January 16, 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: File Code CMS-4208-P: 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

To Whom It May Concern:

On behalf of the Diabetes Advocacy Alliance (DAA), we thank the Centers for Medicare and Medicaid Services for the proposal, as stated in the Executive Summary of the proposed rule, to "reinterpret the statutory exclusion of agents when used for weight loss to allow Part D coverage of anti-obesity medications (AOMs) when used to treat obesity by reducing excess body weight or maintaining weight reduction long-term for individuals with obesity who do not have another condition for which the prescribed use is a medically accepted indication that is covered under the current Part D policy." **We applaud this recognition of obesity as a chronic disease and believe the full range of evidence-based treatments for obesity should be covered like treatments for other chronic diseases and conditions are covered**. People living with obesity deserve access to the full range of physician-prescribed evidence-based treatments, a key step in making America healthy again, including FDA-reviewed AOMs and lifestyle interventions (e.g., Intensive Behavioral Therapy for Obesity interventions, Medical Nutrition Therapy, the Medicare Diabetes Prevention Program, and the National Diabetes Prevention Program), which are a necessary complementary therapy to AOMs. Lifestyle interventions, such as those mentioned above, emphasize the importance of improved nutrition and behavioral therapy in achieving and sustaining weight loss, improving metabolic health, and reducing the risk of chronic diseases like type 2 diabetes. Combining evidence-based lifestyle change with pharmacological treatments empowers individuals to adopt sustainable, healthy behaviors. Failure to provide concurrent coverage will result in an incomplete approach to addressing underlying obesity or the many other chronic conditions that stem from excessive weight.

DAA members are concerned about obesity because of its strong relationship to diabetes and prediabetes. Based on data from the National Health and Nutrition Examination Survey, 2021-2023, the National Center for Health Statistics found that **the prevalence of total, diagnosed, and undiagnosed diabetes increases dramatically with increasing weight status**. Among U.S adults aged 20 or older, only 6.8% of individuals with normal or below normal weight have diabetes. Among those in the overweight category, the rate of diabetes is 12.3%, and for adults living with obesity, the rate almost doubles, to 24.2%.[1] Regarding individuals at risk for developing diabetes, the CDC estimates that 38% of all U.S. adults aged 18 and older are living with prediabetes, and for adults aged 65 and older, the figure is 49%.[2] The CDC does not provide an estimate of how many of these adults with prediabetes are living with obesity. However, we anticipate that the percentage is substantial, because the authors of a study in the *Journal of the American Heart Association* in 2021 concluded that approximately 30% to 53% of new U.S. cases of diabetes each year can be attributed to obesity.[3]

Currently, AOMs are only covered by Medicare Part D if they have been prescribed as treatments for individuals living with type 2 diabetes, cardiovascular disease, or other specified medically accepted indications, leaving the chronic condition of obesity without coverage for key components of the evidence-based treatments for obesity. With implementation of the statutory reinterpretation, all FDA-reviewed AOMs, including those with an FDA approved indication for treating obesity, would be covered under Part D. **Such coverage would improve beneficiaries' access to these life-changing medications and contribute to improved health outcomes.** For those already living with diabetes, including many with type 2 diabetes who may be currently undiagnosed, successful treatment with these medications can reduce the risk of the many serious complications of diabetes, and for some adults living with type 2 diabetes, put the disease into remission. For those beneficiaries at risk of diabetes due to excess weight, successful treatment of obesity can effectively lower their risk of developing type 2 diabetes. For example, one clinical trial showed that a GLP-1 medication can reduce the risk of progressing to type 2 diabetes among adults living with both prediabetes and obesity or overweight by 60%.[4]

FDA-approved obesity medications have been shown to be beneficial for people living with diabetes and prediabetes. The American Diabetes Association (ADA), in its Standards of Care in Diabetes – 2025, underscores this point: "Nearly all FDA-approved obesity medications have been shown to improve glycemia in people with type 2 diabetes and delay progression to type 2 diabetes in at-risk individuals, and some of these agents (e.g., liraglutide, semaglutide, and tirzepatide) have an indication for glucose lowering as well as weight management."[5] In guidance for clinicians, the ADA states they should "provide weight management treatment, aiming for any magnitude of weight loss. Weight loss of 3-7% of baseline weight improves glycemia and other intermediate cardiovascular risk factors. Sustained loss of greater than 10% of body weight usually confers greater benefits, including disease-modifying effects and possible remission of type 2 diabetes, and may improve long-term cardiovascular outcomes and mortality."[6]

In summary, obesity contributes to the development of type 2 diabetes and complicates the treatment of diabetes and the health outcomes of people living with the disease. We thank and applaud CMS for recognizing obesity as a serious chronic disease in the reinterpretation of the statutory exclusion of AOMs, and we look forward to having FDA-reviewed AOMs available for all Medicare and Medicaid beneficiaries for whom these medications are appropriate and prescribed.

If you have any questions, please contact Katie Adamson (katie.adamson@ymca.net) or Laura Friedman (lfriedman@diabetes.org). We are pleased to serve as co-chairs of the DAA, a coalition that is diverse in scope, with our 21 members representing patient, professional and trade associations, other non-profit organizations, and corporations, all united to change the way diabetes is viewed and treated in America. Since 2010, the DAA has worked with legislators and policymakers to increase awareness of, and action on, the diabetes epidemic. DAA members share a common goal of elevating diabetes on the national agenda so we may ultimately defeat this treatable, but deadly chronic disease. We are committed to advancing person-centered policies, practical models, and legislation that can improve the health and well-being of people with diabetes and prediabetes.

Sincerely,

Katie Adamson
DAA Co-Chair
Vice President, Health Partnerships & Policy
YMCA of the USA

Laura Friedman
DAA Co-Chair
Vice President, Regulatory Affairs
American Diabetes Association

References:

[1] U.S. Centers for Disease Control and Prevention. National Center for Health Statistics Data Brief, No. 516. November 2024. Accessed on January 1, 2025. https://www.cdc.gov/nchs/data/databriefs/db516.pdf

[2]Centers for Disease Control and Prevention. National Diabetes Statistics Report. May 15, 2024. Accessed on December 29, 2024. https://www.cdc.gov/diabetes/php/data-research/index.html

[3]Cameron NA, Petito LC, McCabe M, et al. Quantifying the Sex-Race/Ethnicity-Specific Burden of Obesity on Incident Diabetes Mellitus in the United States, 2001 to 2016: MESA and NHANES. *J Am Heart Assoc*. 2021;10:e018799. DOI: 10.1161/JAHA.120.018799.

[4]Pope, A. "Transformational" Semaglutide Can Cut Type 2 Diabetes Risk by More Than Half. UAB News. October 25, 2022. https://www.uab.edu/news/research/item/13156-transformational-semaglutide-can-cut-type-2-diabetes-risk-by-more-than-half?utm_source=chatgpt.com. Accessed on January 1, 2025.

[5]Diabetes Care 2025;48(Suppl. 1):S171 | https://doi.org/10.2337/dc25-S008

[6]Diabetes Care 2025;48(Suppl. 1):S168 | https://doi.org/10.2337/dc25-S008