Alliance FOR AGING RESEARCH
Catalyzing Innovation for Healthy Aging

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1/27/2025

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4208–P
P.O. Box 8013
Baltimore, MD 21244–8013

Re: Medicare and Medicaid Programs; 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 [CMS–4208–P]

Dear Administrator,

The Alliance for Aging Research ("Alliance") appreciates the opportunity to comment on the proposed rule related to Medicare Advantage and the Medicare Prescription Drug Benefit Program for contract year 2026. We commend CMS for its ongoing efforts to enhance beneficiary access and streamline processes within these federal programs. The Alliance for Aging Research is the leading nonprofit organization dedicated to changing the narrative to achieve healthy aging and equitable access to care. The Alliance strives for a culture that embraces healthy aging as a greater good and values science and investments to advance dignity, independence, and equity.

For more than 35 years, the Alliance has guided efforts to substantially increase funding and focus for aging at the National Institutes of Health and the Food and Drug Administration; built influential coalitions to guide groundbreaking regulatory improvements for age-related diseases; and created award-winning, high-impact educational materials to improve the health and well-being of older adults and their family caregivers. Our comments are below.

Coverage of Anti-Obesity Medications

The Alliance strongly supports the provision of the proposed rule that allows for the coverage of Anti-Obesity Medications (AOMs). Obesity is a public health crisis, affecting nearly half of all

Americans and significantly increasing the risk of cardiovascular disease, type 2 diabetes, musculoskeletal disorders and cancer.[1] The recent approvals of AOMs for the treatment of obesity have transformed medical care for those who struggle with obesity and related conditions. The Medicare and Medicaid populations deserve equitable access to these potentially life-saving medications, and we appreciate that CMS has acknowledged that the agency has the existing authority to cover AOMs for beneficiaries who need them to reduce excess body weight and maintain weight reduction long-term. CMS coverage of AOMs will vastly transform the long-term health and quality of life for millions of Americans.

Although CMS has historically interpreted the SSA to prohibit Medicare Part D coverage for AOMs, CMS does—in fact—have the regulatory flexibility to cover AOMs under Medicare Part D without legislation. CMS could cover AOMs for the purpose of treating the medical condition of obesity, not for weight loss for cosmetic purposes. When Congress allowed medicines for weight loss to be excluded from Part B, and excluded them from Part D, the legislators intended to target the use of prescription medicines for weight loss for cosmetic purposes—not for treatment of obesity, which is a medical condition. Thus, CMS has now denied coverage for AOMs for obesity based on a false premise and an incorrect statutory interpretation. CMS itself has taken this position. In 2005, CMS stated that: "[D]rugs are excluded from coverage under Part D when used as agents for certain conditions may be considered covered when used to treat other conditions not specifically excluded by section 1927(d)(2) of the Act" provided that they meet other requirements for coverage.[2] Critically, CMS went on to state that: "To the extent this is the case, and a drug is dispensed for a 'medically accepted indication' as described in the statute, weight loss agents may be covered for the treatment of morbid obesity..."[3]

Since the 1927(d)(2) statutory exclusion for weight loss was implemented, the understanding of obesity has significantly evolved in the medical community. The fact that obesity is a medical condition, which should be managed with medication, is now well-documented. Human genetics studies have found that DNA predisposes some individuals to develop obesity.[4] In 2004, the Department of Health & Human Services (HHS) recognized obesity as an illness.[5]

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[1] Chris M. Hales, M.D. et al., Dep't of Health & Human Servs., CDC, Prevalence of Obesity Among Adults and Youth: United Stated, 2015-2016 (Oct. 2017). https://www.cdc.gov/nchs/data/databriefs/db288.pdf

[2] CMS, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,194, 4,230 (Jan. 28, 2005, https://www.govinfo.gov/content/pkg/FR-2005-01-28/pdf/05-1321.pdf.

[3] *Id.*

[4] Ruth J. F. Loos & Giles S.H. Yeo, *The Genetics of Obesity: From Discovery to Biology*, Nature Review Genetics (Sept. 23, 2021), https://www.nature.com/articles/s41576-021-00414-z.

[5] CMS removed language stating that "obesity is not an illness" from its *Coverage Issues Manual*, which removed a significant obstacle to further progress coverage for obesity-related medical services. CMS, National Coverage Analysis (NCA) Tracking Sheet for Obesity as an Illness (CAG-00108N) (2004), https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=57&TAId=23&IsPopup=y&bc=AAAAAAAAAgAAAA%3D%3D&.

Following the agency's reassessment of obesity in 2004, CMS issued a National Coverage Determination providing coverage for bariatric surgery under Medicare in 2006.[6] The American Medical Association (AMA) also recognized obesity as an illness in 2013,[7] and in 2023, affirmed its recognition of obesity as a disease that involves genetic, metabolic, and behavioral aspects that require medical support.[8] There are numerous International Classification of Diseases (ICD) codes related to the treatment of obesity and Body Mass Index (BMI).[9]

A 2019 study concluded that "obesity may be viewed as a multifactorial pathology and chronic low grade inflammatory disease."[10] Further, it found that people affected by obesity had a greater risk of developing comorbidity and morbidity.[11] A 2014 study described obesity as a "significant public health hazard" which increases the risks for diseases such as Type II diabetes, cardiovascular disease, hyperlipidemia, hypertension, stroke, breast and colon cancer, and degenerative arthritis.[12]

Congress excluded drugs for "anorexia, weight gain, or weight loss" in the context of high rates of use of certain medicines for cosmetic weight loss. CMS coverage of GLP-1 medications for cosmetic weight loss would not be permissible or appropriate. However, treatment for obesity, in accordance with the FDA-approved label for GLP-1 medications, falls outside the scope of the statutory exclusion, and may be covered. For example, Wegovy is a GLP-1 receptor agonist indicated, in part, to reduce excess body weight and maintain weight reduction long term in: (1) adults and pediatric patients aged 12 years and older with obesity; and (2) adults with overweight in the presence of at least one weight-related comorbidity.[13] Wegovy and other AOMs are not indicated for use for cosmetic purposes, and do not carry the same health risks as those medications that initially spurred Congress to allow for exclusion of weight loss medications.

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[6] CMS, Decision Memo for Bariatric Surgery for the Treatment of Morbid Obesity (CAG-00250R) (2006), https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=160&ver=32&NcaName=Bariatric+Surgery+for+the+Treatment+of+Morbid+Obesity+(1st+Recon)&bc=BEAAAAAAEAgA.

[7] American Medical Association, Recognition of Obesity as a Disease (Resolution 420) (2013), https://media.npr.org/documents/2013/jun/ama-resolution-obesity.pdf.

[8] American Medical Association, Recognition of Obesity as a Disease H-440.842 (2023), https://policysearch.ama-assn.org/policyfinder/detail/obesity?uri=%2FAMADoc%2FHOD.xml-0-3858.xml.

[9] E.g., ICD-10-CM E66.01 (morbid (severe) obesity caused by excess calories); ICD-10-CM E66.8 (other obesity); ICD-10-CM E66.9 (obesity, unspecified); ICD-10-CM E663 (overweight).

[10] Antonio De Lorenzo, et al. *Why primary obesity is a disease*? J. Transl. Med. 17 169 (2019), https://doi.org/10.1186/s12967-019-1919-y.

[11] *Id.*

[12] Howard Rosen, *Is Obesity A Disease or A Behavior Abnormality? Did the AMA Get It Right?* Mo Med. 2014 Mar-Apr;111(2):104-108. PMID: 30323513; PMCID: PMC6179496, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6179496/.

[13] Wegovy, Highlights of Prescribing Information (Initial U.S. Approval: 2017; Revised: 2024), https://www.novo-pi.com/wegovy.pdf.

Medicare Prescription Payment Plan

The Medicare Prescription Payment Plan (MPPP) represents a critical, patient-centered component of the Inflation Reduction Act (IRA) designed to empower Medicare beneficiaries to "smooth" their out-of-pocket payments for prescription drugs over the course of the year. We appreciate CMS for mobilizing with urgency to implement the program on a rapid timeline for 2025. However, significant effort is still required to educate Medicare beneficiaries about this new payment option. In fact, recent polling from the PAN Foundation's Center for Patient Research highlights the need for continued education on Medicare Part D reforms for beneficiaries. According to the national survey, most people enrolled in Medicare (87%) have not seen, read, or heard about the upcoming Medicare Part D reforms.[14] This gap highlights the need for stakeholders to support the older adult and disability communities in the enrollment process and help beneficiaries understand how the plan will help them manage their prescription drug payments.

The MPPP will play a critical role in supporting already vulnerable patient populations who manage complex chronic conditions such as cancer, diabetes, and severe autoimmune conditions in affording and accessing their prescription medications. For these individuals, consistent and unrestricted access to their medicines is critical to enable them to manage their health and well-being. However, older adults with chronic illnesses experience financial challenges when attempting to access and adhere to their prescription medications.

Additionally, recent data from the Centers for Disease Control and Prevention (CDC) shows that cost-related nonadherence to prescription medications is more than twice as likely among older adults reporting fair or poor health or with disabilities compared with those in excellent, very good, or good health, or without disabilities.[15] The success of MPPP will, in part, be dictated by our collective ability to reach these individuals and help them understand their new option to enroll and smooth their out-of-pocket payments over the course of the year. Accordingly, we submit the following for your consideration.

1. **Support for the Auto-Renewal Provision**

We strongly support CMS's proposal to implement automatic renewal for beneficiaries participating in the MPPP and thank CMS for removing this otherwise significant administrative burden. This auto-renewal provision aligns with our shared vision of making the program more efficient and user-friendly for Medicare beneficiaries. Without automatic renewal,

[14] PAN Foundation. "Medicare Reform Awareness Research Among Medicare Beneficiaries." July 2024.
[15] Centers for Disease Control and Prevention: National Center for Health Statistics. "Prescription Medication Use, Coverage, and Nonadherence Among Adults Age 65 and Older: United States, 2021–2022." September 2024.

beneficiaries could face the additional hurdle of opting back into the program annually. This unnecessary step could lead to lower participation rates, particularly among vulnerable populations who may already face challenges navigating the Medicare system. Automatic renewal alleviates this concern while still maintaining flexibility for beneficiaries, as they retain the ability to de-enroll at any time.

Additionally, this simplification of the renewal process will improve retention and ensure beneficiaries can consistently access the benefits of the MPPP without unnecessary obstacles.

While not specifically addressed by this proposed regulation, we urge CMS to consider the following for inclusion in the final regulation to amplify the impact of this important program:

- CMS should expand educational outreach efforts for the 2026 program year to ensure that beneficiaries that are likely to benefit are fully informed about MPPP's benefits. Strengthening plan requirements around beneficiary communication is essential for widespread awareness and engagement.

- Enrollment options should be broadened to include seamless processes, such as enrolling through the Medicare Plan Finder or re-enrolling automatically for each new plan year.

- CMS should consider incorporating a point-of-sale enrollment option at the pharmacy counter. This approach would provide an immediate and accessible way for beneficiaries to enroll, while also leveraging pharmacies for targeted outreach to encourage participation.

- Release data on MPPP participation and modify the Part D plan deadline for MPPP reporting to occur on a more regular basis (e.g., quarterly) rather than simply the quarter following a given plan year (as outlined in the final Part D reporting requirements HPMS memo released on December 5, 2024)

- Provide transparent reporting on prescription drug event (PDE) data associated with those enrolled in MPPP to enable stakeholders to understand how we can best serve the agency in closing gaps in enrollment among patient populations who stand to benefit from the program.

We urge CMS to finalize the auto-renewal provision and continue to refine the MPPP with these enhancements in mind to ensure the program becomes a cornerstone of streamlined access to prescription drug benefits for Medicare beneficiaries.

2. **Election Requests Received Via Phone or Web in Real-Time**

While we commend CMS for the proposal to enable plans to process election requests received via phone or web in real-time starting in 2026, we believe that this measure alone will not fully address the practical barriers many patients face in accessing critical prescription medications. The time, effort, and potential confusion associated with navigating phone or web enrollment processes may deter patients from completing the enrollment process in real time, ultimately leading to delays or abandonment of needed medications. This is particularly concerning for vulnerable populations who already face challenges in accessing healthcare.

To mitigate these issues, we strongly urge CMS to incorporate point-of-sale (POS) enrollment options at pharmacy counters as soon as possible, as the Alliance and 45 partner organizations suggested in a letter to the Agency early last year. Pharmacy-based enrollment provides a critical, real-time solution for beneficiaries who may lack access to or familiarity with digital platforms, ensuring they can seamlessly enroll when their healthcare needs are most immediate. This approach not only reduces administrative burden for beneficiaries but also fosters inclusivity by addressing the unique challenges faced by underserved populations, such as older adults, individuals in rural areas, and those with limited internet connectivity. By leveraging the trusted role of pharmacists and the accessibility of pharmacy locations, this enhancement would significantly reduce enrollment barriers and ensure timely access to life-saving medications.

Expansion of "Alzheimer's Disease" List of Core Chronic Diseases Within the Medicare Therapy Management Program

The Alliance supports the provision of the proposed rule to expand "Alzheimer's disease" to include other dementias within the Medicare Therapy Management program as it will facilitate and promote greater adherence to medications that treat neurocognitive impairment. The science of treating Alzheimer's disease and other major neurocognitive disorders is advancing rapidly, so we applaud CMS for removing potential hurdles for beneficiaries with those conditions to maintain adherence to critical medications.

Clarification of $0 Cost Sharing for Part D Vaccines

Under this rule, CMS proposes to implement the requirements related to $0 cost-sharing for adult vaccines recommended by ACIP under Part D for 2026 and all subsequent plan years, as enacted under the IRA. The Alliance strongly supports the inclusion of this provision. Vaccine access promotes overall public health and benefits all Americans.

Utilization Management

The Inflation Reduction Act (IRA) included a broader redesign of the Part D program which increases plan liability for drug costs once a beneficiary has reached the annual out-of-pocket limit ($2,000 in 2025, indexed to growth in Part D expenditures in subsequent years). We remain highly concerned that this change in liability will incentivize increased use of utilization management (UM) tools and that, absent further action by CMS, these changes could have unintended consequences for patients.

As we have previously commented to the agency, this would be problematic, as UM efforts like prior authorization, step therapy, and cost sharing lead to increased patient and administrative burden, worse long-term outcomes, stress, costly out-of-pocket expenses, and an inability for a patient to work with their care provider to determine the best course of treatment.

We appreciate that CMS has indicated it will monitor changes in formulary design, but we are disappointed that the proposed rule is not more responsive to the growing patient-focused concerns with respect to the unintended consequences of the Part D redesign for beneficiaries. We strongly believe more action is needed to protect beneficiaries' access to medically necessary therapies in 2025 and beyond.

We respectfully urge the agency to take additional steps to support patients by increasing transparency regarding the use of UM by prescription drug plans, enhancing efforts to educate beneficiaries about potential changes to their plans related to UM (including making this information more readily available on and in beneficiary facing materials, such as the plan finder), and provide additional details about what actions CMS is taking to ensure that there is no inappropriate UM activity. More options are outlined in the Manatt report, "Patient Impact of the Inflation Reduction Act" which was commissioned by the Alliance.

We encourage CMS to take a more holistic and proactive approach to Part D redesign UM concerns as the agency looks to support beneficiary access to medically necessary therapies, including developing and making publicly available, as appropriate, the metrics and benchmarks the agency is looking at to measure and assess the access impacts of UM and changes as a result of the implementation of Part D redesign. We encourage the agency to consider, and provide opportunities for public comment on, what further programmatic actions within CMS's current statutory authority are necessary to protect beneficiary access to medically necessary therapies beyond the steps the agency is currently taking as part of the current Part D formulary review process.

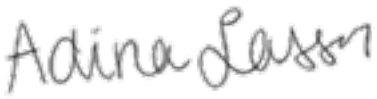
This problem will only continue to grow as new aspects of the IRA are implemented. CMS must take action to protect beneficiaries now.

Conclusion

We appreciate CMS's dedication to improving Medicare programs and look forward to continuing our collaboration with CMS to achieve these shared goals. With questions, please reach out at alasser@agingresearch.org.

Thank you for considering our comments.

Sincerely,



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