

January 22, 2025

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted Electronically to <http://regulations.gov>

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)

To Whom It May Concern:

On behalf of the Endocrine Society, thank you for the opportunity to submit comments on the Contract Year 2026 Medicare Advantage and Medicare Part D Prescription Drug proposed rule. We are writing to comment specifically on the Part D Coverage of Anti-Obesity Medications (AOMs) (§ 423.100) and Application to the Medicaid Program provision of the rule. Founded in 1916, the Endocrine Society represents approximately 18,000 physicians and scientists engaged in the management and research of endocrine disorders, including obesity. Our members evaluate and treat obesity as well as other weight-related diseases, such as type 2 diabetes. The Society has authored clinical practice guidelines on the Pharmacological Management of Obesity and Pediatric Obesity.

On behalf of our members, which include over 11,000 clinicians who are on the front lines of treating obesity, we urge you to finalize and adopt the AOM coverage provision of the proposed rule. We strongly support this provision because it would remove a major barrier which has prevented millions of Americans from receiving appropriate and evidence-based obesity treatment and care. This proposal is a much-needed solution that could be part of the Make America Healthy Again initiative to address the burden of chronic diseases in the United States.

As you know, obesity has become a nationwide epidemic impacting millions of Americans across the country. It is currently estimated that over 42% of adults and almost 20% of children are living with obesity in the United States. Over the past three decades, obesity rates have drastically increased. According to a recent study published in *The Lancet*, between 1990 and 2021 the obesity rate doubled in adults to more than 40% and nearly tripled to 29% amongst girls and women aged 15 to 24. The same study estimates that by



the year 2050 there will be 213 million people living with obesity in the United States.¹ There are also numerous studies showing the impact obesity has had on rural Americans. One recent study estimated that obesity is approximately 6.2 times higher in rural America compared to urban areas.² Obesity is already highly prevalent, and rates continue to rise affecting Americans across country. This proposed rule would take an important step forward in addressing this epidemic and the millions of Americans that have been impacted.

The Endocrine Society is pleased that the proposed rule acknowledges that obesity is a chronic disease. The Society has long considered obesity to be a chronic disease. We worked alongside other medical societies to pass the resolution in the American Medical Association (AMA) House of Delegates recognizing obesity as a chronic disease. The Society was one of seven organizations to co-sponsor that resolution adopted by the AMA, which is also cited in the agency's proposed rule.³ In addition to the AMA, there are many other organizations with expertise in health and medicine who recognize obesity as a disease including the National Academy of Medicine.⁴ The International Classification of Diseases has provided diagnosis codes used by physicians and other healthcare providers for obesity treatment for over a decade. These codes reflect that obesity is a chronic disease and ensure accurate diagnosis, treatment, and care for people living with obesity.⁵ The proposed rule also echoes the opinion of other agencies including the Food and Drug Administration, and the U.S. Preventative Services Taskforce.^{6,7} We applaud CMS for acknowledging what is now widely regarded as scientific fact. This acknowledgement also aligns CMS with other government agencies, leading scientific organizations, and the physician community.

¹ The Lancet. National-level and state-level prevalence of overweight and obesity among children, adolescents, and adults in the USA, 1990–2021, and forecasts up to 2050. Accessed on January 16, 2025.

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(24\)01548-4/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)01548-4/fulltext)

² Cureus. The Burden of Obesity in the Rural Adult Population of America. Accessed on January 16, 2025:

<https://pmc.ncbi.nlm.nih.gov/articles/PMC8290986/>

³ American Medical Association House of Delegates. Resolution 420. Recognition of Obesity as a Disease.

Accessed on January 16, 2025: <https://media.npr.org/documents/2013/jun/ama-resolution-obesity.pdf>

⁴ National Academies. Weighing the Options: Criteria for Evaluating Weight-Management Programs.

Accessed on January 17, 2025: <https://www.ncbi.nlm.nih.gov/books/NBK236743/>

⁵ Obesity Medicine Association. New ICD-10 Codes for Obesity Treatment: Advancements in Accurate Diagnosis and Care. Accessed on January 22, 2025: <https://obesitymedicine.org/blog/new-icd-10-codes-for-obesity-treatment-advancements-in-accurate-diagnosis-and-care/>

⁶ Food & Drug Administration. Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body. Accessed on January 17, 2025:

<https://www.federalregister.gov/documents/2000/01/06/00-53/regulations-on-statements-made-for-dietary-supplements-concerning-the-effect-of-the-product-on-the>

⁷ United States Preventative Services Taskforce. Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Behavioral Interventions. Access on January 17, 2025:

<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/obesity-in-adults-interventions>



The Society strongly supports the provision of the proposed rule that would allow Medicare Part D and state Medicaid programs to cover anti-obesity medications when prescribed for their intended purpose, i.e., the treatment of obesity. This proposal will ensure that millions of beneficiaries across the country are eligible to receive access to AOMs and which will help prevent the onset of other chronic conditions that are directly linked to obesity. As you may know, people living with obesity are at increased risk of developing over 230 complications including a wide range of diseases and other health conditions such as cancer, type 2 diabetes, heart disease, liver diseases, and kidney diseases. People living with obesity are nearly six times more likely to develop type 2 diabetes.⁸⁹ Being overweight or obese can also raise the risk of developing certain types of cancers.¹⁰ Numerous studies have also demonstrated a link between obesity and a higher risk of chronic kidney disease (CKD).¹¹ Obesity is also the leading cause of liver disease leading to cirrhosis and liver cancer.¹² Obesity is also a major risk factor of musculoskeletal conditions which can lead to disabilities.¹³ Obesity also has behavioral health effects and can negatively impact mental health.¹⁴ By allowing beneficiaries to access AOMs, our members will be able to more easily treat obesity and prevent these other costly and devastating chronic conditions. Our members who treat obesity have said that physicians are often waiting too long to prescribe AOMs due to insurance coverage issues. When patients are forced to delay treatment, it puts them at increased risk of developing other conditions. Removing this barrier and providing coverage of these medications will ensure that patients receive the appropriate treatment when needed.

⁸ The American Journal of Managed Care. Obese Individuals Nearly 6 Times More Likely to Develop T2D, Study Finds. Accessed on January 22, 2025: <https://www.ajmc.com/view/obese-individuals-nearly-6-times-more-likely-to-develop-t2d-study-finds>

⁹ Diabetologia. Obesity, unfavourable lifestyle and genetic risk of type 2 diabetes: a case-cohort study. Accessed on January 22, 2025: <https://link.springer.com/article/10.1007/s00125-020-05140-5>

¹⁰ National Institutes of Health. Health Risks of Overweight & Obesity. Accessed on January 16, 2025. <https://www.niddk.nih.gov/health-information/weight-management/adult-overweight-obesity/health-risks?dkrd=/health-information/weight-management/health-risks-overweight>

¹¹ National Institutes of Health. Chronic Kidney Disease: Its Relationship With Obesity. Accessed on January 16, 2025. <https://pmc.ncbi.nlm.nih.gov/articles/PMC9675899/>

¹² Metabolism. Obesity and nonalcoholic fatty liver disease: From pathophysiology to therapeutics. Accessed on January 21, 2025: <https://pubmed.ncbi.nlm.nih.gov/30502373/>

¹³ Clinical Anatomy. The effects of obesity on the human body, part 1: Skin and musculoskeletal. Accessed on January 21, 2025: <https://onlinelibrary.wiley.com/doi/abs/10.1002/ca.23683>

¹⁴ Molecular and Cellular Endocrinology. The effect of obesity on health outcomes. Accessed on January 21, 2025: <https://pubmed.ncbi.nlm.nih.gov/19628019/>



This proposal will also address the economic costs of obesity in the United States. Obesity is an expensive disease which impacts both our economy and overall healthcare spending. Obesity is estimated to account for \$173 billion in higher medical costs each year.¹⁵ There is also a direct link between obesity and productivity and employment. Costs from worker absenteeism due to obesity range between \$3.38 billion and \$6.38 billion. This is between \$79 and \$132 per year per individual living with obesity. The same study found that people living with obesity were 194% more likely to use paid time-off than their colleagues who did not have obesity.¹⁶ The rising prevalence of obesity is also related to indirect costs resulting from morbidity and mortality.¹⁷ Implementing this proposal will result in healthcare spending reductions associated with obesity. A recent study found that adults with obesity who successfully lowered their BMI by 5% were estimated to spend 7% less on healthcare expenses. Those who lowered their BMI by 25% spent 30% less on healthcare costs.¹⁸ These results were similar for Medicare beneficiaries. This study is just one example of numerous studies which show that by allowing CMS to cover these medications it will decrease healthcare spending and improve the overall economy.

Unfortunately, obesity has negatively affected our nation's military recruitment, which is a threat to our national security. Just over 1 in 3 young adults is too heavy to serve in the military. Meanwhile only 3 in 4 young adults who meet weight requirements report having physical activity levels that appropriately prepare them for the challenges faced during basic training. Consequently, this means that only 2 in 5 young adults are both weight-eligible and adequately physically active to serve.¹⁹ In 2022, the U.S. Army fell 25% short of its recruitment goal and that number continues to rise.²⁰ Finalizing this rule will ensure that future military recruits have access to the treatment they need if diagnosed with obesity. Allowing AOM coverage under Medicaid will provide access to anti-obesity medications for lower-income young adults and adolescents living with obesity. Providing coverage under Medicare Part D may also result in increased AOM coverage in private health plans

¹⁵ PLOS One. Association of body mass index with health care expenditures in the United States by age and sex. Accessed on January 17, 2025: <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0247307>

¹⁶ BMJ Open. Productivity loss due to overweight and obesity: a systematic review of indirect costs. Accessed on January 17, 2025: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5640019/>

¹⁷ BMJ Open. Productivity loss due to overweight and obesity: a systematic review of indirect costs. Accessed on January 21, 2025: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5640019/>

¹⁸ JAMA Network Open. Estimated Reduction in Health Care Spending Associated With Weight Loss in Adults. Accessed on January 17, 2025:

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2827550>

¹⁹ Centers for Disease Control and Prevention. Unfit to Serve. Accessed on January 17, 2025:

<https://www.cdc.gov/physicalactivity/downloads/unfit-to-serve-062322-508.pdf>

²⁰ <https://www.cdc.gov/physicalactivity/resources/unfit-to-serve/index.html>



and other public programs across the United States. These changes will ensure that obesity does not prevent a military recruit from joining the armed forces.

If this proposal is adopted, it will help make anti-obesity medications more accessible and affordable for patients. The price of GLP-1 medications, for example, is significantly higher in the United States compared to other countries. In the U.S., a month supply of Wegovy costs \$1,349 per month while the same medication costs only \$296 in Denmark.²¹ CMS recently announced that semaglutide has been selected for the agency's price negotiation program. Allowing the agency to negotiate lower prices for AOMs will result in drastically lower out-of-pocket costs for patients. For example, the first round of medications negotiated by CMS this year have discount rates between 38 to 79 percent compared to the list price. In 2026, Medicare beneficiaries are estimated to save \$1.5 billion in personal out-of-pocket costs because of these negotiated prices.²² Finalizing this rule will ensure that AOMs prescribed for the management of obesity are included in future rounds of price negotiations. Consequently, this will reduce costs for the federal government.

Thank you again for the opportunity to comment on this proposed rule. On behalf of our members and the patients they treat, we urge you to finalize the AOM coverage provision of the rule. Adopting this provision will improve the health of millions of Americans living with obesity. It will also improve our economy and address our national security. If you have any questions, please reach out to Rob Goldsmith, Director, Advocacy and Policy, at rgoldsmith@endocrine.org.

Sincerely,

Robert Lash, MD
Chief Medical Officer
Endocrine Society

²¹ Peterson-KFF Health Systems Tracker. How do prices of drugs for weight loss in the U.S. compare to peer nations' prices? Accessed on January 17, 2025: <https://www.healthsystemtracker.org/brief/prices-of-drugs-for-weight-loss-in-the-us-and-peer-nations/#List%20prices%20of%20drugs%20used%20for%20weight%20loss%20in%20the%20U.S.%20and%20peer%20nations>

²² Centers for Medicare and Medicaid Services. HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations in Continued Effort to Lower Prescription Drug Costs for Seniors. Accessed on January 17, 2025: <https://www.cms.gov/newsroom/press-releases/hhs-announces-15-additional-drugs-selected-medicare-drug-price-negotiations-continued-effort-lower>