DIABETES PATIENT ADVOCACY COALITION

February 13, 2026

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

RE: PDAB February 23 Meeting - Preliminary Policy Recommendations for Ozempic and Trulicity

Dear Members of the Maryland Prescription Drug Affordability Board,

DPAC appreciates the opportunity to comment on the Board's staff preliminary policy recommendations for Ozempic and Trulicity, specifically with respect to the proposed non–Upper Payment Limit (non-UPL) policy solutions. Set forth below are DPAC's comments on two of the proposed non-UPL policy approaches:

State Participation in CMMI models (Both Ozempic and Trulicity)

DPAC applauded the announcement by CMS to test a new approach to reduce prices of and improve access to GLP-1 drugs through the BALANCE model. However, significant uncertainty remains regarding how the model will operate in practice and what it will mean for Medicare and Medicaid beneficiary access. Key coverage details, including which beneficiaries and which drugs will be included, depend on participation by drug manufacturers, states, and Part D sponsors. Patients may also be subject to coverage qualifications determined through negotiations. In addition, it is unclear what types of lifestyle interventions will be required or offered under the model. We encourage the state to consider participating in the model, provided that its design and implementation would meaningfully expand access to GLP-1 medications.

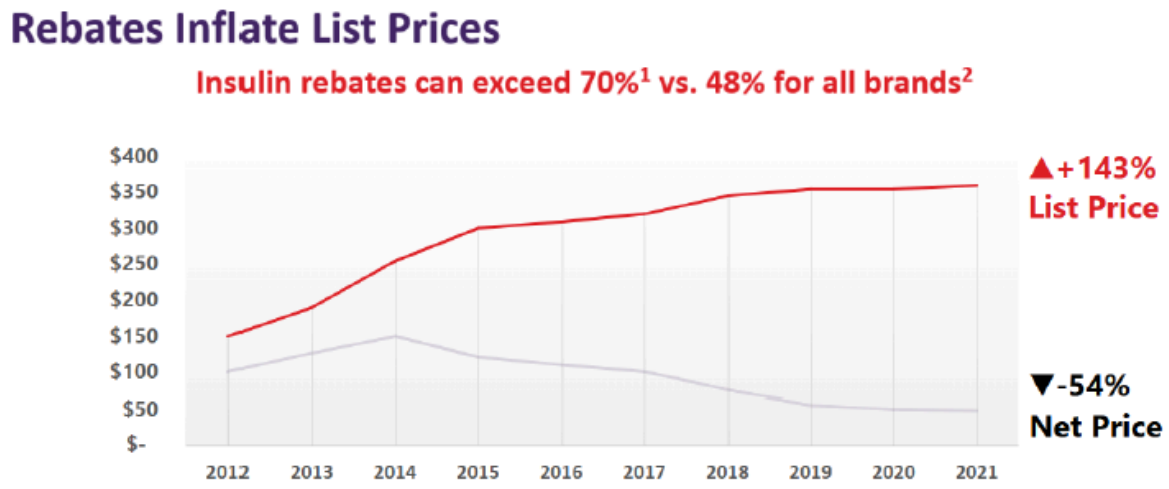
With respect to the GENEROUS model, we note that drug prices used for comparison in many foreign countries are derived from explicit cost-effectiveness frameworks that frequently rely on Quality-Adjusted Life Years (QALYs). QALYs set out guidelines about whose health gains are "worth" public investment, raising longstanding concerns in the United States regarding equity for people with disabilities, chronic conditions, and complex health needs. Before adopting an MFN approach, the state should carefully consider whether anchoring prices to systems that

rely on QALY-based thresholds aligns with its own policy goals, nondiscrimination principles, and commitment to ensuring access to medically necessary treatments for all patients.

Plan Design and PBM Reform Study and Recommendations (Both Ozempic and Trulicity)

While we welcome the Board's increased interest in pharmacy benefit manager (PBM) reform, we are concerned that a recommendation for a study will delay policies for which there is already substantial evidence to support action. This includes the Board's prior recommendation to support legislation delinking PBM compensation from rebates.

Delinking PBM compensation from drug list prices will limit future increases in list price, as it will remove incentives to inflate list prices and provide higher rebates to PBMs. It will ensure that patients benefit from the lowered list prices. The chart[1] below demonstrates the incentive to inflate list price by showing how insulin list prices increased from 2012 to 2021 while the net price decreased because of negotiated savings. The Board already noted that there is evidence that delinking compensation from the list price of a drug could lower overall drug spending by about 15%.[2]



There is strong evidence supporting rebate pass-through policies that require insurers and PBMs to pass negotiated savings directly to patients at the point-of-sale. West Virginia, Indiana, and Arkansas passed such legislation in 2021, 2023 and 2024, respectively. Following implementation, rate filings for plans in Indiana and Arkansas saw no increase in premiums

[1] U.S. Senate Finance Committee on Finance. Insulin: examining the factors driving the rising cost of a century old drug. January 14, 2021. https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf; Kakani P, Chernew M, Chandra A. Rebates in the pharmaceutical industry: evidence from medicines sold in retail pharmacies in the U.S. March 2020. NBER Working Paper 26846. https://www.nber.org/papers/w26846; Sanofi 2021 Pricing Principles Report. March 3, 2021 https://www.sanofi.us/en/pricing-principles-report. Sanofi is a member of the DLC Industry Advisory Board.

[2] Joyce G. The cost of misaligned incentives in the pharmaceutical supply chain. Health Aff Sch. 2025;3(7):qxaf126. Published 2025 Jun 25. doi:10.1093/haschl/qxaf126

attributable to these policy reforms.[3] In West Virginia, the Office of the Insurance Commissioner has recently released data demonstrating that rebate pass-through has in fact reduced rate increases for plans by 0.7% to 14%.[4]

Finally, we respectfully reiterate our request that the Board prioritize the evaluation and advancement of non–Upper Payment Limit (non-UPL) policy options as it continues to work through its processes. Non-UPL approaches offer evidence-based pathways to improve affordability while minimizing the risk of unintended access disruptions. Advancing these strategies should be central to the Board's efforts to protect patient access and affordability.

Sincerely,

George Huntley
Chief Executive Officer
Diabetes Patient Advocacy Coalition

[3] Klein, M., & Holzer, H. (January 2024). Premium Impacts of POS Rebate Implementation in the ACA Market in the State of Arkansas. Milliman. Available at https://dfr.oregon.gov/pdab/Documents/Constituent-testimony-2.pdf; Robb, M., & Holzer, H. (January 2025). Premium Impacts of POS Rebate Implementation in the ACA Market in the State of Indiana. Milliman. Available at https://edge.sitecorecloud.io/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/2025-Articles/1-29-25_POS-Filing-Impacts.pdf.

[4] West Virginia Insurance Bulletin No. 25-01 (February 13, 2025). Available at https://www.wvinsurance.gov/Portals/0/pdf/pol_leg/IB_25-01_Prescription_Drug_Rebate_Impact_to_Commercial_Health_Insurance.pdf?ver=2025-02-13-125517-883.

Eli Lilly and Company

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February 18, 2026

By Electronic Submission

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

Dear Members of the Maryland Prescription Drug Affordability Board ("Board" or "PDAB"):

Eli Lilly and Company ("Lilly") appreciates the opportunity to offer updated comments on materials for the Board Meeting originally scheduled to be held on January 26, 2026, including the Cost Review Study Process Preliminary Policy Recommendations presentation slides (the "Policy Presentation") and the updated upper payment limit ("UPL") framework for Trulicity® (the "Trulicity® UPL Framework").[1]

Lilly is proud to make Trulicity®, a once-weekly injectable prescription medicine for certain patients with type 2 diabetes to improve blood sugar (glucose) or to reduce the risk of major cardiovascular ("CV") events. Trulicity® is affordable and widely accessible, including for patients and health care entities in Maryland. Lilly shares the Board's goal of improving patient outcomes by making effective treatments accessible, but Lilly continues to have serious concerns that the Board's cost review activities threaten to jeopardize patients' access to vital medicines, including Trulicity®.[2] To that end, Lilly urges the Board to take into consideration the concerns and recommendations outlined below particularly regarding factors determining affordability and identified policy options to address affordability.

I. A UPL Is Not a Reasonable Policy Recommendation for Trulicity

The Board should not pursue a UPL policy for Trulicity® because it lacks authority under the governing legal standards, and it will do nothing to make Trulicity® more affordable for patients. The Board itself acknowledges that gross spending, one of its two affordability findings, does not support a UPL recommendation; and, for the reasons outlined below, a UPL would not address the purported affordability challenges tied to Trulicity®'s WAC.

Patient Experience and Affordability

[1] *See* Board, Cost Review Study Process Preliminary Policy Recommendations Presentation (Jan. 16, 2026), available here; Board, Trulicity® UPL Framework (Jan. 16, 2026), available here; Board, Trulicity® UPL Framework Presentation (Jan. 16, 2026), available here.

[2] In filing this letter, Lilly expressly reserves all available arguments regarding the legality of the PDAB statute and its implementation, and reasserts and incorporates by reference its prior comment letters.

Lilly reiterates that the primary focus of any cost review by the Board should be on patients, and Trulicity® is broadly affordable for Maryland patients. As addressed in our prior letters and as acknowledged by the Board, Trulicity® does not present an affordability challenge to patients in Maryland.[3] Indeed, the Board's affordability finding on the basis of WAC and gross spending does not measure patient costs. The Policy Presentation itself recognizes that the GLP-1 class has experienced marked price reductions as a natural product of market competition in recent years, and these therapies already "are subject to multiple national and state efforts to promote affordability and access."[4]

Assessing Affordability and Policy Drivers

Lilly reiterates our concern with the underlying methodology and metrics the Board is using to determine affordability. The Board must base Trulicity®'s affordability on more reliable and accurate metrics of the cost of our medicine to the state and its residents. These determinations should be derived from a complete and holistic picture of the costs that purchasers and patients in the state actually incur when they interact with the healthcare system. Furthermore, aggregate spending metrics disconnected from per-patient data will consistently and disproportionately identify medications for common chronic diseases for "affordability reviews" – without regard for the obvious fact that the size of the eligible treatment population is often responsible for the utilization observed.

Trulicity®'s WAC is not a meaningful measure of affordability.[5] Although the Board may consider WAC in the cost review process, its ultimate statutory directive is to identify whether a drug "has led or will lead to affordability challenges," a determination which cannot reasonably rest on WAC.[6] The Board itself has acknowledged that WAC does not "represent the final net cost of the drug" because rebates and other price concessions "can dramatically impact the final 'net cost'" incurred by payors (including state payors).[7] It is unclear how WAC increasing faster than inflation could "lead to affordability challenges for the State health care system"

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[3] *See* Eli Lilly Comments on Stakeholder Informational Hearing, December 16, 2025; Letter from Lilly to Board (Nov. 12, 2025); Letter from Lilly to Board (Sept. 4, 2025).

[4] Policy Presentation at 14–15, 83. As noted in prior comments, Lilly recently announced direct-to-patient purchasing options making Trulicity widely available at a 50-60% discount off of the list price. Letter from Lilly to Board at 3 (Nov. 12, 2025).

[5] *See* Board, Notice of Informational Hearing 2 (Dec. 16, 2025) ["Notice of Informational Hearing"], available here.

[6] Md. Code, Health-Gen. § 21-2C-09(b)(1), (b)(2)(i); *see Md. Off. of People's Couns. v. Md. Pub. Serv. Comm'n*, 461 Md. 380, 399–40 (2018) (explaining that an agency may not exercise discretion "unreasonably or without a rational basis" and reviewing courts "may look for consistency with the policy goals stated in the pertinent statutes or regulations").

[7] Supply Chain Report – Health General Article § 21-2C-07 at 11 (Sept. 10, 2024) ["Supply Chain Report"], available here.

when WAC does not measure the cost to the system[8] (and given that list price growth in excess of inflation is offset by the net prices offered by manufacturers to state purchasers).

The Board has noted that an increasing WAC "*may* directly impact patients by influencing patient cost sharing" but has not presented any evidence of such an impact for Trulicity®, much less an impact that rises to the level of "affordability challenges for the State health care system or high out-of-pocket costs for patients."[9] In fact, the Board reviewed patient cost information for Trulicity® and, unlike in the case of other drugs under review, did not identify patient costs as a circumstance reflecting an affordability challenge—only WAC and percentage of gross prescription drug spending, neither of which measures Trulicity®'s costs to patients. It is unclear how Trulicity®'s WAC has led to an affordability challenge simply because it "may" influence patient cost sharing when patient costs have not been deemed to present an affordability challenge.[10] Lilly urges the Board to make affordability determinations based not on assumptions but on a holistic and reasoned review of reliable data.

The stated basis for the UPL recommendation is "[e]nsur[ing] that affected entities' net costs are protected from WAC increases . . . by establishing a ceiling net price that is not contingent on WAC increases."[11] Board staff advance this recommendation despite acknowledging its mechanism has more weaknesses than strengths.[12] Specifically, the Policy Presentation acknowledges that (1) the "[i]mpact of the savings to the state is based on the net price that the entity is currently paying," *not* the list price; (2) "Trulicity may have biosimilar competition as soon as 2027," further driving down costs over the natural course of the pharmaceutical lifecycle; and (3) GLP-1s in particular are subject to additional affordability measures.[13] Thus, the Board's own analysis suggests that a UPL for Trulicity® will not generate savings or otherwise improve affordability.

The Policy Presentation reports that the WAC finding is driven by underlying market dynamics; as detailed below, Lilly urges the Board to focus on policy solutions that address those underlying drivers rather than wasting time and resources on UPLs which ultimately will not benefit patients or payors.[14] A UPL would not reduce the

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[8] Md. Code, Health-Gen. § 21-2C-09(b)(1); *see generally, e.g.*, *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."). Lilly continues to urge the Board to focus on net costs to assess affordability in accordance with its statutory purpose. *See* Letter from Lilly to Board 7 (Jan. 10, 2025); Letter from Lilly to Board 6, 12 (Aug. 26, 2024).

[9] Policy Presentation at 31; Md. Code, Health-Gen. § 21-2C-09(b)(1).

[10] *See generally Md. Dep't of the Env't v. Cnty. Comm'rs*, 465 Md. 169, 201–02 (2019) (explaining that a reviewing court defers to an agency "when the record supports [its] findings and inferences").

[11] Policy Presentation at 83–85.

[12] *Id.* at 83.

[13] *Id.*

[14] *See id.* at 31–32.

prices paid by State health care entities, reduce patient cost sharing, nor otherwise meaningfully make prescription drugs more affordable.

Similarly, Trulicity®'s percentage of gross prescription drug spending is not a meaningful measure of affordability.[15] Gross spending, like WAC, does not reflect the underlying costs incurred by commercial and government payers. Both plan premiums and medical loss ratio ("MLR") calculations are derived from net drug spending.[16] Cost analyses that omit or overlook this information by focusing on gross spending provide an insufficient basis for finding an affordability challenge.[17]

Furthermore, as stated above, high aggregate spending on a drug could be the simple outgrowth of it being highly effective at treating a widespread chronic condition. Such treatments cannot plausibly represent an affordability challenge unless the proportion of total spending attributable to a given drug is inappropriate for its utilization and value. Affordability determinations cannot be fairly ascertained without consideration of the estimated net spending impact per patient – inclusive of medical cost offsets attributable to the drug that ultimately accrue to state purchasers. Although the Board *may* consider a variety of individual factors for its cost review process, its ultimate statutory directive is to identify whether a drug "has led or will lead to affordability challenges". Such a determination should rest on a more accurate and holistic picture of financial impact, rather than a conclusory focus on gross spending in aggregate. The Board should instead re-assess its determination with a focus on net expenditures per patient – inclusive of treatment costs offsets derived from clinical value to the system – while factoring in a broader range of metrics that includes patient out of pocket experience, manufacturer assistance provided, and a recognition that health plan costs (as reflected in premiums) are calculated based on net drug costs after manufacturer rebates.

The Policy Presentation itself attributes Trulicity®'s gross spending to high utilization, recognizing the medicine's "special place in therapy for treating patients with comorbidities, which represents a large portion of patients with diabetes."[18] The Policy Presentation adds that, in this case, "the price is high on both a list and net basis, so

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[15] *See* Notice of Informational Hearing 2.

[16] CMCS Informational Bulletin. Medical Loss Ratio (MLR) Requirements Related to Third-Party Vendors. May 15, 2019. Available here.

[17] *See Md. Off of People's Couns.*, 461 Md. at 399. Board members commented that 1% or more represents a "significant" portion of drug spend but did not explain how it determined that threshold nor make any attempt to contextualize that spending. July 2025 Meeting Recording 2:42:19. It is not clear that the Board even cross-referenced these percentages to patient counts much less weighed the data against the burden of disease, reductions in health care expenditures, or other relevant factors. One Board member noted the drugs' effectiveness, but there was no meaningful discussion of how the data combine to impact affordability. *See* July 2025 Meeting Recording 2:50:25. Presumably, the threshold at which the portion of total spending indicates an affordability challenge differs based on the particular medicine under review, but it is not evident how the Board is taking these considerations into account, if at all.

[18] Policy Presentation at 33.

high gross spend is associated with a high net spend."[19] But importantly, the Board never made an affordability finding based on net price or net spending, suggesting the data did not support such finding. The Board should not circumvent due process by resting policy recommendations on affordability concerns that the Board did not substantiate in the first instance.[20] Lilly asks the Board to decline to find affordability challenges based on gross spending or other metrics that do not measure affordability.

Identified Policy Options

UPLs Do Not Address Underlying System Incentives

Aside from the fact that a decision to set a UPL on Trulicity® would flow from a flawed and misguided methodology, such a policy would not meaningfully improve patient affordability or access. On the contrary, UPLs are more likely to *harm* patient access in the long run, given underlying incentives within the pharmaceutical supply chain in need of reform.

Plan formulary designs continue to be driven by rebates and fees often calculated as a percentage of a drug's list price. To the extent that a UPL leads to a reduction in such price concessions to PBMs, formulary access to such products may be disfavored for alternative treatments that continue to offer rebates. This is not simply a theoretical concern.[21] A survey of large regional and national payers found most (83%) anticipated moderate or major disruption to formulary design due to state price controls and 50% expected increased copays or coinsurance on a drug subject to state price setting.[22] Additionally, a recent survey of independent pharmacies indicates most are considering not stocking drugs subject to Maximum Fair Prices (MFPs), and about one-fifth have already decided not to stock such drugs, signaling a further risk to access if a UPL is set at the MFP.[23] These very real risks underscore that state policy efforts should be aimed at addressing underlying system incentives.

Lilly continues to have reservations about the use of Domestic Reference Pricing as a UPL framework for any drug, particularly in light of the updated UPL framework.[24]

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[19] *Id.*
[20] *See, e.g.*, COMAR 14.01.05.03.B ("The purpose of the policy review process is to: (1) Based on the best available information, confirm the drivers and market conditions causing the affordability challenge phenomena; and (2) Identify the policies that may *address those drivers and redress the affordability challenges*." (emphasis added)).
[21] *See generally, e.g.*, Magnolia Market Access, IRA Payer Insights Survey (Summer 2024), available here (reporting that more than half of surveyed payors anticipate adding utilization management or other coverage restrictions for drugs subject to Medicare MFPs in favor of non-negotiated drugs).
[22] Update: Health Plans' Perceptions of PDABs and UPLs, Avalere Health. Available here.
[23] National Community Pharmacists Association. Report for Medicare Drug Price Negotiation Program and Financial Health of Pharmacy, available here.
[24] *See* Letter from Lilly to Board at 11 (Aug. 26, 2024).

Lilly also continues to stress that a UPL should not be set at the MFP itself.[25] When Congress enacted the Inflation Reduction Act ("IRA"), it expressly chose to limit the scope of the MFP to the Medicare population, which differs significantly in demographics, age, and diversity from the Maryland patients who would be affected by a UPL. Extension of the MFP to non-Medicare populations by states would fundamentally disrupt the careful balance that Congress struck in enacting the IRA, compromising patient access to and hindering innovation of new and potentially life-saving medicines. In addition to being unsound public policy, use of the MFP would raise serious preemption concerns by expanding the reach of the MFP beyond what Congress ever intended, thereby fundamentally disrupting the structure of the federal scheme and create increasing disincentives to participation in the Medicare program.

The Board Should Consider Alternative Policies to UPLs

As noted above, any actions to meaningfully address affordability will require targeting underlying incentives in the pharmaceutical supply chain in need of reform, rather than misguided policies like UPLs. Lilly is encouraged that the Board is considering non-UPL policy options and voted to pursue some of those options with respect to other drugs under review, but the Board subsequently has focused on developing only the UPL recommendations. The robust list of non-UPL policy options recommended for Trulicity® underscores the complexity of the drug pricing supply chain and the need for broad-based reforms. We urge the Board to prioritize policy options in accordance with each policy's ability to address the root drivers of any affordability challenges, as supported by reliable evidence.

Lilly believes certain policy alternative recommendations would meaningfully address issues in the pharmaceutical payment system without inviting the unintended consequences inherent with UPLs. The Board should move forward with policy reforms that address warped supply chain incentives and preferences for higher list prices that can expose patients to higher cost-sharing obligations under benefit designs. Addressing such issues would enable lower costs for patients at the point of sale and create the conditions for downward pressure on drug prices. These policies would create the structural reform necessary to reduce the divergence between list and net prices.

In addition, Lilly is encouraged to see the Board considering participating in voluntary CMMI demonstrations that are designed to reduce pharmaceutical costs for state Medicaid programs. Rather than spending significant state resources on designing and implementing a UPL, the Board should further analyze the opportunities these demonstrations provide to potentially generate savings across a broad portfolio of medicines.

II. The Board Must Vote on Policy Recommendations and UPL Frameworks in Separate Meetings

[25] *See* Letter from Lilly to Board at 9 (Aug. 26, 2024).

Lilly continues to have serious concerns about the Board's processes in general and, in particular, the Board's apparent intent to vote on policy recommendations and consider a specific UPL framework for Trulicity® during the same Board meeting.[26] Although the meeting agenda notes that the framework discussion is contingent on the Board deciding to pursue a UPL, this clarification is not an adequate safeguard to facilitate sound agency decision-making.

The contemplated concurrent decision-making means that Board staff have already considered and developed UPL frameworks before the Board weighs available policy options and determines that a UPL is an appropriate policy solution for the identified affordability challenges. This process not only diverges from the Board's treatment of other drugs under review, for which these steps were performed at separate meetings with separate comment opportunities, but also contravenes the Board's own regulations. If the Board chooses to "pursue development of a UPL as a policy option," it may "direct Board staff to provide recommendations concerning the frameworks and contextual information that may be used to set a UPL."[27] Thus, unless and until the Board decides to pursue development of a UPL policy for Trulicity®, Board staff lack authority to develop a UPL framework.

Sequential decision making is essential to provide meaningful opportunities for public comment, including sharing "free-flowing information from a broad range of interests" to facilitate a "genuine interchange" of "information, concerns, and criticisms" to the Board.[28] Stakeholders should have the opportunity to comment on and engage in each of these processes separately, and the Board must meaningfully respond to those comments before proceeding onto the next step. Combining these steps impairs the integrity of the Board's decision-making, encouraging conclusory decisions that do not fully account for the full range of stakeholder feedback and perspectives relevant to each distinct decision.

Furthermore, such concurrent decision-making suggests that the Board will pre-judge the outcome of its policy review before considering all the information and public input provided during the review process. Ultimately, this creates undue risk that the Board would impose a UPL without fully evaluating the appropriateness of such a price control, which risks not only arbitrary decisionmaking but significant consequences for patients in a rushed conclusion that may fail to fully consider the potential negative outcomes of a UPL on patient access across Maryland.

III. The Board Must Provide Meaningful Opportunities for Comment

[26] Board, Meeting Agenda (Jan. 26, 2026), available here; *see* Letter from Lilly to Board at 2–3 (Aug. 26, 2024); Letter from Lilly to Board at 2–4 (Feb. 10, 2025).
[27] COMAR 14.01.05.05.C(4).
[28] *Adventist Healthcare Midatlantic, Inc. v. Suburban Hosp., Inc.*, 350 Md. 104, 123 (1998); *Conn. Light and Power Co. v. Nuclear Reg. Com'n*, 673 F. 2d 525, 530 (D.C. Cir. 1982).

The Board must also allow sufficient time for meaningful public and stakeholder participation in the affordability review process before rendering decisions.[29] The Board's practice of setting unreasonably short comment periods for stakeholders raises significant concerns about the ability for stakeholders to meaningfully review materials and provide comment. As noted above, in January, the Board released a UPL framework as well as policy options for consideration with fewer than five business days for stakeholders to review the documents and submit public comment – including fewer than three business days for the UPL frameworks posted the Friday before a federal holiday weekend. This window is wholly inadequate for stakeholders to review over one hundred pages of complex policy analysis and develop thoughtful insights to aid the Board's decision-making. Materials for the rescheduled meeting were also released shortly before a federal holiday weekend. Unfortunately, this is not the first time the Board has opted for a highly abbreviated timeline for public comment, seriously inhibiting the ability of patients, manufacturers, and other stakeholders to meaningfully comment on the Board's proposals.[30]

Lilly appreciates the opportunity to comment on the Board meeting and looks forward to continued engagement with the Board on these topics. Please do not hesitate to reach out if you have any questions or need clarifications.

Sincerely,

Senior Director, Government Pricing & Payer

Lilly USA, LLC

[29] *Adventist Healthcare Midatlantic, Inc. v. Suburban Hosp., Inc.*, 350 Md. 104, 123 (1998) (noting that the Maryland APA notice-and-comment procedures are designed "to afford fair notice and a *meaningful* opportunity comment to all persons who may be affected by the proposed regulation" (emphasis added)); *Fogle v. H & G Restaurant, Inc.*, 337 Md. 441, 462–63 (Md. Ct. App. 1995) (finding comment opportunity was meaningful and compliance with Maryland APA because "[s]everal public hearings were held," "[a] multitude of documentary evidence was submitted," and the published decision "set[] forth [the Commissioner's] explanation for the choices that he made in promulgating [the regulation] in light of the evidence presented to him throughout the rule-making process").

[30] For example, the cost review dossier for discussion at the Board's May 19, 2025, meeting was posted on May 12, 2025, just *two days* before the May 14 comment deadline. *See* 2025 Board Meetings, available here. A previous policy review presentation for the Board's September 2025 meeting similarly was posted less than four business days before the comment deadline. *Id.*

MARYLAND TECH COUNCIL
ADVANCING LIFE SCIENCES AND TECHNOLOGY

February 13, 2026

Submitted via email: comments.pdab@maryland.gov

Re: Cost Review Study Process

Dear Members of the Prescription Drug Affordability Board,

On behalf of the Maryland Tech Council and our members, particularly those in the life sciences industry, we are pleased to submit the following comments for consideration at the February 2026 Informational Hearings on the Cost Review Study Process.

As we have in prior communications to the PDAB, we begin by highlighting the strength of the life sciences ecosystem in the State of Maryland and its overall importance to the Maryland economy. Maryland's life sciences ecosystem includes 2,700 companies and 54,000 workers. These innovative companies and workers develop therapies, cures, and treatments that millions of patients depend on. According to the 2024 annual rankings from *Business Facilities*, Maryland ranks as the third-best State in the country for life sciences, behind only Massachusetts and California. Assets such as proximity to the National Institutes of Health ("NIH") and other federal Research and Development funding agencies, strong academic and medical institutions, and a highly skilled workforce all combine to make Maryland a competitive state for life sciences. These are some of the reasons Governor Moore has rightly highlighted life sciences as one of the three "lighthouse industries of the future" and stated that his Administration wants Maryland to be the capital of biotech.

Despite Maryland's life sciences advantages, recent actions by the Federal government have put the industry under unprecedented threat and strain. Cuts to NIH grant funding, delays, freezes, and terminations of other grant and research activities, along with other reductions, have put the Maryland life sciences ecosystem at significant risk. Maryland policymakers, therefore, must be intentional about supporting this industry and the economic, job, and tax benefits it provides. As the MTC has consistently stated, we must seek opportunities to build on the life sciences industry's strengths. All too often, however, the industry feels that decisions made at the State level create a higher tax burden, foster uncertainty, and create an overall environment that feels more hostile than welcoming.

Maryland's Prescription Drug Affordability Board (PDAB) cost review study process is increasingly interpreted by the life sciences sector as a signal that the state's policy environment may be moving away from being welcoming to investment. Although the PDAB was established with the goal of addressing affordability concerns, the mechanism it uses, retrospective cost reviews that can lead to payment limits, introduces a layer of regulatory uncertainty that is particularly sensitive for companies making long-term research and commercialization investments. Drug development timelines often span a decade or more and require substantial upfront capital; when the potential pricing environment is unclear or subject to state-level intervention after market entry, firms may perceive greater financial risk in launching new therapies.

The MTC has consistently expressed skepticism that Upper Payment Limits (UPLs) will be effective in reducing patients' out-of-pocket costs. While we recognize that UPLs are the only tool available to the PDAB by law, we encourage a faster, more thorough examination of non-UPL alternatives. For example, when PDAB staff provided a briefing to the Senate Finance Committee earlier this Session, they

stated that they were supportive of legislation to increase transparency about Pharmacy Benefit Managers (PBMs) and how they influence the prices of prescription drugs. At the September PDAB meeting, PDAB Board members requested additional plans for non-UPL options, including a real-time benefit tool for patients and prescribers, a patient navigator program, and delinking PBM compensation from rebates to offset wholesale acquisition cost increases. We have seen little movement on these options in the months since. We recommend greater emphasis on pursuing additional legislative requirements and authority, rather than continuing to pursue UPLs, which will do little to reduce the amount that Maryland patients pay for prescription drugs. With the 2026 Legislative Session more than one-third complete already, the time for additional legislative action on non-UPL solutions that could directly benefit patients is now.

As leaders in the State, we have a choice – we can either continue to embrace innovation and build an environment open to research and development, economic growth, and job creation, or we can take actions that drive investment to our competitors. The pursuit of unproven and potentially ineffective strategies such as UPLs is consistent with the latter. For these reasons, we continue urge the PDAB to reconsider using UPLs as a strategy to achieve our shared goal of making prescription drugs more affordable for Maryland patients. Thank you for the opportunity to comment and for considering our comments.

Sincerely,

Kelly Schulz
CEO, Maryland Technology Council

February 10, 2026

Informational Hearing Written Testimony Submitted in Lieu of Verbal Testimony

Submitted By: Terry Wilcox, Co-Founder and Chief Mission Officer, Patients Rising

Re: Cost Review Study Process (COMAR 14.01.04.01, et seq.) and Policy Review Procedures (COMAR 14.01.05.01, et seq.)

The Maryland Prescription Drug Affordability Board has requested public written comment, submitted in lieu of verbal testimony, on the Cost Review Study Process (COMAR 14.01.04.01, et seq.) and Policy Review Procedures (COMAR 14.01.05.01, et seq.). I submit this testimony on behalf of patients who are directly affected by the Board's actions and whose stability depends on continued access to medically necessary treatment.

After five years of operation[1], the Board must answer a central question:

Where is the patient in this process — structurally, analytically, and measurably?

I. Five Years of Operation Without Demonstrated Patient or System Savings

The Board has existed for approximately five years. During that time:

- Administrative infrastructure has expanded
- Regulatory authority has broadened
- Consultants and external experts have been engaged
- Rulemaking has advanced

Yet there is no publicly documented evidence demonstrating measurable reductions in patient out-of-pocket costs attributable to PDAB activity.[2] If the Board's mission is affordability, the metric must be patient-level savings and not administrative progress.

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[1] Maryland General Assembly, HB 768 (2019), establishing the Maryland Prescription Drug Affordability Board; see also Maryland PDAB website, https://pdab.maryland.gov

[2] Maryland Prescription Drug Affordability Board, Annual Reports (2019–2025), https://pdab.maryland.gov/Pages/reports.aspx.

Before expanding toward Upper Payment Limits under COMAR 14.01.05.01, the Board should provide:

- Documented evidence of reduced patient out-of-pocket costs
- Identification of affected patient populations
- Clear baseline comparisons

Without patient-evidence data, expansion of authority is premature.

II. Upper Payment Limits Are Not Proven to Reduce Patient Costs

COMAR 14.01.05.01 authorizes the Board to establish Upper Payment Limits (UPLs).[3] However, the regulations do not require proof that a UPL will reduce patient out-of-pocket spending.

A state-imposed reimbursement cap does not automatically:

- Reduce deductibles
- Lower coinsurance
- Prevent formulary exclusions
- Eliminate prior authorization

The Board regulates payment benchmarks. It does not regulate insurer benefit design. If payors respond to compressed reimbursement by tightening utilization management, patients will face greater barriers, not fewer.[4] Affordability cannot be assumed. It must be demonstrated.

III. The Board Has Acknowledged Implementation and Market Risks

In its September 29, 2025 public meeting, Board leadership and members expressed concern regarding the Board's progress, available data, and the operational complexity of Upper Payment Limits. The Chair noted concerns about the Board's return on investment and lack of tangible outcomes. Staff acknowledged that available data to assess savings impacts remains limited. Members also expressed reservations about moving forward absent scoring or clearer evidence of savings.[5]

These statements, made in the Board's own deliberations, underscore the need for caution before expanding implementation authority.

- Operational enforcement challenges
- Legal complexities

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[3] COMAR 14.01.05.01.
[4] Kaiser Family Foundation, "How Health Plan Cost-Sharing Affects Consumers," https://www.kff.org/private-insurance/issue-brief/how-health-plan-cost-sharing-affects-consumers/; see also Kaiser Family Foundation, "Prior Authorization in Medicare Advantage Plans," https://www.kff.org/medicare/issue-brief/prior-authorization-in-medicare-advantage-plans/.
[5] Maryland Prescription Drug Affordability Board Public Meeting, September 29, 2025, available at: https://www.youtube.com/watch?v=X8RW4rH8zeU (see approximately 1:55:03–1:55:50; 2:20:00–2:20:48; 1:25:49–1:26:07; 1:33:09–1:33:15).

- Market response uncertainty
- Administrative burden

These concerns are not speculative criticisms. They are issues raised within the Board's deliberations. Proceeding toward UPL implementation without resolving these acknowledged risks exposes patients to unintended consequences.

IV. The Cost Review Study Process Lacks Structural Patient Integration

COMAR 14.01.04.01, et seq. outlines detailed procedures for cost review, including financial data analysis and manufacturer submissions.

What it does not require is:

- A mandatory patient impact assessment
- Access certification prior to any payment cap
- Modeling of non-medical switching consequences
- Evaluation of downstream utilization management expansion
- Analysis of provider stocking risk

Patients may provide testimony. That is not the same as embedding patient impact into the analytical framework. Public comment is not structural protection.

V. Upper Payment Limits Risk Access Instability

Maryland is one state within a national pharmaceutical market.

Significant divergence in reimbursement benchmarks can predictably lead to:[6]

- Altered distribution strategies
- Reduced provider willingness to stock affected therapies
- Narrowed formularies
- Increased prior authorization and step therapy

Patients living with cancer, autoimmune conditions, rare disease, and other life-sustaining treatment needs cannot absorb policy instability. Affordability cannot come at the cost of availability.

[6] National Conference of State Legislatures, "State Prescription Drug Affordability Boards," https://www.ncsl.org/health/state-prescription-drug-affordability-boards; Avalere Health, "State Prescription Drug Affordability Boards Consider Cost Containment Measures," https://avalere.com/insights/state-prescription-drug-affordability-boards-consider-cost-containment-measures.

VI. Recommendation

Before implementing Upper Payment Limits under COMAR 14.01.05.01, the Board should:

1. Publish documented evidence of patient-level savings achieved to date;
2. Adopt mandatory patient impact assessments prior to any UPL determination;
3. Establish enforceable safeguards preventing increased utilization management;
4. Certify that access will not be reduced as a result of Board action;
5. Demonstrate legal and operational feasibility without cost-shifting to other parts of the system.

Absent these safeguards, the Cost Review Study Process functions primarily as a fiscal mechanism — not a patient protection policy.

Patients are not economic variables in a reimbursement model. After five years of operation, the Board should demonstrate results before expanding power. Upper Payment Limits are not a patient-centered reform unless and until the Board proves they improve patient affordability without compromising access.

Respectfully submitted,

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