Biotechnology Innovation Organization
1201 New York Avenue NW
Suite 1300
Washington, DC, 20005
202-962-9200

VIA Electronic Delivery July 13, 2026

Mr. Van Mitchell, Chair

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

Re: Maryland PDAB COMAR 14.01.06- Implementation and Monitoring of Upper Payment Limits

Dear Chairman Mitchell:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Maryland Prescription Drug Affordability Board's (PDAB or Board)'s draft COMAR 14.01.06- Implementation and Monitoring of Upper Payment Limits (Draft Regulation).

The Biotechnology Innovation Organization (BIO) is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies – all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives. BIO also organizes the BIO International Convention and a series of annual conferences that drive partnerships, investment, and progress within the sector.

BIO and our members have long argued that the underlying structure and utilization of an upper payment limit (UPL) is flawed and should not be enacted. UPLs will harm patient access to lifesaving medication while failing to protect patients from harmful plan designs, and other restrictive coverage strategies and barriers imposed by plans and PBMs. It is evident that setting UPLs without consideration for the drug coverage ecosystem and supply chain could have profound negative repercussions for patient access. Unfortunately, the Draft Regulation falls short of addressing critical patient access considerations and puts emphasis on arbitrary cost factors rather than providing a holistic assessment of drug value, including clinical and non-clinical benefits.

The Draft Regulation does not protect patients from higher out-of-pocket costs or preserve access to care.

As BIO has stated in previous comments, UPLs do not address affordability or access concerns for patients because they do not address barriers to access imposed by plans and PBMs, including formulary tiering, cost sharing, and utilization management. The Draft Regulation does not prohibit health plans from increasing patient cost-sharing, imposing additional utilization management requirements, or reducing coverage for affected prescription drugs. As a result, patients could face higher out-of-pocket (OOP) expenses,

greater administrative barriers to treatment, or loss of coverage.

Although the proposal requires certain monitoring and reporting by payers, it does not establish any accountability or enforcement mechanism if plans respond to a UPL by restricting access or shifting costs to patients. Additionally, the proposed reporting requirements do not capture important indicators of patient disruption, such as treatment delays or prescription abandonment.

The Draft Regulation also fails to ensure adequate reimbursement for providers and pharmacists. Without appropriate reimbursement, providers and pharmacies may face financial challenges that could reduce their ability or willingness to furnish these therapies, ultimately affecting patient access.

The Draft Regulation does not address the substantial operating complexity associated with implementing a UPL. The regulation does not explain how manufacturers, wholesalers, pharmacies, providers, health plans, and other entities throughout the pharmaceutical supply chain would operationalize what will be a highly complex and administratively burdensome payment system. Without a clear implementation framework, stakeholders will face significant uncertainty, increased administrative costs, and operational challenges that could disrupt the delivery of care.

Finally, the establishment of UPLs is likely to be found unconstitutional. A recent federal district court decision, *Amgen v. Mizner*, found that the establishment of UPLs in Colorado likely conflicts with federal patent law and the Supremacy Clause of the US Constitution[1] The court found that the UPL would cause irreparable harm by undermining the balance between innovation and affordability embedded in patent rights and incentives established by Congress. Given the court's reasoning, states should carefully reconsider any establishment of UPLs, particularly for any drugs that remain under federal patent protections.

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BIO appreciates the opportunity to provide feedback to the Board through the Implementation and Monitoring of Upper Payment Limits Draft Regulation. We look forward to continuing to work with the Board to ensure that Marylanders can access medicines in an efficient, affordable, and timely manner. Should you have any questions, please do not hesitate to contact us at 202-962-9200.

Melody Calkins

Director, Health Policy

Biotechnology Innovation Organization (BIO)

[1] Amgen Inc. v. Mizner, No 1:25-cv-03452-DDD-STV, Order Granting Plantiffs' Motion for Preliminary Injunction (D. Colo. July 1, 2026.)

AIMED ALLIANCE

July 13, 2026

Via Electronic Correspondence

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

RE: Recommendation to Enhance UPL Data Reporting Requirements to Protect Patient Access and Outcomes

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 forward with the UPL process, Aimed Alliance is concerned that the current reporting requirements under COMAR 14.01.06, *Implementation and Monitoring of Upper Payment Limits* (UPL) focus primarily on financial transactions, such as gross spend, net cost, net system ingredient cost, formulary placement, unit volume, and weighted average UPL calculations. While these metrics provide insight into a UPL's fiscal impact, they fail to capture the clinical drivers behind formulary shifts or how these changes affect a patient's ability to obtain access to necessary care.

To ensure that UPL implementation does not inadvertently restrict access to treatments, we respectfully recommend that the Board incorporate the following data points into the annual reporting requirements:

- Utilization Management: Report on the total number of prior authorization approval rates and the number of step therapy requirements UPL drugs are subject to. This will enable the Board to determine if access is being reduced through utilization management changes rather than direct pricing.

- Therapeutic Interchange Patterns: Require data on the frequency of and rationale for switches from a UPL-restricted drug to an alternative therapy, including therapies within the same therapeutic category, defined as therapies used to treat the same medical condition or disease. This transparency is important for the Board to assess whether these substitutions are clinically appropriate or a consequence of UPL implementation.

- Patient Out-of-Pocket (OOP) Impact: Require the reporting of average patient cost-sharing, such as copays and co-insurance, for these products pre- and post-implementation. This is necessary to determine if savings are being achieved and benefitting consumers.

- Treatment Adherence and Abandonment: Request data on abandonment rates and reasoning for products under a UPL. It is important to track whether patients are forced to discontinue

their prescribed therapy due to plan-imposed utilization restrictions or costs. Additionally, a decrease in utilization may be reported as "cost savings" but if that decrease is driven by patients being unable to afford or access their medication, it represents failure of the policy.

Without these additional metrics, the Board risks receiving reports that demonstrate financial "savings" while avoiding continued access and affordability barriers facing Maryland consumers.

Aimed Alliance acknowledges that standard administrative claims data often lacks the clinical nuance required to fully capture these impacts. Consequently, the Board's reporting mandate must be supplemented by direct, formal engagement with the provider community. Without this input, the Board cannot distinguish between clinically indicated treatment adjustments and those driven solely by UPL-induced utilization management. By establishing a structured mechanism for physician feedback, the Board can effectively evaluate whether treatment switches are clinically sound or a consequence of UPL implementation.

In conclusion, Aimed Alliance urges the Board to incorporate these patient-centered data points and provider engagement strategies to strengthen the integrity and accountability of the UPL monitoring process.

Sincerely,

Olivia Backhaus
Staff Attorney

Boehringer Ingelheim

July 13, 2026

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

Re: Final Regulations COMAR 14.01.06 (Implementation and Monitoring of Upper Payment Limits)

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 14.01.06 (Implementation and Monitoring of Upper Payment Limits). These regulations outline how UPL will apply in practice, the contracting requirements imposed on payers, and the reporting obligations for state entities.

Boehringer Ingelheim respectfully disagrees with the Board's implementation and monitoring regulations. 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. Additionally, COMAR 14.01.06 does not account for the effectuation of the UPL. Medicare's MFP is based upon detailed guidance and has a dedicated Medicare transaction facilitator, to effectuate the MFP through plans and pharmacies. Under current draft regulations, the Maryland UPL framework lacks the operational infrastructure or direction for efficient implementation of UPL. Without a proper framework, UPL implementation and application will be difficult for stakeholders to operationalize which could increase the risk of improper payment and potential disruption to patient access.

Additionally, Boehringer is concerned about the reporting requirements included in the draft regulation, COMAR 14.01.06, as they raise significant confidentiality concerns. Because the regulations require detailed disclosure of gross spending, net costs, utilization, and formulary placement, the PDAB may receive competitively sensitive pricing information that reveals effective rebate levels and proprietary contracting strategies. Also, Pharmacy Benefit Managers (PBM) control most of the reported data; the reporting regime may amplify the PBM negotiation leverage and create perverse incentives to shift costs or tighten access to Jardiance®. Boehringer asks that the data reported by government entities to the Maryland PDAB be in aggregate form and not publicly disseminated.

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.

Recent litigation in Colorado underscores the legal and operational uncertainty associated with state UPL frameworks. On July 1, 2026, a federal judge granted Amgen a preliminary injunction blocking Colorado's Prescription Drug Affordability Board from enforcing its UPL for Enbrel®[1]. This decision underscores the need for Maryland's PDAB to carefully assess whether a UPL could raise similar legal and operational challenges and, in turn, create risks to patient access.

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

[1] *Amgen Inc. v. Mizner et al.*, No. 1:25-cv-03452-DDD-STV, slip op. at 10 (D. Colo. July 1, 2026) (granting preliminary injunction)

DIABETES PATIENT ADVOCACY COALITION

July 13, 2026

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

Re: COMAR 14.01.06 – Implementation and Monitoring of Upper Payment Limits

Dear Ms. Shaklee:

The Diabetes Patient Advocacy Coalition (DPAC) appreciates the opportunity to comment on the proposed regulations implementing and monitoring Upper Payment Limits (UPLs).

DPAC shares the Board's commitment to making prescription medications more affordable for Maryland patients. For people living with diabetes, access to affordable medications is essential to managing their condition, preventing complications, and maintaining quality of life. At the same time, DPAC remains concerned that UPLs may not achieve the intended goal of lowering patients' out-of-pocket costs and could create unintended barriers to care.

Although these regulations establish an administrative framework rather than specific UPLs, they are a critical component of how the UPL program will be implemented and evaluated. As drafted, the regulations focus primarily on contracting and financial reporting. While these measures are important, they do not provide a complete picture of whether the program is achieving its intended purpose for patients.

For individuals living with diabetes, affordability cannot be measured solely by expenditures or reimbursement levels. Patients may still face high deductibles, coinsurance, or other out-of-pocket costs even if a UPL is established. Likewise, changes in formulary placement, increased prior authorization requirements, or other utilization management tools could delay or complicate access to medically necessary medications. Without evaluating these patient-centered outcomes alongside financial metrics, it will be difficult to determine whether implementation of a UPL has improved affordability in a meaningful way.

Because these regulations establish the framework for monitoring the impact of UPLs, they should ensure that implementation is evaluated based not only on spending, but also on whether patients can obtain the medications prescribed by their health care providers without

new barriers or disruptions to care. For people living with chronic conditions such as diabetes, uninterrupted access to treatment is itself a critical measure of a successful affordability policy.

DPAC appreciates the opportunity to provide these comments and encourages the Board to ensure that, as implementation moves forward, patient experience and access to care remain central to evaluating the effectiveness of any UPL. Ultimately, the success of an affordability initiative should be measured not only by its effect on spending, but by whether it improves patients' ability to access and afford the medications they need.

Sincerely,

George Huntley
Chief Executive Officer
Diabetes Patient Advocacy Coalition

EACH PIC COALITION

July 13, 2026

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

RE: Comments on COMAR 14.01.06 Implementation and Monitoring of Upper Payment Limits

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 rule for implementation and monitoring of upper payment limits (UPL). We urge the board to substantially improve the oversight and monitoring of upper payment limits; further, we urge the board implement patient protections prior to the implementation of any upper payment limit.

Limitations of Upper Payment Limits

While we all share the goal of lowering patient costs for prescription drugs, we have long opposed upper payment limits because they remain untested, unproven, and risk creating new barriers between patients and their medically necessary treatments.

At their core, UPLs focus on system-level spending rather than patient-level costs. They cap what insurers or the state pay, not what patients pay. In our complex healthcare system, price ceilings rarely translate into patient savings, and instead can lead to new restrictions, including formulary reshuffling, prior authorization requirements, and non-medical switching. In practice, this means patients risk losing access to the medications that work best for them.

In short, a UPL does not address the real problems patients identify. Instead of layering a new and untested pricing mechanism onto a system already stacked against patients, the board should focus on reforms that tackle these systemic drivers of unaffordability directly.

Implement Stronger Monitoring and Patient Protections

We urge you to ensure this experiment does not cause harm by including regulations or passing legislation to **increase oversight and implement proactive patient protections before implementing a UPL in the state.**

Patients will bear the immediate consequences of insurer and PBM responses to UPLs, while any corrective action could take months or years. Monitoring the effects of a UPL after implementation cannot be a substitute for proactive protections.

EACH PIC COALITION

Transparent Monitoring

The PDAB must establish a robust monitoring system around any upper payment limit. The currently proposed monitoring system is inadequate to ensure patients are protected from increased utilization management and the potential for them to be non-medically switched. At a minimum, we propose that the following should be monitored for the **entire therapeutic class** where one or more drugs is subject to an upper payment limit:

- Collect and publish data from insurers and pharmacy benefit managers (PBMs) on formulary placement, tiering, utilization management, and cost-sharing changes for UPL drugs.
- Track provider-level impacts, including reimbursement rates, prescribing patterns, and patient access in physician offices, infusion centers, and pharmacies.
- Include independent evaluation to determine whether payer savings are being passed on to patients or retained by insurers and PBMs.

Legislative Guardrails

At the same time, the board should work with the legislature to establish statutory protections to ensure UPLs do not create new barriers to care. Guardrails should include:

- Prohibiting non-medical switching of patients stabilized on a therapy.
- Banning new prior authorization or step therapy hurdles on UPL-affected drugs.
- Preventing adverse formulary shifts that push UPL drugs to higher tiers or exclude copay assistance.
- Protecting provider reimbursement so physicians, clinics, and pharmacies are not forced to absorb unsustainable financial losses.

We thank the board for its consideration of our comments.

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

HDA

Healthcare Distribution Alliance

HEALTH DELIVERED

July 10, 2026

Maryland Prescription Drug Affordability Board
c/o Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Submitted via electronic mail to the Maryland Prescription Drug Affordability Board

Re: Comments on Proposed Upper Payment Limits for Jardiance and Ozempic and COMAR 14.01.06 – Implementation and Monitoring of Upper Payment Limits

Dear Chair, Members of the Board, and Staff:

On behalf of the Healthcare Distribution Alliance (HDA), thank you for the opportunity to provide comments regarding the Maryland Prescription Drug Affordability Board's proposed implementation and monitoring of Upper Payment Limits (UPLs) for Jardiance and Ozempic.

HDA is the national trade association representing healthcare wholesale distributors, the vital link between pharmaceutical manufacturers and more than 450,000 pharmacies, hospitals, long-term care facilities, physician offices, clinics, and other healthcare settings nationwide. Every day, HDA members safely and securely deliver millions of medicines and healthcare products, helping ensure that patients receive timely access to the therapies they need.

HDA supports efforts to improve prescription drug affordability for Maryland patients. However, as the Board seeks to move forward with implementing its first UPLs, we encourage careful attention to the operational impacts throughout the healthcare supply chain to ensure affordability initiatives do not unintentionally affect patient access.

The Role of Wholesale Distributors in the Pharmaceutical Supply Chain

Wholesale distributors serve a critical logistics function within the healthcare system. They do not manufacture prescription drugs, establish list prices, negotiate rebates, determine insurance coverage, design pharmacy benefits, set reimbursement rates, or determine what patients ultimately pay at the pharmacy counter. Their role is to purchase, store, secure, and deliver medicines to pharmacies, hospitals, physician practices, and other providers in response to customer demand.

The proposed UPLs do not change manufacturers' national pricing structures, wholesalers' acquisition costs, or the contractual arrangements through which medicines move across the country. Regardless of how the Board intends UPLs to function, providers and governmental purchasers must continue acquiring prescription drugs through existing national purchasing and distribution systems before any UPL can be applied.

Implementation Through Government Health Plans and Other Payors

To the extent the Board intends for UPLs to operate through reimbursement by government health plans, pharmacy benefit managers (PBMs), third-party administrators (TPAs), or other entities administering prescription drug benefits on behalf of the State or local governments, HDA respectfully requests that the final regulations clearly describe that implementation mechanism. The regulations should expressly state that responsibility for implementing and administering a UPL rests with the governmental payor or its contracted administrator, not with wholesale distributors. Likewise, wholesale distribution transactions, including the purchase, sale, distribution, rebate, chargeback, and delivery of prescription drugs, should not be interpreted as mechanisms through which UPLs are effectuated.

This issue is particularly important for high volume therapies such as Jardiance and Ozempic. Pharmacies, hospitals, and physician practices typically purchase these products in advance, maintain inventory, and seek reimbursement only after a medication has been dispensed or administered. At the time inventory is acquired, providers generally cannot know which patients will ultimately receive a particular product or whether those patients will be covered by a governmental health plan subject to a UPL. If reimbursement mechanisms are delayed, incomplete, or otherwise fail to account for providers' acquisition costs, providers may face financial losses that influence stocking decisions or limit their ability to continue offering these therapies.

Implementation for Direct Government Purchases

The proposed regulations also apply to situations in which government-operated facilities purchase prescription drugs directly, including state hospitals, correctional facilities, and university medical centers. These transactions present different operational considerations than those involving third-party reimbursement.

In these circumstances, the regulations should clearly identify how the Board expects a UPL to be implemented and which party bears responsibility for ensuring compliance. For example, if a state hospital or correctional facility purchases a prescription drug at a price above the established UPL, the regulations do not explain whether the governmental purchaser or another entity is expected to absorb the difference between the acquisition cost and the UPL. Wholesale distributors operate on extremely thin margins and cannot absorb these costs without a mechanism that ensures they are made whole.

HDA respectfully requests that the Board clearly describe how UPLs are intended to function in these direct-purchase scenarios. If the Board anticipates that compliance will be achieved through manufacturer rebates, chargebacks, or another funding mechanism, that process should be expressly described in the final regulation, to ensure stakeholders understand how the Board expects UPLs to operate in practice. Providing this clarity will ensure stakeholders understand how the Board expects UPLs to operate in practice and will help avoid unintended disruptions to the pharmaceutical supply chain. Without a clearly defined funding mechanism, the regulations create uncertainty for supply chain participants and risk disrupting the efficient distribution of prescription drugs to Maryland patients.

Monitoring Implementation and Evaluating Outcomes

As Maryland implements its first UPLs, the Board also has an opportunity to establish a strong evidence base before considering any future expansion of the program beyond governmental

purchasers and health plans covered by the current proposal. In addition to tracking realized savings, HDA encourages the Board to monitor provider participation, patient access, product availability, operational impacts, and any unintended effects on the pharmaceutical supply chain. Collecting and publicly reporting implementation data, including provider participation, patient access, operational impacts, and realized patient savings, will help ensure that future policy decisions are informed by real-world experience.

Conclusion

HDA appreciates the Board's commitment to thoughtful implementation and stakeholder engagement. We respectfully request that the Board provide additional clarity regarding how UPLs will be operationalized in both reimbursement and direct-purchase settings, identify the entities responsible for implementation, and expressly confirm that wholesale distributors are not responsible for effectuating UPLs through ordinary distribution transactions.

We welcome the opportunity to continue serving as a resource as Maryland evaluates the effectiveness of its affordability program while preserving a safe, secure, and reliable pharmaceutical supply chain for Maryland patients.

Thank you for your consideration.

Sincerely,

Juan Carlos Payero
Director, State Government Affairs
Healthcare Distribution Alliance
jcpayero@hda.org

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

July 6, 2026

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

Re: Maryland COMAR 14.01.06 Implementation and Monitoring of Upper Payment Limits

Dear Ms. Shaklee,

On behalf of our members operating in Maryland, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to provide comments on the Maryland Prescription Drug Affordability Board's ('the Board') proposed regulations regarding the implementation and monitoring of upper payment limits (UPLs). As the state looks to improve prescription drug affordability for Marylanders and support efforts to enhance transparency, NACDS urges the Board's careful consideration to ensure that the implementation of upper payment limits does not create negative access and quality of care barriers for Marylanders due to the downstream operational and financial inefficiencies on healthcare providers and settings such as community pharmacies.

Community pharmacies are trusted, accessible healthcare destinations that strengthen access to medications, preventive services, and clinical care in surrounding neighborhoods. Of particular concern, COMAR 14.01.06, as proposed, states that pharmacy benefit managers (PBMs) and other entities may negotiate reimbursement rates below an established UPL. While intended to establish a reimbursement ceiling, a UPL should not become the benchmark upon which downward reimbursement is negotiated or established. Without appropriate safeguards, the UPL may become the de facto reimbursement target rather than an upper payment limit. Accordingly, the Board should establish UPLs that accurately reflect true pharmacy costs and incorporate guardrails to ensure reimbursement methodologies remain fair and accurate.

Without appropriate guardrails, payers may fail to account for the difference between the UPL and a pharmacy's actual acquisition and dispensing costs, resulting in reimbursement that falls below the pharmacy's cost of providing the medication. Such reimbursement practices could force pharmacies to operate at a loss, limit their ability to stock certain medications, or, in some cases, cease operations altogether. These consequences would reduce patient access to community pharmacy services, particularly in medically underserved areas, and could contribute to lower medication adherence, increased prescription abandonment, poorer health outcomes, and higher downstream healthcare costs. Therefore, we strongly urge the Board to carefully consider the impact on pharmacies and the communities they serve, ensuring that the implementation of the UPL promotes affordability while preserving patient access to essential medications.

NACDS appreciates the Board's leadership as the state looks to implement this initiative. We respectfully request that the Board remain mindful that community pharmacies serve as the final link in the prescription drug supply chain and are viewed as the most accessible healthcare providers within their communities. Thus, we encourage the Board to incorporate appropriate pharmacy access considerations into its implementation of the upper payment limits proposed regulations.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores (NACDS)

July 13, 2026

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

VIA ELECTRONIC MAIL TO pdab.regs@maryland.gov

RE: Proposed Rule: COMAR 14.01.06 Implementation and Monitoring of Upper Payment Limits

Dear Members of the Maryland Prescription Drug Affordability Board,

Novo Nordisk appreciates the opportunity to submit written comments to the Maryland Prescription Drug Affordability Board ("Board") regarding the Proposed Rule COMAR 14.01.06 Implementation and Monitoring of Upper Payment Limits, published in the June 12, 2026, issue of the Maryland Register. As we have expressed in previous comments, we share the Board's interest in making prescription medications affordable and accessible to all Marylanders.

We write this comment to respectfully raise two points. First, we understand this rule to properly establish January 1, 2028, as the earliest possible mandatory upper payment limit ("UPL") compliance deadline for any UPL that goes into effect. Because January 1, 2028, is the earliest mandatory UPL deadline, that date and not any earlier date must be understood as the operative date from which all compliance obligations and statutory timelines flow, including the one-year period that must elapse before the Board may consider expanding its UPL authority. Second, January 1, 2028, may not provide adequate time for manufacturers, eligible governmental entities, and other stakeholders to achieve compliance because there is still a significant lack of clarity over how stakeholders will implement the various operational, contractual, and system changes required for a UPL.

I. Proposed Rule COMAR 14.01.06 Provides January 1, 2028, as the Earliest Date that a UPL Could Be In Effect.

Proposed Rule COMAR 14.01.06 rightly clarifies that the earliest possible date by which a UPL could be in effect is January 1, 2028. Specifically, it provides that

> An eligible governmental entity shall require that the provisions specified in §B of this regulation [referencing specific UPL regulations] be included in all contracts:
> 1) Through which prescription drug products are paid for or purchased by, or on behalf of, the eligible governmental entity;
> 2) That are executed or amended on or after January 1, 2028, and take effect on or after January 1, 2028.[1]

[1] Proposed Rule COMAR 14.01.06.02(A).

This clarification is welcome, as there was previously confusion on this point. Stakeholders previously expressed concern over earlier dates named in other proposed regulations, noting that the Board's contemplated UPL regulations for Ozempic® and Jardiance stated they apply "to payments for drugs dispensed, administered, or purchased on or after January 1, 2027."[2] During the Board's April 13, 2026, meeting, MD PDAB Executive Director Andrew York explained that January 1, 2028, is the mandatory UPL compliance deadline, but "there might be some subset of eligible governmental entities that put these provisions into their contracts voluntarily earlier than January 1, [20]28," and in those cases, the Board "want[s] them to be able to implement as early as January 1, 2027."[3] The Proposed Rule eliminates any ambiguity by making clear the earliest date by which a UPL will be "in effect"—that is, actually binding or almost entirely binding—is January 1, 2028.[4]

This Proposed Rule's clarification on the earliest date by which any UPL is in effect is important not only for implementing the current proposed UPLs but also for identifying the earliest date by which the Board could begin the process of considering UPLs on private transactions. Under Md. Code Ann., Health-Gen. § 21-2C-16, the Maryland General Assembly allows the Board to begin the process to consider applying a UPL to private transactions only after the Board has "set[] [UPLs] on two prescription drugs" and "each [UPL] [has been] in effect for 1 year."[5] Specifically, after UPLs on two prescription drugs have been in effect for one year, the Board must provide notice to the Department of Legislative Services.[6] If notice is timely received, then "Section 2 of this Act shall take effect" on that date.[7]

The statute is prescriptive in the process that the Board must follow in order to promulgate a new UPL to apply to private transactions. Specifically, the Board, in consultation with the Prescription Drug Affordability Stakeholder Council, must determine whether, in addition to setting UPLs for eligible governmental entities, it is in the best interest of the state for the Board to establish a process for setting UPLs for purchases and payor reimbursements of prescription drug products in Maryland that the Board determines have led or will lead to an affordability challenge.[8] In determining whether such a process is in the state's best interest, the Board must consider any contract and budget data provided to the Board that demonstrates "savings to the State or local governments as a result of [UPLs] set in accordance with" the UPL Action Plan approved in October 2024 and expected savings from Medicare Maximum Fair Prices set by the Centers for Medicare & Medicaid Services pursuant to the drug price negotiation program created by the Inflation Reduction Act.[9] The Board must also consider the success of setting UPLs in other states.[10] Thus, determining whether imposing a UPL on private

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[2] The Proposed Rules for Ozempic® and Jardiance UPLs have been published in the June 26, 2026, issue of the Maryland Register.

[3] *See* MD PDAB April 13, 2026 Meeting Recording at 19:10.

[4] *See* Merriam Webster Dictionary, *In Effect* ("In substance: Virtually"); Merriam Webster Dictionary, *Virtually* ("almost entirely").

[5] Acts 2025, c. 610, § 3(a); Acts 2025, c. 611, § 3(a).

[6] Acts 2025, c. 610, § 3(b); Acts 2025, c. 611, § 3(b).

[7] Acts 2025, c. 610, § 3(c); Acts 2025, c. 611, § 3(c).

[8] Md. Code Ann., Health-Gen. § 21-2C-16(a)(1).

[9] *Id.* § 21-2C-16(a)(2).

[10] *Id.*

transactions would be in the best interest of the state will also depend on legal developments. So far, three federal courts—including one reviewing the Colorado PDAB's first UPL—have all held that federal patent law preempts any effort by a state or local government to impose price controls on patented products.[11] These cases make clear that any effort by the Board to impose price controls on patented pharmaceutical products would not be in the best interest of the state, as it will only invite litigation that will halt those price controls. If the Board, however, makes a determination to move forward with price controls, then it must establish that process.[12] The Board must use the already-approved UPL Action Plan "to the extent appropriate."[13] It is only through this process and subject to the certain triggers discussed above that the Board could expand its UPL authority to private transactions.

The Board will not be able to ultimately evaluate whether UPLs have created a positive or negative effect or whether it is "in the best interest of the State for the Board to establish a process for setting [UPLs] for purchases and payor reimbursements of prescription drug products in the State" before achieving widespread adoption through mandatory compliance.[14] Treating a voluntary date of January 1, 2027, as the start of the one-year period would undermine the legislature's carefully constructed, phased framework and deprive the Board of comprehensive, real-world data that would inform whether broader UPL authority is warranted for Maryland.

Interpreting January 1, 2028, as the earliest possible date by which a UPL could be in effect is not only required as a matter of law, it is also necessary for the legislative and regulatory scheme to function. The legislature elsewhere uses the "in effect" language to trigger a reporting obligation from the Board. Specifically:

> If the Board sets a new [UPL], to the extent practicable, the Board shall include in the first [annual] report … after the [UPL] has been in effect for 1 year information on the effects of the [UPL], based on available timely data, for the following:
>
> (1) Patient out-of-pocket costs including whether the [UPL] was associated with increases or decreases in what patients pay for prescription drug products;
> (2) Patient health insurance premiums, including whether the [UPL] is associated with increases or decreases in health insurance costs for patients;
> (3) Pharmacies operating in the State, including the impact on reimbursement rates and financial viability of retail and independent pharmacies;
> (4) Patient health insurance formularies, including whether the prescription drug product subject to the [UPL] remained on formularies;

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[11] *See, e.g.*, *Amgen Inc. v. Mizner*, No. 1:25-cv-03452-DDD-STV (D. Colo. July 1, 2026) (enjoining the Colorado PDAB from enforcing a UPL for Enbrel as "caps on the price of patented drugs like Enbrel are preempted by federal law"); *Biotechnology Indus. Org. v. D.C.*, 496 F.3d 1362, 1374 (Fed. Cir. 2007) (holding that federal patent laws preempted a D.C. City Council ordinance prohibiting any patented drug from being sold in the District for an excessive price); *Camargo v. AbbVie, Inc.*, 2026 WL 115068, at *8 (N.D. Ill. Jan. 14, 2026) (concluding that where plaintiffs attempt to use state law "to penalize high prices and limit the full exercise of the exclusionary).

[12] *Id.* § 21-2C-16(b).

[13] *Id.*

[14] Md. Code Ann., Health-Gen. § 21-2C-16(a)(1).

(5) Provider-administered medications subject to the [UPL], including whether providers were able to acquire the prescription drug product subject to the [UPL] at a rate to account for acquisition costs and whether there was an impact on provider reimbursement;
(6) Patient access to the prescription drug product subject to the [UPL], which may include:
    (i) Whether prescription drug product shortages or other supply disruptions occurred after the [UPL] took effect;
    (ii) Whether 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 a[] [UPL] over a prescription drug product subject to a[] [UPL];
    (iii) Whether the distribution and delivery of specialty or rare disease medications from out-of-state pharmacies to providers, pharmacies, or patients was impacted;
    (iv) Whether patients in communities of color, patients who are women, patients with a rare disease, or patients in rural areas experienced disproportionate access challenges; and
    (v) Whether cost differences as a result of the [UPL] affected patients, pharmacies, or providers and, if the cost difference resulted in an increase in costs, who was ultimately responsible for bearing the increased cost;
(7) Covered entity providers participating in the 340B drug discount program, including the impact of the [UPL] on the operations of the providers and their contracted pharmacies; and
(8) The biotechnology industry in the State, including the impact on pharmaceutical research and development, investment, and job growth.[15]

There will be no way to fully report on these effects of the UPL if a UPL is not actually in effect. Because a UPL is a novel mechanism, its consequences are unknown and potentially harmful to patients and to the broader health care system. Indeed, the Board admits that it is unclear how stakeholders will respond to a UPL.[16] As Novo Nordisk has repeatedly emphasized to the Board, a UPL could exacerbate the flawed infrastructure of the existing system of pharmaceutical payment and reimbursement, which hinges on rebate competition amongst manufacturers for PBM formulary placement. Imposing a UPL based on a disruptively low price risks destabilizing the pharmaceutical supply chain, potentially leading pharmacies to limit or cease stocking impacted products (and possibly other treatments, as their revenues decline).[17]

In light of the above, Novo Nordisk appreciates that the Board is taking a measured approach and clarifying in this regulation that the earliest date by which a UPL can be deemed "in effect" is January 1, 2028.

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[15] Md. Code Ann., Health-Gen. § 21-2C-09(d).

[16] MD PDAB April 13, 2026 Meeting Recording at 28:20 (Board member Gerard Anderson noted "We anticipate how people will respond to the UPLs, but we won't always get it right, so we're going to have to make continual revisions of the process as we gather more data," and "[s]ometimes, we anticipate how industry or the patient will respond, and sometimes, we don't have a great crystal ball as to how they're going to do it.").

[17] For more details, we refer the Board to our February 17, 2026, letter.

II. A proposed implementation date of January 1, 2028, may not afford sufficient time to comply with requirements of this scope and complexity.

Maryland law requires the Board to implement UPLs in accordance with the UPL Action Plan. Under that UPL Action Plan, the Board must provide "a prospective [UPL] effective date that provides sufficient time for implementation."[18] In other words, the Board must, as a matter of law, ensure that the eligible governmental entities are fully capable of implementing the UPLs before imposing them.

Here, the regulated governmental entities and unregulated drug manufacturers still have no clear plan on how the UPL will be effectuated. The Board's regulations acknowledge this point plainly: "The Board and staff shall work with eligible governmental entities to develop the best method for implementing the UPL for the entity and a prospective effective date that provides sufficient time for implementation."[19] Though the Board plans to recommend that UPLs be effectuated by manufacturers providing supplemental rebates to eligible governmental entities,[20] Director York emphasized that the implementing mechanism will be specific to each eligible governmental entity, as the Board seeks to grant "flexibility" on this point.[21] Because each eligible governmental entity may adopt a unique internal process for implementation, sufficient time is necessary to build infrastructure for each potentially unique approach.

We appreciate the Board's honesty that there is not yet any clear plan for how any UPLs shall be implemented. Because UPLs are untried, stakeholders need sufficient time to assess and discuss implementation, particularly during what could be an already complicated contract negotiation period. Until the Board "work[s] with eligible governmental entities to develop the best method for implementing the UPL for the entity,"[22] we ask the Board to hold back from implementing any mandatory compliance deadline. We understand the Board's sense of urgency in making prescription medications affordable and accessible to all Marylanders.[23] An unstudied "solution" effectuated under a compressed timeframe, however, benefits none and could harm many. And Maryland law recognizes exactly that. With additional time and consideration, all stakeholders—eligible governmental entities, manufacturers, the Board, patients, and more—would be better equipped to address the complexities posed by the inaugural implementation of a UPL.

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

[19] Md. Code Regs. 14.01.05.08(A)(2).

[20] The "Estimate of Economic Impact" accompanying the Proposed Rule acknowledges, "The savings effected through the [UPL] may ultimately be realized through a decrease in revenue by the manufacturer."

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

[22] Md. Code Regs. 14.01.05.08(A)(2).

[23] Novo Nordisk has a long history of affordability initiatives. In the most recent of these, we announced significant changes to provide cost savings to patients without insurance coverage or those who choose to self-pay without using their insurance. Though the outdated data in the Board's cost review of Ozempic® fails to reflect this point and others, we detailed this development in our February 17, 2026, comment to the Board.

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In sum, Novo Nordisk supports the Board's goal of improving affordability and access, and we appreciate the Board's stakeholder engagement as it seeks to implement a UPL for eligible governmental entities, as demonstrated through a voluntary compliance period followed by a mandatory deadline (currently proposed for January 1, 2027, and January 1, 2028, respectively). We reiterate the Board's statement that the date provided in COMAR 14.01.06 will provide the sole mandatory compliance deadline. That date accordingly is the earliest possible date by which a UPL could be deemed in effect and trigger the one-year period that enables the Board's ability to consider promulgating a UPL that binds private transactions. We also remain concerned that even the January 1, 2028, deadline may fall afoul of Maryland law because it may not provide adequate time for stakeholders to complete the operational, contractual, and systems planning required by this novel mechanism. We respectfully ask the Board to consider extending the mandatory deadline proposed in COMAR 14.01.06 beyond January 1, 2028, to allow a more proportionate and practicable implementation period, or to wait on imposing any mandatory deadline until the relevant entities have formed a plan to implement the UPLs.

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

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

By Electronic Submission

July 13, 2026

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

RE: Proposed Regulations – New Regulations COMAR 14.01.06 (Implementation and Monitoring of Upper Payment Limits)

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 Implementation and Monitoring of Upper Payment Limits (COMAR § 14.01.06) ("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 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 processes overall.

[1] *See* Proposed New Regulation – COMAR 14.01.06 (Implementation and Monitoring of Upper Payment Limits), *available at* https://dsd.maryland.gov/MDRIssues/5312/Assembled.aspx#_Toc231805119. In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to Md. Code Ann., 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 (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* Md. Code, Health Gen. §§ 21-2C-01–16.

[3] *See* comments cited *supra* note 1.

I. Lack of Clear and Meaningful Standards for UPL Implementation and Monitoring

PhRMA reasserts the following, non-exhaustive examples of areas where clear and meaningful standards are needed for UPL implementation and monitoring:

A. UPL Reconsideration Process

- **Reconsideration of Maximum Fair Price ("MFP")-Based UPLs.** PhRMA remains concerned that the Board has proposed using the Medicare MFP as a UPL benchmark.[4] 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 proposed 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.[5] However, the Proposed Regulations do not address how it will monitor and respond to MFP changes. 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.[6] PhRMA also urges the Board to address how it will monitor MFP changes and establish clear timelines for reconsidering UPLs and modifying or repealing accordingly.

- **Reconsideration of UPLs for Drugs in Shortage.** As noted in previous comment letters,[7] the PDAB Statute specifically authorizes the Board to "reconsider or suspend" a UPL if there is a shortage and directs the Board not to apply a UPL to a drug on the FDA shortage list.[8] Additionally, Board regulations provide that "the Board shall reconsider" a UPL "[i]f the Board becomes aware of a shortage . . . in the State."[9] 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 included such a process in the Proposed Regulations' implementation and monitoring provisions.[10] The Board should revise its regulations to specifically address how it will monitor for shortages.

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[4] *See* 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.

[5] 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.

[6] *See* COMAR § 14.01.05.09; 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. This approach would be similar to the Board's regulations regarding drug shortages and UPL-setting, which require "automatic suspension of the UPL for the time that" a drug is on the FDA shortage list. COMAR § 14.01.05.08(A)(4).

[7] *See* 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; Letter from PhRMA to Board (Feb. 10, 2025) *supra* note 1 at 3; Letter from PhRMA to Board (Nov. 8, 2024) *supra* note 1 at 9; Letter from PhRMA to Board (Aug. 26, 2024) *supra* note 1 at 4.

[8] *See* Md. Code, Health Gen. § 21-2C-13(c)(1)-(2); *see also* COMAR § 14.01.05.09(A)(2); Letter from PhRMA to Board (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.

[9] *See* COMAR § 14.01.05.09(A)(2).

[10] 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").

B. **Monitoring Patient Access and Affordability.** PhRMA remains concerned that the Proposed Regulations do not provide adequate processes for the Board to monitor patient access challenges or to assess 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.[11] 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 affordability and ability to access needed medications.[12] 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.[13] For these reasons, PhRMA recommends that the Board establish robust measures to monitor benefit design, including utilization management practices, for the impact of UPLs on patient access and affordability.

C. **Confidentiality.** PhRMA remains concerned that the Board has not addressed how it will implement statutory confidentiality protections and protect confidential, proprietary, and trade secret information against public disclosure.[14] These concerns are further heightened in light of the governmental entity reporting requirements contemplated under the Proposed Regulations.[15] PhRMA urges the Board to amend the Proposed Regulations to include express protections for confidential, proprietary, and trade secret information that may be disclosed to the Board.

D. **Net Cost.** Under the Proposed Regulations, eligible governmental entities would be required to report a drug's "final net cost to the eligible governmental entity."[16] As PhRMA has previously requested, the Board should clarify the meaning of the term "net cost" as it remains unclear how the Board intends to calculate the metric.[17]

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[11] *See* Md. Code, Health Gen. § 21-2C-09(d)(6)(requiring the first annual Board report to include information on "[p]atient access to the prescription drug product subject to the upper payment limit"); 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.

[12] Proposed Regulation § 14.01.06.04(A)(4); *see* Md. Code, Health Gen. § 21-2C-09(d)(1), (6) (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").

[13] *See* Md. Code, Health Gen. § 21-2C-09(d)(1)-(2), (4), (6).

[14] Proposed Regulation § 14.01.06.04. *See* Md. Code Ann., Health-Gen. § 21-2C-10 ("Only Board members and staff may access trade secrets and confidential and proprietary data and information ... that is not otherwise publicly available"; "all information and data" shall be "considered to be a trade secret and confidential and proprietary information" and "is not subject to disclosure under the Public Information Act" if it is obtained by the Board "and is not otherwise publicly available."); 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 3-4.

[15] Proposed Regulation §§ 14.01.06.02, 14.01.06.04.

[16] Proposed Regulation § 14.01.06.04(A)(2).

[17] *See* Letter from PhRMA to Board Regarding Draft Regulations (Mar. 30, 2026) *supra* note 1 at 4; Letter from PhRMA to Board (Feb. 10, 2025) *supra* note 1 at 3.

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

PhRMA also reiterates the following, non-exhaustive examples of areas where clear and meaningful standards are needed in the UPL-setting process generally:

A. **UPL Development.** PhRMA remains concerned by 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.[18] We urge the Board to establish meaningful standards to guide its actions and limit the risk of arbitrary decision-making.

B. **Stakeholder Comment.** PhRMA also notes 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. 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,[19] 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.[20] In addition, PhRMA requests details regarding how the Board will incorporate and address all feedback that it receives.[21]

* * *

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

[18] *See* COMAR § 14.01.05.02(B)(2); *see, e.g.*, Letter from PhRMA to Board Regarding Draft Regulation (May 1, 2026) *supra* note 1 at 3; Letter from PhRMA to Board (Mar. 4, 2026) *supra* note 1 at 2-3; Letter from PhRMA to Board (Feb. 10, 2025) *supra* note 1 at 2-4.
[19] *See* Md. Code, State Gov't §§ 10-101–10-305.
[20] *See* 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) *supra* note 1 at 5-6; Letter from PhRMA to Board (Aug. 26, 2024) *supra* note 1 at 2-3.
[21] *See, e.g., id*.

Value of Care Coalition

July 13, 2026

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

Re: COMAR 14.01.06 – Implementation and Monitoring of Upper Payment Limits

Dear Ms. Shaklee:

The Value of Care Coalition appreciates the opportunity to comment on the proposed regulations implementing and monitoring Upper Payment Limits (UPLs).

Although these regulations do not establish specific UPLs, they create the administrative framework necessary to implement a policy that the Coalition believes will harm patient access without ensuring patient savings and has consistently opposed. As detailed in our previous comments to the Board, we remain concerned that UPLs could have unintended consequences for Maryland patients, including disruptions in access to needed medications, reduced treatment options, and uncertainty for the public programs and health plans that patients rely upon. These proposed implementation regulations do not address those fundamental concerns.

The Coalition appreciates staff's recognition during multiple Board meetings—including the February 23, April 13, and May 18, 2026 meetings—that patient access considerations will continue to be an important component of the Board's work as it develops and implements future Upper Payment Limit policies. However, the Board has indicated that access concerns will be addressed through future regulatory and policy development, while these proposed implementation regulations do not themselves establish meaningful safeguards to ensure that Upper Payment Limits can be implemented without disrupting patient access to medically necessary prescription drugs. Accordingly, the Coalition encourages the Board to amend these regulations to ensure that future actions include clear, transparent, and enforceable protections to preserve timely patient access to medically necessary prescription drugs.

The Coalition is also concerned that the proposed economic impact statement understates the practical implications of these regulations. While the proposal concludes that the contracting and reporting requirements will have only a minimal impact, in practice implementation will

require substantial administrative coordination among State and local governmental entities and the organizations that administer prescription drug benefits on their behalf. Those resources ultimately come from public programs that should remain focused on serving patients and ensuring access to care.

In addition, significant aspects of these regulations depend on future guidance, including the Reporting Submission Manual, leaving stakeholders without a complete understanding of their future compliance obligations. Proceeding with implementation before those requirements are fully articulated makes it difficult to evaluate the true administrative burden and the potential effects on the governmental entities responsible for providing prescription drug coverage to Marylanders.

The Coalition appreciates the opportunity to provide these comments. We note that the Coalition has previously submitted comments to the Board regarding the operational and patient access concerns associated with Upper Payment Limits, and those comments are part of the public record. Those concerns remain applicable as the Board considers regulations designed to implement the UPL framework.

The Coalition urges the Board to carefully consider the cumulative impact of these regulations on patients' timely access to medically necessary prescription drugs and to ensure that future regulatory actions include meaningful safeguards to preserve access to medically necessary therapies.

Sincerely,

Derek Flowers
Value of Care Coalition