



One Park Place | Suite 475 | Annapolis, MD 21401-3475
1-866-542-8163 | Fax: 410-837-0269
aarp.org/md | md@aarp.org | twitter: @aarpmc
facebook.com/aarpmc

July 23, 2026

Maryland Prescription Drug Affordability Board
Attn: Christina Shaklee
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Dear Chair Mitchell, Members of the Prescription Drug Affordability Board, and Staff:

On behalf of AARP Maryland, I want to thank the Prescription Drug Affordability Board for its diligent work over the past year. We appreciate the Board's efforts to develop the Upper Payment Limit regulations published in the June 26, 2026, edition of the Maryland Register.

The proposed regulations will help make prescription medications more affordable for Maryland residents and for the State's health care system. When the first upper payment limits take effect in January 2027, the taxpayer savings are likely to be significant. With cost reviews and UPL determinations now completed for two medications, Maryland is also well-positioned to realize even broader savings when Upper Payment Limit authority extends to commercial markets in 2028. Projected annual savings range from \$9 million to \$16 million for Jardiance and could reach as high as \$164 million for on-label use of Ozempic.

Beyond reducing costs, these measures could expand access to lifesaving medications. Greater affordability may also allow more patients to start treatment and continue taking their prescribed medications, thereby improving adherence and potentially increasing appropriate utilization.

We commend the Board for its thoughtful and thorough work and heartily recommend the adoption of the proposed regulations for Upper Payment Limits for both Jardiance and Ozempic.

Ensuring that Marylanders can afford the medications they need is central to AARP's commitment to improving health and financial security, and we will continue working with the Board and other partners to advance meaningful prescription drug cost relief.

Sincerely,

A handwritten signature in black ink, appearing to read "Sara M. Westrick".

Sara M. Westrick





July 27, 2026

Via Electronic Correspondence

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: COMAR 14.01.07 UPL: .01 Upper Payment Limit for Jardiance (empagliflozin); and .02 UPL for Ozempic (Semaglutide).

Dear Maryland PDAB:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. We appreciate the Maryland Prescription Drug Affordability Board's ("PDAB" or "Board") commitment to addressing high prescription drug costs.

As the Board moves through the upper payment limit (UPL) rulemaking process for Jardiance and Ozempic, Aimed Alliance urges the Board not to pursue UPLs, given the risk of unintended consequences and legal challenges. If the Board chooses to proceed, we urge the Board to exercise caution, prioritize patient well-being, and establish clear safeguards to monitor and mitigate the UPL's effects on access and care.

A. Maryland's Proposed UPLs Face Legal Vulnerability

In light of a recent federal court ruling, Aimed Alliance urges the Board to not move forward with establishing UPLs as any UPL will likely be struck down for violating federal preemption requirements.

The Colorado PDAB planned to implement a UPL on Enbrel beginning January 1, 2027. Amgen, the manufacturer of Enbrel, sued the Colorado PDAB alleging that the UPL could not be implemented due to various types of federal preemption.¹ On July 1, 2026, the United States District Court for the District of Colorado agreed with Amgen and granted a preliminary injunction against the Colorado PDAB's UPL for Enbrel. In that decision, the District Court reasoned that Amgen is "substantially likely to succeed on the merits," of its case, meaning that the Court believes UPLs will likely be preempted by federal law. The Court specifically discussed the patent scheme developed by Congress and how UPLs contradict the congressional intent of that program.² This ruling signals that Maryland's proposed UPLs will likely be struck down. The challenges with the Colorado PDAB's UPL are not procedural errors, but rather fundamental challenges to how UPLs interact with federal law. Proceeding with these caps risks costly litigation expenses and a scenario where the policy is blocked by the courts before it can ever take effect. Continuing down this path risks committing the Board's limited time, funding, and administrative

¹ *Amgen Inc. v. Mizner*, Case No. 1:25-CV-03452 (D. Colo. July 1, 2026).

² *Amgen Inc. v. Mizner*, Case No. 1:25-CV-03452 (D. Colo. July 1, 2026).

capacity to a lengthy and costly legal defense with a high likelihood of being overturned. Those valuable resources would be far more productively directed toward alternative, legally sound strategies capable of delivering practical and immediate financial relief to patients.

Therefore, Aired Alliance strongly encourages the Board to pause the UPL process to avoid these legal and operational hurdles, and instead pursue alternative reforms that provide actual, immediate financial relief to patients.

B. Prioritize the Patient Experience as a Trusted Data Source During the UPL Rulemaking Process

Aired Alliance appreciates the Board's commitment to providing time to hear the patient voice and learn about the patient experience throughout the affordability review and UPL-setting process. However, because patients are the individuals most directly affected by the Board's decisions, their experiences and perspectives must be treated as necessary, actionable evidence rather than commentary that is simply acknowledged. One way to do this is by drawing on best practices established by international patient organizations with extensive experience implementing drug-pricing mechanisms.³

Across health technology assessment systems globally, widely recognized best practices highlight the importance of including patient perspectives directly into affordability and reimbursement decisions. These practices include establishing consumer-engagement frameworks that prioritize transparent communication and timely notification, elevating consumer evidence and input, and maintaining a structured feedback mechanism to connect patient recommendations to reimbursement decisions.⁴ Integrating patient feedback in this manner can also help the Board determine whether supplemental reforms may be more appropriate than a UPL. For example, if patients report that a drug is unaffordable primarily due to payer policies rather than the drug's actual price, it is critical for the Board to reconcile this information before moving forward.

Implementing a UPL for a drug whose affordability issues are not price-driven could lead to ineffective policy choices and increased time and spending on solutions that fail to address the underlying problem. For these reasons, Aired Alliance urges the Board to meaningfully prioritize the patient experience as it considers whether to impose a UPL for Jardiance and Ozempic. We encourage the Board to closely evaluate and reconcile the feedback it has gathered with its ultimate decisions, ensuring that patient input is treated as a formal data source.

C. Monitor the UPL's Effects on Patients and Establish Clear Safeguards

If the Board decides to move forward with imposing UPLs, it is essential that it closely and intentionally monitors their effects on patients. Because the Board's mission includes protecting Maryland consumers from excessive prescription drug costs, it should ensure not only that those UPLs lower costs for consumers, but also that they do not inadvertently reduce access to medically

³ Australian Government Department of Health and Aged Care, *Enhance HTA: An Enhanced Consumer Engagement Process in Australian Health Technology Assessment A Report of Recommendations* (June 2024), <https://www.health.gov.au/sites/default/files/2024-09/enhance-hta-an-enhanced-consumer-engagement-process-inaustralian-health-technology-assessment-a-report-of-recommendations.pdf>.

⁴ Id.

necessary therapies. This requires ongoing monitoring of utilization management practices adopted by health plans following implementation, for both Jardiance and Ozempic and for their therapeutic alternatives. Without this oversight, patient access issues may go undetected, and the Board will not have the information needed to correct such unintended consequences. These considerations raise several important process questions regarding implementation. For example:

- What will constitute “sufficient harm” to warrant withdrawal of a UPL?
- Will the threshold apply only to patient harm, or also to harm experienced by providers?
- What data sources will be used to assess impact, and how will data be collected and measured?

As we detailed in our July 13, 2026 letter (which outlined the specific data points and metrics that should be collected), establishing a thorough framework prior to implementation is vital. Without a transparent and enforceable mechanism to monitor patient impact, it is unclear how the Board would effectively and swiftly identify and address unintended consequences. We therefore urge the Board to develop a deliberate process that meaningfully tracks UPL impacts and provides patients with opportunities to engage the Board when access challenges arise.

D. UPLs May Fail to Deliver Out-of-Pocket Savings for Patients

Lastly, Aimed Alliance restates its long-standing opposition against UPLs, as they do not provide meaningful guarantees to improved access or affordability for patients. UPLs apply only to what payers reimburse pharmacy benefit managers (PBMs), not to what patients pay at the pharmacy counter. As a result, they offer no guarantee of meaningful out-of-pocket savings for patients. Moreover, existing research suggests that UPLs may produce adverse effects on access and affordability. A recent *Avalere* study found that health plans anticipate increasing the use of utilization management tools, such as step therapy and prior authorization, when UPLs are imposed on certain drugs.⁵ Plans are also expected to modify formularies by shifting drugs and their therapeutic alternatives into different tiers.⁶ Thus, these changes risk raising costs for patients and restricting access to necessary medications, underscoring the need for caution when implementing UPLs.

UPLs may also undermine patient access in other ways. Providers may stop dispensing medications if reimbursement rates fall below acquisition costs. Payers may also prioritize drugs that are not subject to UPLs or may steer patients toward alternative therapies, as many PBM rebates are tied to the drug’s price, reducing PBMs’ incentives to offer these options. Conversely, even if UPLs operate as intended, patients who are clinically stable on therapeutic alternatives may be subject to non-medical switching to drugs targeted by these UPLs. In each of these scenarios, continuity of care may be disrupted, health outcomes compromised, and safety-net providers strained, ultimately increasing overall healthcare costs. Some of these consequences have already manifested in Medicare as a result of MFP implementation. Aimed Alliance supports addressing the underlying systems and practices that steer patients to certain drugs and interfere with the patient-provider relationship. Therefore, Aimed Alliance urges the Board to not move forward with UPLs for Jardiance and Ozempic.

⁵ Avalere Health, *Update: Health Plans’ Perceptions of PDABs and UPLs* (Mar. 28, 2025), <https://advisory.avalerehealth.com/insights/update-health-plans-perceptions-of-pdabs-and-upls>.

⁶ *Id.*

E. Conclusion

In conclusion, Aired Alliance commends the Board for its commitment to addressing the rising cost of prescription drugs for Maryland patients. However, we urge the Board to proceed with caution. This must include carefully evaluating the legal sustainability of UPLs, prioritizing patient feedback throughout the process, and establishing a plan for the ongoing monitoring of utilization management practices adopted by health plans following UPL implementation. If you have any questions or wish to discuss these matters further, please contact us at policy@airedalliance.org.

Sincerely,

Olivia Backhaus
Staff Attorney



**Delaware-Maryland Synod
Evangelical Lutheran Church in America**

Comment Prepared for the
Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
July 23, 2026

Chair Mitchell, Members of the Prescription Drug Affordability Board, and Staff,

Thank you for the opportunity to provide comments on the proposed regulations for the drugs Jardiance and Ozempic. I am Reverend Melody Hession-Sigmon, director of the Lutheran Office of Public Policy in Maryland for the Delaware-Maryland Synod of the Evangelical Lutheran Church in America, a faith community with congregations in every part of the state.

Our church body has a history of advocating for expanded access to health care for all people in Maryland. We write today continuing that legacy, in support of the recommended Upper Payment Limits for both Jardiance and Ozempic.

We appreciate that this is an important step in your work to make life-changing prescription drugs more affordable for ordinary people. We believe that healthcare is not meant to be a commodity. “Although health care goods and services may be bought and sold, health care is above all an activity of caring that grows out of relationships of mutual responsibility, concern, and trust—and that cannot be reduced to a commodity.” (*Caring for Health: Our Shared Endeavor*, ELCA, 2003) Your efforts in setting Upper Payment Limits on prescription drugs that reduce the impact and burden of injury, illness, and disability are a step closer towards these values. Thank you.

Thank you for stewarding your responsibilities well, keeping your board on track to engage with your expanded authority in 2028, to set UPLs in commercial markets. We hope regulating the markets for these two medications is just the beginning.

Please adopt the proposed Upper Payment Limits for both Jardiance and Ozempic.

Rev. Melody Hession-Sigmon



July 27, 2026

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: Comments on COMAR 14.01.07.02 Upper Payment Limit for Ozempic

Dear Members and Staff of the Maryland Prescription Drug Affordability Board:

The Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC) is a two-part coalition that unites patient organizations and allied groups (EACH), as well as patients and caregivers (PIC), to advocate for drug affordability policies that benefit patients.

We appreciate the opportunity to comment on the board's proposed upper payment limit (UPL) rulemaking for Ozempic. We urge the board not to move forward with the proposed UPL since it does not directly address patient needs and alternative policy solutions have not yet been fully considered or evaluated by the board.

UPLs Do Not Guarantee Savings for Patients

We continue to underscore the limitations of a UPL in addressing patient affordability. UPLs may change what insurers or the state pay for a medication, but they do not cap or guarantee reductions in patient out-of-pocket costs. As our coalition has cautioned before, these policies can introduce new incentives for insurers and pharmacy benefit managers (PBMs) that may ultimately restrict access to needed treatments through greater utilization management, formulary reshuffling, or adverse tiering. These shifts risk delaying or disrupting care, and as our [Patient Experience Study](#) has demonstrated, insurance barriers, not price alone, are often the real drivers of patient hardship and perceived "unaffordability."

Furthermore, patients [reported](#) that treatments are not interchangeable and that accessing the correct medication is critically important for patients with chronic conditions. Therefore, while intended to reduce costs, implementing a UPL without complementary patient protections could worsen the very challenges patients already face.

We urge the board to establish clear safeguards before advancing any UPL frameworks and to continue exploring its policy alternatives, including reforms that directly address PBM and insurance practices that most influence patient costs.

Limitations of Applying Medicare MFP

Maryland's proposal to apply the "maximum fair price" (MFP) established by the Medicare Drug Price Negotiation Program (MDPNP) to state programs is concerning because those prices were negotiated specifically for the Medicare population and benefit design. Those rates reflect the structure and cost-sharing rules of Medicare, which are not the same as those that apply in state-regulated coverage. Applying those prices outside of Medicare assumes the markets function the same way, and they do not.

Further, the establishment of UPLs at MFP rates does not guarantee any savings for patients. Patients could instead face higher copay or coinsurance rates to retain access to that drug or alternatively be forced to switch to a more expensive drug, which results in higher profits for their PBM. Recent research from the [Pioneer Institute](#) has shown that patient out-of-pocket costs have increased by an average of 32 percent under the MDPNP even before the maximum fair price caps for the first round of drugs went into effect on January 1st.

Simply importing Medicare pricing may create disruption without meaningfully improving what patients actually pay or experience.

Consider More Effective, Patient-Centered Reforms

We have long cautioned that UPLs are not a patient-centered solution and have urged the board to seek the authority to implement alternative reforms that will better address patient problems. We urge once again that the board ensures non-UPL policy alternatives are given equal weight alongside UPL proposals.

In the [February 2025](#) comment letter on the rules and regulations concerning the UPL process submitted by the EACH Coalition and signed by more than 25 organizations, we raised this issue:

“[W]e continue to urge the board to seek authority to implement policy alternatives before proceeding with the UPL process. The board currently has no authority to implement alternative policies nor has it outlined any alternatives under consideration. Proceeding with the UPL process without taking these important steps increases the likelihood that the board will resort to implementing UPLs simply because other policy solutions have not been explored and are therefore not available to implement.”

Unfortunately, the scenario we outlined has now come to fruition. The board is moving forward with establishing UPLs. Meanwhile, alternative policy options that may better address the needs of Maryland patients are advancing more slowly because the board lacks the authority to pursue them directly. Whether by design or simply ease of authority, the board has now demonstrated that UPLs are its preferred mechanism for intervention.

Moving forward with implementing UPLs will place more value on lowering system costs than on addressing real patient needs. We therefore urge the board not to move forward with approval of the UPL for Ozempic until the alternative policy recommendations under consideration also move forward.

Conclusion

We appreciate the board’s willingness to consider alternatives to UPLs and its ongoing engagement with patient stakeholders. We stand ready to work collaboratively with the board to advance policies that address the real drivers of patient affordability while preserving timely access to the treatments patients rely on.

Sincerely,



Tiffany Westrich-Robertson

Tiffany Westrich-Robertson

tiffany@aiarthritis.org

Ensuring Access through Collaborative Health (EACH) Coalition Lead

Vanessa Lathan

Vanessa Lathan

vanessa@aiarthritis.org

Patient Inclusion Council (PIC) Coalition Lead



Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
Attn: Christina Shaklee

July 1, 2026

Chair Mitchell, Members of the Prescription Drug Affordability Board, and Staff;

Maryland Health Care for All is writing on behalf of the over 450 members of the Prescription Drug Affordability Coalition to express gratitude for your work that has culminated in the proposed Upper Payment Limit regulations published in the June 26, 2026 edition of the Maryland Register. The proposed regulations mark an important milestone in the Board's work to make prescription drugs more affordable for Marylanders and our health care system, and we look forward to seeing realized savings for our taxpayers when these first upper payment limits go into effect in January of 2027.

The economic impact analyses demonstrate why the Board should vote to formally move forward with these regulations. At a time when our health care system and government budgets face increasing strain and direct attacks from the federal government, this Board's work can offer meaningful relief by addressing the skyrocketing costs of prescription drugs. Importantly, since cost reviews and UPL determinations have been performed for two prescription drug products, this puts our state on track to see expansive savings once the Upper Payment Limit authority can be expanded in 2028 to include commercial markets. For Jardiance, those savings are estimated to be between \$9-16 million/year, with the estimated Ozempic savings reaching as much as \$164 million/year for on-label use.ⁱ

In addition to potential savings, these measures can be expected to improve access to these lifesaving medications. Lower costs will make it more likely that patients can start therapy and remain adherent, meaning that as affordability improves, utilization may increase. This could offset reductions in revenue to manufacturers, which is often an industry concern.

We appreciate the Board's dedicated and thorough approach throughout this process and respectfully urge the adoption of the proposed Upper Payment Limits for both Jardiance and Ozempic.

ⁱ <https://healthcareforall.com/uplestimates/>



July 27, 2026

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

VIA ELECTRONIC MAIL TO pdab.regs@maryland.gov

RE: Proposed Rule: COMAR 14.01.07.02 Upper Payment Limit for Ozempic (Semaglutide)

Dear Members of the Maryland Prescription Drug Affordability Board,

Novo Nordisk appreciates the opportunity to submit written comments to the Maryland Prescription Drug Affordability Board (“Board” or “PDAB”) regarding Proposed Rule COMAR 14.01.07.02 Upper Payment Limit for Ozempic (Semaglutide), published in the June 26, 2026, issue of the Maryland Register. As we have expressed in previous comments, we share the Board’s interest in making prescription medications affordable and accessible to all Marylanders. We are, however, significantly concerned by the proposal of this upper payment limit (“UPL”) for Ozempic®.

The proposed UPL conflicts with the statutory and regulatory scheme in three distinct ways. **First**, the Board has proposed the UPL without making any finding that government entities are facing difficulty purchasing Ozempic®, as required by state statute. Maryland law allows the Board to propose a UPL only after it makes a determination that the price of a drug has caused an “affordability challenge” for government entities—i.e., that these entities are struggling to afford the drug.¹ But the Board has never made that determination. Instead, the only circumstance the Board has found to justify the UPL is that Ozempic® purchases accounted for 4.87% of gross prescription drug spend for state and local governments in 2023.² **Second**, the Board has proposed the UPL without tailoring it to the affordability challenge currently facing the government entities, as the law demands. Maryland law requires a UPL to be tailored to the exact affordability challenge confronting government entities. But the Board here uses only improper and outdated data to find an affordability challenge and then appears to jettison that data in favor of adopting the “maximum fair price” (“MFP”) of Ozempic®—a benchmark determined by the Centers for Medicare & Medicaid Services (“CMS”) for certain federal sales. **Third**, the Board has proposed a January 1, 2027, implementation date that it elsewhere has acknowledged is unrealistic. The Maryland General Assembly requires the Board to set “a prospective [UPL] effective date that provides sufficient time

¹ See Md. Code Ann., Health-Gen. §§ 21-2C-13 to -14.

² See MD PDAB, [Ozempic \(semaglutide\) – Cost Review Study Report](#) 6 (May 11, 2026) (detailing the preliminary determination, which the Board finalized on May 18, 2026); [MD PDAB May 18, 2026 Meeting Recording](#) at 34:40-37:10.

for implementation.”³ In a separate proposed regulation, Maryland has identified January 1, 2028, as that date.⁴ The proposed UPL’s purported date of January 1, 2027, is inconsistent with Maryland law and the competing proposed regulation. The Board should accordingly, at a minimum, change that date to January 1, 2028, or postpone issuing a regulation until there is clarity over how the UPL will be implemented.

Failure to follow Maryland’s laws in issuing the UPL raises serious practical and legal concerns. Maryland has designed its scheme to attempt to minimize risk while reducing prescription drug costs for government entities. Subverting the scheme to prioritize reductions in drug costs and ignoring the serious risks that could result may cause harm to Maryland government entities, citizens, and public health. Moreover, issuing legally flawed regulations exposes the Board to significant legal risk. A court in Colorado, for example, just enjoined a UPL imposed by the Colorado PDAB based on its legal flaws.⁵ Instead of opening up a battle in court, the Board should take the time to follow the law and determine (1) whether an affordability challenge for government entities exists; (2) what payment limit will address that affordability challenge while minimizing other risks; and (3) when such a payment limit can be realistically implemented.

I. The Board has failed to follow the statutory requirement to determine whether Ozempic® is difficult for government entities to afford.

Before setting a UPL, Maryland law requires the Board to make “a final determination of whether the prescription drug has or will create an affordability challenge.”⁶ In Maryland, “[t]he cardinal rule of statutory interpretation is to ascertain and effectuate the real and actual intent of the [General Assembly],” which “begin[s] with the normal, plain meaning of the statute.”⁷ The ordinary meaning of the word “affordable” is “able to be afforded” or “able to bear the cost of.”⁸ And the ordinary meaning of the word “challenge” is “a difficult task or problem.”⁹ The statute thus directs the Maryland PDAB to make a final determination of whether the cost of a prescription drug product has made

³ MD PDAB, [UPL Action Plan](#) 12 (Sept. 10, 2024); Md. Code Ann., Health-Gen. § 21-2C-14 (permitting the Board to set UPLs in accordance with the approved UPL Action Plan).

⁴ See MD PDAB, Implementation and Monitoring of Upper Payment Limits, 53:12 Md. Reg. 567 (proposed June 12, 2026) (to be codified at COMAR 14.01.06) [hereinafter Proposed Rule COMAR 14.01.06].

⁵ Order Granting Motion for Preliminary Injunction at 4, 10, *Amgen Inc. v. Mizner*, No. 1:25-cv-03452 (D. Colo. July 1, 2026), ECF No. 66 (finding that federal patent law preempts price caps on patented drugs and preliminarily enjoining enforcement of the Colorado PDAB’s UPL for Enbrel).

⁶ See Md. Code Regs. 14.01.05.07(A)(1)(a); Md. Code Ann., Health-Gen. § 21-2C-13(a).

⁷ *State v. Bey*, 452 Md. 255, 265 (2017).

⁸ Merriam-Webster, [Affordable](#); Merriam-Webster, [Afford](#).

⁹ Merriam-Webster, [Challenge](#).

it difficult for Maryland government entities to be able to bear the cost of the drug before imposing any UPL.

The Board has never made that determination. Instead, the Board claimed that “the use of Ozempic® has created an affordability challenge to the state healthcare system”¹⁰ based on a single identified statistic: that “total gross spending for Ozempic® for state and local governments [in 2023] exceeds 4.87% of gross prescription drug spend for state and local governments (public session).”¹¹ The Board never explains what percentage of spending is the threshold for an affordability challenge—1%, 4%, 4.5%? Nor has the Board explained how a percentage alone can show an affordability challenge either as a matter of law or as a matter of fact. Indeed, despite stakeholders raising concerns for years, the Board has *never* offered any explanation of how it has interpreted the term “affordability challenge.”¹²

As a matter of ordinary meaning, an affordability challenge is not coterminous with a budget percentage. Whether government entities are able to bear the cost of a certain drug depends largely on the amount of money they have at their disposal. In 2023, Maryland state and local employment health plans spent a bit over \$30 million in gross spend for Ozempic®.¹³ Maryland’s state budget for 2027, in contrast, exceeds \$70.8 *billion*.¹⁴ Spending on Ozempic®, in other words, is tantamount to a fraction of a percent of Maryland’s state budget (approximately 0.04%). It is simply implausible to conclude that such a small percentage of overall spending makes it difficult for government entities in Maryland to afford Ozempic®.

The Board’s decision to look to a single percentage is even more problematic because early research suggests that the use of Ozempic® may lead to *decreased* spending on other medical issues. For example, a retrospective claims-based study of U.S. patients with type 2 diabetes and cardiovascular disease found that those who initiated a GLP-1 receptor agonist, a class that includes Ozempic®, experienced a 24% lower risk of cardiovascular-related hospitalization and a 15% lower risk of all-cause hospitalization compared to patients on standard glucose-lowering therapy, with substantially lower inpatient and outpatient costs offsetting the medication’s higher drug costs.¹⁵ Likewise, a decision-analytic modelling study built on data from four head-to-head randomized trials

¹⁰ MD PDAB May 18, 2026 Meeting Recording at 34:40-37:10.

¹¹ See *id.*; MD PDAB, [Ozempic \(semaglutide\) – Cost Review Study Report](#) 6 (May 11, 2026) (detailing the preliminary determination, which the Board finalized on May 18, 2026).

¹² See, e.g., Letter from Community Access National Network to MD PDAB 1–2 (Sept. 23, 2025) (“[T]he Board’s paradigm of affordability appears nebulous, thus making it hard to envision how specific remedies can be created without well-defined concerns.”); [MD Prescription Drug Affordability Stakeholder Council November 4, 2024 Meeting Recording](#) at 1:19:00–1:19:53.

¹³ MD PDAB, [Ozempic \(semaglutide\) – Cost Review Study Report](#), Appendix A at 23 (May 11, 2026).

¹⁴ Bryan P. Spears, [Moore, legislative leaders sign \\$70.8 billion budget into law](#), Maryland Matters (Apr. 9, 2026).

¹⁵ Marc Evans et al., [Healthcare Costs and Hospitalizations in US Patients with Type 2 Diabetes and Cardiovascular Disease: A Retrospective Database Study \(OFFSET\)](#), 24 Diabetes Obesity & Metab. 1300, 1300 (2022).

found that semaglutide-based treatment regimens for type 2 diabetes were consistently associated with lower costs of treating diabetes-related complications compared to empagliflozin, canagliflozin, or sitagliptin.¹⁶ The Board’s myopic focus on the percentage of all government entities’ gross prescription drug spend ignores any potential long-term cost savings.

That the Board should have considered potential cost savings as opposed to focusing exclusively on a single spend percentage is a simple concept and one that stakeholders have previously raised. For example, as we have explained to the Board, patients who are not receiving the standard of care for the treatment of diabetes are more likely to face complications that require further medical care, which subsequently places additional burdens on the patient and the healthcare system.¹⁷ Inpatient hospital care, ER visits, and outpatient office visits accounted for \$169.5 billion (55.2%) of the \$307 billion in total direct diabetes medical costs in 2022, while non-insulin antidiabetic drugs like Ozempic® accounted for only 8% (\$24.7 billion).¹⁸ A simplistic example illustrates the point: If an individual begins riding the train to work instead of driving, his train fare may start to form a large percent of his overall commuting spend. But the train would still be the affordable option if the individual is able to forgo costlier expenditures on gas, parking, and wear-and-tear on his vehicle. This example holds true as the Board acknowledged that “the use of Ozempic was associated with higher spending but better health outcomes.”¹⁹ The failure to even consider cost savings shows that the Board did not make the affordability challenge determination required by law.

Moreover, a proper affordability analysis cannot stop at cost considerations alone; it must also account for the value received from a purchase. An individual may find it affordable to spend 20% of his income on housing but unaffordable to spend 20% of his income on vacation. Ozempic® is a remarkable and innovative pharmaceutical product that brings enormous value to Maryland and to Maryland citizens. Indeed, the Board’s own proceedings recognize that the driver of Ozempic® spend is primarily related to high levels of utilization “consistent with FDA label indications (e.g., diabetes) rather than off-label uses” (as confirmed by Board staff).²⁰ High utilization in Maryland, then, does not reflect improper use but rather the high prevalence and burden of diabetes in Maryland, along with clinicians’ recognition of the drug’s clinical value to treat diabetes. Evaluating affordability only by aggregate gross spending ignores this context and penalizes

¹⁶ Ryan Pulleyblank & Nikolaj Birk Larsen, [*Cost-Effectiveness of Semaglutide vs. Empagliflozin, Canagliflozin, and Sitagliptin for Treatment of Patients with Type 2 Diabetes in Denmark: A Decision-Analytic Modelling Study*](#), 7 *PharmacoEconomics Open* 579, 579 (2023).

¹⁷ Letter from Novo Nordisk Inc. to MD PDAB (May 10, 2024).

¹⁸ *Id.*; see also Letter from Novo Nordisk Inc. to MD PDAB (Sept. 4, 2025) (detailing, “[t]he ability of Ozempic® to prevent costly cardiovascular hospitalizations—including heart attacks and strokes, which can cost \$55,000–\$75,000 per event and about \$108 billion nationally—is unmatched by drugs such as metformin.”); Letter from Novo Nordisk Inc. to MD PDAB (Feb. 17, 2026) (explaining the cost effectiveness of Ozempic®).

¹⁹ MD PDAB, [*Ozempic \(semaglutide\) – Cost Review Study Report 2*](#) (May 11, 2026).

²⁰ See Letter from Novo Nordisk Inc. to MD PDAB (Feb. 17, 2026).

treatments for chronic disease, subjecting them to continual scrutiny even when they deliver strong clinical value for patients and generate long-term cost offsets and savings described above. The Board's reliance on gross spend alone ignores any consideration of how Ozempic® has brought enormous value to individuals with diabetes.

In sum, the Board's affordability determination for Ozempic® cannot withstand scrutiny. The Board never made the legally sufficient "affordability challenge" finding that Maryland law requires, instead substituting a single outdated budget percentage for the reasoned determination the statute demands. That approach is not only legally deficient but factually unsound, as it ignored cost-offset evidence showing that Ozempic® may reduce overall healthcare spending by lowering rates of hospitalization and diabetes-related complications. A proper cost review must weigh the clinical value a drug delivers against its cost, not simply tally gross spending.

These deficiencies carry consequences beyond the Board's own proceedings. Maryland has already spent more than \$4 million establishing and operating the PDAB through Fiscal Year 2024, with another \$3.9 million allocated from the state budget for Fiscal Years 2025-2027.²¹ Yet, to date, the Board has not identified a single dollar in savings for patients or the state. Allowing the Board to compound that record by issuing a legally defective UPL would impose further unnecessary costs on Maryland taxpayers without any corresponding benefit. Because an agency regulation is invalid if it is inconsistent with its enabling statute,²² the Board should take its time to follow the law and actually determine whether government entities are facing an affordability challenge instead of promulgating a legally flawed UPL.

II. The Board's process for adopting this UPL defies the statutory and regulatory scheme.

After making the final affordability challenge determination, the Board is instructed to issue a UPL that narrowly resolves that affordability challenge. Specifically, the Board "shall determine that a[] [UPL] is an appropriate tool to address the driver(s) of the affordability challenge identified for the prescription drug product."²³ Here, the Board relied on outdated data to make its "final determination" and now proposes a UPL that ultimately defers to the federal government's MFP instead of tailoring a price to address the identified affordability challenge. In doing so, the proposed UPL defies the statutory and regulatory scheme.

²¹ Value of Care Coalition, *PDABs Cost Money, Where are the Savings?* (Jan. 31, 2025); [Acts 2024, c. 716](#), § 1 (appropriating \$1,247,411 to the PDAB for Fiscal Year 2025); [Acts 2025, c. 602](#), § 1 (appropriating \$1,279,825 to the PDAB for Fiscal Year 2026); [Acts 2026, c. 4](#), § 1 (appropriating \$1,348,049 to the PDAB for Fiscal Year 2027, bringing the Fiscal Year 2025-2027 total to \$3,875,285).

²² See *In re R.S.*, 215 A.3d 392, 407 (Md. Ct. Spec. App. 2019), *aff'd*, 235 A.3d 914 (Md. 2020).

²³ MD PDAB, [UPL Action Plan](#) 3 (Sept. 10, 2024); Md. Code Ann., Health-Gen. § 21-2C-14 (permitting the Board to set UPLs in accordance with the approved UPL Action Plan).

The Board’s purported “affordability challenge” determination—that spending on Ozempic accounts for a certain percentage of overall prescription drug spend by government entities—is based on outdated data and identical to its preliminary determination. Maryland law establishes a deliberately sequential process for reaching that determination. Under the statute, the Board conducts a cost review to determine whether use of a prescription drug product “has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients,” and in making that determination, the Board “shall consider” a series of enumerated factors, including the drug’s wholesale acquisition cost, “[t]he average monetary price concession, discount, or rebate the manufacturer provides to health plans,” the price of therapeutic alternatives, and “[a]ny other factors as determined by the Board in regulations adopted by the Board.”²⁴ The UPL Action Plan, which the General Assembly incorporated into the statute,²⁵ makes clear that this cost review culminates in two distinct determinations, not one. The UPL Action Plan provides that “[a]fter reviewing data, analyses, and public input from the cost review study process, the Board makes a preliminary determination.”²⁶ But the Plan expressly cautions that “[a] preliminary determination is non-final and subject to revision and modification.”²⁷ Only “[a]fter considering public comments”—including new data and analysis submitted by stakeholders—may the Board “vote to finalize” (or not finalize) “the preliminary determination and approve the draft cost review report as final.”²⁸ Once a final determination is reached, any resulting UPL must be tailored to the specific identified driver of the affordability challenge, not a generic or externally derived substitute. The UPL Action Plan defines a UPL as a “policy tool that may be used to redress the factors that cause (hereinafter ‘drivers’) the phenomenon of an affordability challenge” and explains that the Board’s assessment must determine “whether a UPL is an appropriate policy solution to redress the driver(s) of the affordability challenge.”²⁹ And the Board must “set a[] [UPL] in a way to minimize adverse outcomes and the risk of unintended consequences.”³⁰

Instead of incorporating the updated analysis and data submitted by stakeholders to reach a final determination of an affordability challenge, the Board simply decided to adopt the preliminary determination based exclusively on that preliminary analysis and data. That decision defies statutory and regulatory scheme which contemplates both a preliminary determination and a separate final determination.³¹ If a final determination could simply restate a preliminary one without any analysis or incorporation of intervening changes to the underlying data, analyses, or public input, the instruction that

²⁴ Md. Code Ann., Health-Gen. § 21-2C-09(b)(1)–(2).

²⁵ *Id.* § 21-2C-14.

²⁶ MD PDAB, [UPL Action Plan](#) 4 (Sept. 10, 2024).

²⁷ *Id.*

²⁸ *Id.* at 5.

²⁹ *Id.* at 2.

³⁰ *Id.* at 3.

³¹ *Id.* at 4–5, 12; *see also* Md. Code Ann., Health-Gen. § 21-2C-14 (permitting the Board to set UPLs in accordance with the approved UPL Action Plan).

the Board act only “[a]fter considering public comments” would be rendered meaningless, as would its disclaimer that a preliminary determination is “non-final and subject to revision and modification.”³²

The Board cannot avoid the requirement to make a final determination based on new data and inputs by arguing that it only needs to find an affordability challenge at some point in the past. In response to a comment explaining that market changes may have impacted the Board’s affordability challenge preliminary determination, Board staff explained that the Board was determining only whether the use of Ozempic® “has led” to an affordability challenge at some point in the past—not whether there was currently an affordability challenge.³³ That view is inconsistent with the statute’s ordinary meaning. The requirement to determine that a prescription drug product “has led ... to an affordability challenge” requires an ongoing affordability challenge—not merely an affordability challenge at some point in history.³⁴

The Board’s decision to turn the preliminary determination into a final determination without further analysis of intervening data also makes it impossible to fit the UPL to that affordability challenge. The state of pharmaceutical sales has changed substantially since 2023, and as explained to the Board, these market changes may well have altered the “affordability challenge” the Board preliminarily identified. We maintain that Ozempic® has always been broadly affordable for Marylanders, and we remain committed to ensuring patients living with diabetes can afford our medications. This fact is only reinforced by our recent announcement of significant changes to provide cost savings to patients without insurance coverage or those who choose to self-pay without using their insurance. In mid-2025, Novo Nordisk announced that Ozempic® would be made available to self-paying patients with type 2 diabetes with a prescription through NovoCare® Pharmacy.³⁵ Ozempic® is now available for as low as \$199 per month from NovoCare® Pharmacy and other partner direct-to-patient platforms.³⁶ Novo Nordisk will also lower prices and expand patient access and affordability for Ozempic® in Medicaid as part of an agreement with the White House, announced in November 2025.³⁷ Assessments of the affordability of Ozempic® that fail to account for substantial net price reductions and other recent actions to expand access ignore the complete picture and are constrained by stale data, rather than reflective of current market conditions.

Without any data or insight into whether there is a current affordability challenge for government entities, the Board had no way to tailor its UPL to the challenge and instead merely latched onto the MFP set forth by CMS. This is inconsistent with the law.

³² MD PDAB, [UPL Action Plan](#) 4 (Sept. 10, 2024).

³³ [MD PDAB May 18, 2026 Meeting Recording](#) at 34:00-34:40.

³⁴ Md. Code Ann., Health-Gen. § 21-2C-09(b)(1).

³⁵ Letter from Novo Nordisk Inc. to MD PDAB (Feb. 17, 2026).

³⁶ *Id.*

³⁷ *Id.*

Under Maryland law, the PDAB must consider the statutory “criteria for setting upper payment limits,” including: “(1) [t]he cost of administering the prescription drug product; (2) [t]he cost of delivering the prescription drug product to consumers; (3) [t]he effect the [UPL] will have on providers of 340B drugs; (4) ...the impact of the [UPL] on patients with rare diseases; and (5) [o]ther relevant administrative costs related to the prescription drug product.”³⁸ The UPL proposed by the Board is not a targeted price limit informed by the drivers of the affordability challenge identified; nor is it an obvious response to the statutory criteria—it is deference to the price chosen by a federal agency for an entirely different market. Whereas the MFP applies only to Medicare sales, the UPL would apply to purchases by Maryland eligible governmental entities. The Board’s uncritical application of MFP shows that the PDAB is not focused on addressing what the law requires: An affordability challenge faced by Maryland government entities. Using the MFP to dictate a UPL will likely replicate the unintended effects already observed following MFP introduction—higher patient cost-sharing, more restrictive utilization management, formulary exclusions, and stress on the supply chain—all of which only serve to reduce patient access.³⁹

In sum, the Board’s process underlying this proposed UPL is riddled with defects that, taken together, defy the statutory and regulatory scheme, ultimately rendering the Board’s actions arbitrary and capricious. To cure these defects, the Board should decline to finalize the proposed UPL, reopen proceedings to issue a new final affordability challenge determination grounded in current data, and, if it identifies an affordability challenge, propose a UPL, derived from a robust independent analysis, that is narrowly tailored to address the specific driver(s) of that challenge.

III. The UPL effective date is governed by COMAR 14.01.06, not this Proposed Rule, and may still require extension.

Maryland law requires that any UPL provide “sufficient time for implementation” before it goes into effect.⁴⁰ In a separate proposed regulation, the Board has indicated that January 1, 2028, is the earliest date by which a UPL could be binding on government entities and thus in effect.⁴¹ This Proposed Rule, in contrast, provides that the UPL “applies to payments for drugs dispensed, administered, or purchased on or after January 1, 2027.”⁴² Novo Nordisk understands this date to refer to something other than the

³⁸ Md. Code Ann., Health-Gen. § 21-2C-13(b). Even with these criteria, the PDAB operates under a standardless paradigm. The statute does not impose any meaningful constraint on the Board’s power to dictate prices. There are no standards of reasonableness or fairness. It is unclear how the factors enumerated by statute should affect the Board’s decision, if at all.

³⁹ Letter from Novo Nordisk Inc. to MD PDAB (Feb. 17, 2026).

⁴⁰ MD PDAB, [UPL Action Plan](#) 12 (Sept. 10, 2024); Md. Code Ann., Health-Gen. § 21-2C-14 (permitting the Board to set UPLs in accordance with the approved UPL Action Plan).

⁴¹ Proposed Rule COMAR 14.01.06.02(A).

⁴² MD PDAB, Upper Payment Limit for Ozempic (Semaglutide), 53:13 Md. Reg. 608 (proposed June 26, 2026) (to be codified at COMAR 14.01.07.02).

effective date. But to the extent the Board intends to claim that January 1, 2027, is the effective date for this UPL, that would conflict with Maryland law and its other regulation. We refer the Board to our comment letter dated July 13, 2026, on Proposed Rule COMAR 14.01.06 Implementation and Monitoring of Upper Payment Limits, published in the June 12, 2026, issue of the Maryland Register, for more details on the points we reiterate here.

Maryland law requires “sufficient time for implementation.”⁴³ A UPL is a drastic change from the status quo. It will thus require significant operational, contractual, and systems planning changes. Even now, the Board has acknowledged that there is no clarity over how government entities will implement UPLs, whether it be through rebates or some other process.⁴⁴ The Board’s decision to grant eligible governmental entities “flexibility” on this point is deliberate.⁴⁵ The Board must therefore afford stakeholders sufficient time to build the infrastructure that each potentially unique approach will require. Maryland law recognizes this, specifically requiring the Board to give adequate time to incorporate, adopt, and implement the UPL.

Proposed Rule COMAR 14.01.06 sets that earliest possible date by which a UPL could be in effect as January 1, 2028. Specifically, it provides that an eligible governmental entity shall require specific provisions referencing UPLs be included in all contracts: (1) through which prescription drug products are paid for or purchased by, or on behalf of, the eligible governmental entity; and (2) that are executed or amended on or after January 1, 2028, and take effect on or after January 1, 2028.⁴⁶ That January 1, 2028, date is thus the earliest possible date from which all compliance obligations and statutory timelines flow, including the one-year period that must elapse before the Board may consider expanding its UPL authority to private transactions under Md. Code Ann., Health-Gen. § 21-2C-16.⁴⁷

The Proposed Rule at issue here, however, states that the UPL for Ozempic® applies “to payments for drugs dispensed, administered, or purchased on or after January 1, 2027”—a full year before the mandatory compliance date that COMAR 14.01.06 establishes. It is unclear what purpose this 2027 date has. As MD PDAB Executive Director Andrew York has explained, January 1, 2028, is the mandatory UPL compliance deadline.⁴⁸ So any earlier date, including January 1, 2027, reflects only the possibility

⁴³ MD PDAB, [UPL Action Plan](#) 12 (Sept. 10, 2024); Md. Code Ann., Health-Gen. § 21-2C-14 (permitting the Board to set UPLs in accordance with the approved UPL Action Plan).

⁴⁴ See [MD PDAB April 13, 2026 Meeting Recording](#) at 11:51–13:50; see also MD PDAB, [UPL Action Plan](#) 12 (Sept. 10, 2024) (providing, “The Board and staff shall work with Eligible Governmental Entities to develop the best method for implementing the UPL for the entity.”).

⁴⁵ See [MD PDAB April 13, 2026 Meeting Recording](#) at 11:51–13:50.

⁴⁶ Proposed Rule COMAR 14.01.06.02(A).

⁴⁷ [Acts 2025, c. 610, § 3\(a\)](#); [Acts 2025, c. 611, § 3\(a\)](#).

⁴⁸ See [MD PDAB April 13, 2026 Meeting Recording](#) at 19:10.

that some subset of eligible governmental entities could voluntarily put these provisions into their contracts ahead of the mandatory deadline.⁴⁹

January 1, 2027, cannot be deemed the effective date of this proposed UPL. A voluntary early adoption by certain entities is not the same as a lawful mandatory compliance date for all eligible governmental entities, and the Proposed Rule's January 1, 2027, date cannot be squared with COMAR 14.01.06's controlling January 1, 2028, timeline. Moreover, the January 1, 2027 date does not "provide[] sufficient time for implementation."⁵⁰ We reiterate to the Board that regulated governmental entities and unregulated drug manufacturers still have no clear plan on how the UPL will be effectuated, and the Board's own regulations acknowledge this point plainly, providing that "[t]he Board and staff shall work with eligible governmental entities to develop the best method for implementing the UPL for the entity and a prospective effective date that provides sufficient time for implementation."⁵¹

Accordingly, the Board should, at minimum, correct the Proposed Rule's effective date to conform to COMAR 14.01.06's January 1, 2028, compliance deadline. Even that corrected date, however, may not suffice. As Novo Nordisk explained in its comment on that rule, there is still a significant lack of clarity over how stakeholders will implement the various operational, contractual, and system changes required for a UPL, and because UPLs are untried, stakeholders need sufficient time to assess and discuss implementation, particularly during what could be an already complicated contract negotiation period. We therefore respectfully ask the Board, consistent with our July 13, 2026, letter, to consider extending the mandatory deadline proposed in COMAR 14.01.06 beyond January 1, 2028, to allow a more proportionate and practicable implementation period, or to wait on imposing any mandatory deadline until the relevant entities have formed a plan to implement the UPLs.

⁴⁹ See *id.*

⁵⁰ MD PDAB, [UPL Action Plan](#) 12 (Sept. 10, 2024).

⁵¹ Md. Code Regs. 14.01.05.08(A)(2).

In sum, we respectfully urge the Board to decline to adopt the proposed UPL for Ozempic®. As set forth above, the rule is unsound because the underlying “affordability” determination relies on myopic considerations and outdated data; the Board’s proposal of MFP impermissibly substitutes an extrinsic benchmark for the statutory criteria governing UPL determinations; and the Proposed Rule’s designation of January 1, 2027, as the operative date conflicts with the deadline proposed in COMAR 14.01.06, which independently establishes the UPL compliance deadline from which all statutory timelines must run, though meaningful compliance in any event requires an extended implementation period. We request that the Board refrain from finalizing the proposed Ozempic® UPL until these deficiencies are addressed.

Thank you for the opportunity to provide comments and for your consideration of the issues raised in this letter. Should you have any questions or concerns, please contact Stephanie Kutler, Head of Policy, at NSTK@novonordisk.com for additional information.

By Electronic Submission

July 27, 2026

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715
pdab.regs@maryland.gov

RE: New Proposed Regulations -- COMAR 14.01.07 Upper Payment Limit: .01 Jardiance and .02 Ozempic

Dear Members of the Maryland Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) is writing in response to the Maryland Prescription Drug Affordability Board’s (the “PDAB’s” or “Board’s”) request for written comments on its proposal to adopt new regulations regarding Upper Payment Limits for Jardiance (COMAR § 14.01.07.01) and Ozempic (COMAR § 14.01.07.02) (“Proposed Regulations”).¹ PhRMA represents the country’s leading innovative biopharmaceutical research companies, which are 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. PhRMA member companies have invested more than \$850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

PhRMA has previously commented on various aspects of the Board’s work to implement and carry out its responsibilities under the Maryland PDAB Statute (“PDAB Statute”).² We have expressed our concerns in detail regarding the Board’s process for setting upper payment limits (“UPLs”) and its activities more

¹ See Proposed Regulations – COMAR 14.01.07.01 (Upper Payment Limit for Jardiance (empagliflozin) and COMAR 14.01.07.02 (Upper Payment Limit for Ozempic (Semaglutide)) available at https://dsd.maryland.gov/MDRIssues/5313/Assembled.aspx#_Toc233194367 (“Proposed Regulations”). In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to Md. Code, Health Gen. §§ 21-2C-01–16 (the “PDAB Statute”) and the Board’s implementation of the PDAB Statute. PhRMA also incorporates by reference all comments, concerns, and objections that it has previously raised regarding the Board’s implementation of the PDAB Statute. See, e.g., Letter from PhRMA to Board (July 13, 2026); Letter from PhRMA to Board (June 26, 2026); Letter from PhRMA to Board (June 1, 2026); Letter from PhRMA to Board Regarding Draft Cost Review Study Report for Comment (May 1, 2026); Letter from PhRMA to Board Regarding Draft Regulation – New Regulation COMAR 14.01.07.02 (Upper Payment Limit); Ozempic: Calculations and Analyses Underpinning Potential UPL Values (May 1, 2026); Letter from PhRMA to Board Regarding Draft Regulations – New Regulation COMAR 14.01.06 (Implementation and Monitoring of Upper Payment Limits); New Regulation – COMAR 14.01.07 (Upper Payment Limit) (Mar. 30, 2026); Letter from PhRMA to Board Regarding Draft Cost Review Study Reports for Comment (Mar. 30, 2026); Letter from PhRMA to Board (Mar. 4, 2026); Letter from PhRMA to Board (Feb. 10, 2026); Letter from PhRMA to Board (Feb. 10, 2025); Letter from PhRMA to Board (Dec. 2, 2024); Letter from PhRMA to Board (Nov. 8, 2024); Letter from PhRMA to Board (Aug. 26, 2024); Letter from PhRMA to Board (July 16, 2024); Letter from PhRMA to Board (July 12, 2024); Letter from PhRMA to Board (May 10, 2024); Letter from PhRMA to Board (Apr. 24, 2024); Letter from PhRMA to Board (Oct. 23, 2023); Letter from PhRMA to Board (June 30, 2023); Letter from PhRMA to Board Regarding Confidential, Trade-Secret, and Proprietary Information Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule (May 4, 2023); Letter from PhRMA to Board Regarding Draft Regulations on Public Information Act (May 4, 2023); Letter from PhRMA to Board (May 1, 2023); Letter from PhRMA to Board (Sept. 12, 2022).

² See *id.*; Md. Code, Health Gen. §§ 21-2C-01–16.

broadly, and we encourage the Board to consider these previously submitted comments.³ In addition, we provide below select comments and concerns with respect to the Proposed Regulations and the Board's UPL-setting process in general.

I. Lack of Clear and Meaningful Standards for the UPL-Setting Process

PhRMA continues to have concerns regarding the lack of clear and meaningful standards governing the Board's UPL-setting process, including its process for reconsidering a UPL after it is set.⁴

A. Reconsideration of UPLs

- **Reconsideration of Maximum Fair Price ("MFP")-Based UPLs.** PhRMA remains concerned that the Board has proposed using Medicare MFPs as the UPL benchmarks for Jardiance and Ozempic.⁵ A drug subject to an MFP may be subject to renegotiation under the Medicare Drug Negotiation Program ("MDPNP") or may cease to be subject to an MFP altogether, but the Board has not established clear and meaningful standards and processes for reconsideration of an MFP-based UPL in such circumstances. The Board has recently indicated that it intends to amend the regulations to allow for reconsideration of MFP-based UPLs if the MFP is renegotiated.⁶ PhRMA urges the Board to provide for automatic UPL reconsideration if the corresponding MFP is renegotiated or the drug is no longer subject to an MFP.⁷ PhRMA also urges the Board to address how it will monitor MFP changes and establish clear timelines for reconsidering UPLs and modifying or repealing them accordingly.
- **Reconsideration of UPLs for Drugs in Shortage.** The Proposed Regulations provide that UPLs be "automatically suspended for the time that the prescription drug product is identified by the federal Food and Drug Administration as currently in shortage on the prescription drug shortage list" and "automatically lifted when . . . identified as resolved."⁸ However, while the Proposed Regulations provide that Board staff will post notice of the suspension and lifting of UPLs on the Board website, they do not establish a system for directly alerting all stakeholders to the suspension and lifting of a UPL.⁹ In addition, the Board's regulations provide that "the

³ See comments cited *supra* note 1.

⁴ See, e.g., Letter from PhRMA to Board (July 13, 2026) at 2-4; Letter from PhRMA to Board Regarding Draft Regulation (May 1, 2026) *supra* note 1 at 2-3; Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 2-4; Letter from PhRMA to Board (Mar. 4, 2026) at 2-3; Letter from PhRMA to Board (Aug. 26, 2024) at 1-7.

⁵ See Letter from PhRMA to Board (July 13, 2026) at 2; Letter from PhRMA to Board Regarding Draft Regulation (May 1, 2026) *supra* note 1 at 2; Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 2; see also Letter from PhRMA to Board (July 13, 2026) at 2.

⁶ UPL Regulations: Implementation and Monitoring of Upper Payment Limits, PDAB Meeting Materials, Apr. 13, 2026 ("April 13 Meeting Materials") at 9, available at <https://pdab.maryland.gov/Documents/meetings/2026/April%2013%2c%202026/2026.04.13.UPL%20Regulations-%20General%20Provisions.pdf>.

⁷ See Letter from PhRMA to Board (July 13, 2026) at 2; Letter from PhRMA to Board Regarding Draft Regulation (May 1, 2026) *supra* note 1 at 2; Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 2.

⁸ Proposed Regulations, COMAR §§ 14.01.07.01(C)(1), .01(C)(3), .02(C)(1), .02(C)(3).

⁹ Proposed Regulations, COMAR §§ 14.01.07.01(C)(2), 01(C)(4), .02(C)(2), .02(C)(4).

Board shall reconsider” a UPL if it “becomes aware of a shortage . . . in the State.”¹⁰ However, as discussed in our previous comment letters, neither existing regulations nor the Proposed Regulations establish a process to monitor for such shortages.¹¹ While the Board’s regulations require it to “develop a program for monitoring the availability of any prescription drug product for which it sets a UPL,” the Board has not yet developed such a program.¹² Moreover, the regulations do not define what constitutes a shortage *in the state* or explain what the reconsideration process entails. The Board should revise its regulations to specifically address how it will notify stakeholders about UPL suspensions and reinstatements, as well as how it will monitor for and identify shortages in the state and reconsider UPLs in a timely, consistent, and non-arbitrary manner.¹³

B. Other Concerns with the UPL-Setting Process

The Board continues to lack clear and meaningful standards for other aspects of the UPL-setting process. PhRMA restates the following, non-exhaustive examples and encourages the Board to review its previously submitted comments for further discussion.¹⁴

- **Monitoring Patient Access and Affordability.** PhRMA remains concerned that the Proposed Regulations do not provide adequate processes for monitoring patient access challenges or assessing the potential impact on affordability for drugs subject to a UPL, as required in the Board's first annual report on the effects of the UPL for each drug.¹⁵ In addition to requiring reporting of formulary placement, the Board's regulations should require eligible government entities to report information on other benefit design practices, including utilization management and patients' out-of-pocket costs, as both directly impact patient

¹⁰ COMAR § 14.01.05.09(A)(2); *see* Letter from PhRMA to Board (July 13, 2026) at 2; Letter from PhRMA to Board Regarding Draft Regulation (May 1, 2026) *supra* note 1 at 2-3; Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 2-3; *see also* COMAR § 21-2C-13(c)(1).

¹¹ *See, e.g.*, Letter from PhRMA to Board (July 13, 2026) at 2; Letter from PhRMA to Board Regarding Draft Regulation (May 1, 2026) *supra* note 1 at 2; Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 2-3; Letter from PhRMA to Board (Feb. 10, 2025) at 3.

¹² COMAR § 14.01.05.08(B)(1); *see* COMAR § 14.01.05.08(B)(2) (“If monitoring discloses a shortage of the prescription drug product in the State, the Board may suspend or modify the UPL”); Letter from PhRMA to Board (July 13, 2026) at 2-4; Letter from PhRMA to Board Regarding Draft Regulation (May 1, 2026) *supra* note 1 at 3; Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 3.

¹³ *See e.g., Mortimer v. Howard Res. & Dev. Corp.*, 83 Md. App. 432, 442 (1990); *Harvey v. Marshall*, 389 Md. 243, 302 (2005) (“[A]n agency action nonetheless may be ‘arbitrary or capricious’ if it is irrationally inconsistent with previous agency decisions.”); *Hines v. Petukhov*, No. 0594, Sept. term, 2020, 2021 WL 4428781 at *8 (Md. Ct. Spec. App. Sept. 27, 2021) (holding it arbitrary and capricious where an agency “applied different standards and drew irreconcilable and inconsistent conclusions” in its review of a second licensing request, relative to the review of the first request).

¹⁴ *See, e.g.*, Letter from PhRMA to Board (July 13, 2026) at 2-4; Letter from PhRMA to Board Regarding Draft Regulation (May 1, 2026) *supra* note 1 at 3-4; Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 3-4; Letter from PhRMA to Board (Mar. 4, 2026) at 2-3.

¹⁵ *See* Md. Code, Health Gen. § 21-2C-09(d) (requiring the first annual Board report to include information on patient access and affordability, including out-of-pocket costs, health insurance premiums, health insurance formularies, and “[p]atient access to the prescription drug product subject to the upper payment limit”); Letter from PhRMA to Board (July 13, 2026) at 3; Letter from PhRMA to Board Regarding Draft Regulation (May 1, 2026) *supra* note 1 at 3; Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 3.

affordability and ability to access needed medications.¹⁶ While formulary placement is an important indicator of coverage, many other utilization management and benefit design factors can create additional access and affordability issues, as recognized in the PDAB statute.¹⁷ For these reasons, PhRMA urges the Board to establish robust measures to monitor benefit design, including utilization management practices, for the impact of UPLs on patient access and affordability.¹⁸

- **UPL Development.** PhRMA continues to have concerns with the lack of clear standards and processes governing the development of proposed UPLs, including with respect to selecting information to consider, choosing UPL framework parameters and amounts, and determining the appropriateness of a UPL.¹⁹ We urge the Board to establish meaningful standards to guide its actions and limit the risk of arbitrary decision-making.²⁰
- **Stakeholder Comment.** PhRMA also remains concerned that the lack of clear and specific standards for the Board's UPL-setting processes impacts the ability of stakeholders to fully and meaningfully comment on its UPL-setting activities.²¹ The Board should provide clear opportunities for comment on each step in the Board's UPL-setting processes. In addition to complying with notice and comment procedures required under the Maryland Administrative Procedure Act for formal rulemakings,²² the Board should post all materials that are subject to public comment but not part of a formal rulemaking (e.g., draft proposed regulations) on the PDAB website and distribute to stakeholders and distribution lists a minimum of 14 days prior to the comment deadline to allow for meaningful feedback and stakeholder participation.²³ In addition, PhRMA requests details regarding how the Board will incorporate and address all feedback that it receives.²⁴

¹⁶ Proposed Regulation § 14.01.06.04(A)(4); see Md. Code, Health Gen. § 21-2C-09(d) (requiring the first Board report to include information on "[p]atient out-of-pocket costs including whether the upper payment limit was associated with increases or decreases in what patients pay for prescription drug products" and information on patient access, which may include "[w]hether formulary placement or plan design changes made the prescription drug product subject to the upper limit more difficult for patients to access, including if insurance plans preferred a prescription drug product without an upper payment limit over a prescription drug product subject to an upper payment limit"); see also Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 3.

¹⁷ See Md. Code, Health Gen. § 21-2C-09(d).

¹⁸ See Letter from PhRMA to Board (July 13, 2026) at 3; Letter from PhRMA to Board Regarding Draft Regulation (May 1, 2026) *supra* note 1 at 3; Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 3.

¹⁹ See COMAR § 14.01.05.02(B)(2); see also, e.g., Letter from PhRMA to Board (July 13, 2026) at 4; Letter from PhRMA to Board Regarding Draft Regulation (May 1, 2026) *supra* note 1 at 3; Letter from PhRMA to Board (Mar. 4, 2026) at 2-3; Letter from PhRMA to Board (Feb. 10, 2025) at 2-4.

²⁰ See *supra* note 13.

²¹ See, e.g., Letter from PhRMA to Board (July 13, 2026) at 4; Letter from PhRMA to Board Regarding Draft Regulation (May 1, 2026) *supra* note 1 at 4; Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 4; Letter from PhRMA to Board (Nov. 8, 2024) at 5-6; Letter from PhRMA to Board (Aug. 26, 2024) at 2-3.

²² See Md. Code, State Gov't §§ 10-101–10-305.

²³ See *supra* note 21.

²⁴ See, e.g., *id.*

II. MFP Is an Inherently Flawed Metric for State Use and Could Create Access Challenges for Patients

PhRMA remains concerned about the Board's proposed use of MFPs as benchmarks for setting Maryland UPLs.²⁵ MFPs are specifically developed for the Medicare program and patient population under the statutory framework of the Inflation Reduction Act, but the Proposed Regulations would apply these prices to an entirely different market and patient population. In doing so, the Board would be disregarding the unique market dynamics and affordability challenges that patients in Maryland may be facing. As PhRMA has previously expressed, MFP-based UPLs raise serious concerns about patient access, particularly if expanded to the commercial market.²⁶

CMS sets its MFPs through the MDPNP but because the program is still at an early stage, many operational and legal issues remain unresolved. The MFPs for the initial set of drugs only recently went into effect. Although it will be years before the effects of MFPs on patient affordability and access are fully understood, recent evidence shows that out-of-pocket costs for Medicare patients have significantly increased and the number of patients benefiting from MFPs has remained relatively small. Avalere Health's analyses of 2025 and 2026 Part D plan formularies found Part D plans were tightening access to branded medicines, changes that could translate into fewer therapeutic alternatives within classes that contain drugs with an MFP.²⁷ Further, analyses of 2025 and 2026 Part D plan formularies found that Part D plans have increased utilization management, shifted tier placement, and limited access to drugs subject to an MFP.²⁸ The downstream effects of an MFP on patient access will likely be exacerbated by their use in state populations. Using MFP as a benchmark is therefore premature, and PhRMA is concerned by the Board moving forward with MFP-based UPLs without fully understanding the patient impact from the MDPNP.²⁹

Finally, the Proposed Regulations are silent on the fundamental question of how UPLs will be effectuated. At the federal level, even CMS's process has outstanding key issues not yet resolved, and the MFP applies only to Medicare—raising serious doubts about how Maryland will effectuate UPLs given that the U.S. pharmaceutical market and distribution strategies function nationally. In the case of the MFP, the federal government has designed a specific process for implementing the price for patients insured by Medicare—this system does not apply to other markets. This is a significant shortcoming that Maryland cannot disregard, because an unworkable approach could lead to access challenges for patients. Without understanding how UPLs will work in practice, the Board will not be able to meaningfully assess the impact on the supply chain and patients.

²⁵ See, e.g., Letter from PhRMA to Board (July 13, 2026) at 2; Letter from PhRMA to Board Regarding Draft Regulation (May 1, 2026) *supra* note 1 at 2; Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 4-5; Letter from PhRMA to Board (Mar. 4, 2026) at 3-4; Letter from PhRMA to Board (Nov. 8, 2024) at 10.

²⁶ See, e.g., Letter from PhRMA to Board (June 1, 2026) at 7; Letter from PhRMA to Board Regarding Draft Regulation (May 1, 2026) *supra* note 1 at 4-5; Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 4-5; Letter from PhRMA to Board (Mar. 4, 2026) at 3-4; Letter from PhRMA to Board (Nov. 8, 2024) at 10.

²⁷ Avalere Health, 2025 Part D Formularies Shift to More Coinsurance and UM (Oct. 2024); Avalere Health, Part D Formulary Management Tightens in 2026 (Nov. 2025).

²⁸ *Id.* In addition, a 2025 physician survey by Avalere found that nearly all providers (92%) would be somewhat or very likely to stop stocking Part B drugs subject to an MFP. See Avalere Health, White Paper: Provider Survey on Part B Negotiation (Sept. 2025).

²⁹ See, e.g., Letter from PhRMA to Board (June 1, 2026) at 8; Letter from PhRMA to Board Regarding Draft Regulation (May 1, 2026) *supra* note 1 at 4-5; Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 4-5; Letter from PhRMA to Board (Mar. 4, 2026) at 3-4; Letter from PhRMA to Board (Nov. 8, 2024) at 10.

III. Legal Considerations

PhRMA also notes that consideration of UPLs raises significant legal concerns. The recent decision in *Amgen Inc. v. Mizner*, No. 1:25-cv-03452, — F.Supp.3d —, 2026 WL 1943512 (D. Colo. July 1, 2026), underscores the significant legal concerns raised when a state-imposed UPL suppresses the economic value of a patented medicine. In preliminarily enjoining a UPL set by Colorado’s PDAB, the court explained that under controlling Federal Circuit precedent, federal patent law preempts state measures that “change the bargain struck by Congress,” including altering Congress’s chosen balance between rewarding pharmaceutical innovation and promoting access to medicines.³⁰ The court also recognized that such measures are preempted even when they regulate downstream transactions rather than a manufacturer’s initial sale of a drug.

* * *

On behalf of PhRMA and our member companies, thank you for your consideration of our comments. Although PhRMA remains concerned about the Proposed Regulations, we continue to stand ready to be a constructive partner in this dialogue. Please contact Kristin Parde at kparde@phrma.org with any questions.

Sincerely,



Kristin Parde
Deputy Vice President, State Policy



Alexandra Hussey
Senior Director – Law

³⁰ *Amgen*, 2026 WL 1943512 at *3; see *BIO v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007).



1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

July 27, 2026

Comments on Proposed Regulations for Upper Payment Limits for Ozempic and Jardiance

Public Citizen is a nonprofit consumer advocacy organization with more than one million members and supporters around the country, including many in Maryland. Public Citizen advocates for the public interest, including with respect to access to prescription drugs.

We appreciate the work that the Maryland Prescription Drug Affordability Board (PDAB) is doing to support affordability, including through [regulations](#) that propose Upper Payment Limits for Ozempic and Jardiance. We urge the Board to adopt these regulations.

The pharmaceutical industry often fights efforts to rein in prescription drug costs by claiming that attempts to make drugs more affordable will harm the ability to invest in research and development for new medicines. In reality, pharmaceutical companies do not set prices based on a drug's research and development cost. Rather, insulated from competition by monopoly protections, companies set prices based on what the market will bear and reap large profits in the process. Below, we provide relevant information related to Ozempic and Jardiance.

Ozempic

Ozempic (semaglutide) is manufactured by Novo Nordisk and approved by the FDA to help control blood sugar levels, reduce the risk of cardiovascular disease, and reduce the risk of worsening kidney disease in patients with type 2 diabetes.

Novo Nordisk's pricing and revenues for Ozempic cannot be explained by research and development (R&D) spending. The company has made over \$69.5 billion in sales revenue from Ozempic since the drug's launch in 2018. These revenues are an order of magnitude higher than even the most generous estimates of research and development costs that take into account failed candidates and a reasonable return on investment. Since Novo Nordisk launched Ozempic, the company has spent over \$56.3 billion on share repurchases and shareholder dividends—1.7 times as much as it spent on R&D across its entire portfolio (\$32.6 billion).¹

Novo Nordisk sells the same drug at much lower prices in comparable countries and still makes a profit at those prices. Based on net price estimates, Ozempic is as much as five times as expensive in the U.S. as in peer countries. Meanwhile, researchers estimate that the drug could be profitably manufactured for as little as around [\\$3](#) for a monthly supply.

Novo Nordisk's patenting tactics could stave off generic competition — a proven way to lower prices — keeping prices higher for longer. Follow-on patents for semaglutide, many of which cover minor modifications, provide patent protections until [2042](#), ten years after the patent covering the drug substance expires.

¹ Public Citizen analysis of company financial reports 2018–2025.

Jardiance

Jardiance (empagliflozin) is sold by Boehringer Ingelheim and Eli Lilly and is used to treat diabetes and heart failure.

Jardiance's list price is 11.7 times higher than the average price across comparable countries, according to one [analysis](#). Jardiance has generated over \$26.8 billion in sales since its launch in 2014. Revenues obtained through Jardiance sales are nearly 38 times the median cost for research and development of a new drug [estimated](#) by experts.

Boehringer Ingelheim uses predatory patenting tactics to expand monopoly protections over Jardiance. This staves off generic competition — a proven way to lower prices — keeping prices higher for longer. According to Public Citizen [research](#), Boehringer Ingelheim's patents covering methods for screening patients for use of empagliflozin can be exploited to exclude generics until as late as 2034 — an extra five years beyond the expiry of the drug compound patent and almost 20 years beyond the drug's initial approval.

Eli Lilly² spends huge sums on payouts to executives and shareholders, rather than R&D. In 2024 alone, Eli Lilly spent [over \\$7 billion](#) enriching shareholders through stock buybacks and dividends.

We encourage the PDAB to act to reduce Ozempic and Jardiance costs and help ensure that pharmaceutical companies do not put profits over the needs of everyday Americans.

² Eli Lilly and Boehringer Ingelheim commercialized Jardiance together, but the latter company is privately held. Thus, data on self-enriching activities are only available for Eli Lilly.



Value of Care Coalition

July 27, 2026

Christina Shaklee
Health Policy Analyst Advanced
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: COMAR 14.01.07 Regulation Comments – Upper Payment Limit for Ozempic (semaglutide)

The Value of Care Coalition (VCC) appreciates the opportunity to comment on the Maryland Prescription Drug Affordability Board's proposed regulation establishing an Upper Payment Limit (UPL) for Ozempic (semaglutide).

VCC continues to believe that UPLs are not the appropriate policy mechanism to address prescription drug affordability. Affordability policies should not create new risks to patient access, treatment continuity, or the stability of the health care delivery system. Despite the Board electing to move forward with implementation, it is essential that it rigorously evaluate whether the concerns raised by patients, providers, pharmacies, and health plans materialize in practice. We appreciate the Board's recognition throughout its public meetings that protecting patient access must remain a central consideration as UPLs are implemented. As one of the Board's first drug-specific UPL regulations, this is an important test of how that commitment will be reflected in practice.

The Board's affordability determination for Ozempic was based, in part, on increasing utilization for the drug and concluded that utilization is driven primarily by patients receiving treatment consistent with FDA-approved indications. This regulation will therefore primarily affect patients managing a serious chronic disease who rely on continuity of therapy to maintain glycemic control and avoid preventable complications. Any unintended disruption in access has the potential to affect patients for whom the Board has already determined the medication is being used appropriately.

The 2025 legislation expanding the Board's UPL authority directs the Board, once a UPL has been in effect for one year, to report on its effects on patient out-of-pocket costs, health insurance premiums, pharmacy reimbursement and financial viability, formulary placement, provider acquisition and reimbursement, patient access, 340B covered entities, and Maryland's

biotechnology industry. This framework reflects the Legislature's recognition that UPLs should be evaluated on their real-world effects across the health care system, not solely on projected savings. Meaningful evaluation depends on the Board establishing the processes needed to collect baseline and implementation data before the UPL takes effect, rather than after the fact.

The proposed economic impact statement projects approximately \$5.8 million in savings for eligible governmental entities, based on assumptions that patient demand and access will be unaffected, that administrative costs will be minimal, and that existing contracts can accommodate the UPL. If those assumptions do not hold in practice, the Board should reassess whether the policy is producing its intended results. Notably, the statement does not conclude that patients themselves will see improved access or lower costs—only that governments *may* choose to allocate their savings toward that end. Whether patients realize any benefit therefore depends on decisions and assumptions that cannot be validated until implementation occurs, reinforcing the importance of evaluating actual outcomes rather than projected fiscal impacts.

Reimbursement changes, formulary shifts, pharmacy inventory decisions, and provider acquisition challenges can each create barriers to medically necessary treatment even if the medication itself remains available. We understand the Board intends to implement the UPL through a supplemental rebate structure, which carries two distinct risks: whether the rebate ultimately reflects an adequate price for the pharmacies and providers who acquire and dispense the drug, and whether the timing of rebate payment creates a cash-flow burden if pharmacies and providers must front the difference between acquisition cost and the UPL before being made whole. We have seen the burden of the reimbursement lag with the implementation of Medicare's maximum fair price, which falls hardest on independent and safety-net pharmacies operating on thin margins.

We appreciate the inclusion of an automatic suspension when Ozempic is identified by the FDA as being in shortage—patient access should take precedence when supply disruptions occur—but that safeguard alone would not capture the reimbursement, timing or other access risks described above. Consistent with the statutory reporting framework, the Board should monitor these factors throughout implementation, including whether certain patient populations experience disproportionate access challenges and whether cost differences shift the burden to patients, providers, or pharmacies. Doing so throughout implementation—in addition to the one-year report—will allow emerging concerns to be identified and addressed promptly and let the Board determine whether the assumptions underlying its analysis hold in practice.

VCC continues to believe that UPLs present significant risks to patient access while offering uncertain patient benefit. Because the Board has elected to proceed, it bears the responsibility of demonstrating through transparent, evidence-based evaluation that the regulation's assumptions are borne out and that patients are not adversely affected. Should its own monitoring show otherwise, the Board should be prepared to revisit the policy.

We appreciate the opportunity to provide these comments and look forward to continued engagement with the Board.

Sincerely,

Derek Flowers
Value of Care Coalition