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