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January 27, 2025

VIA ELECTRONIC SUBMISSION

The Honorable Jeff Wu
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4208-P
P.O. Box 8010
Baltimore, MD 21244-8016

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 Acting Administrator Wu,

Eli Lilly and Company (Lilly) appreciates the opportunity to provide comments on the above-referenced Proposed Rule.[1] Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines. Ultimately, our goal is to develop products that save and improve patients' lives.

As a member of both the Pharmaceutical Researchers and Manufacturers Association of America (PhRMA) and the Biotechnology Innovation Organization (BIO), Lilly largely joins those groups in their comments on this Proposed Rule and encourages CMS to carefully consider the input of those organizations. That said, Lilly offers these comments to highlight certain topics and Lilly-specific positions.

The Proposed Rule includes several innovative proposals to modernize Medicare and Medicaid, address chronic diseases more effectively, improve health outcomes for older adults and Medicaid beneficiaries, and lower long-term healthcare costs. Lilly commends CMS for including these forward-thinking policy changes and strongly urges CMS to finalize many of these provisions, including the proposal to include coverage for anti-obesity medications (AOMs)[2] under Medicare and to expand this coverage within Medicaid.

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[1] See Proposed Rule at 89 Fed. Reg. 99340 (Dec. 10, 2024).

[2] Anti-obesity medications (AOMs) refer to modern FDA-approved glucagon-like peptide-1 (GLP-1) receptor agonists and dual-activating GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 medications. This term is used throughout this letter to maintain consistency with the Proposed Rule, although the term "obesity management medication" (OMM) is becoming more common as it reflects the broader purpose of these therapies and aligns with patient-centered language.

Obesity, a serious chronic disease and a leading driver of related chronic diseases,[3] is projected to impact nearly half of Medicare and Medicaid populations by 2030. Finalizing this policy would be a transformative step forward — strengthening the healthcare system, benefiting patients, and bolstering the economy. Access to obesity medications is highly popular among Medicare beneficiaries, with 69% of seniors expressing that Medicare should provide access to obesity medications on the same terms it covers other chronic diseases.[4] The potential impact on beneficiaries could not be clearer: a recent study analyzing data from the Department of Veterans Affairs—a federal agency already providing AOM coverage—revealed that GLP-1 medications may also reduce the risk of numerous health conditions, including Alzheimer's disease, dementia, addiction, seizures, blood-clotting disorders, heart disease, and infectious illnesses, among patients with type 2 diabetes, many of whom have excess body weight.[5]

Our comments proceed as follows:

I. CMS's Reinterpretation of the Statutory Exclusion of Agents for "Weight Loss" to Allow Part D Coverage of Anti-Obesity Medications (AOMs) Reflects an Approach Grounded in Contemporary Scientific Evidence, Accurate Statutory Interpretation, and Adherence with Administrative Law;
II. Part D Sponsors Should Be Permitted to Define Obesity for Prior Authorization (PA) Criteria, Provided Definitions Align with FDA Labeling for AOMs;
III. CMS Should Consider Extending AOM Coverage to Individuals with Overweight and at Least One Weight-Related Comorbid Condition, Consistent with FDA Labeling;
IV. Coverage of AOMs is Sound Public Policy that Will Improve Outcomes and Reduce Healthcare Costs;
V. CMS Should Promote Transparency for Pharmacies and Protecting Beneficiaries from Disruptions; and,
VI. Lilly Supports CMS's Proposal to Use Artificial Intelligence and Automated Systems in a Manner that Preserves Unbiased Access to MA Services.

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I. CMS's Reinterpretation of the Statutory Exclusion of Agents for "Weight Loss" to Allow Part D Coverage of Anti-Obesity Medications (AOMs) Reflects an Approach Grounded in Contemporary Scientific Evidence, Accurate Statutory Interpretation, and Adherence with Administrative Law

[3] Yuen, M.M., et al. (n.d.). A systematic review and evaluation of current evidence reveals 236 obesity-associated disorders. Massachusetts General Hospital & George Washington University.
[4] JL Partners. (2025, January). Nationwide registered voters polling – January 2025. [Poll of 1,009 registered voters]. Conducted January 10–12, 2025, with a margin of error of ±3.4%. Retrieved from https://jlpartners.com/nationwide-registered-voters-polling-january-2025
[5] Xie, Y., Choi, T. & Al-Aly, Z. Mapping the effectiveness and risks of GLP-1 receptor agonists. Nat Med (2025). https://doi.org/10.1038/s41591-024-03412-w

Lilly supports the proposed reinterpretation of the statutory exclusion of agents when used for weight loss to allow Part D coverage of anti-obesity medications (AOMs) under section 1860D-2(e)(2)(A) of the Social Security Act (the "Act") for three key reasons: (1) it represents a contemporary interpretation grounded in scientific evidence; (2) it aligns with accurate statutory interpretation, and; (3) it adheres to administrative law.

A. CMS's Reinterpretation of the Statutory Exclusion of Agents When Used for "Weight Loss" to Allow Part D Coverage of AOMs is Based on the Contemporary Scientific Understanding of Obesity as a Chronic Disease

CMS's reinterpretation is based on the contemporary scientific understanding of obesity, which has evolved significantly since CMS first interpreted section 1860D-2(e)(2)(A) in the 1990s. Specifically, CMS's acknowledgement that "weight loss" is distinct from the chronic disease of obesity is now strongly supported by scientific evidence and endorsed by other government agencies and prominent professional medical societies. Recent data also demonstrate that AOMs used for the treatment of obesity can prevent and ameliorate other conditions related to obesity, underscoring that treating obesity may confer preventive benefits. Lilly, therefore, supports CMS's recognition of obesity as a chronic disease, the treatment of which is not only reasonable and necessary in itself but also an essential preventive measure against various other costly and detrimental diseases.

i. <u>The Basis for CMS's Determination that Obesity is a Chronic Disease Distinct from Mere "Weight Loss" Is Based on a Large Body of Contemporary Evidence, And Supported by Both Government Agencies and Professional Societies</u>

Today, obesity is understood to be a multifactorial, chronic, progressive, relapsing disease that presents a risk to health and requires lifelong care.[6] Obesity is also highly—and increasingly—prevalent. According to the Centers for Disease Control and Prevention (CDC), 41.5% of seniors currently live with obesity, and by 2030, nearly half (47%) of Medicare beneficiaries may be affected.[7,8] Today, nearly 40% of Medicaid beneficiaries have obesity with similar future prevalence assumptions.[9] This is a public health crisis.

In the Proposed Rule, CMS notes that numerous medical and scientific organizations classify obesity as a chronic disease. The agency also describes obesity as a disease "characterized by increased adiposity (body fat)" and as a "hormonal disease state with impaired functioning of multiple metabolic processes," which is accurate and grounded in

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[6] Theilade, S., Christensen, M. B., Vilsbøll, T., & Knop, F. K. (2021). An overview of obesity mechanisms in humans: Endocrine regulation of food intake, eating behaviour and common determinants of body weight. *Diabetes Obesity and Metabolism, 23*(S1), 17–35. https://doi.org/10.1111/dom.14270
[7] U.S. Centers for Disease Control and Prevention (CDC). (2024, May 14). Adult Obesity Facts. https://www.cdc.gov/obesity/php/data-research/adult-obesity-facts.html.
[8] Goldman, D., & Gaudette, É. (2015, June 4). Medicare's big fat problem, fiscal and otherwise. *Brookings.* https://www.brookings.edu/articles/medicares-big-fat-problem-fiscal-and-otherwise/
[9] MACStats: Medicaid and CHIP Data Book. (2018). In *MACStats: Medicaid and CHIP Data Book.* https://www.macpac.gov/wp-content/uploads/2018/12/December-2018-MACStats-Data-Book.pdf

science. Furthermore, CMS correctly highlights obesity as a "chronic disease state with adiposity-based complications and pathophysiologic processes resulting from the dysregulated secretion of inflammatory and hormonal factors from fat cells."

In addition to CMS's thorough explanation supporting this reconsideration, Lilly emphasizes additional key points:

- The U.S. Government recognizes obesity as a distinct disease:
  - The Food and Drug Administration (FDA) categorically states that "obesity is a chronic disease characterized by excess adiposity."[10]
  - The National Institutes of Health (NIH) recognizes that "obesity is a complex multifactorial chronic disease developing from interactive influences of numerous factors—social, behavioral, physiological, metabolic, cellular, and molecular."[11]
  - The U.S. Centers for Disease Control and Prevention (CDC) identifies obesity as "a common, serious, and costly chronic disease."[12]

- Multiple medical societies also recognize obesity as a distinct disease:
  - The American Medical Association (AMA), composed of over 190 state and specialty medical societies and other critical stakeholders, issued a 2013 resolution[13] referenced in the Proposed Rule, that "recogniz[es] obesity as a disease with multiple pathophysiological aspects requiring a range of interventions to advance obesity treatment and prevention."[14]
  - The American Association of Clinical Endocrinology, a leading endocrinology professional organization, recognized obesity as a disease in 2012.[15]
  - The National Obesity Education Initiative of the National Heart, Lung, and Blood Institute (NHLBI), in cooperation with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), convened the first Expert Panel on the Identification, Evaluation, and Treatment of Overweight

[10] U.S. Food and Drug Administration. (2024). Guidance for industry: Obesity and Overweight: Developing Drugs and Biological Products for Weight Reduction. Retrieved from https://www.fda.gov/media/71252/download
[11] National Institutes of Health. (1998). Clinical Guidelines on the identification, evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report. *NIH Publication No. 98-4083*. https://www.nhlbi.nih.gov/files/docs/guidelines/ob_gdlns.pdf
[12] Centers for Disease Control and Prevention. (n.d.). About adult obesity. Retrieved from https://www.cdc.gov/obesity/php/about/index.html
[13] American Medical Association House of Delegates. (2013). Recognition of obesity as a disease. In D. W. Martin, *Resolution: 420.* https://media.npr.org/documents/2013/jun/ama-resolution-obesity.pdf
[14] American Medical Association. (2013) Recognition of Obesity as a Disease H-440.842.https://policysearch.ama-assn.org/policyfinder/detail/obesity?uri=%2FAMADoc%2FHOD.xml-0-3858.xml.
[15] American Association of Clinical Endocrinology. (n.d.). All about obesity. Retrieved from https://www.aace.com/disease-and-conditions/nutrition-and-obesity/all-about-obesity

and Obesity in Adults to develop clinical practice guidelines for primary care practitioners and recognized obesity as disease in 1995.[16]

- This perspective on obesity as a disease requiring a range of interventions is consistent with statements from leading medical organizations, such as the Cleveland Clinic and the Mayo Clinic.[17,18]

ii. CMS's Reinterpretation of the Statutory Exclusion on AOMs Is Also Supported by Recent Clinical Developments Demonstrating that AOMs Can Prevent or Treat Additional Diseases

Obesity is more than a standalone disease; it is a multifactorial metabolic disease intricately connected to more than 200 other health issues.[19] Recent data, published over the last 18 months, provides CMS with additional scientific grounds for reinterpreting the statutory coverage exclusion with respect to AOMs. Specifically, this recent evidence allows CMS to further justify AOM coverage on the basis that these medicines prevent multiple other diseases from occurring or from becoming worse by treating the underlying obesity. In the Proposed Rule, CMS noted that obesity "increases the risk of, or exacerbates, hypertension, dyslipidemia, type 2 diabetes, cardiovascular disease, obstructive sleep apnea, nonalcoholic steatohepatitis (NASH)/metabolic dysfunction-associated steatohepatitis (MASH), and some cancers, among other conditions."[20] There is overwhelming data to underscore this point (See Appendix A), revealing that 63.0% of Medicare beneficiaries with obesity also have co-occurring conditions such as type 2 diabetes, obstructive sleep apnea, a history of atherosclerotic cardiovascular disease (ASCVD), and/or heart failure with preserved ejection fraction (HFpEF).

Given the complexity of obesity, its related diseases, and the importance of advancing the scientific understanding of how modern AOMs treat obesity and its related diseases, Lilly has completed or is conducting around 100 clinical trials across its AOM portfolio.

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[16] National Institutes of Health. (1998). Clinical Guidelines on the identification, evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report. *NIH Publication No. 98-4083*. https://www.nhlbi.nih.gov/files/docs/guidelines/ob_gdlns.pdf

[17] Cleveland Clinic. (2021). Class III Obesity (Formerly Known as Morbid Obesity). https://my.clevelandclinic.org/health/diseases/21989-class-iii-obesity-formerly-known-as-morbid-obesity (noting that obesity "is a serious medical condition that can contribute to the development of several conditions," listing among them metabolic syndrome, type 2 diabetes, heart disease, hypertension, atherosclerosis, certain cancers, sleep disorders, breathing issues, osteoarthritis, and depression).

[18] Mayo Clinic. (2023). Obesity. https://www.mayoclinic.org/diseases-conditions/obesity/symptoms-causes/syc-20375742 ("Obesity is a complex disease involving having too much body fat. Obesity isn't just a cosmetic concern. It's a medical problem that increases the risk of many other diseases and health problems. These can include heart disease, diabetes, high blood pressure, high cholesterol, liver disease, sleep apnea, and certain cancers.").

[19] Yuen, M.M., et al. (n.d.). A systematic review and evaluation of current evidence reveals 236 obesity-associated disorders. Massachusetts General Hospital & George Washington University.

[20] See Proposed Rule at 89 Fed. Reg. 99340 (Dec. 10, 2024).

The groundbreaking effectiveness of AOMs in addressing these interconnected conditions is evident in the following findings:

- Reducing the Burden of Heart Failure: Over 80% of patients with coronary heart disease (CHD) have overweight or obesity.[21] Tirzepatide (brand names Zepbound® and Mounjaro®) reduced the risk of cardiovascular death or worsened heart failure in those with heart failure with preserved ejection fraction (HFpEF) by 38% and reduced risk of hospitalization by 56% compared to placebo.[22] Additionally, semaglutide (brand names Wegovy® and Ozempic®) is indicated for the reduction of risk of Major Adverse Cardiovascular Events (MACE). Clinical trial data showed a 20% reduction in such events in adults with overweight or obesity.[23] Additionally, in recent research, treated patients reported improvement in physical limitations associated with HFpEF.[24]

- Preventing Type 2 Diabetes: Nearly 90% of adults with type 2 diabetes have overweight or obesity.[25] Recent studies show that treatment with tirzepatide demonstrated a 94% reduction in the risk of progression to type 2 diabetes for people with pre-diabetes. [26]

- Resolving the Liver Condition MASH: Obesity is one of the leading causes of metabolic dysfunction-associated steatohepatitis (MASH).[27] Among adults living with MASH, 73% achieved resolution without worsening fibrosis when treated with tirzepatide 15 mg dose. [28]

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[21] Ades, P. A., & Savage, P. D. (2017). Obesity in coronary heart disease: An unaddressed behavioral risk factor. *Preventive Medicine*, *104*, 117–119. https://doi.org/10.1016/j.ypmed.2017.04.013
[22] Packer, M., Zile, M. R., Kramer, C. M., Baum, S. J., Litwin, S. E., Menon, V., Ge, J., Weerakkody, G. J., Ou, Y., Bunck, M. C., Hurt, K. C., Murakami, M., & Borlaug, B. A. (2024). Tirzepatide for Heart Failure with Preserved Ejection Fraction and Obesity. *New England Journal of Medicine*. https://doi.org/10.1056/nejmoa2410027
[23] Novo Nordisk. (2023). Semaglutide 2.4 mg reduces the risk of major adverse cardiovascular events by 20% in adults with overweight or obesity in the SELECT trial. https://www.novonordisk.com/news-and-media/news-and-ir-materials/news-details.html?id=166301
[24] Kosiborod, Mikhail N., et al. "Semaglutide in patients with heart failure with preserved ejection fraction and obesity." New England Journal of Medicine 389.12 (2023): 1069-1084.
[25] U.S. Centers for Disease Control and Prevention. (2024). National Diabetes Statistics Report. https://www.cdc.gov/diabetes/php/data-research/index.html
[26] Jastreboff, A. M., Roux, C. W. L., Stefanski, A., Aronne, L. J., Halpern, B., Wharton, S., Wilding, J. P. H., Perreault, L., Zhang, S., Battula, R., Bunck, M. C., Ahmad, N. N., & Jouravskaya, I. (2024). Tirzepatide for obesity Treatment and diabetes prevention. *New England Journal of Medicine*. https://doi.org/10.1056/nejmoa2410819
[27] Li, L., Liu, D.-W., Yan, H.-Y., Wang, Z.-Y., Zhao, S.-H., and Wang, B. (2016) Obesity is an independent risk factor for non-alcoholic fatty liver disease: evidence from a meta-analysis of 21 cohort studies. Obesity Reviews, 17: 510–519. doi: 10.1111/obr.12407
[28] Loomba, R., Hartman, M. L., Lawitz, E. J., Vuppalanchi, R., Boursier, J., Bugianesi, E., Yoneda, M., Behling, C., Cummings, O. W., Tang, Y., Brouwers, B., Robins, D. A., Nikooie, A., Bunck, M. C., Haupt, A., & Sanyal, A. J. (2024). Tirzepatide for Metabolic Dysfunction–Associated Steatohepatitis with Liver Fibrosis. *New England Journal of Medicine*, *391*(4), 299–310. https://doi.org/10.1056/nejmoa2401943

- Reversing and Treating Obstructive Sleep Apnea: Obstructive sleep apnea affects nearly 30 million Americans, and an estimated 80% of cases remain undiagnosed.[29] Untreated sleep apnea can lead to serious health consequences including cardiovascular disease, stroke, diabetes, and depression.[30] Recent studies show that more than half of sleep apnea patients treated with Zepbound® (tirzepatide) no longer met the criteria for sleep apnea by the end of the study.[31] FDA approval for this indication was granted on December 20, 2024.

B. CMS's Reinterpretation of the Statutory Exclusion of Agents When Used for "Weight Loss" to Allow Part D Coverage of AOMs Reflects the Best Reading of the Relevant Statute in Light of Contemporary Scientific Evidence and Legislative History

Considering this overwhelming scientific evidence, CMS had a reasoned basis to reconsider the term "agents when used for… weight loss" as defined in sections 1927(d)(2) and section 1860D-2(e)(2)(A) of the Act.[32] These provisions exclude from the definition of a "Covered Part D Drug" those "[a]gents when used for anorexia, weight loss, or weight gain." CMS has historically interpreted this exclusion as barring Part D coverage of AOMs, classifying them as "[a]gents […] used for […] weight loss." Excluding AOMs regardless of their use defies the statute's plain language in light of the current scientific evidence described above.

Specifically, the statute requires CMS to classify drugs based on what they are "used for," not whether they belong to a broad group of so-called "weight loss agents." The statute also reflects the understanding that a given agent may have multiple purposes, but it is excluded only "when used for" an excluded purpose. CMS thus cannot create a blanket exclusion for "weight loss agents." Instead, CMS must determine, on a case-by-case basis, whether a particular agent is "used for […] weight loss."

As explained above, while AOMs reduce excess body weight, they are specifically used to treat the medical condition of obesity. [33] In fact, the "reduction in excess body weight" is not the end goal of treatment. Rather, as with the reduction of excess blood pressure, "bad"

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[29] Celmer, L. (2023). New national indicator report details importance of prompt sleep apnea diagnosis and treatment. American Academy of Sleep Medicine – Association for Sleep Clinicians and Researchers. https://aasm.org/new-national-indicator-report-details-importance-prompt-sleep-apnea-diagnosis-treatment/

[30] *Id.*

[31] Malhotra, A., Grunstein, R. R., Fietze, I., Weaver, T. E., Redline, S., Azarbarzin, A., Sands, S. A., Schwab, R. J., Dunn, J. P., Chakladar, S., Bunck, M. C., & Bednarik, J. (2024). Tirzepatide for the treatment of obstructive sleep apnea and obesity. New England Journal of Medicine, 391(13), 1193–1205. https://doi.org/10.1056/nejmoa2404881

[32] Additionally, we agree with CMS that since both the Medicaid and Medicare statutes reference the Medicaid definition of covered outpatient drugs in section 1927(k)(2) of the Act and rely on section 1927(d)(2)(A) of the Act to define "[a]gents when used for…weight loss," CMS should apply a consistent interpretation of these provisions across both programs.

[33] ZEPBOUND® is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated in combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition.

lipids, or blood glucose for other chronic diseases, reducing excess body weight delivers the beneficial outcomes described throughout this letter for patients undergoing treatment for obesity. Therefore, when used in accordance with their FDA-approved labeling and within the defined patient populations, AOMs are not "[a]gents […] used for […] weight loss." Rather, they are interventions prescribed to treat beneficiaries diagnosed with obesity.

The reinterpretation of these provisions to extend coverage to AOMs also accords with the relevant legislative history. As the Supreme Court has recently reiterated, the "Court normally interprets a statute in accord with the ordinary public meaning of its terms at the time of enactment."[34] "Because the law's ordinary meaning at the time of enactment usually governs, we must be sensitive to the possibility a statutory term that means one thing today, or in one context, might have meant something else at the time of its adoption."[35] Indeed, under *Loper Bright*, a statutes' "single, best meaning" is partly determined by the *timing of its enactment:* "That is the whole point of having written statutes; 'every statute's meaning is fixed at the time of enactment.'"[36]

When the exclusion reflected in Part D was enacted in 1993, medical historians have noted that the phrase "[a]gents when used for […] weight loss" would largely have referred to drugs like Dexatrim and Fen-Phen, which were either ineffective, dangerous, or both. In fact, Congress's understanding of "weight loss" at the time was without today's scientific and medical understanding of obesity. Today, we know that obesity is a complex, multifactorial chronic disease with numerous dangerous comorbidities; the early 1990s saw only the beginnings of this shift. For example, the Expert Panel on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults, which led to the NIH's landmark 1998 clinical guidelines on obesity, was not convened until 1995. Even then, the panel noted that traditional definitions of having overweight—such as the 85th percentile of BMI for young adults—had little correlation with specific disease risks[37] underscoring that obesity was not widely recognized as a chronic disease at that time.

Thus, the "ordinary meaning" of "[a]gents when used for […] weight loss" in 1993 referred to treatments that were often unsafe, minimally effective, and unrelated to addressing obesity as a disease. Congress could not have anticipated the AOMs available today or the

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[34] *Bostock v. Clayton Cty.*, 140 S. Ct. 1731, 1750 (2020). *See also E.B. v. United States Dep't of State*, 583 F. Supp. 3d 58, 63 (D.C. Cir. 2022) (interpreting the terms "foreign affairs" and "function" in the Administrative Procedure Act on the basis of their meanings "at the time of the APA's enactment"); *Carcieri v. Salazar*, 555 U.S. 379, 380 (2009) (interpreting the term "now" in light of its meaning "at the time of enactment"); *MCI Tele-comm. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 228-29 (1994) (noting that the time of enactment is "the most relevant time for determining a statutory term's meaning").

[35] *Bostock*, 140 S. Ct. at 1738.

[36] 144 S. Ct. 2244 (2024).

[37] National Institutes of Health. (1998). Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report. *NIH Publication No. 98-4083*. https://www.nhlbi.nih.gov/files/docs/guidelines/ob_gdlns.pdf (emphasis added).

significant advancements in medical science over the past two decades.[38] The scientific advancements that have led to the development and use of today's AOMs highlight the need for CMS's reinterpretation, which not only aligns with the plain language of the statute but also appropriately acknowledges the critical role of AOMs in effectively managing obesity as a chronic disease.

C. CMS's Reinterpretation of the Statutory Exclusion of Agents When Used for "Weight Loss" to Allow Part D Coverage of AOMs Is Consistent with, and Possibly Necessitated by, the Administrative Procedures Act's Mandate that Agencies Refrain from Arbitrary and Capricious Rulemaking

It is well-established that "[w]here an agency applies different standards to similarly situated entities and fails to support this disparate treatment with a reasoned explanation and substantial evidence in the record, its action is arbitrary and capricious and cannot be upheld."[39] "A long line of precedent has established that an agency action is arbitrary and capricious when the agency offer[s] insufficient reasons for treating similar situations differently."[40] In the Medicare coverage context, courts have found that covering one item or service but failing to provide coverage for a highly similar item or service constitutes arbitrary and capricious decision-making.[41]

Therefore, we agree with CMS that the proposed reinterpretation aligns with longstanding policy interpreting the phrase "[a]gents when used for…weight gain" in section 1927(d)(2)(A) to not include drugs used to treat acquired immunodeficiency syndrome (AIDS) wasting and cachexia (73 FR 20490). Although Serostim ***causes*** weight gain, it is not "used for […] weight gain" as section 1927(d)(2)(A) of the Act uses that term; rather, weight gain is the effect by which Serostim treats HIV-related wasting. In much the same way, AOMs are not "used for […] weight loss," but rather to treat the underlying physiologic causes of obesity. For this reason, Serostim and AOMs are similarly situated therapies; in the absence of a reasoned scientific explanation for why the section 1927(d)(2)(A) exclusion applies to AOMs but does not apply to Serostim, the disparate treatment of those therapies is arbitrary and capricious.

II. Part D Sponsors Should Be Permitted to Define Obesity for Prior Authorization (PA) Criteria, Provided Definitions Align with FDA Labeling for AOMs

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[38] It is important to emphasize that the Treat and Reduce Obesity Act (TROA), introduced in the 177th Congress, does not suggest that CMS currently lacks the authority to act. Rather the bill would clarify the scope of CMS's authority and underscores wide stakeholder support for coverage.

[39] *Burlington N. & Santa Fe Ry Co. v. Surface Transp. Bd.*, 403 F.3d 771, 777 (D.C. Cir. 2005).

[40] *Cty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1022 (D.C. Circ. 1999) (quoting *Transactive Corp. v. United States*, 91 F.3d 232, 237 (D.C. Cir. 1996)). *See also Petroleum Commc'ns, Inc. v. F.C.C.*, 22 F.3d 1164, 1172 (D.C. Cir. 1994) ("We have long held that an agency must provide adequate explanation before it treats similarly situated parties differently."); *Local 777, Democratic Union Org. Comm., Seafarers Int'l Union of N. Am., AFL-CIO v. N.L.R.B.*, 603 F.2d 862, 872 (D.C. Cir. 1978) (stating that agencies may not "arbitrarily treat similar situations dissimilarly").

[41] *See, e.g., Kort v. Burwell*, 209 F. Supp. 3d 98, 111-12 (D.D.C. 2016).

We support CMS's proposal to allow Part D sponsors the flexibility to define obesity for the purposes of their prior authorization (PA) criteria, provided that these criteria are not more restrictive than the FDA labeling for the specific AOM. This approach aligns with CMS's established practice for other disease states, where the agency does not mandate specific diagnostic criteria but ensures that Part D plan-submitted PA criteria are clinically appropriate.

As outlined in the Proposed Rule, while body mass index (BMI) has limitations as a diagnostic tool, and is increasingly viewed as a screening measure, it remains a standard, low-cost, and widely utilized metric. BMI is also used as diagnostic criteria in the recently updated International Classification of Diseases, Tenth Revision (ICD-10) diagnosis codes[42] and is commonly recorded in electronic health records when a patient's height and weight are documented. Lilly acknowledges the limitations of BMI and specific challenges associated with BMI in accurately diagnosing obesity across racial and ethnic communities and we encourage sponsors and clinicians to exercise flexibility in diagnosing and treating obesity in these populations, recognizing that diagnostic BMI thresholds may differ from those represented in ICD-10 codes. Nevertheless, at present, payers or others may have a hard time utilizing these more appropriate measures.

Furthermore, Lilly would not support discontinuing coverage of an AOM based solely on the attainment of a reduced BMI, including a BMI that no longer indicates obesity. Given the chronic and relapsing nature of the disease, ongoing care should be determined by the treating clinician's professional judgment and not restricted by rigid diagnostic criteria.

Lilly also recognizes and encourages the advancement of anthropometric and body composition measurements in obesity diagnosis, treatment decision-making, and outcomes assessment.[43] While these measures are not currently included in ICD-10 diagnosis codes, they are becoming increasingly prevalent in care and are likely to become standardized diagnostic and care management tools over time.

For the purposes of defining obesity under Part D plan and Medicaid PA criteria, Lilly encourages that such criteria should not be more restrictive than the ICD-10 codes for diagnosing obesity. When combined with other health status assessments and metrics, this multifactorial approach acknowledges the complexity of obesity as a disease while ensuring patients receive appropriate care without undue barriers.

Finally, Lilly encourages the recognition of significant heterogeneity in obesity and thereby the need for patient centric and evidence-based approaches to care. Fundamental to this

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[42] American Board of Obesity Medicine. (2024). *New ICD-10-CM diagnosis codes for adult and childhood obesity*. https://dmiusd4kl5bx2.cloudfront.net/PDF-Files/Adult-ICD_10_CM-Codes-Fact_Sheetv2-002-1.pdf

[43] Rubino, F., Batterham, R. L., Koch, M., Mingrone, G., Roux, C. W. L., Farooqi, I. S., Farpour-Lambert, N., Gregg, E. W., & Cummings, D. E. (2023). Lancet Diabetes & Endocrinology Commission on the Definition and Diagnosis of Clinical Obesity. *The Lancet Diabetes & Endocrinology*, *11*(4), 226–228. https://doi.org/10.1016/s2213-8587(23)00058-x

care, and as indicated in medical literature and product label, such care should include patient guidance and support for a reduced-calorie diet and increased physical activity.

III. CMS Should Consider Extending AOM Coverage to Individuals with Overweight and at Least One Weight-Related Comorbid Condition, Consistent with FDA Labeling

In response to CMS's proposal to restrict the reinterpretation of the statutory exclusion in Section 1927(d)(2) of the Act to individuals with obesity—thereby excluding coverage of AOMs for individuals with overweight, even when weight-related comorbid conditions are present—we urge CMS to broaden the reinterpretation. Specifically, we recommend aligning it with the full scope of FDA-approved labeling for AOMs, which includes indications for chronic weight management in individuals with overweight and at least one weight-related comorbid condition.

While CMS asserts that overweight is not recognized as a disease, it is crucial to acknowledge that the FDA-approved indications for many AOMs explicitly include individuals with overweight with at least one weight-related comorbid condition. Many of these comorbidities are serious, chronic diseases that significantly affect outcomes and are often closely tied to excess weight. While certain conditions, such as type 2 diabetes, established cardiovascular disease, or sleep apnea, already qualify individuals for AOM treatment under approved indications, obesity is linked to more than 200 chronic diseases.[44] Many of these can be mitigated or resolved with appropriate treatment, including AOMs.

By excluding AOM coverage for individuals with both overweight and related comorbidities, CMS risks creating an inequitable divide between patients facing similar health challenges. As noted earlier, certain racial and ethnic communities may experience obesity at a lower BMI than traditionally considered diagnostic. Notably, Asian Americans, based on World Health Organization criteria are considered to have overweight at BMI of 23–27.5 kg/m^2 and obesity at BMI of ≥ 27.5 kg/m^2.[45] Obesity-related comorbidities often develop along a continuum, and addressing these issues in the earlier stages—when patients are classified as having overweight—can prevent progression to obesity and help reduce the overall burden on the healthcare system. And, as noted in an earlier section, these medications can be instrumental in preventing other conditions from developing or worsening.

The FDA-approved labeling for AOMs provides a clinically robust framework, including specific indications for individuals with overweight and obesity related comorbidities. Restricting coverage to a narrower subset of these indications undermines the comprehensive, evidence-based evaluation conducted by the FDA and its associated approvals. Moreover, this limited approach may discourage the timely use of AOMs for

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[44] Yuen, M.M., et al. (n.d.). A systematic review and evaluation of current evidence reveals 236 obesity-associated disorders. Massachusetts General Hospital & George Washington University.
[45] Li, Z., Daniel, S., Fujioka, K., & Umashanker, D. (2023). Obesity among Asian American people in the United States : A review. *Obesity*, *31*(2), 316–328. https://doi.org/10.1002/oby.23639

individuals who could benefit significantly but do not meet CMS's proposed narrower definition of obesity. As highlighted in the Proposed Rule, such restrictions could even create a perverse incentive for individuals to gain weight to qualify for coverage.

We urge CMS to broaden the scope of the reinterpretation to align with the FDA-approved labeling for AOMs, including the use of these medications for individuals with overweight and at least one weight-related comorbidity. This approach ensures equitable access to life-changing treatments, recognizes the progressive nature of the disease and the continuum of weight-related health risks, and upholds the intent of the FDA-approved indications for these therapies. Failing to extend coverage in this way would represent a missed opportunity to comprehensively address the public health challenges posed by both overweight and obesity.

IV. Coverage of AOMs Is Sound Public Policy That Will Improve Outcomes and Reduce Healthcare Costs

Expanding Medicare coverage to include AOMs and broadening such coverage in Medicaid is not only legally and medically justified, as set forth above, but is also good public policy. CMS has consistently acknowledged the importance of sustained weight loss interventions in managing obesity and its associated comorbidities. This rationale is further supported by historical precedent in Medicare coverage for obesity treatments and the consensus of federal agencies and experts on the necessity of comprehensive obesity treatment. Such treatment options include lifestyle interventions, AOMs, and surgical treatment. Dependent on clinician assessment and treatment plan development, there may be need for some or all these treatment methods to be used. Further, there may be need for variable use of these treatment methods across the patient's care journey.

A. Medicare Already Covers Obesity Treatments, Just Not Medicines

CMS already covers obesity treatments, but these treatments are more expensive or in some cases less effective, than AOMs. Specifically:

- Bariatric Surgery Coverage (2006): Since 2006, Medicare has covered bariatric surgery for beneficiaries with a BMI ≥ 35, at least one obesity-related comorbidity, and a history of unsuccessful medical treatment. CMS justified this decision by highlighting bariatric surgery's ability to achieve sustained weight loss and alleviate obesity-related conditions.
- Intensive Behavioral Therapy (IBT) Coverage (2011): In 2011, CMS began covering Intensive Behavioral Therapy (IBT) for obesity, emphasizing its effectiveness in preventing and detecting obesity-related illnesses early. However, the current IBT National Coverage Determination (NCD) restricts its provision to primary care settings, which limits accessibility. Expanding IBT services to include other qualified providers—such as registered dietitians, clinical psychologists, specialty physicians, nurse practitioners, and physician associates—would enhance access for Medicare

beneficiaries. Doing so could lead to improved care delivery and better health outcomes.

These precedents underscore CMS's recognition of the essential role that reducing excess weight plays in addressing obesity-related comorbidities. Extending this standard to include AOMs, supporting access to comprehensive care options as recently endorsed by the Lancet Commission,[46] would reaffirm the agency's commitment to improving health outcomes through effective, evidence-based obesity treatments and would enable CMS to more proactively address a chronic disease that affects a significant and growing share of Medicare and Medicaid patients.

B. Federal Employees and Beneficiaries of Other Federal Programs Have Access to AOMs But Medicare Beneficiaries Do Not

Several federal agencies, including the Internal Revenue Service, Social Security Administration (SSA), Office of Personnel Management (OPM), and Department of Veterans Affairs, have recognized obesity as a disease and already provide coverage for AOMs as part of comprehensive obesity management strategies. It is long overdue for Medicare to align with these federal partners.

Moreover, while the SSA treats obesity as a medically determinable impairment for Social Security Disability purposes, individuals qualifying for Medicare due to obesity-related disability often cannot access AOMs under Medicare. CMS's current interpretation of the term "weight loss" thus creates a troubling inconsistency: individuals can be deemed disabled and covered by Medicare because of obesity, but these same individuals would not have access to AOMs, a treatment for the very disease contributing to their disability.

C. Failing to Cover Obesity Medicines is Bad for the Economy

Obesity, if left unaddressed, imposes significant and lasting economic burden on U.S. citizens and the economy, undermining the nation's global economic standing and competitiveness. According to economists from the bipartisan Congressional Joint Economic Committee (JEC), in 2023 alone, obesity led to an average of $5,155 in excess annual medical costs per affected individual.[47] This contributed to an astonishing $520 billion in additional healthcare expenditure for that year. Over the next decade, obesity is projected to drive $8.2 to $9.1 trillion in excess medical costs.[48]

These rising healthcare costs are only part of the story. Beyond escalating medical expenses, obesity negatively affects the broader economy through diminished workplace

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[46] Rubino, F., Cummings, D. E., Eckel, R. H., Cohen, R. V., Wilding, J. P. H., Brown, W. A., ... Mingrone, G. (2025). Definition and diagnostic criteria of clinical obesity. The Lancet Diabetes & Endocrinology. Advance online publication. https://doi.org/10.1016/S2213-8587(24)00316-4

[47] Joint Economic Committee Republicans, & Schweikert, D. (2024). *THE 2024 JOINT ECONOMIC REPORT*. https://www.jec.senate.gov/public/vendor/accounts/JEC-R/2024RepublicanResponse.pdf

[48] *Id.*

productivity, reduced quality of life, and shortened life expectancy. The same JEC report estimates that, over the next ten years, obesity will reduce the size of the U.S. economy by $13.5 to $14.7 trillion compared to its potential.[49] This economic drag is expected to result in $2.4 to $2.6 trillion in lost tax revenue, further illustrating the far-reaching consequences of untreated obesity.[50]

As important as the macroeconomic obesity related costs are, so too are costs borne by people with obesity. Women suffer disproportionate higher economic issues associated with their obesity. While a man with obesity may have 7% lower odds of employment and equitable earnings, a woman with obesity suffers 20% lower odds of employment and as much as 9% lower earnings compared to a woman without obesity.[51] Across a given lifespan, this reduction in income can have substantial short-and long-term impact. Thought of in terms of the Medicaid population specifically, obesity care may aid in improved health, increased employment opportunities, and thereby better economic outcomes.[52]

Importantly, market dynamics associated with list prices and net cost of AOMs reflect the benefit of competition and productive access negotiations with payers. The second to market modern AOM, Zepbound®, launched at a 20% lower list price compared to the first to market modern AOM, Wegovy®. Further, peer-reviewed literature reports rebates for certain AOMs at 41% with public reports indicating rebates at 50% or greater, in some cases.[53,54,55] Notably, a recent report from the Congressional Budget Office (CBO) forecasted similar levels of rebates, "Per AOM user, the average direct federal cost would be roughly $5,600 in 2026, decreasing to $4,300 in 2034."[56] At current list prices for Zepbound®, as an example, these forecasted net cost figures would reflect an approximate discount of 56% and 68%, respectively. Finally, improved access to modern obesity care will spur additional research and development, competition, and market dynamics, resulting in expanded medication delivery methods, increased healthcare provider and patient choice, improved health outcomes, and enhanced scientific and business innovation.

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[49] *Id.*
[50] *Id.*
[51] GlobalData. (2023). Obesity impact per million population: United States. Retrieved from https://www.globaldata.com/health-economics/US/perMillion/Obesity-Impact-Per-Million-Population.pdf
[52] GlobalData. (2024.). Overweight and obesity: Impact on employers. https://www.globaldata.com/health-economics/US/Employers/Overweight-Obesity-Impact-on-Employers.pdf
[53] Hernandez, I., & Sullivan, S. D. (2024). Net prices of new antiobesity medications. *Obesity*, *32*(3), 472–475. https://doi.org/10.1002/oby.23973
[54] Secretariat International. (2024). *How much will covering anti-obesity drugs cost Medicare?* Retrieved from https://secretariat-intl.com/wp-content/uploads/2024/05/How-Much-Will-Covering-Anti-Obesity-Drugs-Cost-Medicare.pdf
[55] Axelsen, K., & Fendrick, A. M. (2024, December 20). *Coverage of obesity medications can make America healthier (again).* RealClearHealth. Retrieved from https://www.aei.org/op-eds/coverage-of-obesity-medications-can-make-america-healthier-again/
[56] *How would authorizing Medicare to cover Anti-Obesity medications affect the federal budget?* (2024, October 1). Congressional Budget Office. https://www.cbo.gov/publication/60816

Amid these dynamics, compelling evidence highlights the potential for cost savings through comprehensive obesity care. A recent study revealed that Medicare beneficiaries with obesity and at least one chronic illness could achieve significant healthcare cost reductions through effective obesity treatment. Annual savings were estimated at up to 38%, equating to nearly $10,000 in medical cost savings per beneficiary.[57] Building on this, research from the USC Schaeffer Center demonstrates that expanding coverage for new obesity treatments could offset approximately $175 billion in Medicare costs over the next 10 years.[58] Over a 30-year period, these savings could grow to an impressive $700 billion.[59]

D. Medicare as a Catalyst for System-Wide Obesity Coverage

Including coverage for AOMs under Medicare, as well as expanding such coverage within Medicaid, is likely to drive broader adoption of AOM coverage in commercial and employer-sponsored insurance markets. This outcome will ultimately benefit Medicare by improving the health of individuals as they age into Medicare coverage.

For example, one study found that a $1.00 increase in Medicare reimbursement fees resulted in a $1.16 increase in private insurer payments for corresponding services.[60] Similarly, a study published in the Journal of Health Economics examined how changes in Medicare's coverage policies influence physician behavior and private market practices.[61] When Medicare lifted a ban on coverage for ambulatory surgery center (ASC) use for a specific procedure, surgeons increased their ASC utilization for both Medicare and commercially insured patients. Notably, surgeons were 70% more likely to use ASCs for the policy-targeted procedure among their non-Medicare patients.[62] These findings demonstrate the far-reaching, system-wide impacts of Medicare policy decisions, even when those decisions do not explicitly account for externalities affecting non-Medicare payer groups.

By extending coverage to include AOMs, CMS can catalyze a similar transformation across the healthcare system, encouraging more private insurers to adopt comprehensive obesity treatment policies. This would create a unified approach to addressing obesity, benefiting patients across all payer groups.

Additionally, enabling beneficiaries to age into Medicare with lower obesity rates aligns with CMS's goals of reducing chronic disease prevalence and healthcare costs. In fact,

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[57] Thorpe, K. E., & Joski, P. J. (2024). Estimated reduction in health care spending associated with weight loss in adults. *JAMA Network Open*, *7*(12), e2449200. https://doi.org/10.1001/jamanetworkopen.2024.49200
[58] USC Schaeffer. (2023). *Medicare coverage of weight loss drugs could significantly reduce costs*. https://healthpolicy.usc.edu/article/medicare-coverage-of-weight-loss-drugs-could-significantly-reduce-costs/
[59] *Id*.
[60] Clemens J, Gottlieb JD. In the Shadow of a Giant: Medicare's Influence on Private Physician Payments. J Polit Econ. 2017 Feb;125(1):1-39. doi: 10.1086/689772. Epub 2016 Dec 16. PMID: 28713176; PMCID: PMC5509075.
[61] Geruso M, Richards MR. Trading spaces: Medicare's regulatory spillovers on treatment setting for non-Medicare patients. J Health Econ. 2022 Jul;84:102624. doi: 10.1016/j.jhealeco.2022.102624. Epub 2022 May 14. PMID: 35580506; PMCID: PMC10371213.
[62] *Id.*

Medicare coverage of AOMs would save federal taxpayers as much as $245 billion in the first 10 years of coverage alone, if private insurers were to follow Medicare's lead.[63]

In conclusion, finalizing the proposal to reinterpret the statute to extend coverage for AOMs under both Medicaid and Medicare represents sound policy and economic judgment. It aligns with CMS's precedent of covering effective obesity interventions, reflects evolving scientific consensus, and provides a significant opportunity to reduce the economic and public health burden of obesity. By empowering beneficiaries with access to comprehensive obesity management, this policy would address a critical gap in care while driving substantial long-term cost savings for federal healthcare programs. Moreover, compelling evidence highlights Medicare's ability to influence private payer policies, fostering a coordinated and impactful approach to managing obesity across the broader healthcare system.

V. CMS Should Promote Transparency for Pharmacies and Protecting Beneficiaries from Disruptions

Although Lilly is not a pharmacy our patients rely on a thriving pharmacy sector. We support CMS's efforts to improve patient access by rationalizing various pharmacy provisions.

A. CMS Should Finalize Pro-Patient, Pro-Pharmacy Provisions at § 423.505(i)

The Proposed Rule begins to address the growing market challenges that pharmacies face in Medicare and the negative impacts that those challenges have on Medicare beneficiaries. CMS rightly notes that pharmacies have little leverage to negotiate fair contracting terms with Part D sponsors (or their first tier, downstream, or related entities - FDRs) that provide pharmacies with the transparency necessary to effectively serve their customers.[64] Indeed, this issue transcends Medicare: pharmacies servicing Medicaid beneficiaries and commercial market plan enrollees also are being squeezed by unfavorable contracts to the detriment of patients.

Accordingly, Lilly supports CMS's two proposals to put guardrails on pharmacy contracting in Medicare. The first proposal will require Part D sponsors or their FDRs to inform networked pharmacies of which plans they will be in network for in the forthcoming plan year.[65] Today, pharmacies and patients lack a transparent and efficient way of determining if a pharmacy will be in-network for a plan. Often, beneficiaries find out only after enrolling in a Part D plan that their preferred pharmacy is not in-network, leading to confusion and possible treatment delays. CMS, by requiring Part D sponsors to provide networked pharmacies a list of plans that they are in-network for by October 1 will help them

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[63] USC Schaeffer. (2023). Medicare coverage of weight loss drugs could significantly reduce costs. https://healthpolicy.usc.edu/article/medicare-coverage-of-weight-loss-drugs-could-significantly-reduce-costs/

[64] See Proposed Rule at 89 Fed. Reg. 99381. (Dec. 10, 2024).

[65] *Id.*

communicate with patients as they decide which Part D plan is right for them. This will help patients make better decisions while also helping pharmacies more efficiently provide patient care at the beginning of year by reducing consumer confusion.

The second pro-patient, pro-pharmacy proposal will prevent the asymmetric contract termination notice terms common in Part D plan-pharmacy contracts.[66] Today, Part D plans or their FDRs favorably contract far shorter termination clauses for themselves than they do their networked pharmacies. As CMS notes, pharmacies may need to wait over a year – sometimes up to three years – to terminate their contract with a Part D plan.[67] Pharmacies may have no choice but to accept these terms because the market power of the Part D sponsor or their contracted FDRs. CMS requiring that the termination notice requirements for both pharmacies and PDP plan sponsors or FDRs be equivalent, will begin to address the lopsided contracting term present in the market.

These two policies together will begin to address the challenges that pharmacies face participating in Medicare which will in turn improve the consumer experience. We encourage CMS to continue advancing pro-patient and pro-pharmacy policies in future rulemaking.

B. Lilly Supports CMS's Formulary Review Process Update to Promote Cost-Effective Access to Medicines for Patients

The goal of prescription drug formularies and utilization management should be to safely and effectively provide patients with cost-effective access to their prescribed medicines. Unfortunately, as CMS notes, this is not always the case based on available evidence.[68] For example, HHS' Office of Inspector General concluded that Part D plans' formulary designs contributed to higher-than-expected utilization of reference products versus biosimilars which contributed to higher patient and Medicare program costs.[69] Biosimilars, like generics, are safe and potentially cost-effective options for patients that play an important role in helping patients' affordably access the care they need when prescribed by their provider. As such, we support CMS updating their formulary review process to holistically "check that Part D sponsors provide broad access to generics, biosimilars, and other lower cost drugs."[70]

We encourage CMS to consider the underlying challenges of patient affordability embedded in Part D plans' formulary designs. The robust negotiation in Medicare between pharmaceutical manufacturers and Part D sponsors generates significant price concessions

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[66] *Id*. at 99383-99384.
[67] *Id.*
[68] *Id.* at 99470-99471.
[69] U.S. Department of Health & Human Services Office of Inspector General. (2022, March 29). Medicare Part D and beneficiaries could realize significant spending reductions with increased biosimilar use. https://oig.hhs.gov/reports/all/2022/medicare-part-d-and-beneficiaries-could-realize-significant-spending-reductions-with-increased-biosimilar-use/.
[70] 89 Fed. Reg. 99472. (Dec. 10, 2024).

from the list price of medicines.[71] These negotiated net prices after manufacturer price concessions may in fact be lower than a biosimilar or generic's price. If the plan chooses to pass those savings on to the patient, the reference product can be less expensive overall than the biosimilar product. The issue therefore is not simply if a reference product is preferred to a biosimilar or other lower list-price product, but rather, if the patient benefits from the price concessions the manufacturer provided to the PBM or Part D plan sponsor. If a Part D plan chooses not to pass on the savings to its patients, and a patient is still in their deductible or their medicine is on a coinsurance tier, they may be exposed to out-of-pocket costs based on the unnegotiated price rather than the negotiated price.[72] Accordingly, CMS should closely examine if PDP sponsors' formularies put patients in a position to benefit from the robust negotiation present in Part D. Otherwise, formularies may not be serving the best interest of patients by being cost-effective. In those cases, patients may even be paying more out-of-pocket than what the Part D sponsor pays.[73]

VI. Lilly Supports CMS's Proposal to Use Artificial Intelligence and Automated Systems in a Manner that Preserves Unbiased Access to MA Services

Lilly commends CMS for its proposed policy to establish guardrails for artificial intelligence (AI) to protect all Medicare Advantage (MA) enrollees and encourages CMS to finalize the proposal. While AI has immense positive potential to transform the health care system, it is imperative that AI is implemented in such a manner that provides unbiased care. As such, Lilly supports the development of AI regulations to ensure that AI is used in a responsible manner. Acknowledging the recent House Bipartisan Task Force on AI report, Lilly is encouraged that CMS's Proposed Rule aligns with a central theme of the report that AI technology must be thoughtfully applied in a nondiscriminatory way. CMS's proposed approach should advance this aim by reducing redundancy and ambiguity while ensuring a rational approach to AI regulation.

As AI systems and algorithms become more widely used within the health care ecosystem, it is critical that such systems and algorithms are transparent and accountable to all stakeholders. Leveraging AI responsibly includes ensuring unbiased and fair outcomes resulting from the use of such technology. Data collection, deployment, and other AI interactions should employ approaches to mitigate algorithmic bias to ensure the safety of patients and the public. Ultimately, stakeholders using AI technology must assume responsibility for its application and aspire to foster health advancements.

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[71] Medicare Payment Advisory Commission. (2022, September). Analysis of Part D data on drug rebates and discounts. https://www.medpac.gov/document/analysis-of-part-d-data-on-drug-rebates-and-discounts/.
[72] N.B., Lilly supports rebate pass through to patients so that patients' out-of-pocket cost is based on the negotiated price of the drug rather than the unnegotiated list price.
[73] Medicare Payment Advisory Commission. (2022, September). Analysis of Part D data on drug rebates and discounts. https://www.medpac.gov/document/analysis-of-part-d-data-on-drug-rebates-and-discounts/.

Lilly believes that all players in healthcare, including health plans, should be accountable for responsibly using AI in their decisions and understand why an algorithm produces the output it does and how the output is being used in the decision process. Currently, there is a lack of clarity and transparency in how plans are using algorithms to make coverage decisions. Over 30 million Americans are MA beneficiaries. These are some of the most vulnerable Americans who need consistent and reliable access to care; prior authorization denials can delay, or in some cases prevent, access to care for patients. We encourage CMS to closely review denials and get a deeper understanding of when, and to what extent, algorithms were used as a part of the decision-making process.

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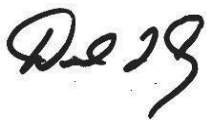
Lilly is grateful for the opportunity to comment on the CY 2026 Medicare Advantage (MA) and Part D Policy and Technical Changes Proposed Rule. We sincerely appreciate your thoughtful consideration of the issues discussed in this letter and look forward to working with you in the future on these topics. Please do not hesitate to contact Derek Asay at Asay_Derek_L@Lilly.com with any questions.

Sincerely,



Derek L. Asay
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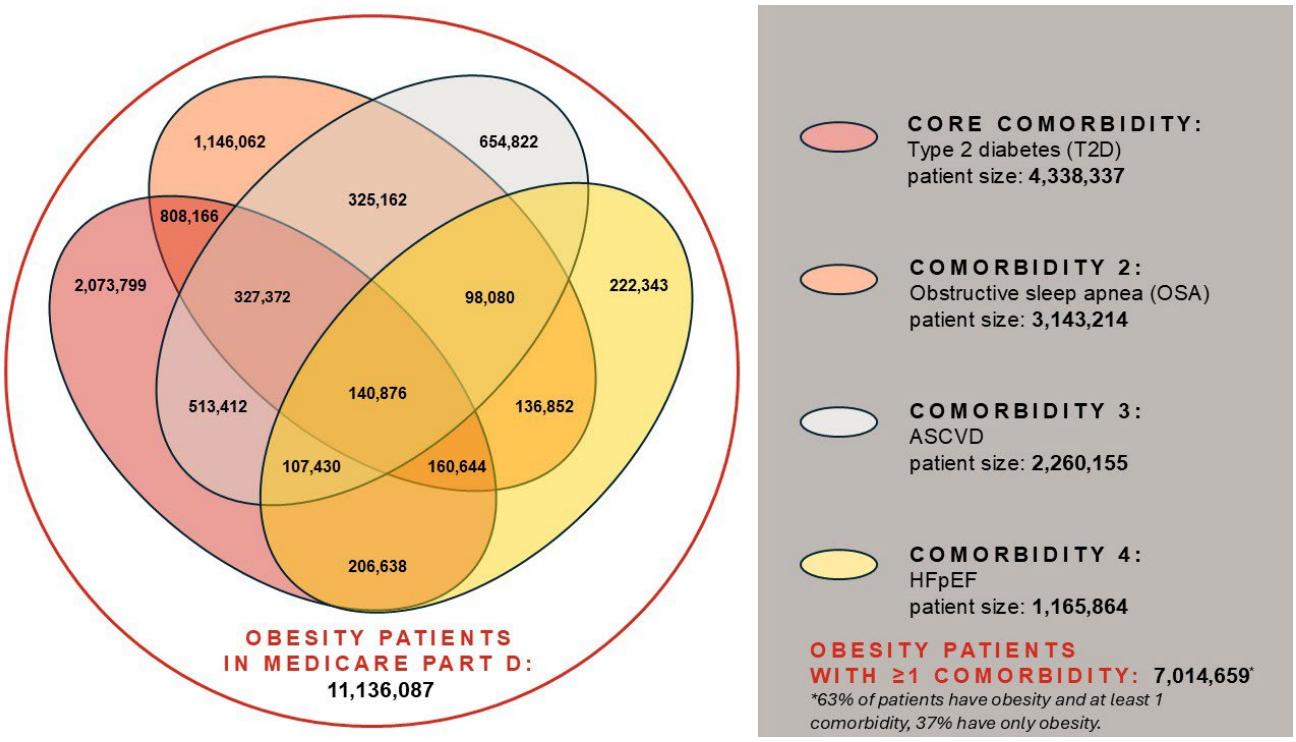
Appendix A



Information:
The Venn Diagram above, shows the Medicare Part D patient population with type 2 diabetes, OSA, history of ASCVD, and HFpEF filtered by people who have obesity.

63.0% of Medicare beneficiaries with obesity have co-occurring T2D, OSA, history of ASCVD, and/or HFpEF.

Source: IQVIA LAAD

Methodology: The dashboard includes all active patients in the IQVIA LAAD Database from January 2023-October 2024 who were diagnosed with at least one comorbidity of interest between January 2020-October 2024.