluate the impact on patient access. We believe that CMS shares the kidney care community's interest in making sure that individuals enrolled in MA plans are able to receive

the same services available in Traditional Medicare and, when provided by the MA plan, additional services to augment those.

The lack of access to innovative products amounts to a *de facto* lack of coverage for these products and creates a significant health inequity. As CMS has noted in previous rulemaking and requests for information, individuals who require dialysis are "disproportionately young, male, disabled, Black/African- American, low income as measured by dually eligible Medicare and Medicaid status, and reside in an urban setting."[1] The most recent USRDS report notes that of the individuals with earlier stages of CKD (those before kidney failure) only 22 percent have a seen a nephrologist.[2] Most have multiple comorbidities, including diabetes, cardiovascular disease, and heart failure[3] that have not been managed prior to their diagnosis with kidney failure. These are the very individuals who may wish to enroll in MA plans to obtain additional services, such as dental, to which they have not previously had access. They should not be placed in a position where in order to get coverage for these additional and critically important health care services they must give up access to innovative therapies available to individuals enrolled in traditional Medicare.

Addressing this problem is a top priority for KCP. It is especially important to our patient and patient advocate members, who rightly emphasize that the ESRD population has not enjoyed the innovation that people living with other diseases have experienced. MA program should avoid perpetuating the health inequities that many individuals who require dialysis have experienced. As we requested last year, we ask that CMS adopt a more patient-centric approach. Consistent with policy for other innovative technologies, KCP recommends that CMS reimburse dialysis facilities directly for the TDAPA and TPNIES payments. Because of the unique health equity issues involved and role of Medicare as the predominant insurer for individuals with kidney failure, the payments should occur during the entire TDAPA period. This approach would be consistent with other MA policies related to new coverage requirements and would support the President's health equity executive order and other initiatives.

B. KCP requests that CMS provide more guidance as to the shift of oral only drugs from Part D to Part B and the impact on MA ESRD rates.

The Advance Notice indicates that CMS is removing oral only drugs from Part D to incorporate them into Part B in 2025. KCP supports legislative efforts to delay the implementation of this shift, but to the extent it occurs, we ask that CMS ensure that there are no gaps in coverage for individuals enrolled in MA plans. CMS should coordinate with the Part B program regarding the timing of the transition and related policies.

Moreover, we are concerned that there is not greater transparency around the shift of the dollars from Part D to Part B. While we recognize that in previous TDAPA situations, CMS has indicated that the funding for the TDAPA payments is incorporated into the ESRD MA rates, the Advance Notice is silent as to how the proposed rates account for oral-only drugs being added to the bundle in 2025. We call on CMS to indicate in the final letter the way in which the rate accounts for this policy change and how CMS will protect patient access to these drugs.

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[1] 87 *Fed. Reg.* 38464, 38524 (June 28, 2022).
[2] USRDS. Annual Report. Ch. 1 (2023).
[3] *Id.*

We also encourage CMS to consider applying a policy similar to the separate payment amount that is provided to other products when there is a change in CMS coverage policy. While the cost of an individual phosphate binder or phosphate lowering drug may not meet the cost threshold of the current policy, if the cost is considered in terms of the ESRD population (rather than the entire MA population) the total impact of adding these drugs to the base rate is significant. As we saw with Korsuva and the calcimimetics, it is important to address the decision of some plans not to recognize the TDAPA adjustment to ensure patient access to these products. Because more than 60 percent of patients require phosphate binders or phosphate lowering drugs,[4] it is critically important that CMS be proactive in addressing this challenge.

C. KCP encourages CMS to continue to refine the determination of MA ESRD rates to ensure that (1) MA plans receive adequate funding to support high-quality dialysis services and (2) MA plans reimburse dialysis facilities and nephrologists appropriately to support the care of individuals who require dialysis treatments.

KCP supports the decision to continue to set MA ESRD rates on a state basis (instead of the county level) using updated FFS costs each year. We believe a smaller geographic unit would not provide adequate data to establish appropriate rates. We also ask CMS to consider ways to take into account uncompensated care when setting these MA rates. The current methodology may overestimate the amount of maximum out-of-pocket expenses that can be collected. As a result, the rates for MA plans may be set lower than they should be. For the patients who wish to remain in MA plans, it is critically important that the MA rates acknowledge the higher uncompensated care amounts to ensure adequate reimbursement to support the care and services they need.

As more individuals who require dialysis services enroll in MA plans, we urge CMS to closely monitor the program and plan behavior. While KCP understands the Congressional mandates related to not interfering between plans and providers, the Medicare ESRD program is unique for many reasons, not the least of which is the fact that Medicare provides coverage to the vast majority of individuals who require thrice-weekly dialysis services. No other part of the Medicare program allows individuals to become eligible for services three months after the onset of their disease. As a result, CMS should be particularly vigilant to ensure that MA payment policy does not create barriers that could prevent patients from receiving the services they need.

II. KCP urges CMS to increase transparency by requiring MA plans to report additional data.

As we have noted in previous letters, we are concerned that the MA program does not provide the same level of transparency that the FFS program does when it comes to patient outcomes and similar data. We hope that these data will provide a consistent flow of information to the USRDS as well. We strongly encourage CMS to require MA plans to provide data similar to that collected in the FFS program with regard to ESRD enrollees. As more Medicare-eligible patients

[4]GAO. "End Stage Renal Disease: CMS Plans for Including Phosphate Binders in the Bundled Payment" (Nov. 2023) 5 ("In 2020, over 60 percent of Medicare ESRD dialysis patients with Part D coverage were prescribed phosphate binders, and Medicare Part D plans paid almost $1 billion for these drugs.")

select MA coverage, it is crucial that ESRD-related data available for patients with Medicare FFS as their primary coverage be extended to include MA enrollees.

III. Conclusion

Thank you again for providing KCP with the opportunity to comment on the Advance Notice. KCP continues to support dialysis patients who enroll in MA plans. It is important that the payment rates to MA plans 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 look forward to continuing to work with CMS on this important matter as it refines the methodology and data collection for individuals with CKD or ESRD who are enrolled in MA plans. 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,

Mahesh Krishnan MD MPH MBA FASN
Chairman
Kidney Care Partners

Appendix A: 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
Centers for Dialysis Care
Cormedix
CSL Vifor
DaVita
Dialysis Care Center
Dialysis Patient Citizens
Fresenius Medical Care
Greenfield Health Systems
Kidney Care Council
NATCO
Nephrology Nursing Certification Commission
Renal Healthcare Association
Renal Physicians Association
Renal Support Network
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Unicycive