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January 27, 2025

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

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

Dear Acting Administrator Wu:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit comments on 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* (CY 2026 MA and Part D proposed rule).[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States. Consistent with that mission, PhRMA companies are committed to the continued success of the Medicare Prescription Drug Benefit Program (Part D).

It has been two decades since enactment of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). In that time, Medicare Part D has enabled access to a wide range of innovative treatments and led to substantial improvements in health outcomes for millions of seniors and people with disabilities.[2] Beneficiaries have received a continually evolving array of medicines, greatly improving treatment across a range of illnesses. Even as treatments have expanded, improved, and become more personalized, Medicare Part D costs have remained steadily below original projections as a result of effective competition and plan negotiation, and annual spending growth in recent years has been smaller than other parts of Medicare.[3] Moreover, by providing affordable access to medicines that effectively treat serious diseases and chronic conditions, Medicare Part D has been found to reduce other health care spending.[4]

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[1] 89 Fed. Reg. 99340 (Dec.10, 2024).
[2] KFF. An Overview of the Medicare Part D Prescription Drug Benefit. October 2024. https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/#:~:text=In%202023%2C%2050.5%20million%20Medicare,alone%20PDPs%20(Figure%206)
[3] Congressional Budget Office. Medicare Baseline Projections. May 2022. Available at: https://www.cbo.gov/system/files/2022-05/51302-2022-05-medicare.pdf
[4] De Avila, J. L. M., D.O.; Zhang, J.X. (2021). Prevalence and Persistence of Cost-Related Medication Nonadherence Among Medicare Beneficiaries at High Risk of Hospitalization. In JAMA Network Open (Vol. 4, pp. e210498).

Unfortunately, flaws in the Inflation Reduction Act of 2022 (IRA) threaten the choice for beneficiaries and competition across plans in Part D. The distinctive features of the Part D program allow millions of beneficiaries the opportunity to compare coverage and access to medicines and annually choose the Part D plan that meets their specific needs. After two decades of growth in plan choices and stable, low premiums, for 2025, beneficiaries in enhanced standalone Part D plans faced a 33% decrease in plan choices and 26% increase in premiums.[5] While outside the scope of this proposed rule, we encourage the new Administration to take steps that, in concert with our recommendations below, can ensure the program remains on solid footing in the years ahead while strengthening coverage and access to needed medicines.[6]

Please find our detailed comments on specific sections of the CY 2026 MA and Part D proposed rule below. A summary of our comments on key sections of the proposed rule are as follows:

- **Coverage of AOMs: CMS should finalize its reinterpretation of the statutory exclusion in Section 1927(d)(2) of the Act to clarify that anti-obesity medications (AOMs) used for treating obesity and that otherwise meet the definition of Part D drug are not agents for weight loss, but treat a severe chronic disease, obesity, and would no longer be excluded from Part D coverage.** Obesity is a serious chronic disease impacting over 40% of Americans. Along with lifestyle changes and non-clinical health interventions, anti-obesity medicines offer an important solution for improving Americans' health, which can be advanced via coverage in Medicare and Medicaid.

- **Monitoring access under Part D: PhRMA appreciates the recognition that as plans respond to changes made by the IRA, the agency should increase monitoring and review of Part D formularies to ensure plans are providing broad access to clinically appropriate treatment options.** As CMS considers how to best protect beneficiaries from excessive costs, it should require Pharmacy Benefit Managers (PBMs) and health plans to share the savings they receive from manufacturers on medicines directly with patients at the pharmacy counter. CMS should work to ensure that patient costs do not increase because of price setting, and that patients never pay more than the payer. The sick should not subsidize their insurer.

- **Strengthening Medicare Advantage oversight: CMS should finalize proposals to strengthen oversight of Medicare Advantage to ensure that competition provides beneficiaries with appropriate access to medicines and all other benefits to which they are entitled under the Medicare program.** This is reflected in our comments on several proposals, including:

[5] Number of Part D Plan Choices Declines for 2025. Avalere. Oct. 8, 2024. https://avalere.com/insights/number-of-part-d-plan-choices-decline-for-2025

[6] See: PhRMA Comments on "Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191-1198 of the Social Security Act for the Initial Price Applicability Year 2027, and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027" and associated Appendix. July 2, 2024.

- **Supplemental Benefits:** PhRMA recommends CMS regularly analyze and report plan-level data on supplemental benefits to assess their impact on health outcomes compared to the use of rebate dollars to lower out-of-pocket costs.
- **Guardrails for Artificial Intelligence (AI):** CMS should finalize policies to establish patient-focused guardrails for AI when used by plans in ways that impact patient access and interactions. While AI represents a powerful tool in health care that can create certain efficiencies by reducing administrative burden, it must be responsibly used with appropriate accountability mechanisms so as not to further impede or delay access to care.
- **Enhancing Prior Authorization Reporting:** CMS should finalize its proposal to require plans to disaggregate the required analysis metrics by each item and service.
- **Network Adequacy:** PhRMA strongly supports ongoing efforts to enhance network adequacy requirements to ensure timely access to care.
- **Medical Loss Ratio (MLR) standards and oversight:** PhRMA appreciates the consideration of steps in the proposed rule to strengthen standards and oversight of MLR requirements for MA plans and offer recommendations for further strengthening these standards beyond what the agency proposes. These steps are needed to address concerns that current rules may not be adequate to address new challenges created by large vertically integrated plans and their PBM and provider affiliates.
- **Internal Coverage Criteria**: CMS should extend its efforts to increase oversight and transparency of MA coverage and consider how greater oversight of utilization management practices would further promote beneficiary access to basic Medicare benefits, including medicines.

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Part D Coverage of AOMs (§ 423.100) and Application to the Medicaid Program

CMS should finalize its reinterpretation of the statutory exclusion in Section 1927(d)(2) of the Act to clarify that anti-obesity medications (AOMs) are not agents for weight loss, but medicines that treat a severe chronic disease, obesity and otherwise meet the definition of Part D drug and would no longer be excluded from Part D coverage.

As the proposed rule notes, obesity is a serious chronic disease impacting over 40% of Americans. Importantly, obesity, like many other chronic diseases, does not occur in isolation. Chronic diseases are often highly interrelated and cannot be treated without consideration of the collective role they play in a patient's health. Obesity itself is associated with many other illnesses including heart disease, stroke, type 2 diabetes, kidney disease, fatty liver disease, arthritis, respiratory problems, depression, sleep apnea, Alzheimer's disease, musculoskeletal problems, and many forms of cancer.[7] Overweight is also linked to co-morbidity with many of these illnesses.[8]

Chronic diseases are a leading driver of health care costs, imposing a heavy burden on our health care system and economy. Six in ten Americans have one or more chronic conditions and 42% have two or more.[9] The cost of treating chronically ill patients accounts for 90% of the nearly $4 trillion spent on health care in the United States each year.[10,11] Looking ahead, the number of individuals with three or more chronic conditions is projected to nearly double by 2030, greatly increasing the economic burden imposed by these illnesses.[12]

Much of this impact is expected to be borne by public programs. For example, over the next 10 years, the combined Medicare and Medicaid spending on obesity and obesity-related chronic illness alone is projected to total $4.1 trillion.[13] The combined impact of the obesity and overweight epidemic also has a profound impact on our economy more broadly, with an estimated annual cost of $1.72 trillion (or 9.3% of GDP)—including $481 billion in direct health care costs and $1.24 trillion in lost economic productivity.[14]

The proposed rule represents an important step forward in making sure these programs not only keep pace with advances in medicine and clinical practice but drive value in our health care system. Treating and preventing chronic illness through expanding coverage of AOMs for the treatment of obesity will have substantial benefits for Medicare and Medicaid beneficiaries and

[7] Health Risks of Overweight & Obesity. National Institutes of Health. https://www.niddk.nih.gov/health-information/weight-management/adult-overweight-obesity/health-risks
[8] Health Risks of Overweight & Obesity. National Institutes of Health. https://www.niddk.nih.gov/health-information/weight-management/adult-overweight-obesity/health-risks
[9] Buttorff C, Ruder T, Bauman M. Multiple Chronic Conditions in the United States. Rand Corporation, 2017.
[10] National Center for Chronic Disease Prevention and Health Promotion, Health and Economic Costs of Chronic Diseases.
[11] Buttorff C, Ruder T, Bauman M. Multiple Chronic Conditions in the United States. Rand Corporation, 2017. National Health Expenditure Data: Historical. Center for Medicare & Medicaid Services. December 15, 2021.
[12] Partnership to Fight Chronic Disease. What is the Impact of Chronic Disease on America?
[13] The 2023 Joint Economic Report 118th Congress. (2023–2024). https://www.jec.senate.gov/public/_cache/files/c7df7ee3-2562-44f9-bcc0-fb038ff9967c/the-2023-joint-economic-report.pdf.
[14] America's Obesity Crisis: The Health and Economic Costs of Excess Weight. Milken Institute. Accessed. September 29, 2023. https://milkeninstitute.org/report/americas-obesity-crisis-health-and-economic-costs-excess-weight.

the health care programs that serve them. Research has repeatedly demonstrated substantial clinical and economic benefits of treatment of patients with obesity as well as those who have overweight with weight-related chronic illness. Across our health care system, AOMs, along with lifestyle changes and other non-clinical interventions, offer the opportunity for a more sustainable path forward focused on preventing chronic disease rather than only bearing its consequences. Better disease management and improved health achieved through optimal use of medicines has long been credited with avoiding health complications and spending on other costly health care services such as emergency room visits, hospital stays, surgeries and long-term care. Notably the ability for medicines to reduce spending on other costly medical care has also been shown to curb overall health care spending growth. In fact, between 1999 and 2012, Medicare experienced a marked slowdown in spending growth. Research shows that one quarter of that slowdown can be attributed to greater use of cardiovascular medicines that prevent or mitigate cardiovascular disease complications.[15]

AOMs offer similarly transformative benefits, with evidence pointing to substantial economic benefits of weight loss due to reduced chronic illness. In fact, a recent analysis estimated that, in Medicare, just a 5% reduction in individuals' weight among those living with overweight or obesity was estimated to reduce spending by $1,262 (7%) per person annually, and a 25% reduction was estimated to reduce spending by $5,442 (31%) per person annually.[16] Another analysis by Goldman Sachs concluded that increased utilization of GLP-1 medications for weight loss broadly in the population could add as much as 1% to U.S. GDP over the next four years due to reduced health problems such as heart attacks, strokes and diabetes.[17]

Beyond the benefits of weight loss and reduction in weight-related chronic diseases more generally, optimal use of AOMs can yield substantial downstream cost offsets through avoided comorbidities and reduced physician visits and hospital admissions.[18] For example, researchers at the University of Southern California have projected that expanding insurance coverage of weight loss therapies would lead to cost offsets of $175 billion in Medicare alone over the next 10 years through reduced hospital inpatient stays and other costs in Parts A, B, and D.[19] Moreover, AOMs are already providing significant value in the treatment of chronic illnesses and can be expected to continue to do so in the years ahead. These medicines compete in highly competitive classes with discounts and rebates lowering the net prices anywhere between 41% to 59% across public and private payers.[20] As AOMs continue to be researched and developed for chronic illnesses that are often weight related, such as heart disease, sleep apnea, metabolic dysfunction-associated steatohepatitis (MASH), and chronic kidney disease,

[15] DM Cutler, K Ghosh, KL Messer, TE, Raghunathan, ST Stewart, and AB Rosen, Health Affairs. February 2019. Explaining the Slowdown in Medical Spending Growth Among the Elderly.
[16] Estimated Reduction in Health Care Spending Associated With Weight Loss in Adults. Kenneth E. Thorpe, PhD, and Peter J. Joski, MSPH. December 5, 2024. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2827550?resultClick=1
[17] Matthew Fox. The more Americans who take Ozempic, the faster the US economy could grow, Goldman Sachs says, Business Insider. April 26, 2024. https://www.businessinsider.com/us-economy-faster-growth-ozempic-glp-1-weight-loss-drugs-2024-2.
[18] CMS Has the Legal Authority to Cover Anti-Obesity Medications (and Should): A Legal, Regulatory and Policy Assessment. The Alliance for Aging Research, in partnership with Akin Gump Strauss Hauer & Feld LLP. November 13, 2024. /https://www.akingump.com/a/web/3aAqBfEp52AU42kSpikPyB/cms-has-the-legal-authority-to-cover-anti-obesity-medications-and-should.pdf.
[19] Alison Sexton Ward P, Bryan Tysinger P, PhuongGiang Nguyen M, Dana Goldman P, Darius Lakdawalla P. Benefits of Medicare Coverage for Weight Loss Drugs. April 18, 2023. doi:10.25549/4rf9-kh77.
[20] Hernandez I, Sullivan SD. Net prices of new antiobesity medications. *Obesity (Silver Spring)*. 2024; 32(3): 472-475.

subsequent FDA approvals will continue to drive both competition and progress in the years ahead. But importantly, they will also continue to provide clinical economic benefits through the treatment and prevention of a broad range of chronic diseases, including those affecting persons living with obesity or overweight.

Proposed Reinterpretation

Not only will CMS's proposed reinterpretation of statute to cover AOMs for the treatment of obesity yield substantial economic and clinical benefits, it is also the best reading of the language and intent of Section 1927(d)(2) of the Act.

The Act's language excludes agents only when "used for . . . weight loss." Nothing in that language purports to exclude agents for the treatment of a chronic disease such as obesity. As CMS correctly notes, categorizing AOMs as an agent used for "weight loss" reflects an "outdated medical understanding." Over the last decade, two dozen leading health organizations, including the American Medical Association, have recognized that obesity is a serious chronic disease rooted in biology and caused by a complex interplay between genetics, nutrition, the environment, and a range of other factors such as hormones, sleep, and use of certain medications.[21, 22, 23] Focusing on the metabolic, pathological and physiologic effects of obesity more accurately describes the disease and its treatment and distinguishes AOMs from "agents…when used for…weight loss."

This proposal is also more consistent with CMS's prior precedent in interpreting Section 1927(d)(2) in other contexts. For example, this would be consistent with how CMS covers AOMs for the treatment of other disease states, such as cardiovascular disease, sleep apnea, and diabetes, where the mechanism of the treatment (as with obesity) is characterized not just by weight reduction, but other hormonal and physiological consequences that the medicines have been shown to address. And in a closely related example, CMS has interpreted Section 1927(d)(2) to permit coverage of Serostim®, a drug used to treat wasting/cachexia resulting from acquired immunodeficiency syndrome (AIDS). Even though the drug increases the patient's weight, coverage is possible under Section 1927 since the drug is not merely for cosmetic weight gain, but instead a treatment for cachexia.[24]

Finally, the proposal is supported by the legislative history of Section 1927(d)(2) itself. Congress adopted section 1927(d)(2) as part of the Omnibus Budget Reconciliation Act of 1990, which established the Medicaid Drug Rebate Program.[25] That program requires state Medicaid agencies to cover drugs of manufacturers with rebate agreements, but permits these Medicaid

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[21] *What Is Obesity?* Obesity Medicine Association. July 31, 2023. https://obesitymedicine.org/blog/what-is-obesity/.
[22] Recognition of Obesity as a Disease H-440.842. (2023). https://policysearch.ama-assn.org/policyfinder/detail/obesity?uri=%2FAMADoc%2FHOD.xml-0-3858.xml.
[23] Anti-Obesity Medications as Medicare Part D Drugs Legal and Health Policy Rationales. Michael Kolber, Rachel Sher and Daniel Weinstein. September 2023. https://www.manatt.com/Manatt/media/Documents/Pfizer_Obesity-Drugs-Part-D-Coverage_2023-09_c.pdf
[24] See National Library of Medicine (NIH), After Protests, HCFA Requires Coverage of Anti-Wasting Drug, 14(8) AIDS Policy & Law 11. (1999). https://pubmed.ncbi.nlm.nih.gov/11366530/. National Library of Medicine (NIH), HCFA Reverses Ruling on AIDS Wasting Treatment, 14(6) AIDS Alert 69. June 1999. https://pubmed.ncbi.nlm.nih.gov/11366412/. Centers for Medicare & Medicaid Services (CMS), Medicaid Drug Rebate Program Release #88. Mar. 5, 1999. https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-088.pdf.
[25] Pub. L. No. 101-508 November 5, 1990.

programs to exclude specific drugs or classes of drugs, or their medical uses from coverage. A report accompanying the law explained the list of drugs excludable constituted those that were at the time "commonly subject to exclusion or restriction by State Medicaid programs."[26] Contemporaneous documentation makes clear that the products "commonly" excluded at that time by state Medicaid agencies bore no similarity to today's AOMs.[27] At the time, Maryland excluded coverage for "central nervous system stimulants and anorectic agents used for weight control." Nebraska would not cover "weight control and appetite depressant drugs." New York declined coverage for "amphetamines and other drugs whose sole clinical use is for reduction of weight." North Dakota did not cover "anorectics" and "high protein weight reduction supplements." West Virginia's program did not extend to "drug products for weight control." And Idaho excluded "diet supplements."

This is not surprising as first-generation weight loss drugs—those sold between 1940 and 1980—were primarily used for cosmetic weight loss and have been largely withdrawn from the market due to significant side effects that rendered the associated drugs unsafe for long-term use.[28] However, scientific advances over the past 30 years have produced a groundbreaking class of AOMs, in particular GLP-1 and GIP receptor agonists, that are not only far more effective in the treatment of obesity and its hormonal and physiological consequences but have profiles that are safe and effective for long-term treatment.[29]

Scope and Implementation of Reinterpretation in Part D

CMS should finalize the proposal to ensure that Part D sponsors fully cover AOMs for obesity consistent with criteria that are not more restrictive than the FDA labeling for the particular AOM.

To ensure Part D sponsors are defining obesity appropriately and adhering to this rule, we encourage CMS to refer to clinical practice guidelines as well as the recently updated International Classification of Diseases, Tenth Revision (ICD-10) codes, which include body mass index (BMI) as a diagnostic tool, to inform review of Part D plan-submitted prior

[26] 136 Cong. Rec. 30515. October 18, 1990. https://www.congress.gov/101/crecb/1990/10/18/GPO-CRECB-1990-pt21-3-1.pdf.
[27] National Pharmaceutical Council, Pharmaceutical Benefits Under State Medicaid Programs. (1989). https://www.npcnow.org/sites/default/files/media/1989%2520Pharmaceutical%2520Benefits%2520Under%2520State%2520Medical%2520Assistance.pdf.
[28] Haslam, D., Weight Management in Obesity – Past and Present, 70(3) Int. J. Clin. Pract. 206–217. February 26, 2016. https://pmc.ncbi.nlm.nih.gov/articles/PMC4832440/; Coulter, A.A., Greenway, F.L., and Rebello, C.J., Centrally Acting Drugs for Obesity: Past, Present, and Future, 78(11) Drugs 1113–1132. July 2018. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6095132/.
[29] Popoviciu, M.S., et al., Emerging Role of GLP-1 Agonists in Obesity: A Comprehensive Review of Randomised Controlled Trials, 24(13) Inter. J. of Molecular Sci. 10449 (Jun. 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10341852; Tak, Y.J., and Lee, S.Y., LongTerm Efficacy and Safety of Anti-Obesity Treatment: Where Do We Stand?, 10(1) Curr. Obesity Rep. 14 (Mar. 2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC7787121/.

authorization (PA) criteria for clinical appropriateness and protect against inappropriate access limitations for Part D beneficiaries.[30,31]
As CMS noted, and the relevant guidelines acknowledge, body mass index (BMI) alone may not be appropriate in defining obesity and other diagnostic criteria should be considered. At the same time, BMI remains an important evaluation criterion that is widely available and one of several factors that inform a clinical diagnosis of obesity—including in different treatment populations. For example, clinical practice guidelines recommend that lower thresholds of BMI as well as waist circumference be considered in diagnosing obesity in certain ethnic groups as the health risks associated with obesity in these populations can be observed at lower levels of BMI. These nuances highlight the importance of ensuring treatment guidelines reflecting the most recent scientific evidence, clinical recommendations, and diagnosis criteria (including BMI), are considered in ensuring Part D plan coverage does not inappropriately impede patient access.

Application to Medicaid

PhRMA supports application of the proposed reinterpretation of the Medicaid rebate statute to ensure coverage of AOMs in Part D and Medicaid. Since both programs rely on the same statutory provision to define coverage exclusions, it follows that CMS should apply the same interpretive principles and not permit state Medicaid plans to exclude or otherwise restrict coverage of AOMs when used for treatment of obesity. Under the Medicaid Drug Rebate Program established in Section 1927, drug manufacturers pay significant rebate payments to state Medicaid programs on the outpatient drugs (such as AOMs) in exchange for state coverage of these medicines. This rebate program allows states to get effectively the lowest net price among payers and provides Medicaid with a significant discount, on average, on brand name drugs.[32] Specifically, CMS estimates in the proposed rule that in 2023 rebates offset Medicaid gross costs by approximately 2/3 for these medicines.[33] States also have flexibility to negotiate supplemental rebates in addition to the mandatory rebates manufacturers pay. States can also use appropriate tools to lower any potential financial burden as they begin to cover AOMs more broadly.

PhRMA appreciates CMS's statement that while states would continue to have the discretion to utilize preferred drug lists and PA to establish certain limitations on the coverage of these drugs, such practices "must be consistent with the requirements of section 1927(d) of the Act to ensure

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30 https://www.ahajournals.org/doi/full/10.1161/01.cir.0000437739.71477.ee?rfr_dat=cr_pub++0pubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org.

31 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. Michael D. Jensen, MD, Donna H. Ryan, MD, Caroline M. Apovian, MD, FACP, Jamy D. Ard, MD, Anthony G. Comuzzie, PhD, Karen A. Donato, SM, Frank B. Hu, MD, PhD, FAHA, Van S. Hubbard, MD, PhD, John M. Jakicic, PhD, Robert F. Kushner, MD, Catherine M. Loria, PhD, FAHA, Barbara E. Millen, DrPH, RD, Cathy A. Nonas, MS, RD, F. Xavier Pi-Sunyer, MD, MPH, June Stevens, PhD, Victor J. Stevens, PhD, Thomas A. Wadden, PhD, Bruce M. Wolfe, MD, and Susan Z. Yanovski, MD. November 12, 2013. https://www.endocrinepractice.org/action/showPdf?pii=S1530-891X%2820%2944630-0.

32 MACPAC. Trends in Medicaid Drug Spending and Rebates. October 2022 https://www.macpac.gov/wp-content/uploads/2022/10/07_Trends-in-Medicaid-Drug-Spending-and-Rebates-Chris.pdf

33 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. Federal Register Vol. 89, No. 237 Tuesday, December 10, 2024. P. 99520 CMS–4208-P

appropriate utilization" and states should not impose conditions for coverage that may unreasonably restrict access to these drugs.

Treatment of Obesity

As we note above, AOMs represent just one important tool in the treatment of obesity, along with lifestyle changes and other interventions. While this new generation of AOMs represents a significant breakthrough in the medical treatment of obesity, CMS and its partners in other parts of the federal government should also continue to take steps to battle chronic obesity with every tool available. Taking these steps aligns with CMS's prior actions to expand coverage of evidence-based obesity interventions which recognize the importance of reducing the burden of chronic illness and its consequences, such as bariatric surgery and intensive behavioral therapy.

Lifestyle modifications are a cornerstone of treatment for many chronic illnesses today. In fact, each of the FDA approved labels for these medicines indicate that they are intended to be used alongside a reduced calorie diet and an increase in physical activity in the treatment of obesity. Some AOMs are also approved alongside these interventions for treatment of patients with diabetes, cardiovascular disease, and sleep apnea.

The supplementary goal of treatment with AOMs is also reflected in clinical treatment guidelines, which recommend the use of AOMs adjunctively to lifestyle, behavioral and surgical obesity interventions, aligning with a patient's individual treatment plan and needs. These recommendations are rooted in research that demonstrates that the addition of these interventions produces improved health outcomes compared to lifestyle modifications alone.

Thus, it is important that CMS consider ways to support Medicare and Medicaid beneficiaries to help them achieve adjunctive, evidence-based lifestyle modifications and other treatment options that complement use of AOMs.

Formulary Inclusion and Placement of "Lower-cost" Medicines

CMS should enhance its monitoring of drug coverage and access in Part D plan formularies post-IRA, both for "lower-cost" drugs and other treatment alternatives. The agency should place emphasis on drug classes with one or more medicines subject to MFP price-setting, which are particularly vulnerable to access disruptions. CMS should ensure evaluation of "lower cost" medicines is based on net cost and require plans and PBMs to share savings with patients at the point of sale.

PhRMA agrees that as plans respond to changes made by the IRA, the agency must increase its monitoring and review of Part D formularies to ensure plans are providing broad access to clinically appropriate treatment options. This need for robust formulary oversight is particularly important as many of the IRA's changes to the Part D benefit take effect in CY 2025, and the first medicines are available at MFP in 2026. Plans face increased risk for the cost of drugs, particularly in the catastrophic phase, and will respond by limiting coverage through narrower formularies and more restrictive utilization management, illustrated in a 2024 survey in which

nine in ten Part D sponsors said they intend to increase coverage restrictions on medicines in the coming years because of the IRA.[34]

Though not limited to drugs selected for MFPs, CMS's oversight of formularies is particularly important to ensure broad access for IRA selected drugs and competitors in their classes. CMS's own draft guidance on MFP cautioned that "Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs."[35]

As PhRMA has noted in comments on CMS' IPAY 2027 MFP guidance, this issue will be important both for MFP-selected drugs and competing medicines.[36] As a result, any beneficiary taking a drug in several classes of serious, prevalent chronic conditions may be at risk for disruptions due to increased UM requirements and/or increased OOP costs. Recent analysis suggests about 4.8 million beneficiaries that are taking anticoagulants, 4.1 million beneficiaries treated for diabetes and 550,000 beneficiaries treated for heart failure could be at risk for formulary disruption because of IRA government price-setting in 2026.[37]

Every patient should benefit from the lower net costs plans and PBMs receive. However, as shown in recent analysis, plan and PBM practices mean that many patients still pay more than the plan does for some lower-cost medicines in Part D.[38] As CMS considers how to best protect beneficiaries from excessive costs, it should require PBMs and health plans to share the savings they receive on medicines directly with patients at the pharmacy counter. This would at long last address the problem of plans hoarding rebates after the point of sale, while beneficiaries pay excessive coinsurance on undiscounted prices.

Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices Under Medicare Part D (§§ 423.100 and 423.120) and Appropriate Cost-Sharing for Covered Insulin Products Under Medicare Part D (§§ 423.100 and 423.120)

CMS should finalize its proposal to codify its existing guidance on vaccine coverage in Part D to ensure that cost is not a barrier to beneficiaries choosing vaccines that can help them prevent and reduce the severity of illness.

Vaccines are an essential public health tool for disease prevention and supporting healthy aging. Every year, the flu vaccine prevents 3.7 million influenza-associated medical visits and

[34] Inflation Reduction Act Payer Insights Report; Chartbook: Summary of Key Findings. August 2024. IRA Payer Insights Report Chartbook Summary of Key Findings.
[35] Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027.
[36] https://phrma.org/en/resource-center/Topics/Open-Letter/PhRMA-Comments-on-IRA-IPAY-2027-Price-Setting-Draft-Guidance
[37] IRA Negotiations May Affect Millions of Medicare Beneficiaries. September 2024. https://avalere.com/insights/ira-negotiations-may-affect-millions-of-medicare-beneficiaries.
[38] Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiaries Spending. GAO 23-105270. September 5, 2023. https://www.gao.gov/products/gao-23-105270

more than 100,000 hospitalizations.[39] Vaccines have also greatly reduced the severity and toll of some diseases across patient's lifespan. For example, respiratory syncytial virus (RSV), a respiratory illness which causes up to 160,000 hospitalizations in older adults annually, can now be prevented with a single dose vaccine which prevents more than 80% of cases.[40]

Medicare Prescription Payment Plan (§§ 423.137, 423.2265, 423.2267, and 423.2536)

CMS should finalize the proposed codification of guidance implementing the Medicare Prescription Payment Plan (MPPP), and its proposal for automatic annual renewals. We continue to urge CMS to implement a true, real-time point-of-sale election option for beneficiaries likely to benefit from the MPPP and support CMS's openness to reconsider the cost thresholds used by plans and the agency for targeted beneficiary outreach.

Among its major changes to the Part D benefit, the IRA enacted a maximum monthly cap on cost sharing program in which Part D enrollees may elect to participate, a program CMS named the Medicare Prescription Payment Plan.

Ensuring successful implementation of the MPPP requires careful policy development and effective outreach to beneficiaries likely to benefit from the program, and we appreciate the opportunity to provide input throughout the development of CMS's implementation. PhRMA has provided extensive input on CMS implementation of the MPPP over the past two years, and we appreciate that some of our recommendations have been incorporated into the guidance that CMS is proposing to codify.[41,42] Therefore, we support the proposal to codify this guidance, and we support the proposed modifications and additions of new requirements to the MPPP for 2026, as detailed below.

Annual Election and Notification

PhRMA supports the proposed automatic annual election renewal process for beneficiaries to continue their participation in the program from year to year. We agree that this process reduces burden for Part D enrollees who would like to remain in the program. It is also consistent with general plan election procedures, where a beneficiary's plan choice remains the same from year to year under CMS's policies for automatic renewal of Part D plan enrollment.

In order for beneficiaries to understand how their MPPP election will continue from year to year, CMS should finalize the proposed requirement for plans to transmit an annual renewal notice to beneficiaries by the end of the annual enrollment period informing them that their participation will continue into the next year, unless they opt out. For this purpose, CMS should develop a model notice, consistent with the model "Likely to Benefit" and "Notice to Acknowledge

[39] Centers for Disease Control and Prevention. Benefits of the Flu Vaccine. https://www.cdc.gov/flu-vaccines-work/benefits/?CDC_AAref_Val=https://www.cdc.gov/flu/vaccines-work/vaccineeffect.htm

[40] Melgar M, Britton A, Roper LE, et al. Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023. MMWR Morb Mortal Wkly Rep 2023;72:793–801. DOI: http://dx.doi.org/10.15585/mmwr.mm7229a4

[41] RE: Medicare Prescription Payment Plan Guidance – Part One. Pharmaceutical Research and Manufacturers of America. September 20, 2023. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/P-R/PhRMA-Comments-on-MPPP-Guidance_Final-92023.pdf.

[42] RE: Medicare Prescription Payment Plan Guidance – Part Two. Pharmaceutical Research and Manufacturers of America. March 15, 2023. https://phrma.org/resource-center/Topics/Medicare/PhRMA-Comments-on-Medicare-Prescription-Payment-Plan-Draft-Part-Two-Guidance

Acceptance of Election" documents CMS has already created for the MPPP. The use of a standard notice for renewals across different plan sponsors will ensure consistency and clarity of message.

We ask that CMS provide a draft notice for public comment, whether through the Paperwork Reduction Act review or other process. This will allow all stakeholders to share input into its development. At a minimum, CMS should work with patient groups and other interested stakeholders for targeted feedback before publication of the notice.

Eligibility and Election

PhRMA reiterates our recommendation for CMS to require a real-time point-of-sale (POS) election option. Much of the benefit of Congress's requirement that pharmacies notify individuals that they would be likely to benefit from MPPP will be lost if the individual cannot immediately act on that notification to elect to participate and avoid the high OOP payment that otherwise could prompt them to abandon their prescription(s). PhRMA appreciates the recognition of this challenge and interest in solutions to address it. We strongly support every effort that moves towards effectuating a true POS option, which would eliminate potential confusion and undue burden for beneficiaries.

Though PhRMA supports the proposal for a plan-facilitated, real-time POS election process, we view this as a temporary solution that can provide a bridge to a truly seamless, pharmacy-facilitated, real-time POS election into MPPP. This option has potential to serve as a stopgap for beneficiaries to elect at the POS while CMS resolves the technological challenges associated with true POS election facilitated by pharmacies.

To better implement this interim approach, we request that CMS provide plans with additional guidelines and requirements for this process to ensure that it is operationalized uniformly and consistently by sponsors. These additional guidelines could include requirements for ensuring beneficiaries can speak to a plan representative in a timely manner to elect over the phone. CMS could also establish firm timeframes for a plan to effectuate a phone or web election request, to reduce the time beneficiaries are waiting at the pharmacy.

Further, we request that CMS adopt additional outreach and education requirements associated with the new plan-facilitated POS election option. For example, the "likely to benefit" notices that pharmacies give beneficiaries at the point-of-sale should explicitly explain how beneficiaries may call or contact their plan online to enroll while at the point of sale and provide clear steps for how beneficiaries can use that option.

The plan-facilitated election process described by CMS may work as an interim solution. But it still falls short for beneficiaries in many respects. The multistep process that CMS describes in the proposed rule is unduly burdensome, and the solution of having beneficiaries make telephone calls to plans by cell phone while standing to the side of the pharmacy counter is not ideal. The amount of time this process could take for beneficiaries, even if their election is made effective immediately, could still result in the abandonment of medications at the pharmacy counter. Additionally, some beneficiaries might not know to return to the pharmacy counter after election to ask the pharmacist to reprocess the claim in order to fill the prescription with no immediate out-of-pocket cost. All of this, as noted above, will require additional education for beneficiaries on how to use this option.

We therefore urge CMS to continue its multi-stakeholder efforts to enact a true pharmacy-facilitated POS election process. We recognize that CMS has researched the technological challenges in adopting this process, concluding that an investment of time and coordination are needed to implement the necessary updates to the National Council for Prescription Drug Programs Telecommunication Standard as well as plan and/or pharmacy benefit manager (PBM) systems. However, this should not pose a barrier to implementation, but instead be a call to action. We urge CMS to begin work with relevant stakeholders towards implementing a true POS election option.

Thresholds for Part D Enrollee Targeted Outreach
Finally, PhRMA appreciates efforts to evaluate and revisit in future rulemaking the threshold at which a plan must make targeted outreach to beneficiaries and notify them they are likely to benefit from election into MPPP.

We agree with CMS's current overall framework for determining these thresholds. In the future we suggest CMS also investigate the following:

a. Mean and median annual and average monthly out-of-pocket costs of enrollees who elect to participate in MPPP. This will allow CMS to "pressure test" its assumptions of who will benefit from MPPP against beneficiaries' own assessments.
b. Mean and median annual and average monthly out-of-pocket costs of enrollees notified that they were likely to benefit but who did not elect to participate. Like data on those who participated, this data will also allow CMS to investigate which beneficiaries disagreed with CMS's assessment of likelihood of benefit. This assessment should investigate each mechanism of notification (at the POS, by the plan sponsor prior to the plan year, and by the plan sponsor during to the plan year).
c. Enrollees who met the annual out-of-pocket cap. Assessing the number of enrollees who meet the annual out-of-pocket cap and determining which ones were notified or not notified that they were likely to benefit from MPPP, as well as the distribution of the month in which they met the cap, should provide a good point of comparison for CMS's estimates.

Monitoring, Compliance and Data Submission Requirements

PhRMA continues to support and encourage CMS's efforts to conduct oversight and monitoring of the implementation of MPPP at both the plan and beneficiary levels. Through this oversight, CMS must ensure that the program is implemented in a manner that is fair and equitable to all Medicare beneficiaries.

To bolster this effort, we encourage CMS to collect and evaluate MPPP-related data in ways that capture any differences in MPPP outreach efforts against certain beneficiary groups, including those with lower incomes or certain health conditions or diagnoses within Part D. Additionally, we recommend that CMS annually report MPPP data on total enrollment with more detailed data breakdowns by beneficiary subgroups and demographics.

Part D Medication Therapy Management Program Eligibility Criteria (§ 423.153(d)(2))

CMS should finalize its proposal to create an expanded "Alzheimer's disease and dementia" classification as part of the program. In addition, CMS should finalize proposals considered, but not adopted, in 2024 rulemaking to reduce the maximum number of Part D drugs that may be required for targeted MTM enrollment, and to set the MTM cost threshold at the average cost of five generic drugs.

The Medication Therapy Management (MTM) program is designed to improve medication use, reduce the risk of adverse events, and improve medication adherence among individuals with chronic conditions who take multiple medications to ensure the best therapeutic outcomes for patients. The MTM services are important for Medicare beneficiaries, two-thirds of whom have at least two or more chronic conditions requiring treatment with medication, and we appreciate efforts to strengthen the program and maximize its effectiveness.[43]

The proposed change to expand to a combined "Alzheimer's disease and dementia" classification responds to comments to CMS's CY 2025 proposed rule and will give greater access to MTM to a vulnerable population who would benefit from it.

CMS should continue to carefully evaluate its MTM eligibility criteria each year to ensure the program is achieving its objectives of improving pharmaceutical care and health outcomes. To this end, we ask that CMS prioritize review of beneficiary-level MTM program data to evaluate the MTM program's effectiveness and identify further potential improvements.

Finally, we recommend that CMS finalize two proposals considered but not adopted in the CY 2024 rulemaking. CMS did not adopt a proposal to decrease from eight to five the maximum number of Part D drugs a sponsor may require for targeted MTM enrollment. CMS also did not finalize the proposal to set the MTM cost threshold at the average cost of five generic drugs.[44] These changes are important to address the risk that, if eligibility is limited to beneficiaries with high drug use and high spending, the program would systematically exclude nonadherent beneficiaries who could benefit from these services. At the time, CMS noted "concerns about increased burden and costs, current pharmacy and vendor shortages, and other resource challenges due to the combination of Medicare Advantage (MA) and Part D program policy changes plan sponsors must implement over the next several years" as grounds for not finalizing this proposal.[45] As any upcoming rulemaking on this topic would not be effective until CY 2027, when plans will have completed the implementation of the IRA's Part D benefit redesign, it may be time to reconsider plan capacity for undertaking this expansion of the MTM program. We encourage CMS to propose in future rulemaking to decrease the number of required drugs and associated cost threshold for MTM eligibility.

Finally, we would caution that as health plan pharmacists engage patients in MTM services to identify potential medication interactions and other potential challenges, MTM programs should not be a substitute for health care decision-making that takes place between patients and their physicians.

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[43] Yengar RN, LeFrancois AL, Henderson RR, Rabbitt RM. Medication Nonadherence Among Medicare Beneficiaries with Comorbid Chronic Conditions: Influence of Pharmacy Dispensing Channel. J Manag Care Spec Pharm. 2016 May;22(5):550-60. doi: 10.18553/jmcp.2016.22.5.550. PMID: 27123916.
[44] 89 Fed. Reg. at 30478.
[45] 89 Fed. Reg. 30448, 30477 (April 23, 2024).

Administration of Supplemental Benefits Coverage through Debit Cards (§§ 422.2, 422.102, 422.102, 422.111, and 422.2263)

CMS should continue its efforts to better understand MA supplemental benefits and should analyze and report on health outcomes comparing impact of supplemental benefits compared to using rebate dollars to lower out-of-pocket costs for medicines.

Rebates received by MA plans have more than doubled since 2018, with some MA plans receiving a record high average rebate of $3,090 per member per year to use toward supplemental benefits or lowering beneficiary out-of-pocket costs in 2024.[46] However, the percentage of the rebate that plans are predicted to use to reduce beneficiaries' premium costs has decreased in recent years, from 43% in 2021 to 39% in 2023.[47] While reduced premiums provide a direct benefit to enrollees, the impact of other types of supplemental benefits, such as non-Medicare services, is less clear.

PhRMA agrees it is important to better understand the use and impact of supplemental benefits through recent encounter data submission requirements and through the clarity surrounding use the use of debit cards specifically that this rule seeks to provide**.** Given that spending on MA supplemental benefits has experienced consistent growth in recent years, we recommend CMS regularly analyze and report plan-level data on supplemental benefits to assess their impact on health outcomes compared to the use of rebate dollars to lower premiums beneficiaries must pay. This analysis would help stakeholders to better understand the full range of non-Medicare supplemental benefits and the value of these benefits to beneficiaries compared to directly lowering beneficiary OOP costs.

Ensuring Equitable Access to Medicare Advantage Services – Guardrails for Artificial Intelligence (§422.112)

CMS should take action to establish patient-focused guardrails for AI. We appreciate CMS's reminder that if MA organizations choose to use AI tools or automated systems in any manner, this use must be compliant with all existing Medicare policies. While AI represents a powerful tool in health care that can create certain efficiencies by reducing administrative burden, it must be responsibly used with appropriate accountability mechanisms so as not to further impede or delay access to care.

The use of AI tools in health care holds promising potential to help develop new treatments, improve patient experience with care delivery and outcomes, while reducing administrative burdens and overall health care spending.[48,49] However, as with any new technology, if not used responsibly, AI tools can also be used to systematically deny coverage or discourage enrollment. Similarly, if trained on biased or incomplete data, AI could worsen existing health

[46] MedPAC. October 2024.
[47] MedPAC. March 2023 Report to the Congress: Medicare Payment Policy. March 2023. https://www.medpac.gov/document/march-2023-report-to-the-congress-medicare-payment-policy/.
[48] United States House of Representatives. Bipartisan House Task Force Report on Artificial Intelligence. December 2024. https://www.speaker.gov/wp-content/uploads/2024/12/AI-Task-Force-Report-FINAL.pdf
[49] The White House. Delivering on the Promise of AI to Improve Health Outcomes. December 14, 2023. www.whitehouse.gov/briefing-room/blog/2023/12/14/delivering-on-the-promise-ofai-to-improve-health-outcomes/

disparities in access and outcomes.[50] PhRMA supports guardrails on the use of AI with the shared goal of using AI and deploying AI-tools in a safe, responsible manner that supports early care interventions and disease prevention; fosters well-informed, shared patient-clinician decision-making; and enables patients – including vulnerable populations and those subject to health disparities who have heterogenous health needs – to obtain access to the medicines they need in a more timely manner.

In addition to compliance and enforcement activities, we encourage CMS to consider efforts to increase transparency into the extent to which AI tools are used in health care decision-making, particularly the role of algorithms in utilization management tools. A recent U.S. Senate report outlined concerning examples of how AI and predictive technologies may have contributed to higher volumes of prior authorization denial rates for post-acute care by MA plans.[51] PhRMA has longstanding concerns that the inappropriate use of prior authorization and utilization management in MA is impeding access to clinically important physician-administered (Part B) medicines[52]. Similarly, while UM represents an important tool for health plan negotiation in Part D, we share the concerns of many patient advocates that misuse of UM tools in overly aggressive ways in Part D is creating barriers to access to clinically important treatment options in this program as well[53]. These existing access barriers to services and medicines could be worsened if AI is utilized for decision-making process without guardrails, which is why it is critical that CMS implements safeguards and accountability measures to protect against bias and prevent further exacerbating health inequities.

As CMS considers AI-related policies in the future, it will be important to operate from a common framework and vocabulary to ensure consistency across other federal efforts. We commend the Food and Drug Administration (FDA) on its Digital Health and Artificial Intelligence Glossary,[54] and encourage its broad adoption to facilitate harmonization across other agencies as well as with other regulators. PhRMA also encourages Agency collaboration with the National Institute of Standards and Technology (NIST) and other U.S. government entities in developing and/or adopting best practices and standards that can be used to facilitate understanding and share case studies across industries.

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[50] Consumer Health Advocacy at the NAIC. Artificial Intelligence in Health Insurance: the use and regulation of AI in utilization management. November 14, 2024. https://content.naic.org/sites/default/files/national_meeting/Final-CR-Report-AI-and-Health-Insurance-11.14.24.pdf

[51] U.S. Senate Permanent Subcommittee on Investigations. Refusal of Recovery: How Medicare Advantage Insurers have Denied Patients Access to Post-Acute Care. October 17, 2024. https://www.hsgac.senate.gov/wp-content/uploads/2024.10.17-PSI-Majority-Staff-Report-on-Medicare-Advantage.pdf

[52] See PhRMA Comments on Medicare and Medicaid Programs: Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, etc, 87 Fed. Reg. 76238 (March 13, 2023), https://www.regulations.gov/comment/CMS-2022-0190-0875

53 American Cancer Society Cancer Action Network (ACS CAN). Step Therapy in Medicare Part D Oncology Drugs. May 2024. https://www.fightcancer.org/sites/default/files/acs_can_part_d_formulary_analysis_final.pdf; Joyce, Geoffrey, et al. "Medicare Part D Plans Greatly Increased Utilization Restrictions On Prescription Drugs, 2011–20: Study examines Medicare Part D restrictions." *Health Affairs* 43.3 (2024): 391-397.

[54] FDA. FDA Digital Health and Artificial Intelligence Glossary – Educational Resource. Available at https://www.fda.gov/science-research/artificial-intelligence-and-medical-products/fda-digital-health-and-artificial-intelligence-glossary-educational-resource.

Ensuring Equitable Access – Enhancing Health Equity Analysis: Annual Health Equity Analysis of Utilization Management (§422.137)

CMS should finalize its proposal to strengthen its analysis on the use of prior authorization for items and services.

CMS's proposal to disaggregate the required analysis metrics on PA by each item and service at the plan level is important for assessing the real-world impact of PA. We reiterate our recommendations made in prior comments to establish broader plan reporting requirements to evaluate the impact of PA. CMS has responsibility in its oversight of the MA program to ensure that beneficiaries are receiving medically necessary treatment in a timely manner. PhRMA has supported CMS's efforts in this area through the CY 2024 and CY 2025 rules.
As our prior comment letters to CMS on those rules make clear, we have concerns that the use of PA and other forms of UM in MA can create inappropriate access barriers for patients—not only for services, but for medicines as well.[55,56] While we supported and continue to support these proposed requirements for MA organizations, we urge CMS to adopt a similar approach monitoring PA and other UM tools with respect to medicines.

In response to the specific changes CMS proposes in this rule, PhRMA supports the proposal to change the health equity analysis of the use of PA by requiring plans to disaggregate the required analysis metrics by each item and service. This additional level of transparency is necessary to gain an understanding of how plans are using PA regarding items and services.

In addition, CMS should finalize the proposal to add an executive summary to plans' publicly available report of the results of the health equity analysis. Given CMS's requirement to report by each item and service, it would be beneficial to have the primary findings be highlighted in an executive summary in a manner that is easily understandable and accessible for beneficiaries or other interested members of the public. As such, the executive summary should be required to adhere to accessibility and plain language standards to ensure that the information being provided is clear.

PhRMA understands CMS's caution about beneficiary privacy potentially being put at risk through the disaggregation of metrics with smaller data sets. Therefore, we agree with the allowance of cell suppression for these instances to protect beneficiary privacy. However, we ask that CMS set requirements for how MA plans are allowed to do this to ensure consistency and uniformity. For this purpose, we recommend that CMS use a variation of the current cell suppression policy used for data use agreements.[57]

Finally, we encourage CMS to build on this momentum and establish a similar approach to ensuring proper access to care in Part D. With over 50 million beneficiaries enrolled in Part D plans, PhRMA urges CMS to push further with its data collection authority to better understand Part D plan design and barriers to patient access, and to identify regulatory changes that seek to address these barriers. This is especially important as we confront a new landscape of plan

[55] RE: PhRMA Comments on CY 2025 Policy and Technical Changes to Medicare Advantage and Medicare Part D. January 2024. https://www.regulations.gov/comment/CMS-2023-0187-3047
[56] RE: PhRMA Comments on Medicare Advantage Data RFI. May 2024. https://www.regulations.gov/comment/CMS-2024-0008-0369
[57] CMS. CMS Cell Suppression Policy. November 30, 2024. https://www.hhs.gov/guidance/document/cms-cell-suppression-policy.

liability and the potential that Part D beneficiaries could encounter more restrictive formularies in the future, coupled with insurance market changes that are leaving beneficiaries with fewer plan options.[58]

Medicare Advantage Network Adequacy (§ 422.116)

PhRMA strongly supports continued efforts to enhance network adequacy requirements.

Timely access to care is dependent on beneficiary access to a robust provider network. When an MA plan fails to offer a sufficiently robust network, the health of its enrollees can suffer. Not only do we support conducting network reviews at the plan benefit package level rather than the contract level, PhRMA believes there is an additional opportunity for CMS to expand these efforts by releasing plan-level data and conducting studies on the impact that limited benefits and restrictive provider networks have on beneficiaries' health.

Although network-based MA plans are required to provide, at minimum, 85% to 90% of their enrollees with access to at least one in-network provider/facility of each specialty type within the published time and distance standards,[59] disparities in the adequacy of care and the availability of services for historically underrepresented populations are well-documented.[60,61,62] Regulatory requirements regarding access are driven by policies that consider "time and distance", which can vary substantially.[63] We understand that network-based MA plans must follow network adequacy requirements; however, we remain concerned that, in practice, plan networks may often be too narrow to provide timely, affordable access to in-network providers, especially specialists.

Conducting network reviews at plan level would more narrowly tailor the review to match the actual provider access allowed to specific plans. CMS could reduce burden on itself and plans by allowing plans to attest that specific PBPs have the same network. This would allow CMS to focus its plan level reviews where the plans actually differ. Given the lack of defined requirements beyond time and distance, beneficiaries often must seek care out-of-network, which can result in high OOP costs. For example, while MA enrollees typically have up to 20% coinsurance for Part B drugs, which is already challenging for many patients to afford, beneficiary cost sharing may increase if a drug is administered by out-of-network providers. According to a KFF analysis of MA enrollees with out-of-network coverage, 44% of enrollees

[58] . Medicare Part D in 2024: A First Look at Prescription Drug Plan Availability, Premiums, and Cost Sharing. KFF. November 2023. https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2024-a-first-look-at-prescription-drug-plan-availability-premiums-and-cost-sharing.
[59] CMS. Contract Year 2025 Policy and Technical Changes to the MA Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE). April 2024. https://www.federalregister.gov/documents/2024/04/23/2024-07105/medicare-program-changes-to-the-medicare-advantage-and-the-medicare-prescription-drug-benefit.
[60] Network Adequacy and Health Equity: Improving Private Health Insurance Provider Networks for Communities of Color. Families USA. August 2014. https://familiesusa.org/wp-content/uploads/2019/09/ACT_Network-Adequacy-Brief_final_082214_web.pdf.
[61] Feyman Y, Figueroa J, Garrido M, Jacobson G, Adelberg M, Frakt A. Restrictiveness of Medicare Advantage provider networks across physician specialties. August 2024. Health Serv Res. 59(4):e14308. doi: 10.1111/1475-6773.14308.
[62] CMS. Rural-Urban Disparities in Health Care in Medicare. November 2024. https://www.cms.gov/files/document/rural-urban-disparities-health-care-medicare-2024.pdf
[63] §422.116; CFR-2020-title42-vol3-sec422-116.pdf (govinfo.gov).

(about3.7 million) would be charged cost sharing that is greater than 20% for Part B drugs if administered by an out-of-network provider.[64]

Network adequacy standards can improve access to care for all MA enrollees, including residents of rural counties. PhRMA strongly encourages CMS to study further the health disparities created by unexpected, out-of-network costs. For example, a recent study cited significant barriers for MA beneficiaries in rural areas, with challenges in gaining access to care because of restrictive provider networks.[65] We request that CMS collect and release plan-level data on the number of MA enrollees who receive care out-of-network, including data about beneficiary characteristics, health conditions, and the associated OOP costs.
In addition, CMS should consider conducting more robust studies on the impact that narrow networks have on MA beneficiaries delaying or forgoing care. Further, CMS should continuously monitor and analyze data on provider capacity to evaluate if adequacy requirements are resulting in meaningful access for patients by assessing patient experience and treatment compliance.

Format Medicare Advantage Organizations' Provider Directories for Medicare Plan Finder (§§ 422.111 and 422.2265)

PhRMA supports efforts to require plans to share complete and accurate provider directory data to update Medicare Plan Finder (MPF).

Enrollees in MA plans rely on provider directories to access in-network care. These directories are supposed to be helpful resources to help both prospective and current enrollees understand the breadth of a plan's network or whether their provider of choice is in-network. However, inaccurate provider information in provider directories makes this difficult. In particular, "ghost networks"[66], inaccurate or out-of-date information on which providers are in a health plan's network, misdirects patients toward providers who may no longer be practicing medicine, accepting new patients, or are no longer in-network with their plan. These challenges continue to be a pervasive issue impacting MA enrollees and their caregivers. The burden caused by inaccurate provider directories extends beyond inconvenience and could lead to delayed treatment or unexpected costs if a patient unknowingly sees an out-of-network provider. And the ghost networks appear to be pervasive: a 2023 Senate Finance Committee study of 12 MA plans across six states found that more than 80% of listed mental health practitioners that staff attempted to contact were either unreachable, not accepting new patients, or out-of-network.[67]

[64] Medicare Part B Drugs: Cost Implications for Beneficiaries in Traditional Medicare and Medicare Advantage. KFF. March 2022. https://www.kff.org/medicare/issue-brief/medicare-part-b-drugs-cost-implications-for-beneficiaries-in-traditional-medicare-and-medicare-advantage/#:~:text=Beneficiaries%20enrolled%20in%20Medicare%20Advantage%20plans%20%E2%80%93%20which,in-network%20and%20out-of-network%20cost%20sharing%20combined%20in%202022%29.
[65] Health Affairs. Rural Enrollees in Medicare Advantage Have Substantial Rates Of Switching To Traditional Medicare. (2021). https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01435.
[66] GAO. Mental Health Care: Access Challenges for Covered Consumers and Relevant Federal Efforts. March 2022. https://www.gao.gov/assets/gao-22-104597.pdf.
[67] Senate Finance Committee. Majority Study Findings: Medicare Advantage Plan Directories Haunted by Ghost Networks. May 2023. https://www.finance.senate.gov/imo/media/doc/050323%20Ghost%20Network%20Hearing%20-%20Secret%20Shopper%20Study%20Report.pdf.

Furthermore, inaccurate provider networks may exacerbate challenges in access to healthcare in areas already riddled with provider shortages such as rural and underserved areas.[68,69] MA enrollees should have confidence that the providers their MA plan advertises are truly accessible and available to them, and MA organizations should be held accountable for promptly and accurately updating their directories.

PhRMA supports efforts to require plans to share complete and accurate provider directory data to update Medicare Plan Finder (MPF). As an increasing number of beneficiaries access health care coverage through MA plans, it is critical that beneficiaries and their caregivers are empowered to make informed decisions when selecting a plan that contracts with their preferred providers—and current enrollees should be able to easily find in-network providers when seeking care. PhRMA encourages CMS to regularly monitor plans' directories to measure whether the prevalence of ghost entries declines as a result of these changes, and to consider further oversight if the ghost networks persist. Alternatively, to promote greater accuracy and consistency of directory data, CMS could consider collecting directory data at a centralized point within the Agency, rather than relying on verification from each individual plan.

Timely Submission Requirements for Prescription Drug Event Records (§423.325):

PDE Submission Deadline

PhRMA appreciates the solicitation of comments on the operational considerations of shortening the timeframe for submission of initial PDE records for selected drugs to seven calendar days.

PhRMA shares CMS's goal of ensuring that dispensers receive payment of retrospective Maximum Fair Price (MFP) refunds in a timely manner. We recognize that one way to help achieve timely payment to dispensers is by shortening the PDE record submission window for Part D plans to submit to the Drug Data Processing System. Of note, we caution that shortening this window could impact the volume of claims adjustments that occur during and after the proposed MFP payment window as well as the impact on data integrity. PhRMA requests that CMS monitor whether the shortened timeframe would lead to a higher number of claims adjustments.

Furthermore, PhRMA urges CMS to allow Primary Manufacturers to have the ability to audit the PDE data on selected drugs submitted from Part D plan sponsors. This will ensure heightened scrutiny for data integrity and ensure supplemental mechanisms are in place to address underlying data concerns stemming from implementation of the IRA.

Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements:

Dispenser Participation in the Medicare Transaction Facilitator Data Module (MTF DM)

[68] US Government Accountability Office. Physician Workforce: Locations and Types of Graduate Training Were Largely Unchanged, and Federal Efforts May Not Be Sufficient to Meet Needs. GAO-17–411. US Government Accountability Office; 2017.
[69] Rural Health Information Hub. Physicians per 10,000 People for Metro and Nonmetro Counties, 2019. https://www.ruralhealthinfo.org/charts/109

In order to ensure that access to the MFP is provided to Part D enrollees and dispensing entities in a timely and efficient manner, PhRMA believes all stakeholders that will provide and/or utilize data for purposes of MFP effectuation should participate in the MTF DM. A more robust data set from all participants is necessary for verification. PhRMA previously submitted comments in response to the draft Guidance for IPAY 2027 in which we outline this in more detail, under Section 40.4.1.[70]

Proposed Regulatory Changes to Medicare Advantage and Part D Medical Loss Ratio Standards (§§ 422.2401, 422.2420, 422.2430, 422.2450, 422.2452, 422.2454, 422.2460, 422.2480, 422.2490, 423.2401, 423.2420, 423.2430, 423.2450, 423. 2452, 423.2454, 423.2480, 423.2490)

PhRMA supports consideration of steps to strengthen standards and oversight of MLR requirements for MA plans and offers recommendations for further strengthening these standards beyond what the agency proposes. These steps are needed to address concerns that current rules may not be adequate to address new challenges created by large vertically integrated plans and their PBM and provider affiliates.

Significant vertical integration among health care financing and delivery companies such as health insurers, PBMs, pharmacies, and providers represents a serious barrier to improved competition and efficiency in health care. PhRMA appreciates the recognition of the importance of this issue and urges CMS to take steps in the near-term to address it.

CMS proposes adding regulations to establish an audit process that validates MA organization and Part D sponsors' Medical Loss Ratio (MLR) compliance. If, in establishing this process, CMS finds noncompliance through the audit, CMS would pursue certain actions, including determining remittances owed and issuing Corrective Action Plans. PhRMA asks CMS to reconsider its proposal of limiting audits to contracts with MLRs that exceed an 85% threshold. The fact that a contract falls below 85% and therefore owes a remittance to CMS is not indicative that the reporting is any more accurate than a contract at or above 85%. Plans that expect to fall below 85% may pay lower remittances if MLRs appear as high as possible and should have a similar probability of being audited.

Further, PhRMA is concerned that large MA and Part D plans may be able to manipulate MLR calculations by leveraging their vertical integration with care providers, PBMs, and other affiliates.[71] We highlight here particular areas of concern, including vertically integrated plans/PBMs' ownership of (1) rebate aggregators or so-called "group purchasing organizations" and (2) ownership of pharmacies, providers, and PBM affiliates, but we urge CMS to continue to scrutinize plans' financial relationships with all types of affiliated entities. Plans' potential to manipulate the MLR calculation through vertical integration further supports our recommendation that CMS should not limit its proposed audit process to contracts with an MLR greater than 85%.

Vertical Integration and MLR Reporting in MA and Part D

[70] https://phrma.org/en/resource-center/Topics/Open-Letter/PhRMA-Comments-on-IRA-IPAY-2027-Price-Setting-Draft-Guidance

[71] Axios. Profits Swell When Insurers Are Also Your Doctors. July 2021. https://www.axios.com/2021/07/16/unitedhealth-optum-providers-intercompany-eliminations

CMS requests information on MLR and vertical integration in MA and Part D plans. Vertically integrated relationships between insurers, PBMs, pharmacies, and providers are becoming increasingly common.[72] These relationships are riddled with conflicts of interest, which often go unchecked due to the lack of transparency in the system.
Despite their already considerable negotiating power, each of the three largest insurer/PBM conglomerates have acquired other health care stakeholders, including providers and pharmacies, and have created separated rebate aggregators which they refer to as "group purchasing organizations (GPOs)."[73, 74] These "PBM GPOs," which are responsible for negotiating, collecting, and disbursing manufacturer rebates, introduce an additional non-transparent middleman to an already complex vertically integrated system. Experts have raised concerns that "PBM GPOs" likely increase costs without providing any direct benefits for patients or additional savings for employers and plan sponsors.[75, 76]

Recent events, including a lawsuit settled by a PBM and an Office of Inspector General audit, suggest that "PBM GPOs" may not always report and pass through manufacturer rebates to plan sponsors, and that such improprieties may be occurring in both their commercial and federal health care program lines of business.[77, 78] The Part D MLR regulation requires that all direct and indirect remuneration reduce the plan's MLR numerator, which should include all rebates paid to intermediaries, including "PBM GPOs".[79] CMS should closely scrutinize whether "PBM GPOs" are being used to negotiate or collect rebates in Part D, and if they are being used in Part D, take steps to ensure plans are appropriately reporting amounts collected by their vertically integrated PBMs, "PBM GPOs," and other affiliates.

The common corporate ownership of MA organizations and PDP sponsors and related health care businesses may also allow these corporations to strategically inflate payments to affiliated entities, such as pharmacies and providers, to increase the MLR numerator to the detriment of the intent of the MLR requirement to ensure patient care is prioritized over profits and administrative expenses. These entities also have engaged in commercializing biosimilars through their own affiliates, which they then add to their formularies as preferred products.[80]
For years, plans and PBMs have paid below-cost reimbursement rates to retail and specialty pharmacies, with the effect of driving independent and major non-affiliated specialty pharmacies

[72] Fein. AJ. Mapping the Vertical Integration of Insurers, PBMs, Specialty Pharmacies, and Providers. A May 2024 Update. Drug Channels. May 7, 2024. https://www.drugchannels.net/2024/05/mapping-vertical-integration-of.html
[73] Express Scripts. Group Purchasing Organizations and Ascent. https://express-scriptsfacts.com/key-topics/group-purchasing-organizations-ascent/.
[74] Nephron Research. Optum Launches 'Emisar' Contracting Entity; Navitus Aligns with Ascent via Prime. July 2021.
[75] Livingston S. Powerful drug-industry middlemen have quietly launched businesses to get better deals from drugmakers. It could drive up costs for patients. Business Insider. November 22, 2021. https://www.businessinsider.com/inside-pharmacy-benefit-managers-new-drug-negotiating-businesses-2021-11.
[76] Drug Channels. Five (or Maybe Six?) Reasons that the Largest PBMs Operate Group Purchasing Organizations. May 24, 2023. https://www.drugchannels.net/2023/05/five-or-maybe-six-reasons-that-largest.html.
[77] Silverman E. CVS and its PBM agree to pay $45 million to Illinois for failing to pass drug rebates. STAT+. July 23, 2024. https://www.statnews.com/pharmalot/2024/07/23/cvs-caremark-pbm-illinois-medicines-rebates-ftc/
[78] Office of Personnel Management Inspector General. Audit of the American Postal Workers Union Health Plan's Pharmacy Operations as Administered by Express Scripts, Inc. for Contract Years 2016 through 2021. March 29, 2024. https://oig.opm.gov/reports/audit/audit-american-postal-workers-union-health-plans-pharmacy-operations-administered-0
[79] 42 C.F.R. § 423.2420(b)(2).
[80] Fein AJ. "What's Behind CVS Health's Novel Vertical Integration Strategy for Humira Biosimilars." Drug Channels. September 6, 2023. https://www.drugchannels.net/2023/09/whats-behind-cvs-healths-novel-vertical.html.

out of business or leading to their purchase by an insurance conglomerate.[81] Meanwhile, PBM-owned pharmacies have become a significant source of revenue to their parent organizations.[82] A recent report found that PBMs mark up medicines dispensed at the pharmacies they own by up to thousands of percent. The report found that 63% of the specialty generic drugs dispensed by PBM-affiliated pharmacies were marked up by more than 100%, and 22% had markups over 1,000%.[83]

The net payments Part D plan sponsors make to PBM-owned specialty, mail-order, or retail pharmacies are included in the MLR numerator as a claims expense. For vertically integrated Part D sponsors, PBM, and pharmacy conglomerates, this creates an opportunity to pay an affiliated entity an inflated amount to retain an increased profit from a provider entity that is not subject to an MLR or MLR reporting requirements. Recent analysis by the Medicare Payment Advisory Commission (MedPAC) suggests that such behavior is occurring in Part D, with vertically integrated plan sponsors commonly reimbursing the pharmacies they own at higher rates than non-vertically integrated pharmacies.[84]

Even where unaffiliated pharmacies still exist, the conglomerates are able to use their owned affiliates to manipulate the market. For example, the recent trend of vertically integrated Part D plan sponsors developing subsidiaries to commercialize biosimilars and then placing these drugs on their formularies enables issuers to benefit from the sale of their own products while potentially claiming it as a "cost."[85] For these reasons, we recommend that CMS require vertically integrated issuers to separately report amounts paid to affiliated entities included in the MLR numerator.

Request for Information on MLR Regulatory Calculation Changes

CMS additionally requests further information on potential policies related to how MA and Part D plans calculate MLR to address areas of vertical integration and develop subsequent rulemaking.

Two policies under consideration include: 1) revising the definition of incurred claims to include profits earned by related parties as indirect remuneration to a Part D sponsor or MA organization and not allowable for inclusion in the MLR numerator, and 2) revising the definition of incurred claims to include payments that are net of direct or indirect remuneration by or to the Parent Organization, in addition to the Part D sponsor. These policies would seek to prevent vertically integrated Part D plan sponsors and PBMs from adjusting their reimbursement costs, such as those to pharmacies they own, or for products in which they have a financial interest, to

[81] Federal Trade Commission. Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies. Interim Staff Report. July 2024. https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf
[82] New York Times. The Powerful Companies Driving Local Drugstores out of Business. October 2024. https://www.nytimes.com/2024/10/19/business/drugstores-closing-pbm-pharmacy.html
[83] Federal Trade Commission. Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers. January 2025. https://www.ftc.gov/reports/specialty-generic-drugs-growing-profit-center-vertically-integrated-pharmacy-benefit-managers
[84] MedPAC. Report to the Congress: Medicare and the Health Care Delivery System. June 2023. https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch2_MedPAC_Report_To_Congress_ SEC.pdf
[85] Fein AJ. "What's Behind CVS Health's Novel Vertical Integration Strategy for Humira Biosimilars." Drug Channels. September 6, 2023. https://www.drugchannels.net/2023/09/whats-behind-cvs-healths-novel-vertical.html.

increase or decrease MLR factors. CMS should clarify the Part D rules and MLR reporting instructions to ensure all rebate or similar payments to plan affiliates or intermediaries reduce the MLR numerator. Under subsequent rulemaking, CMS should develop more detailed definitions of the types of vertically integrated entities that are subject to MLR requirements and a more robust reporting structure.

CMS additionally asks for comment on policies to establish a framework for assessing transfer payments made to or by related parties by expanding related-party reporting requirements in the MLR and what types of information CMS could collect about transfer payments to be able to assess what portions of such payments should be reported in the MLR numerator. The use of intercompany eliminations has risen steadily in recent years, and now account for a significant share of vertically integrated organizations' total revenue. For example, more than $49 billion of the combined $273 billion in CVS Pharmacy and CVS Healthcare services' revenues resulted from transactions between these two segments.[86] PhRMA urges CMS to ensure that all vertically integrated insurers and PBMs operating under MA and Part D plans maintain compliance with MLR standards, including through reporting transfer payments that are incurred between vertically integrated entities that seek to evade the intent of MLR regulatory safeguards through the acquisition of other health care system stakeholders such as providers and pharmacies. A framework for assessing transfer payments would be a welcome first step to addressing intercompany eliminations and should include all vertically integrated entities' revenue sources that relate to claims payments.

Enhancing Rules on Internal Coverage Criteria (§ 422.101)

PhRMA has longstanding concerns about MA plans' use of PA and other forms of utilization management, and we applaud efforts to improve transparency and oversight.

While PhRMA remains neutral on the specific Internal Coverage Criteria-related proposals included in this portion of the proposed rule, we applaud efforts to introduce more transparency and oversight into MA organizations' coverage policies of Part A and Part B items and services, including medicines. However, in line with our comments on the December 2022 proposed rule[87], PhRMA reiterates our longstanding concerns that MA plans' use of restrictive network requirements, PA and other forms of utilization management can create access barriers for patients – not only for health care services in Parts A and B but also for medicines.

Section 1852(a) of the Social Security Act requires that MA plans cover the same benefits covered under fee-for-service Part A and Part B.[88] However, we note our concern that patient access to important provider-administered therapies is often made more stringent in MA through network requirements and step therapy (a form of UM). For example, some MA plans have established coverage criteria via accreditation requirements that limit the delivery of chimeric antigen receptor T-cell (CAR-T) therapy to a narrower set of treatment centers than the

[86] Fein A. The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Drug Channels Institute, March 2024.
[87] See PhRMA Comments on Medicare and Medicaid Programs: Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, etc, 87 Fed. Reg. 76238 (March 13, 2023), https://www.regulations.gov/comment/CMS-2022-0190-0875
[88] With certain limited exceptions not pertinent here.

Medicare FFS program.[89] These accreditation requirements conflict with the 2019 CMS Medicare National Coverage Determination (NCD) on CAR-T Therapy for Cancers[90], in which CMS explicitly considered, but rejected requiring CAR-T administration at a Foundation for Accreditation of Cellular Therapy (FACT)-accredited facility. Importantly, MA plans characterize this requirement as a condition of coverage, even though it more closely resembles a network requirement since it governs a provider's ability to furnish CAR-T irrespective of the patient's eligibility for the treatment. This case study is only one example of how MA plans impose barriers to enrollee access.

Further, recent findings illuminate how MA organizations are using increased PA and step therapy in their plans, which in effect are restricting MA beneficiaries' access to comprehensive and clinically appropriate care compared to beneficiaries in original Medicare. For example, a 2022 HHS OIG study analyzed a sample of PA and payment denials from the 15 largest MA organizations and found that 13% of PA denials and 18% of denied payment requests were for services that met Medicare coverage rules and likely would have been covered under traditional Medicare.[91] Further, a 2024 analysis from Avalere found that in 2023, MA enrollees faced step therapy requirements (e.g., requiring patients to try and fail on one or more medicines before covering another medicine) 54% of the time, on average, across a list of ten commonly-used rheumatoid arthritis biologics covered under Part B.[92] Beyond undermining physicians' prescribing autonomy, such step therapy requirements may hinder treatment adherence[93] and lead to worse health outcomes.[94, 95]

CMS states in the proposed rule that "the ability of the MA organization to decide which items and services are subject to PA is not subject to rules on internal coverage criteria at §422.101(b)(6)." CMS also notes, however, that "ensuring access to covered benefits is an important policy goal for CMS in administering the MA program and we have concluded that it is necessary and appropriate to adopt specific requirements for how basic benefits are covered to ensure that MA enrollees receive the items and services for which benefits are available under

[89] See select payer policies (Anthem Centers of Medical Excellence Program, Cigna LIfeSOURCE, Humana National Transplant Network, United/Optum Transplant Network)
[90] CMS. NCD: Chimeric Antigen Receptor (CAR) T-cell Therapy. August 2019. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374
[91] HHS OIG. Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care. April 2022. https://oig.hhs.gov/reports/all/2022/some-medicare-advantage-organization-denials-of-prior-authorization-requests-raise-concerns-about-beneficiary-access-to-medically-necessary-care/.
[92] Avalere. MA Plans Increase Use of Step Therapy for Part B drugs. May 2024. https://avalere.com/insights/ma-plans-increase-use-of-step-therapy-for-part-b-drugs.
[93] Xcenda. The Impact of Step-Therapy Policies on Patients. December 2019. https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/impact-of-step-therapy-on-patients_final_1019.pdf.
[94] Nguyen E., Weeda E.R., Sobieraj D.M., et al. Impact of non-medical switching on clinical and economic outcomes, resource utilization and medication-taking behavior: a systematic literature review. Current Medical Research and Opinion. April 1, 2016. https://www.tandfonline.com/doi/abs/10.1185/03007995.2016.1170673.
[95] PhRMA reiterates its view, as articulated in prior comments to CMS, that CMS lacks statutory authority to permit MA plans to impose step therapy conditions on Part B drugs if such conditions are not required under traditional Medicare. *See* Social Security Act § 1852(a)(1); PhRMA Comments on Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62152 (Nov. 30, 2018), https://www.regulations.gov/comment/CMS-2018-0149-7275; PhRMA Comments on CY 2024 Policy and Technical Changes to Medicare Advantage and Part D, 87 Fed. Reg. 79452 (Dec. 27, 2022), https://www.regulations.gov/comment/CMS-2022-0191-0708.

Parts A and B."[96] Thus, in the spirit of protecting MA beneficiary access to important statutory benefits under Parts A and B, PhRMA remains concerned that MA organizations use utilization management tools, such as step therapy and PA, to frequently restrict access to clinically appropriate medicines.

Particularly as the number of beneficiaries covered by MA plans continues to increase, it is critical that CMS reconsider policies that allow MA organizations to restrict beneficiaries' access to important medicines. PhRMA encourages CMS to extend its efforts to increase oversight and transparency of MA coverage and consider how greater oversight of utilization management practices would further promote beneficiary access to basic Medicare benefits, including medicines.

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PhRMA appreciates the opportunity for constructive discussion and collaboration as part of this comment process. Please do not hesitate to contact Sarah Rayel at srayel@phrma.org or Judy Haron at jharon@phrma.org if we can provide additional information or if we can answer any questions related to our comments.

Sincerely,

__/s/_____
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__/s/_____
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[96] 89 Fed. Reg. 99340, 99459. December 10, 2024.