GERONTOLOGICAL SOCIETY OF AMERICA®

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Meaningful Lives As We Age

January 27, 2025

Jeff Wu
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4208-P
7500 Security Boulevard, Baltimore, MD 21244-1850
Baltimore, MD 21244-8013

RE: CMS-4208-P

Dear Administrator Wu,

The Gerontological Society of America appreciates the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments on the proposed rule, **Contract Year 2026 Policy and Technical Changes to the Medicare Advantage (MA) Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly**, published on December 10, 2024.

The mission of GSA is to foster excellence, innovation, and collaboration to advance aging research, education, practice, and policy; our vision is "meaningful lives as we age." GSA's 6,000 members include gerontologists, health professionals, behavioral and social scientists, biologists, demographers, economists, and many other disciplines. These experts study all facets of aging with a life-course orientation. The multidisciplinary nature of the GSA membership is a valued strength, enabling us to provide a 360-degree perspective on the issues facing our population as we age.

GSA appreciates the opportunity to comment on coverage of anti-obesity medications and vaccine cost sharing provisions.

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

GSA supports CMS' proposal and urges the agency to finalize this proposal to provide access to AOMs in the Medicare and Medicaid programs, located in Section III, Strengthening Current Medicare Advantage, Medicare Prescription Drug Benefit, and Medicaid Program Policies, subsection A titled "Part D Coverage of Anti-Obesity Medications (AOMs) (§ 423.100) and Application to the Medicaid Program."

We applaud CMS's recognition of the prevailing medical consensus classifying obesity as a disease. As a result of its interdisciplinary approach to research, education, and practice, GSA identifies and addresses the chronic disease of obesity as an opportunity to improve health outcomes across the life course. GSA has worked on developing several resources for the care and management of obesity in older people. We know that access to comprehensive obesity care can lower the severity of these diseases, and in some cases cure them entirely.

Current policy unfairly denies coverage and access for people over the age of 65 to vitally important evidence-based treatments, both preventing older people from starting these treatments while on Medicare and disrupting treatment for those who lose access as they age into Medicare. It is crucial that CMS take the steps necessary to end the current unjust policy and ensure that Americans have access to the holistic and comprehensive obesity care necessary to ensure healthy lives. This also means finalizing the rule as it applies to Medicaid and ensuring that the millions of

Medicaid beneficiaries with obesity are able to access treatment. While some states provide Medicaid coverage, not all do, leaving thousands of Americans sick and vulnerable to the problems stemming from obesity.

This includes a useful framework for primary care providers in helping older people with obesity challenges recognize their condition and take action to maintain a healthy weight. The GSA KAER framework—Kickstart, Assess, Evaluate, and Refer (KAER)—supports primary care teams to better meet the needs of older people with obesity and overweight. Using this framework and the tools and resources in the GSA Toolkit for the Management of Obesity in Older Adults, care teams can kickstart the discussion of body size with older people and their families; assess the presence of altered body fat amount, distribution, and/or function; evaluate treatment options for older people with overweight and obesity; and refer older people to community resources.

In 2023, GSA hosted a roundtable discussion in Washington, D.C. with researchers, clinicians, and advocates who were asked to address key questions about obesity as a disease of body weight regulation and how outdated paradigms and perceptions about obesity can be improved among health professionals, policymakers, and the public. That discussion produced valuable information on key aspects of obesity care across the lifespan and particularly in clinical care for older adults. The report, titled "Bringing Obesity Management to the Forefront of Care for Older Adults: Seven Strategies for Success," presents the roundtable's insights, which are discussed in the framework of seven strategies for addressing barriers to quality obesity care for older people.

In 2024, GSA submitted a letter as part of the National Institute of Health's Request for Information on Research Strategies for Addressing Obesity Heterogeneity. In this letter, GSA discussed our understanding of obesity heterogeneity and how obesity presents differently for every patient. We cannot emphasize enough how important this rule is to ensure that Medicare beneficiaries living with obesity can access evidence-based care for their condition. Medicare's coverage of AOMs will ensure that beneficiaries can access treatments as their doctors prescribed and assures that Medicae beneficiaries are receiving the treatment best suited to result in healthier outcomes.

One of more than 40 GSA Interest Groups, the Obesity and Aging Interest Group is an interdisciplinary group of researchers, academics, clinicians, healthcare providers, program administrators, and policymakers focused on the important issues surrounding obesity and aging. Their goal is to foster collaboration, promote advocacy, and drive innovation around the assessment, treatment, and prevention of obesity in older people.

GSA supports CMS's reinterpretation of the phrase "[a]gents when used for...weight loss" in section 1927(d)(2) of the Act. We also fully support the Medicare and Medicaid coverage that would result from this reinterpretation. This CMS action would ensure that AOMs used for treating the chronic disease of obesity would no longer be excluded from Part D coverage. Additionally, it eliminates state Medicaid programs' ability to exclude AOMs from Medicaid drug coverage as "[a]gents when used for...weight loss" when used for weight loss or weight management for the treatment of obesity.

Ensuring all Americans with obesity, including Medicare and Medicaid beneficiaries, can access medical treatment for their condition will support their ability to achieve optimal health and well-being. CMS's proposed policy will provide important improvements in care for Medicare and Medicaid beneficiaries with obesity. We know that access to comprehensive obesity care can lower the severity and complications associated with this disease. The full range of care must include access to AOMs. Comprehensive obesity care includes behavior modification through medical nutrition or intensive behavioral therapies as well as access to medical, pharmaceutical, and surgical interventions. CMS's proposal reflects current clinical guidelines and ensures access to important pharmaceutical interventions for Medicare and Medicaid beneficiaries.

GSA supports a comprehensive approach to treating the chronic disease of obesity, and this includes behavioral interventions. Counseling patients on nutrition, physical activity and behavior change at frequent clinic visits, as proposed by intensive behavioral therapy (IBT), is an effective, proven approach to treating obesity treatment and can reduce the risk of co-morbidities. We support this approach when AOMs are part of treatment for obesity.

RE: Vaccine Cost Sharing Changes

GSA supports codifying that any Advisory Council on Immunization Practices (ACIP)-recommended adult vaccine is exempted from all beneficiary cost sharing for Calendar Year (CY)2026 and beyond and codifying the definition of an "ACIP-recommended adult vaccine". This is in Section II, "II. Implementation of IRA Provisions for the Medicare Prescription Drug Benefit Program," titled "Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices Under Medicare Part D (§§ 423.100 and 423.120)."

We appreciate the proposal to enable enrollees who submit direct member reimbursement (DMR) requests for ACIP-recommended adult vaccines accessed at either out-of-network pharmacies or providers, or at in-network pharmacies or providers to receive the benefit with no added cost sharing.

GSA encourages Part D and Medicare Advantage plans to avoid utilization management strategies that hinder a provider or pharmacy's ability to choose to stock and offer vaccines to Part D beneficiaries. We also appreciate the proposal clarifying that Part D plans must provide coverage without cost sharing once a new or revised recommendation is adopted by the CDC Director and posted on the CDC website.

Through GSA's National Adult Vaccination Program (NAVP), we are focused on collaborating with the multidisciplinary stakeholder community, conducting informative summits and producing meaningful publications, and webinars, advocating for policies that increase access to vaccines, and training champions to increase vaccination rates. Our current aim is to change the dialogue about vaccines from the narrow focus of an individual health benefit offering protection against a single target condition to a broad, far-reaching value to the individual and society.

Through our initiative, "Concentric Value of Vaccination as We Age," we seek to illuminate, individual health benefits (e.g., increased life expectancy, prevention of exacerbation of preexisting conditions) and societal health benefits (e.g., prevention of antibiotic resistance) along with individual and societal economic benefits.

Currently, GSA serves as a co-chair of the Adult Vaccine Access Coalition (AVAC), which includes more than 75 organizational leaders in health and public health who are committed to addressing barriers to adult immunization. With AVAC, GSA advocates for removing barriers to adult vaccinations and improving vaccine infrastructure, with an overarching commitment to quality, efficacy, and evidence-based research.

Research shows that utilization of recommended vaccines minimizes the burden of vaccine-preventable diseases across the life course. However, despite the well-known benefits of immunizations, approximately 50,000 adults die each year from vaccine-preventable disease in the United States, while adult coverage remains below federal goals for most commonly recommended vaccines. Millions more adults suffer from vaccine-preventable diseases, causing them to miss work and leaving some unable to care for those who depend on them.

GSA greatly appreciates the proposed rule seeks to codify language that all ACIP-recommended adult vaccine are exempted from all beneficiary cost sharing, including the annual deductible or any other fees in all phases of the benefit for Calendar Year (CY)2026 and beyond. Studies have shown a direct correlation between high cost-sharing and increased abandonment rates of vaccines in Medicare Part D. Removing cost and other barriers to Medicare beneficiary access will encourage more individuals take advantage of this important preventive benefit, which will drive improved immunization rates for Medicare populations and will ultimately lead to improved direct and indirect health outcomes and lower costs.

In addition to codifying immunization coverage for Medicare Advantage and Prescription Drug Plan beneficiaries without cost-sharing requirements, we feel it vitally important to support a robust network of community qualified providers that is available and accessible to offer and administer vaccines. Vaccines are not equally available across communities, and as such, remain a consistently underutilized, yet valuable prevention tool.

It is vital that CMS provide simple and clear guidance on immunization coverage to Medicare Advantage and Part D plans, their beneficiaries, as well as the range of providers who serve them. GSA appreciates that CMS seeks to build on past regulations and guidance, as described in the proposed rule, by codifying an explicit definition of an "ACIP-

recommended adult vaccine". The proposed rule defines it, "as a vaccine licensed by the FDA for use in adults and administered in accordance with ACIP recommendations." Furthermore, the proposed rule specifies that routine vaccines that are included on the ACIP "Adult Immunization Schedule" as well as, vaccines recommended by the ACIP through shared clinical decision making or recommended for specific population subgroups are all required to be covered by Medicare Advantage and Part D plans at no cost to the beneficiary.

Codification of this definition and these requirements in the final rule will help ensure that plans continue to provide beneficiary Part D coverage at no cost for routine adult vaccines, vaccines recommended through shared clinical decision-making, as well as vaccines that may be recommended to a beneficiary for specific travel reasons or due to an occupational risk.

GSA also supports the CMS proposal to enable enrollees who submit direct member reimbursement (DMR) requests for ACIP-recommended adult vaccines accessed at either out-of-network pharmacies or providers, or at in-network pharmacies or providers, that are otherwise a covered benefit to receive them with no added cost sharing, as required by law. Furthermore, we would urge CMS to also finalize the requirement that Part D plans reimburse the enrollee for the full cash price paid to the pharmacy or provider for an ACIP-recommended adult vaccine in instances where there is a potential difference between the cash price and plan allowance for DMRs.

CMS should encourage Part D and Medicare Advantage plans to avoid utilization management strategies (for example, prior authorization) that would otherwise hinder a provider or pharmacy's ability to choose to stock and offer vaccines that best serve the needs of their patients. The proposed rule notes that "Section 30.2.7 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, Part D sponsors may only use utilization management strategies to assess the necessity of vaccines that are less commonly administered in the Medicare population, facilitate the use of vaccines in line with ACIP recommendations, and evaluate potential reimbursement of vaccines that could be covered under Part B. For instance, a provider will want to ensure they are carrying vaccines that meet the clinical needs a beneficiary, based on their age and any potential health conditions. The employment of utilization management strategies across different Part D and Medicare Advantage plans can complicate and add unnecessary costs to providers who wish to stock and offer vaccines to beneficiaries.

GSA appreciates the proposed rule seeks to ensure that Part D beneficiaries have timely access to recommended vaccines. Specifically, the proposed rule would codify that once a new or revised recommendation is adopted by the CDC Director and posted on the CDC website, Part D and Medicare Advantage plans sponsors must provide coverage for dates of service on or after the "Effective date of the ACIP recommendation". This important clarification will help reduce beneficiary and provider confusion and delays in access and plan coverage of recommended vaccines. We appreciate the proposed rule also directs plans to reimburse beneficiaries for any recommended vaccines that may have been administered after the ACIP recommendation effective date but prior to the recommendation being posted on the CDC website and also provides guidance to Medicare Advantage and Part D plans on vaccine coverage and cost sharing when ACIP modifies a previous recommendation to ensure it remains aligned with FDA medically accepted indications.

Again, we thank you for this opportunity to offer input on this proposed rule. If you have any questions, please contact Patricia D'Antonio, Vice President of Policy and Professional Affairs at pdantonio@geron.org or 202-587-5880, or Jordan Miles, Director of Policy at jmiles@geron.org or 202-587-5884.

Sincerely,

James C. Appleby, BSPharm, MPH, ScD (Hon)
Chief Executive Officer