American Kidney Fund®
FIGHTING ON ALL FRONTS

January 27, 2025

Jeff Wu
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 212441

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:

The American Kidney Fund appreciates the opportunity to provide comments on the proposed rule referenced above issued by the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS).

The American Kidney Fund (AKF) fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 1 in 7 American adults living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. Through programs of prevention, early detection, financial support, disease management, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator and the Platinum Seal of Transparency from GuideStar.

Part D Coverage of Anti-Obesity Medications (AOMs) and Application to the Medicaid Program

AKF strongly supports the proposal to permit Medicare Part D coverage of anti-obesity medications (AOMs) for the treatment of obesity when such drugs are indicated to reduce excess body weight and maintain weight reduction long-term for individuals with obesity. We appreciate CMS's recognition that in the years since the inception of the Part D program, the medical community has come to regard obesity as a chronic disease. Given the rise in the prevalence of obesity in the Medicare population, its link to other chronic diseases, and the availability of multiple safe and effective AOMs, Part D coverage for AOMs is a critical step towards recognizing the important role these treatments can play in improving health and reducing disease.

Permitting Part D coverage would also align with coverage for AOMs that already exists in other federal health programs, including Veterans Affairs (VA), TRICARE, the Federal Employees Health Benefits Program (FEHBP), and Medicaid, where states have the discretion to provide coverage for AOMs, and 13 states currently do. We urge CMS to finalize this proposed statutory reinterpretation to

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permit Medicare coverage for AOMs, which as CMS notes, would also mean that AOMs would no longer be able to be excluded from a state's Medicaid coverage.

Medicare coverage for AOMs could be particularly beneficial in helping address chronic kidney disease (CKD), given that obesity not only increases the risk of developing CKD but also leads to complications. Population-based studies have demonstrated a link between measures of obesity and the development and progression of CKD. For example, numerous studies have shown that "higher body mass index (BMI) is associated with the presence and development of low estimated glomerular filtration rate (GFR), with more rapid loss of estimated GFR over time, and with the incidence of end-stage renal disease (ESRD)."[1] Additionally, elevated BMI levels have been "associated with more rapid progression of CKD in patients with pre-existing CKD."[2]

Relatedly, studies have demonstrated that weight loss in people with obesity and early-stage CKD have been associated with improvements in renal outcomes, particularly with "improvements in microalbuminuria, overt proteinuria and hyperfiltration," and regression analyses have shown that "for each 1 kg weight loss, there was a 110 mg reduction in proteinuria and a 1.1 mg reduction in albuminuria, which is independent of weight loss method and improvements in hypertension."[3]

Allowing coverage of AOMs for Medicare beneficiaries will give patients and providers another important tool to address the health needs of people with obesity, and to help prevent the development of CKD and slow its progression for people with early-stage CKD and obesity.

Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices under Medicare Part D

AKF supports CMS's proposal to codify, for 2026 and each subsequent plan year, the requirements under the Inflation Reduction Act (IRA) that Part D sponsors must not apply the deductible or charge cost sharing on adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP). We also support CMS's proposal to codify the requirements that Part D sponsors must provide coverage for new or revised recommendations on or after the effective date of ACIP's recommendation, and that these cost-sharing requirements apply for ACIP-recommended adult vaccines obtained through either in-network or out-of-network pharmacies or providers. People with kidney disease, people on dialysis, and kidney transplant recipients are immunocompromised and are at a higher risk for infectious diseases. Vaccines are especially important for them to keep a healthy immune system, and codifying these Part D coverage requirements is essential to ensuring patient access to ACIP-recommended vaccines.

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[1] Kovesdy CP, Furth SL, Zoccali C; World Kidney Day Steering Committee. Obesity and Kidney Disease: Hidden Consequences of the Epidemic. Can J Kidney Health Dis. 2017 Mar 8;4:2054358117698669. doi: 10.1177/2054358117698669. PMID: 28540059; PMCID: PMC5433675.

[2] Ibid.

[3] Peter Jacob, Kieran McCafferty, Assessment and management of chronic kidney disease in people living with obesity, Clinical Medicine, Volume 23, Issue 4, 2023, Pages 353-356, ISSN 1470-2118, https://doi.org/10.7861/clinmed.2023-0195.

Medicare Prescription Payment Plan

For Medicare Prescription Payment Plan (MPPP) requirements related to participation renewal year-over-year, CMS proposes an automatic election renewal process that extends a Part D enrollee's participation in the program for the next calendar year, unless the enrollee opts out. We support this proposal. AKF agrees with CMS that the proposed automatic renewal process for the MPPP reduces burden for Part D enrollees and aligns with the existing automatic renewal process for Part D enrollment. For Part D enrollees with chronic diseases and who may need assistance accessing high-cost medications in January of a new plan year, the proposed automatic renewal process will be particularly helpful for them in paying for their medications and adhering to their treatment. Additionally, because enrollees can disenroll from the MPPP at any time, there seems to be little risk in the proposed automatic renewal process.

Ensuring Equitable Access to Medicare Advantage Services—Guardrails for Artificial Intelligence

Given the growing use of artificial intelligence (AI) in health care, CMS proposes to revise 42 CFR 422.112(a)(8) to require MA plans to ensure services are provided equitably, irrespective of delivery method or origin, whether from human or automated systems. CMS also clarifies that in the event that an MA plan uses AI or automated systems, they must comply with existing statute and regulations that require MA plans to provide equitable access to services and not discriminate on the basis of any factor that is related to the enrollee's health status. We support this proposal and appreciate CMS's clarification that the use of AI and automated systems must not hinder equitable access to services or discriminate against MA enrollees with certain conditions. There have been many instances of algorithmic discrimination in health care that have deepened bias and perpetuated health disparities for members of underserved populations and people with social risk factors. Given the growth of MA enrollment and the growing use of AI in health care, it is critical for CMS to ensure equitable access to services for all MA enrollees.

Ensuring Equitable Access—Enhancing Health Equity Analysis of Utilization Management Policies and Procedures

AKF strongly supports the proposal to revise the required metrics for the annual health equity analysis of the use of prior authorization, to include:

- 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.

In the CY 2025 proposed rule, AKF had recommended that CMS should consider requiring MA plans to disaggregate the prior authorization data in their annual health equity analysis in order to see the impact of prior authorization policies on kidney care services, including dialysis treatments and transplant. In the CY 2025 final rule, CMS signaled its intent to propose reporting and posting of disaggregated data in the future, and we appreciate CMS's proposal to do so in this rulemaking by requiring MA plans to report the above prior authorization metrics by each covered item and service. We believe this more granular data will increase transparency and help identify trends in the use of prior authorization for people with certain conditions, including CKD.

Medicare Advantage Network Adequacy

CMS notes it is considering whether conducting network adequacy reviews at the MA plan level would provide greater assurances regarding the adequacy of an MA organization's network, compared to CMS's current practice of conducting network adequacy reviews at the contract level. AKF supports a potential change to network adequacy reviews being conducted at the plan level. We believe it would result in a more accurate representation of the providers available to enrollees in a particular plan under an MA contract. As CMS notes in the preamble, some providers and facilities that participate in a MA organization's contract may not be available to enrollees in a particular plan under that contract. Conducting evaluations at the contract level can result in a MA contract satisfying network adequacy requirements, but an individual plan under the contract not satisfying those requirements. Therefore, a beneficiary enrolled in that plan would not have access to an adequate number of providers. Access to network providers is a key factor for beneficiaries when deciding on an MA plan, and CMS should ensure that network adequacy reviews reflect a true evaluation of the providers available to beneficiaries considering a specific MA plan.

Given the importance of network adequacy requirements and time and distance standards to ensure MA enrollees have access to needed services and providers, we want to reiterate our previous concerns with the CMS policy that eliminated network adequacy requirements for outpatient dialysis facilities and other kidney care providers. We have heard from stakeholders in the kidney community that some patients in MA have faced difficulty accessing kidney care providers near their home. While

we appreciate that CMS has stated it will monitor MA enrollee access to kidney care providers through account management activities, complaint tracking and reporting, and auditing activities, we believe including dialysis facilities, nephologists, and vascular access surgeons in network adequacy requirements is a more efficient and effective way to ensure access to kidney care services, especially for the beneficiary.

Promoting Informed Choice—Expand Agent and Broker Requirements Regarding Medicare Savings Programs, Extra Help, and Medigap

To further promote informed enrollment decisions, CMS proposes to expand the number of required topics that an agent or broker must cover before an individual's enrollment to ensure the individual is educated on important topics and options that may factor into their enrollment decision. Specifically, CMS proposes to require agents and brokers to discuss the individual's potential eligibility for the Low-Income Subsidy (Extra Help) and Medicare Savings Programs, as well as the potential impact of MA enrollment on future Medigap guaranteed issue rights and where an individual might access additional information about these programs. AKF strongly supports this proposal.

Ensuring beneficiaries are equipped with the pertinent information on the impact of their Medigap federal guaranteed issue (GI) rights when making an MA plan enrollment decision is particularly important for beneficiaries with CKD. Data has shown that "people who disenrolled from [MA] had higher Medicare spending [in the year following disenrollment], on average, across all chronic health conditions examined, after adjusting for other health risk factors, than those continuously covered by traditional Medicare."[4] For people with CKD who disenrolled from MA, they had 33% higher Medicare spending, on average, in the year following disenrollment than people with CKD who were continuously enrolled in traditional Medicare.[5] Given this data, it is important for beneficiaries to know what their Medigap federal GI rights are when they are making an MA enrollment decision, because access to a Medigap plan is essential for many beneficiaries to afford their care, especially those with a chronic condition such as CKD and who may decide to switch from MA to traditional Medicare. If they are not aware that generally a beneficiary has a 12-month period under federal law in which they can disenroll from an MA plan and switch to traditional Medicare and purchase a Medigap plan with federal GI rights, they could miss their opportunity to purchase a plan or find that the cost of a plan is not affordable.

We also recommend that CMS require agents and brokers to provide information on state laws regarding Medigap GI rights for those states where the agent or broker is licensed and appointed to sell. As written in the proposed rule, CMS only encourages agents and brokers to do so. Requiring agents and brokers to provide information on state laws that offer additional GI rights is particularly important for Medicare beneficiaries under the age of 65 with ESRD who live in one of the 27 states that require insurers to sell Medigap policies to them.

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[4] Jeannie Fuglesten Biniek, Alex Cottrill, Nolan Sroczynski, and Tricia Neuman, Medicare Spending was 27% More for People who Disenrolled from Medicare Advantage than for Similar People in Traditional Medicare, KFF, Dec 06, 2024, https://www.kff.org/medicare/issue-brief/medicare-spending-was-27-percent-more-for-people-who-disenrolled-from-medicare-advantage-than-for-similar-people-in-traditional-medicare/

[5] Ibid.

Format Medicare Advantage Organizations' Provider Directories for Medicare Plan Finder

To further promote informed choice and transparency, CMS proposes to require MA organizations to make provider directory data available to CMS to allow it to be viewable on Medicare Plan Finder (MPF) for the 2026 Annual Enrollment Period. Specifically, CMS proposes to enhance MPF with searchable provider information for all MA organizations, require MA organizations to attest to accurate provider directory data, and require them to update the data accessed by MPF no later than 30 days after being notified of a change in provider information. AKF strongly supports this proposal. We have heard from MA enrollees with ESRD that they were told their primary care provider and/or nephrologist would be covered under their plan, only to discover after enrolling that they were not in-network. Making provider directories available and updated on MPF will provide another needed tool to ensure beneficiaries have access to the information they need to make informed decisions.

Promoting Informed Choice—Enhancing Review of Marketing and Communications

AKF supports CMS's proposal to eliminate the content standard of the current marketing definition, so that all communications materials and activities that meet the existing intent standard are considered marketing for the purposes of CMS's MA and Part D marketing and communications regulations, and therefore subject to review. We appreciate CMS's continued efforts to enhance its oversight of the marketing and communications materials and activities that are most likely to influence a beneficiary's enrollment decision. We have heard from many beneficiaries about the constant barrage of marketing and advertisements for MA plans that they encounter, and how the information they receive can be overwhelming. We support CMS's goal to ensure that beneficiaries are protected from misleading marketing so that they receive the best information to enroll in a plan that best meets their health care needs. We believe this proposed update to the marketing definition will help enhance CMS's oversight of tactics in which the intent is to influence a beneficiary's decision-making process in selecting a plan or choosing to stay enrolled in a plan, or drawing their attention to a plan.

Thank you for the opportunity to provide comments on this proposed rule.

Sincerely,

LaVarne A. Burton
President and CEO