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January 27, 2025

Jeff Wu
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically via http://www.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]

Dear Administrator Wu:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to the "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" (Proposed Rule), issued on November 26, 2024.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

Coverage of Anti-Obesity Medications

AMCP broadly supports efforts to address obesity and believes that anti-obesity medications can help improve health outcomes. However, AMCP cautions that appropriate guardrails must be in place. AMCP is concerned that reinterpreting the statutory definition of a covered Part D drug to include anti-obesity medications (AOMs) used for weight loss in the treatment of obesity raises serious concerns that should be addressed before finalizing the rule. Among the issues that must be addressed are the lack of a clear definition of obesity, the high costs of AOMs, and developing appropriate guidance on managing the drugs within this class.

A foundational concern for AMCP is the lack of a clear definition of obesity. Generally, obesity has been defined as having a body mass index (BMI) of 30 or greater. However, BMI has been

recognized as a flawed measure of obesity,[1] and CMS notes in the Proposed Rule that using BMI to define obesity has its limitations. Permitting Part D sponsors to individually define obesity for the purposes of prior authorization (PA) criteria provides no guidance for appropriate criteria and is likely to lead to a lack of uniformity across the healthcare system. AMCP is concerned that this may create the potential for a disparate impact on protected classes which should be carefully considered and addressed before finalizing the rule.

Another important consideration is the financial burden that this changed interpretation will create. According to the Congressional Budget Office (CBO), coverage of AOMs in Medicare would increase net federal spending by about $35 billion over the next 8 years.[2] This increased cost burden will impact taxpayers and Part D plan sponsors. Recent efforts to reduce Medicare prescription drug costs through negotiated prices will not alleviate this burden since there are no branded Glucagon-like peptide-1 (GLP-1) receptor agonists indicated for weight loss on the negotiated drug price list. Only GLPs with an indication for diabetes will likely be negotiated in the near term. If coverage is required, Part D sponsors are likely to see utilization of GLP-1s for obesity grow exponentially in their Part D population, further exacerbating the cost issue. Finally, the financial burden is worsened by the lack of risk adjustment for patients with obesity.

Additional guidance on managing the drugs within this class is needed before CMS should require coverage. Additionally, further research into treating obesity as a chronic disease would help to support any such guidance. CMS' current lack of clear guidance on clinically and operationally addressing the AOMs and their expanded indications would pose a challenge to managed care organizations (MCOs) and their ability to appropriately manage costs and utilization.

If CMS proceeds with its new interpretation, CMS should provide a clinically supported definition of obesity, add obesity as a risk adjustment factor to reflect the anticipated increase in utilization, and provide guidance around coverage determinations. Additionally, CMS should consider funding weight loss programs that address nutrition and other lifestyle changes to treat obesity within the healthcare system before the use of drug therapy. To promote healthier outcomes, AMCP and its members suggest CMS require beneficiaries to participate in a weight loss program that includes guidance from a dietitian and a trainer. Additionally, CMS should consider limiting the duration of drug therapies for the treatment of obesity.

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[1] See, e.g., Sweatt, K; Garvey, WT; and Martins, C. Strengths and Limitations of BMI in the Diagnosis of Obesity: What is the Path Forward? Curr Obes Rep. 2024 Sep;13(3):584-595. doi: 10.1007/s13679-024-00580-1. Epub 2024 Jul 3. Erratum in: Curr Obes Rep. 2024 Dec;13(4):831. doi: 10.1007/s13679-024-00584-x. PMID: 38958869; PMCID: PMC11306271 (noting that while BMI is useful as a screening tool, it has limitations as a diagnostic tool due to the lack of accuracy and reliability regarding adiposity). Available at https://pmc.ncbi.nlm.nih.gov/articles/PMC11306271/.

[2] Congressional Budget Office (Oct 2024) How Would Authorizing Medicare to Cover Anti-Obesity Medications Affect the Federal Budget? Available at: https://www.cbo.gov/publication/60816

Inflation Reduction Act – Medicare Transaction Facilitator

AMCP is concerned about CMS' proposal that Part D prescription drug plan (PDP) sponsors use their network participation agreements to require network pharmacies to enroll with the Medicare Transaction Facilitator Data Module (MTF DM). This approach creates operational costs without increased reimbursement for the plan sponsor or pharmacy benefit manager (PBM).

AMCP cautions that the proposed seven-day deadline for submitting prescription drug event (PDE) data by plan sponsors is insufficient to account for pharmacy reversal of claims. AMCP proposes that a 10-day window would help to alleviate this concern, ensure timeliness, and also reduce the administrative burden on smaller plans that may need to submit this data less frequently due to staffing and claims volumes.

Formulary Inclusion and Placement of Generics and Biosimilars

AMCP supports CMS' proposal to adjust the formulary review process to consider access to generics, biosimilars, and other lower-cost drugs. Biosimilars offer a cost-effective alternative to originator biologics, which can lead to significant savings for Medicare beneficiaries. Increasing access to biosimilars is vital for advancing patient-centered care by broadening the treatment options available to Medicare beneficiaries. Furthermore, greater uptake of biosimilars fosters healthy competition and innovation within the biopharmaceutical sector and drives manufacturers to invest in research and development.

AMCP's members would appreciate further clarity and guidance on what CMS would be reviewing as part of this expanded formulary review and what is specifically meant by "broad access." For example, it is important that plans not be penalized in the formulary review process for seeking rebates on branded drugs where possible if they also make generics and biosimilars available. As rebates account for significant saving on total drug costs, plans often favor products with rebates to reduce beneficiary cost sharing. It is especially important that CMS take a holistic view of a plan's approach to its formulary.

Star Ratings

AMCP strongly supports updating the Breast Cancer Screening (Part C) measure to reflect changes to applicable guidance, including expansion of the age range recommended for breast cancer screening. Breast cancer can be detected early with positive outcomes. AMCP supports updating the existing Breast Cancer Screening measure.

AMCP opposes the use of the Initiation and Engagement of Substance Use Disorder Treatment (IET) (Part C) as a measure to manage a population base. The management of substance abuse disorder is patient specific and requires customized decisions based on the patient attributes and history. The incidence of substance abuse disorder in a Medicare population would be difficult to manage outside of the provider office and CMS should consider other ways to impact the decrease in incidence.

AMCP also opposes the use of the Initial Opioid Prescribing for Long Duration (IOP-LD) (Part D) measure as it would be difficult to measure at a population level in a Medicare system. A measure such as this could have negative unintended consequences to the patient because there is not a one-size fits all policy that would allow a patient to be managed appropriately for their unique situation. Population health management is better served in chronic conditions that are more prevalent and have more data to show best practices fora population and not individual patients.

AMCP has concerns about the revisions to the Plan Makes Timely Decisions about Appeals (Part C) and Reviewing Appeals measure as the changes could prove to be unduly burdensome and costly to plans.

Conclusion

AMCP appreciates your consideration of the aforementioned concerns and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact Vicky Jucelin, AMCP's Manager of Regulatory Affairs, at vjucelin@amcp.org or (571) 858-5320.

Sincerely,

Susan A. Cantrell, MHL, RPh, CAE
Chief Executive Officer