AARP Maryland

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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,

Sara M. Westrick

AIMED ALLIANCE

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, Aimed 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

Aimed 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, Aimed 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

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[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.

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[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, Aimed 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@aimedalliance.org.

Sincerely,

Olivia Backhaus
Staff Attorney

Boehringer Ingelheim

July 27, 2026

Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
Ridgefield, CT 06877

Re: COMAR 14.01.07 Upper Payment Limit: .01 Upper Payment Limit for Jardiance (empagliflozin)

At Boehringer Ingelheim, we recognize the challenges within the U.S. healthcare system—particularly the burden patients face when confronted with high out-of-pocket costs at the pharmacy counter. While we agree that action is needed to make medicines more affordable, we believe that government-imposed price controls are not the most effective path forward. Instead, we advocate for solutions that improve patient access, affordability, and support medical innovation.

The Maryland Prescription Drug Affordability Board (PDAB) released final regulations, COMAR 14.01.07 (Upper Payment Limit (UPL): .01 Upper Payment Limit for Jardiance® (empagliflozin)). These regulations outline the final UPL for Jardiance.

Boehringer Ingelheim respectfully disagrees with establishing a UPL for Jardiance. We are committed to ensuring that Jardiance® is affordable for all Maryland patients, but we have significant concerns about applying a UPL benchmarked to Medicare's Maximum Fair Price (MFP) across Maryland's markets. MFP was developed solely for the Medicare population; it does not reflect Maryland specific formulary structures, reimbursement, or utilization. Applying a UPL based on the Medicare MFP without considering Maryland-specific market conditions, reimbursement structures, and patient needs risks creating a pricing benchmark that may not support sustainable patient access to treatment.

Patients face access and affordability barriers driven in part by PBM business practices. Manufacturers are only one part of the broader drug pricing and reimbursement system. A UPL tied to manufacturer list price does not address the role of plans and PBMs, which largely determine the out-of-pocket costs patients face at the pharmacy counter. PBMs may retain rebates and fees tied to higher list prices rather than passing savings through to patients, creating incentives that may discourage adequate coverage and increased utilization management for Jardiance® if reimbursement is capped below current rates. Plans and PBMs may respond to reduced reimbursement limits by tightening formularies, shifting products to higher cost sharing tiers, or increasing utilization management (UM). UM requirements like prior authorization have increased by more than 60% between 2014 and 2023, and step-therapy policies have become one of the most common tools used by PBMs to manage costs, often without much regard for clinical utility or patient adherence and affordability[1].

Results of Maryland UPL implementation may undermine the work manufacturers have done to lower real-world OOP costs in the commercial market through copay assistance and patient affordability programs. However, government price controls threaten these affordability pathways and may lead plans to rebalance costs in ways that directly increase what patients pay. The UPL fails to recognize Jardiance® is more affordable for Maryland patients than the national average. The Maryland average OOP cost of Jardiance®, which is $44.13, while the national commercial average OOP cost of Jardiance® is $44.413. The UPL also does not take into consideration copay assistance available to patients in the state. There is a 47% commercial utilization rate of Boehringer's copay assistance program for Jardiance®[2], providing reduced copays for Maryland state employees and

[1] Tracing The Arc Of Medication Utilization Management Over Time", Health Affairs Forefront, June 3, 2025. DOI: 10.1377/forefront.20250602.396783

[2] IQVIA Longitudinal Access and Adjudication Data (LAAD). Data run September 2024.

commercial patients. In these circumstances, instead of improving access to Jardiance®, a UPL could jeopardize that access, discourage life-changing innovation, and cause harmful, unintended consequences.

The Board's proposed rule to establish a UPL for Jardiance® under COMAR 14.01.07.01 would apply only to purchases made by eligible governmental entities. See Md. Code Ann., Health-Gen. § 21-2C-14. We understand, however, that the Board is considering extending the UPL to apply also to private, commercial transactions***. Any attempt to extend the UPL beyond purchases by Maryland may violate federal law and constitutional requirements.***

A federal district court recently enjoined Colorado's analogous regulation imposing a UPL on Amgen's Enbrel®, finding that "under binding Federal Circuit precedent, caps on the price of patented drugs like Enbrel are preempted by federal law." Order Granting Motion for Preliminary Injunction at 4, Amgen Inc. v. Mizner, No. 1:25-cv-03452 (D. Colo. July 1, 2026), ECF No. 66. The court explained that the state "has a number of ways" to help its citizens afford medications but "one way it cannot do so under the binding precedent of the Federal Circuit [] is by capping the price of a patented drug." Id. at 9. Accordingly, the district court held that Amgen is likely to prevail in showing that federal patent law preempts state efforts to override, through price controls, the exclusive rights and rewards that Congress has provided to patent holders. See id. at 5–7. More broadly, state efforts to regulate the price of drugs based only on purported affordability considerations—without applying meaningful standards to constrain the discretion of state regulators and ensure a fair and reasonable return on investment—violate due process and basic takings principles.

Boehringer supports the Board's mission to improve affordability for Maryland patients. We urge the Board to consider non-UPL approaches that address cost drivers holistically, improve transparency across the supply chain, and maintain continuity of coverage for patients who benefit from Jardiance®. We remain committed to working collaboratively on solutions that sustain patient access while supporting continued medical innovation.

Regards,

Signed by:
Candice Finnegan
F5069C0EFC26442...

Candie Finnegan, ED State Government Affairs

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

EACH PIC COALITION

July 27, 2026

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

RE: Public Comments on COMAR 14.01.07.01 Upper Payment Limit for Jardiance

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 Jardiance. 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.

EACH PIC COALITION

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 OOP 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@aiarthritis.org
Ensuring Access through Collaborative Health (EACH) Coalition Lead

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/

PhRMA
RESEARCH • PROGRESS • HOPE

670 Maine Ave SW WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

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

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[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]

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[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.

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[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).

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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 Lilly[2] 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

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Re: COMAR 14.01.07 Regulation Comments – Upper Payment Limit for Jardiance (empagliflozin)

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 Jardiance (empagliflozin).

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 that protecting patient access must remain a central consideration as UPLs are implemented. As the regulation establishing the Board's new UPL chapter and its first drug-specific UPL, this will set the template against which every subsequent UPL determination is measured, making it an especially important test of how that commitment is reflected in practice.

Jardiance is approved to treat type 2 diabetes, heart failure, and chronic kidney disease. This regulation will therefore affect patients across three distinct — and frequently overlapping — serious chronic conditions who depend on continuity of therapy to maintain glycemic control, reduce the risk of heart failure and cardiovascular death, and slow the progression of kidney disease. Because many Jardiance patients manage more than one of these conditions simultaneously, any unintended disruption in access carries a broader and more complex set of clinical risks than a single-indication therapy would present.

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 estimates that, after accounting for estimated commercial net prices, the Jardiance UPL would reduce spending for participating state and local government health plans by over $300,000, 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.

VCC also notes that the Board's economic impact statement acknowledges that its savings estimate is under-inclusive because data are unavailable for several categories of eligible governmental entities. Likewise, the statement concludes that reduced governmental expenditures *may* have a positive impact on the public because those savings *may* be allocated for other purposes. Similarly, the impact analysis for individuals with disabilities anticipates that savings *may* be allocated to expand access to Jardiance through reduced barriers to care. These projected public benefits are inherently dependent on future policy decisions and assumptions that cannot be validated until implementation occurs. Accordingly, ongoing monitoring and transparent reporting will be essential to determine whether the anticipated benefits are realized and whether any unintended consequences emerge.

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. This risk is not merely hypothetical: as VCC has noted previously, the mechanics of how this UPL will translate into pharmacy reimbursement remain unresolved. Independent and safety-net pharmacies operating on thin margins are least equipped to absorb that uncertainty, and the Board should not finalize this regulation without assurance that pharmacy access will hold once it takes effect.

We appreciate the inclusion of an automatic suspension when Jardiance 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 access risks described above. Reimbursement changes, formulary design, pharmacy participation, and provider acquisition challenges can each limit access even when adequate product supply exists. Consistent with the statutory reporting framework, the Board should monitor these factors throughout

implementation, including whether patient populations managing heart failure or chronic kidney disease alongside diabetes 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 this regulation will serve as the Board's first UPL determination and the model other drug-specific UPLs will follow, it bears particular responsibility for 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