January 24, 2025

Mr. Jeff Wu
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-4208-P: Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

Dear Acting Administrator Wu,

Kidney Care Partners (KCP) appreciates having the opportunity to provide comments on the "Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" (Proposed Rule). 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).

I. Supporting Additional Data Reporting related to Prior Authorization

KCP strongly supports the proposal requiring Medicare Advantage Organizations (MAOs) to report additional data related to the use of prior authorization. We believe these data should be provided independently and not linked to a health equity analysis. To understand the impact of the use of prior authorization on MA enrollees' access to medical services, including dialysis and other ESRD-related services, nephrology and other specialty services related to managing CKD, and transplant services, it is imperative that CMS collect the data points outlined in the proposed rule, which are:

- The percentage of standard prior authorization requests that were approved, reported by each covered item and service.

- The percentage of standard prior authorization requests that were denied, reported by each covered item and service.

- The percentage of standard prior authorization requests that were approved after appeal, reported by each covered item and service.

- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, reported by each covered item and service.

- The percentage of expedited prior authorization requests that were approved, reported by each covered item and service.

- The percentage of expedited prior authorization requests that were denied, reported by each covered item and service.

- The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, reported by each covered item and service.

- The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, reported by each covered item and service.

We also strongly support reporting these data elements by each covered item or service rather than using an aggregate approach to establish transparency and empower patients and their care-partners to make informed health care decisions. It is important to understand the impact of prior authorization on the ability of patients to access CKD services, dialysis, and kidney transplantation.

In addition, we urge CMS to clarify that these data elements should be reported for initial prior authorizations, as well as re-authorization requests. KCP members report that some MA plans are requiring the re-authorization of dialysis services as often as every three months. These prior authorizations can apply to the dialysis treatment itself and to referral to dialysis related providers and medications. KCP patient advocates have experienced challenges related to prior authorizations for transplant-related services as well.

We also support the decision to require an executive summary of the results along with the specific data elements reported by each covered item and service. Such a summary will further support transparency and patient-centered decision-making.

Given the fact that nearly 50 percent of individuals with kidney failure are dually eligible for Medicare and Medicaid,[1] KCP supports stratifying the data by dual eligibility status as well.

We urge CMS to require this information to be provided independently of the health equity analysis. It is important that all enrollees understand the impact of prior authorization (as well as other utilization management tools) on their ability to access services.

II. Addressing Concerns about Network Adequacy for Providers of Dialysis Services

KCP continues to support reinstating the time and distance standards for dialysis services that were once part of the Network Adequacy requirements. As researchers noted in a 2023 article published in the *Journal of the American Medical Association* (JAMA), "MA plans also face incentives to restrict use of high-cost services and have higher disenrollment rates among patients with intensive health care needs."[2] The time and distance standards were one mechanism to counterbalance such incentives for individuals who require dialysis. When CMS removed dialysis services from the areas subject to these standards, it noted that removing them would promote increased utilization of home dialysis. CMS promised to monitor the impact. Unfortunately, USRDS data show that beneficiaries enrolled in Medicare Advantage are more likely to receive in-center dialysis than to select home dialysis.[3] These data suggest that removing the time and distance standards have not increased the use of home dialysis.

KCP asks that, at a minimum, CMS track and report publicly the number of beneficiaries shifting from MA to traditional Medicare annually (including the special enrollment periods (SEPs)). Moreover, it would help to match these data with the patient survey data and share publicly the reason ESRD beneficiaries make this switch to provide insight as to the challenges they may face. Researchers have also noted the importance of tracking and reporting these data points.

> It will be critical for policy makers and MA plans to monitor whether provider networks (e.g., dialysis facilities, nephrology services) were equipped to facilitate access to care for substantially more MA enrollees with ESRD. Future work may also assess changes in use after switches from TM to MA, voluntary disenrollment from MA, experiences of care among beneficiaries in MA plans, and whether some plan types perform better for beneficiaries with ESRD.[4]

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[1] Avalere. "Analysis of Disparities in Kidney Care Service Utilization." (Aug. 2021). https://avalere.com/insights/avalere-analysis-of-disparities-in-kidney-care-service-utilization.
[2] Nguyen KH, Oh EG, Meyers DJ, Kim D, Mehrotra R, Trivedi AN. Medicare Advantage Enrollment Among Beneficiaries With End-Stage Renal Disease in the First Year of the 21st Century Cures Act. JAMA. 2023;329(10):810–818. doi:10.1001/jama.2023.1426
[3] USRDS. ESRD: Chapter 2. *Annual Report*. (2024).
[4] Nguyen, *supra* note 2.

We encourage CMS to begin reporting these data in early 2025 to provide greater transparency and help assess challenges individuals with ESRD may face when enrolled in MA plans.

III. Improving the Accuracy of Provider Directories

KCP strongly supports the proposed changes to the provider directories to streamline the beneficiary experience to improve their access to the information they need to make informed health care choices. We believe that making MA provider directories part of Medicare Plan Finder (MPF) for the 2026 Annual Enrollment Period (AEP) and policies to ensure the accuracy of the data being submitted through MAO attestations support a patient-centered approach to addressing the challenges many individuals with CKD or kidney failure have experienced.

Having access to correct provider information is critically important. KCP patient advocates have shared concerns about individuals with kidney failure losing access to their nephrologists and other clinical specialists. Perhaps most disturbingly, some of these individuals are removed from kidney or kidney/pancreas transplant waitlists because of a change in an MA plan's network that had not been communicated to them. These challenges create another set of barriers to accessing transplant, which is the only curative therapy for the kidney disease. The policies outlined in the Proposed Rule are an important step toward eliminating these problems and providing for continuity of care. KCP looks forward to working with CMS to enhance oversight of MA plans to more fully address these problem and protect access to nephrologists, dialysis facilities, specialists, and transplant.

IV. Protecting Beneficiaries with Enhanced Marketing and Communication Reviews

KCP members agree that it is important for CMS to exercise more oversight of MA plan marketing and communications. Individuals who rely upon Medicare for coverage of CKD and ESRD services have experienced misleading marketing and communications that have interfered with their ability to make meaningful and informed choices about their health care options. Our members also find that individuals who receive primary or secondary insurance through their employer may also be unaware that the contracted insurance product is an MA plan. We strongly encourage CMS not only to exercise more oversight of the accuracy of the information provided in marketing and communications, but also to make sure that such communications provide individuals with chronic diseases, such as CKD and ESRD, an accurate understanding of what they can expect to receive under an MA plan. Taking this approach supports the Administration's efforts to address chronic diseases, would improve transparency, and empower patients.

V. Improving Quality Reporting for ESRD-related Services

In the Proposed Rule, CMS sets forth a series of modifications to the quality metrics used under the MA quality and Five Star programs. Given the recent expansion of MA eligibility for individuals who qualify for Medicare based on their ESRD status and the unique and oversized role Medicare has in covering ESRD-related services, KCP urges CMS to work with the us to identify a subset of measures or ways to stratify existing MA measures to provide greater transparency as to plan performance with regard to CKD and ESRD enrollees. This approach would address gaps in quality data specific to the management of chronic diseases, support transparency, empower patient-centered decision-making.

VI. Improving Coordination for Dual Eligible and Integrated Care

KCP supports the proposals to better coordinate coverage for dual eligibles enrolled in D-SNPs. Integrating identification and health assessments will help streamline the process to improve their interaction with providers and ensure greater coordination and continuity of care in the delivery of their care.

VII. Establishing Innovation Parity between Traditional Medicare and MA

Even though the Proposed Rule does not discuss the issue, KCP urges CMS to address the problem of some MA plans not recognizing the transitional payment for new drugs, biologicals, and devices that are an integral part of traditional Medicare's effort to support innovation in the treatment of kidney failure. There has been little innovation in the treatment options available for individuals with kidney failure during the last 30 years. Studies have shown that the current flat-reimbursement rate disincentivizes the adoption of innovative treatment therapies.[5] The adoption of the Transitional Drug Add-On Payment Adjustment (TDAPA) and the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) is a small, but important step toward address the barriers to patient access created by the current payment system.

While some MA plans recognize the TDAPA and TNPIES adjustments and include them in their payments to dialysis facilities, others do not, despite the fact that CMS has included payments for these add-ons in the benchmark and rate setting processes. Consistent with the statutory requirement that individuals enrolled in MA plans have access to the same items and services available under traditional Medicare, CMS should ensure that dialysis facilities are

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[5]Karaboyas, Angelo1; Zhao, Junhui1; Ma, Junjie2; Moore, Carol2; Saleem, Najma2; Martin, Kevin J.3; Sprague, Stuart M.4,5; Smerdon, Caroline1; Pecoits-Filho, Roberto1; Pisoni, Ronald L1. Incorporation of Calcimimetics into End-Stage Kidney Disease Bundle: Changes in Etelcalcetide Utilization and Parathyroid Hormone Control following End of Transitional Drug Add-On Payment Adjustment Designation. Clinical Journal of the American Society of Nephrology ():10.2215/CJN.0000000583, October 8, 2024. | DOI: 10.2215/CJN.0000000583

reimbursed consistent with the TDAPA and TPNIES add-on amounts available under traditional Medicare.

VIII. Aligning the Reporting of Patient Related Data

Finally, we also urge CMS to increase transparency under the MA program by creating parity in data reporting between MAOs and traditional Medicare. Specifically, we request that MAOs report the same data that traditional Medicare reports for its monitoring programs, including outcomes data collected by the Chronic Care Policy Group, the ESRD QIP, and the ESRD Networks. Similarly, MAOs should report the same data that are reported under traditional Medicare to support the U.S. Renal Data Systems annual report. The definitions related to data format, fields, and content should align precisely with those used in traditional Medicare. Creating parity in reporting these data elements will support the transparency that has been a long-standing successful component of the Medicare ESRD program and the USRDS. Such information has been critically important to policy-makers at all levels to improve access to, as well as accountable for, CKD and ESRD-related services.

IX. Clarifications Regarding Determinations and Beneficiary Notifications of Significant Provider Network Disruption for SEP

While this rulemaking does not directly address the issue of determining a SEP when there is significant provider network disruption, KCP requests that CMS provide separate guidance to clarify the process used to determine the unique circumstances of beneficiaries, such as those with ESRD. Like all beneficiaries with a chronic disease, those with ESRD work with multiple health care professionals to manage their condition. Continuity of care is extremely important for maintaining high quality and positive patient outcomes. Many of these individuals have long-standing provider relationships. When there are network changes involving even only a small number of providers, it can be incredibly disruptive to their continuity of care and result in negative outcomes.

We appreciate the recent guidance, including the “CMS Center for Medicare: NAIC Q&A and Follow-Ups,” issued on December 17, 2024. Although this information is helpful, KCP members would like to better understand the process for making significant network disruption determinations and its expectations regarding MA plans’ responsibilities for notifying their enrollees and providers.

- While CMS’s current guidance does not expressly address the unique provider access issues for beneficiaries with a life-threatening chronic illness, such as those living with ESRD, our interpretation of the current requirements is that CMS will take into account, under the “totality of the unique circumstances” criterion for defining a “significant disruption,” the types of providers, especially those specializing in the treatment of specific chronic diseases, even when only a small number of providers

have been removed from the network. It would be helpful for CMS provide additional guidance confirming this interpretation and to clarify the criteria (such as, the number of enrollees affected, the size of affected service area, etc.) and any thresholds upon which it relies.

- As noted in Section II, we remain concerned that the lack of time and distance standards may create provider access barriers for individuals who require dialysis services. We encourage CMS to take the location of providers into account when deciding whether to grant beneficiaries with a chronic illness, such as ESRD, a SEP related to a significant provider network disruption.

- The recent NAIC document suggests that MA plans must notify affected enrollees about a significant provider network change and other provider terminations, which may allow enrollees access to a SEP under the "exceptional circumstances" policy. We encourage CMS to provide public notification of active SEPs using other methods for notifying beneficiaries, such as providing the information via the CMS website

X. Conclusion

We look forward to continuing to work with CMS to support 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, 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
U.S. Renal Care
Unicycive