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Prescription Drug Affordability Board
Comments on Draft UPL Regulations for Farxiga and Jardiance
March 2026

AARP Maryland, which has about 850,000 members in the state, applauds the Prescription Drug Affordability Board's (PDAB) draft Upper Payment Limit (UPL) regulations for Farxiga and Jardiance that were posted on March 16, 2026, draft COMAR 14.01.06 and 14.01.07.

AARP urges the prompt adoption of the regulations, along with the equally well-conducted and very thorough Cost Review Study Report for each of these vital pharmaceuticals, so that the board can deliver needed drug-price relief to governmental entities throughout the state as quickly as possible.

In its detailed documents, the PDAB is transparent and logical in how it developed and intends to apply UPLs for Farxiga and Jardiance. That is in keeping with the equally clear and well-reasoned process spelled out in the draft Chapter .06 – Implementation and Monitoring of Upper Payment Limits for any prescription drugs that would meet the criteria for Application of Upper Payment limits as spelled out in Section .03. In Section .04, UPL Monitoring and Data Reporting, is equally clear and logical in detailing what data are to be reported, and when, for any prescription drugs for which UPLs have been established.

In the following Chapter .07, Upper Payment Limit specifics for Farxiga and Jardiance, the PDAB is clear and logical in the baseline UPLs it has established for the two drugs, as well as in how it will determine inflation-adjusted UPLs for 2028 and beyond. In its proposed provision requiring the board's staff to post the future inflation-adjusted UPL on its website by July 1 of the prior year, the PDAB's date choice provides ample notice for planning purposes.

AARP Maryland also appreciates that the PDAB has now scheduled a special meeting for April 13, two weeks after the comment period for the regulations discussed above ends. AARP hopes that the board will adopt those UPLs at this meeting.

It would be very helpful for the UPLs to take effect as soon as possible, given the urgent need among government entities in Maryland and the state's residents they serve. The January 1, 2027, effective date is satisfactory if that is what is needed, given prescription-drug-related contract start dates.

March 30, 2026

VIA ELECTRONIC MAIL

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

Re: Draft Proposed Regulations on Implementation and Monitoring of Upper Payment Limits (Draft COMAR 14.01.06) and Upper Payment Limit (Draft COMAR 14.01.07)

Dear Members of the Maryland Prescription Drug Affordability Board:

AbbVie Inc. ("AbbVie") respectfully submits these comments regarding the Board's proposed regulations published on March 16, 2026, regarding the implementation of upper payment limits ("UPLs"), including the proposed UPLs for Farxiga® (dapagliflozin) and Jardiance® (empagliflozin).[1] AbbVie Inc. is a biopharmaceutical company committed to discovering and delivering transformational medicines and products in key therapeutic areas, including immunology, oncology, and neuroscience. AbbVie is using advanced technologies and data science to gain unprecedented insights that help us to target medicines more precisely, identify opportunities for combinations and provide patients and their physicians with actionable diagnostic tools. AbbVie focuses on these areas to accelerate the development of innovative approaches to treat disease and to respond to unmet patient needs. AbbVie has a robust pipeline of potential new medicines, with the goal of finding solutions to address complex health issues and enhance people's lives. AbbVie manufactures and markets SKYRIZI®, one of the products selected by the Board for a "cost review" (or "affordability review").[2]

AbbVie supports the Board's statutory objective of addressing affordability challenges. However, putting aside for now the fact that there is nothing to ensure that UPLs will result in lower out-of-pocket costs for Maryland patients, the proposed regulations do not provide a workable or coherent framework for implementing UPLs in practice. At a fundamental level, the regulations establish a payment ceiling without identifying a mechanism to achieve it. They rely on a contract-based model that regulates only one side of a bilateral relationship, assume that pricing and reimbursement will adjust to meet the UPL without explaining how or by whom, and leave unresolved the central question of who bears the difference between prevailing market conditions and the UPL.

[1] *See* Maryland Prescription Drug Affordability Board, "Draft Proposed Regulations for Comment (Posted: 3/16/2026)," at https://pdab.maryland.gov/Pages/proposed-regs.aspx ("Draft COMAR 14.01.06 - Implementation and Monitoring of Upper Payment Limits" and "Draft COMAR 14.01.07 - Upper Payment Limit") (last visited March 30 2026).

[2] As communicated to the Board, AbbVie is prepared to submit the requested materials for the SKYRIZI cost review. Pursuant to the Board's instructions, AbbVie is awaiting the Board's response regarding confidentiality protections before submitting these materials.

The draft regulations are constitutionally infirm, as well as being arbitrary and capricious, because they impose penalties and compliance and reporting obligations without defining the required standard of conduct.[3] They do not establish what it means to comply with a UPL, how compliance is to be measured, or how retrospective pricing adjustments—such as rebates and other concessions—are to be reconciled with the payment limit. They require reporting of complex net-cost metrics using undefined terms and without regard to whether regulated entities have access to the necessary data. As written, the regulations do not permit regulated entities to determine what is required of them or how compliance will be evaluated.

These deficiencies go to the core of any attempt to implement UPLs responsibly. In the absence of a defined implementation mechanism, any mismatch between the UPL and real-world pricing will necessarily be absorbed elsewhere in the system, creating foreseeable risks for pharmacies, providers, and patients and raising serious concerns about continuity of access. The timing of the regulations reinforces that the framework is not operational: UPLs take effect in 2027, while the Board's own implementation mechanism does not apply until 2028, and no alternative pathway is provided. In these circumstances, the proposed regulations are materially incomplete and should not be finalized without substantial revision. Indeed, the mismatch between effective UPL dates and implementation mechanisms renders the regulations arbitrary and capricious as a matter of law.

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I. The Proposed Regulations Do Not Provide a Workable Framework for Implementing Upper Payment Limits

The proposed regulations do not establish a workable framework for implementing UPLs in practice. While the regulations set a ceiling on payments for certain prescription drug products,[4] they rely on a contract-based implementation model without identifying how that model will achieve alignment between the UPL and existing pricing and reimbursement structures. The regulations assume that transactions will conform to the UPL once they are in effect, but do not explain how that outcome is to be achieved within the existing pharmaceutical supply chain or which entity is responsible for ensuring it. In the absence of a defined mechanism for achieving

[3] *See, e.g., Lussier v. Maryland Racing Comm'n*, 100 Md. App. 190 (1994) (holding that the vagueness doctrine applies to regulations governing commercial or economic activities if its violation can engender penalties); *Harvey v. Marshall*, 389 Md. 243 (2005) (stating that an agency acts arbitrarily and capriciously "when decisions are made impulsively, at random, or according to individual preference rather than motivated by a relevant or applicable set of norms").

[4] Specifically, Maryland applies the regulations to drugs "[p]urchased or paid for by a unit of State or local government or an organization on behalf of a unit of State or local government...[or] [p]aid for through a health benefit plan on behalf of a unit of State or local government[.]" *See* Maryland Prescription Drug Affordability Board, "Draft COMAR 14.01.06 - Implementation and Monitoring of Upper Payment Limits (Posted: 3/16/2026)," at https://pdab.maryland.gov/Documents/meetings/2026/March%2023%202026/2016.03.16.DRAFT.14.01.06.Implementation%20and%20Monitoring%20of%20Upper%20Payment%20Limits%20Regs.v.1.0.pdf (last visited March 30 2026). But in practice, pharmaceutical transactions typically occur through national supply chains where manufacturers sell drugs to wholesalers, often outside of Maryland, who then distribute those drugs to pharmacies across the country. Accordingly, regulated entities cannot even determine upfront whether a specific claim will be subject to the regulations.

UPL pricing, the regulations necessarily leave unresolved how the difference between prevailing market prices and the UPL will be absorbed, creating foreseeable risks for pharmacies, providers, and patients and raising fundamental questions about whether access to affected therapies can be maintained under the proposed framework.

The Board's primary implementation mechanism—a contractual requirement imposed on state and local governmental entities—does not resolve this issue. Proposed COMAR 14.01.06.02 requires eligible governmental entities to include specified UPL compliance language in contracts governing the payment for or purchase of prescription drug products beginning in 2028. However, the regulations address only one side of the contractual relationship. As a threshold matter, the Board is proposing to use state required contract provisions to regulate private pricing behavior indirectly, rather than exercising authority directly—an approach courts routinely view with skepticism.[5]

The structure of the required contractual provision further underscores this concern. The model language in proposed COMAR 14.01.06.02.B is not limited to a defined set of products or a known financial exposure. Rather, it requires compliance with any Maryland UPLs "promulgated in regulation and in effect during the term of the contract." This prospective, open-ended obligation seemingly extends beyond the specific UPLs proposed for Farxiga and Jardiance and purports to bind contractors to all current and future UPLs during the life of the agreement. The regulations do not explain how contractors are expected to evaluate or assume this undefined and potentially expanding financial risk, or how such obligations are to be reflected in contract pricing and negotiation. By adopting a one-size-fits-all contractual device of this scope, the Board has introduced a level of uncertainty that directly implicates the feasibility of contract formation and performance.

More fundamentally, the regulations do not identify who bears responsibility for the economic difference between prevailing market prices and the UPL, or how that difference is to be addressed. The UPL operates as a ceiling on payments, but the regulations do not establish any process for aligning existing pricing and reimbursement structures with the prescribed limit. As a result, the central economic premise underlying UPL implementation—who bears the difference between the UPL and real-world pricing—is left unresolved.

At the same time, the entities expected to operationalize the UPL—such as PBMs and other intermediaries—do not unilaterally control the key variables necessary to do so. These entities may be required, through contractual provisions, to administer benefits in a manner consistent with the UPL, but they do not directly set manufacturer pricing and cannot independently ensure that acquisition costs borne by pharmacies and providers align with the prescribed payment limit. The regulations do not explain how these intermediaries are expected to satisfy their obligations under these conditions or how they are to manage the financial risk created by any mismatch between

[5] *See, e.g.*, *Mayor of Baltimore v. William E. Koons, Inc.*, 270 Md. 231, 236-237 (1973) ("Legislation may not be enacted by an administrative agency under the guise of its exercise of the power to make rules and regulations by issuing a rule or regulation which is inconsistent or out of harmony with, or which alters, adds to, extends or enlarges, subverts, or impairs, limits, or restricts the act being administered." (citation omitted)); *Comptroller of Maryland v. Miller*, 169 Md. App. 321 (Md. App. 2006) (similar); *see also Parker v. State Farm Mut. Auto. Ins. Co.*, 263 Md. 206, 216 (1971) ("The law generally will not permit by indirection or circuity what it will not allow directly.").

the UPL and prevailing market prices. The result is a framework that assigns responsibility for compliance without corresponding control over the factors necessary to achieve it.

In the absence of a defined mechanism for achieving UPL pricing, the regulations create foreseeable consequences for manufacturers, pharmacies, providers, and patients. If the difference between prevailing market prices and the UPL is not resolved upstream, pharmacies may face reimbursement levels that do not cover acquisition costs, creating disincentives to stock or dispense affected drugs. Providers may encounter similar challenges in acquiring and administering products at sustainable rates. These dynamics, in turn, may lead to formulary restrictions, increased utilization management, or other limitations that affect patient access to prescribed therapies. The regulations do not address these consequences or explain how governmental entities are expected to maintain continuity of access for covered beneficiaries if these dynamics disrupt contract negotiations, reimbursement flows, or formulary administration.

Taken together, these features of the proposed regulations demonstrate that the Board has established a payment ceiling without providing a coherent or operational pathway for implementing it. The framework imposes open-ended obligations without defined risk parameters, assigns compliance responsibility to entities that lack direct control over relevant pricing inputs, and leaves unresolved how the gap between existing market conditions and the UPL is to be addressed. In effect, the regulations require compliance with UPLs without identifying any actor that both has the ability and the obligation to achieve that compliance. In these circumstances, the regulations do not present a workable model for effectuating UPLs in practice and, as a result, impermissibly expand the Board's statutory authority by converting an "upper payment limit" into a de facto price control regime without statutory authorization.

The Maryland PDAB statute authorizes establishing UPLs, not mandating redistribution of pricing risk, imposing indirect price concessions, and/or forcing renegotiation of private contracts. By failing to identify *who* must absorb the delta between market pricing and the UPL, the Board is attempting to compel price reductions without a statutory mechanism. The Maryland PDAB may not rely on "implementation gaps" to expand its regulatory reach and here, silence in the statute does not permit implied price-setting authority. Such regulatory overreach is the kind of agency action that Maryland courts regard as *ultra vires*.[6]

[6] *See Thornton Mellon, LLC v. Frederick Cnty. Sheriff*, 252 Md. App. 320 (2021) ("A government official or agency . . . may not act in a way that is 'inconsistent or out of harmony with, or which alters, adds to, extends or enlarges, subverts, impairs, limits, or restricts the [statutory] act being administered.'" (quoting *Bd. of Liquor License Com'rs for Baltimore City v. Hollywood Productions, Inc.*, 344 Md. 2 (1996))); *Holy Cross Hosp. of Silver Spring, Inc. v. Health Servs. Cost Rev. Comm'n*, 283 Md. 677, 393 (1978) (finding that Maryland Health Services Cost Review Commission exceeded its statutory authority, which only authorized the Commission to hold public hearings and conduct investigations, when the Commission attempted to review and set fees charged by physicians in certain medical specialties); *Bd. of Liquor License Comm'rs*, 344 Md. 2 (holding that Baltimore Board of Liquor License Commissioners lacked authority to restrict hours of operation of a licensee's establishment because "if the legislature had intended the [Board] to have this authority, it would have incorporated language to that effect in the appropriate provisions").

II. The Proposed Regulations Fail to Define the Standards Necessary to Administer and Assess Compliance with Upper Payment Limit-Related Requirements

Even setting aside the structural defects discussed above, the regulations impose binding obligations on regulated entities—including payment limitations and detailed reporting requirements—without defining the core terms, methodologies, or processes necessary to determine whether those obligations have been satisfied. In particular, the regulations do not articulate what it means to comply with a UPL, how compliance is to be measured, how retrospective pricing adjustments are to be reconciled with a prospective payment limit, how required reporting metrics are to be calculated, or how financial responsibility is to be allocated among participants in the supply chain. As written, the regulations do not permit regulated entities to determine what is required of them or how compliance will be evaluated.

Most fundamentally, the regulations do not define what constitutes compliance with a UPL in operational terms. The regulations apply UPLs to "payments" for prescription drug products, but do not define what constitutes a "payment" in a system in which pricing is shaped by retrospective rebates, discounts, and other price concessions. Nor do they specify whether compliance is determined at the level of an individual claim, across a contractual arrangement, or on an aggregate basis over a defined period. They likewise do not identify which entity is responsible for ensuring compliance—whether plans, pharmacy benefit managers, pharmacies, providers, or some combination thereof. These are not ancillary details; they are the basic elements of any enforceable payment standard. Without them, regulated entities cannot determine how to structure transactions, contracts, or reimbursement practices to comply with the UPL requirement.

This problem is compounded by a fundamental inconsistency in how the regulations treat pricing. On the one hand, the regulations impose a UPL as a constraint on "payments," which suggests a point-of-sale or transaction-level limit. On the other hand, the regulations require reporting of "final net cost," "final net system ingredient cost," and related metrics that necessarily depend on retrospective price concessions realized after the initial transaction. The regulations do not explain how these concepts interact. If compliance is assessed at the point of sale, entities cannot account for rebates and other concessions that are not yet known or realized at the time of the transaction. If compliance is assessed on a net basis after such adjustments, then the UPL does not function as a true payment limit at the time of payment. The regulations do not resolve this contradiction or provide any methodology for reconciling these competing approaches. As a result, they do not specify how compliance is to be determined at all.

The absence of a defined reconciliation methodology further underscores that the regulations cannot be operationalized as written. The pharmaceutical pricing system relies on post-period adjustments—including rebates, chargebacks, and other concessions—that are applied at different times and across different entities. The regulations impose a payment ceiling without specifying how these mechanisms are to be incorporated into the determination of UPL compliance. They do not indicate whether reconciliation is expected on a claim-by-claim basis, over a defined reporting period, or through some other aggregation method, nor do they provide any process for resolving discrepancies between initial payments and final net costs. Without a defined approach to reconciliation, regulated entities cannot determine whether they are in compliance with the UPL at any point in time, and compliance cannot be assessed or enforced in a consistent manner.

The reporting provisions highlight and exacerbate these defects. The regulations require entities to report "final net cost," "final net system ingredient cost," and, for certain payors, calculations involving "GovUPLs" and weighted averages of those values, yet do not define these terms or provide any methodology for calculating them. Nor do the regulations account for the fact that different entities within the supply chain have access to fundamentally different information. Pharmacies and providers do not have visibility into manufacturer rebates or other price concessions necessary to calculate net costs, while PBMs and plans may have only partial or contract-specific data. The regulations thus require entities to report metrics they may not be capable of calculating and do not establish any standard for how those metrics are derived, validated, or reconciled across entities. In the absence of defined terms and methodologies, the reporting requirements cannot be implemented in a consistent or reliable manner.

Finally, the regulations do not address how financial responsibility is to be allocated among participants in the event that UPL compliance is not achieved. The implementation of a UPL necessarily involves multiple independent actors—plans, PBMs, pharmacies, providers, and manufacturers—whose economic incentives and contractual obligations may not align. The regulations impose a binding payment constraint across this multi-party system but do not specify which entity bears the financial consequences if payments exceed the UPL or if the gap between the UPL and prevailing market prices cannot be closed. Nor do they establish any mechanism for resolving disputes among these actors regarding compliance or financial responsibility.

III. The Proposed Regulations Reflect a Rushed Implementation Framework

The timing and structure of the proposed regulations demonstrate that the Board has moved to implementation before resolving the core operational issues necessary to support any UPL framework. As discussed above, foundational elements remain unresolved at the time of rulemaking, confirming that the Board has advanced to implementation without first establishing a coherent model capable of functioning in practice. Additionally, the Board has neither meaningfully addressed nor resolved concerns regarding how its UPL framework and these draft regulations conflict with federal pricing and reimbursement schemes.

The January 1, 2027 effective date for the initial UPLs provides a concrete illustration of this defect. The product-specific regulations establish UPLs that apply to covered transactions beginning in 2027, while the Board's identified implementation mechanism—contractual provisions required under COMAR 14.01.06.02—applies only to contracts executed or amended on or after January 1, 2028. The regulations provide no alternative mechanism for achieving compliance during this 2027 period. They do not establish any pricing adjustment process, do not impose any direct obligation on upstream actors, and do not define any compliance standard that could be applied in the absence of contractual provisions. As a result, the regulations create a gap in which compliance with the UPL is required but no mechanism—contractual or otherwise—exists to even begin to achieve or assess that compliance. This sequence, combined with the unresolved issues identified in Sections I and II above, demonstrates the Board's failure to systematically address affordability challenge. The proposed regulations are not operational and should not be finalized in their current form.

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abbvie

The deficiencies in the proposed regulations discussed above are not merely technical. They reflect a fundamental failure to translate statutory authority into an administrable regulatory framework. Absent defined standards, compliant actors, risk allocation, reconciliation methodology, or temporal coherence, the regulations cannot function as written. Finalizing them would expose regulated entities to obligations they cannot meet and would invite instability, access disruptions, and legal challenge.

Thank you for the opportunity to provide written comments on the proposed regulations. Please contact me at hfitzpatrick@abbvie.com with any questions.

Sincerely,

Helen Kim Fitzpatrick
Vice President, State Government Affairs
Government Affairs
On behalf of AbbVie Inc.

March 30, 2026

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VIA ELECTRONIC MAIL TO COMMENTS.PDAB@MARYLAND.GOV

Maryland Prescription Drug Affordability Board
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RE: Comments on the Draft COMAR 14.01.06 and Draft COMAR 14.01.07

Dear Members of the Maryland Prescription Drug Affordability Board:

AstraZeneca appreciates the opportunity to provide comments on the draft proposed Upper Payment Limit (UPL) draft rules (COMAR 14.01.06 Implementation and Monitoring of Upper Payment Limits and COMAR 14.01.07 UPL FARXIGA® and Jardiance). We share the Board's goal of supporting Maryland patients while ensuring responsible stewardship of public resources and offer the following observations and recommendations to help ensure any final approach is Maryland specific, consistent with statutory and regulatory requirements, and focused on measurable benefits for patients and programs.

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialization of prescription medicines, primarily for the treatment of diseases in four therapy areas: Oncology, Cardiovascular, Renal and Metabolism, Respiratory, and Rare Diseases. Based in Cambridge, UK, AstraZeneca is committed to developing innovative, lifesaving medicines and making these medicines accessible to patients. FARXIGA® is a first-in-class, oral, once-daily sodium-glucose cotransporter 2 ("SGLT2") inhibitor indicated: (1) to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression; (2) to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure; (3) to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors; and (4) as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Comments on Draft Rules for Establishing an Upper Payment Limit for FARXIGA®

The draft rules lack sufficient operational details for implementing an Upper Payment Limit (UPL) for FARXIGA®, creating uncertainty and potential barriers to effective execution. The proposal does not specify responsible entities for administration, mechanisms for monitoring and enforcing compliance, or interactions with existing rebate structures and pharmacy reimbursement systems. Significantly, the draft regulations contemplate achieving UPLs through state-required contractual provisions imposed on third-party vendors and intermediaries rather than through direct regulatory mechanisms that fails to clearly bind specific parties in the supply chain or define requirements for drug purchases and dispensing. This ambiguity leaves critical aspects unaddressed, such as reimbursement for pharmacies when acquisition costs exceed the UPL, integration with Pharmacy Benefit Manager (PBM) contracts and rebate arrangements, compliance mechanisms across purchasing systems, modifications to claims adjudication processes and associated timelines, prevention of duplicate discounts, and the state's costs for implementation and oversight.

As a threshold matter, the Maryland PDAB statute does not authorize the Board to allocate pricing risk, compel private contracting solutions, or effect price reductions indirectly. Without these details, stakeholders cannot adequately assess the feasibility, administrative burden, or potential unintended consequences of the UPL. This shortfall contravenes the Board's regulatory obligations under COMAR 14.01.05.02B(3) to minimize adverse outcomes. Ultimately, the lack of clarity may hinder rather than enhance affordability, potentially creating access barriers for vulnerable patient populations who rely on medications like FARXIGA®.

Ultimately, the lack of defined compliance standards, reconciliation methodologies, and responsible parties raises serious concerns regarding fair notice and legal enforceability. Imposing payment, compliance, or reporting obligations without clearly articulated standards of conduct or ascertainable methods of compliance renders the regulations arbitrary and capricious and, as applied, inconsistent with due process principles under Maryland law.

CONCLUSION

We urge the Board to slow the UPL process to allow meaningful engagement by all affected parties. Moving forward without adequate operational detail simply to get a "win" in order to obscure the significant taxpayer resources expended thus far with limited tangible results risks implementing a flawed system that could harm patient access to life-saving medications solely to

maintain appearances. We request that the Board provide comprehensive implementation guidance and supply chain impact assessments before finalizing this regulation. Rather than pursuing UPLs, which we adamantly oppose, the Board should redirect efforts toward alternative solutions that address root causes of affordability without undermining innovation or patient access.

While AstraZeneca has focused these comments on the substantial operational and implementation challenges presented by the draft regulations, nothing in these comments should be construed as an acknowledgement that such challenges are curable through additional guidance or refinement of the regulatory text. Indeed, AstraZeneca expressly reserves any rights, defenses, or claims it may have with respect to any final action taken by the Board.

AstraZeneca remains committed to working collaboratively with the Board to ensure Maryland patients have affordable access to FARXIGA®. However, we cannot support policy interventions based on flawed analysis, incomplete data, and violations of statutory and regulatory requirements.

We appreciate the Board's consideration of these comments and welcome the opportunity to discuss these issues further.

Respectfully submitted,

Geoffrey A Gallo
Head of Corporate & State Government Affairs

Written Testimony

Maryland PDAB Informational Hearing

March 30, 2026

Candie Finnegan
ED, State Government Affairs
Boehringer Ingelheim Pharmaceuticals, Inc.

Re: Jardiance: 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 draft regulations on March 16, 2026: COMAR 14.01.06 (Implementation and Monitoring of Upper Payment Limits) and COMAR 14.01.07 (Upper Payment Limits for Farxiga and Jardiance®), to operationalize and enforce upper payment limits (UPL) across state and local government payers. These draft 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 draft 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 commercial and government plan 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 for efficient implementation of UPL. Without a proper framework, UPL implementation and application will be difficult for plans, pharmacy benefit managers (PBMs), and pharmacies to operationalize which could increase the risk of improper payment and potential disruption to patient access.

Patients within the US healthcare system face access and affordability barriers due to the business practices of PBMs. It is important to recognize that manufacturers represent only one part of a much larger drug pricing and reimbursement system. A UPL tied to manufacturer list price does not change the business practices of plans and PBMs, who largely determine the price patients pay out-of-pocket (OOP) at the pharmacy counter. PBMs also benefit from rebates and fees tied to higher list prices, which are not required to be passed through to patients for cost reduction, creating a misaligned incentive that may discourage them from maintaining adequate coverage for Jardiance® if reimbursement is capped significantly below current rates**.** Plans and PBMs may respond to reduced reimbursement limits by tightening formularies, shifting products to higher cost sharing tiers, or increasing utilization management (UM). UM requirements like prior authorization have increased by more than 60% between 2014 and 2023, and step-therapy policies have become one of the most common tools used by PBMs to manage costs, often without much regard for clinical utility or patient adherence and affordability.[1]Additionally in 2024, 93% of physicians reported that prior authorization led to delays to patients' access to care, and 82% reported that increased UM may lead to decreased patient adherence for their recommended medication[2]. These are steps that restrict access and shift more of the OOP cost burden on patients with chronic conditions who require stable, uninterrupted therapy.

Results of Maryland UPL implementation may undermine the work manufacturers have done to lower real-world OOP costs in the commercial market through copay assistance and patient affordability programs. However, government price controls threaten these affordability pathways and may lead plans to rebalance costs in ways that directly increase what patients pay. The UPL fails to recognize Jardiance® is more affordable for Maryland patients than the national average. The Maryland average OOP cost of Jardiance®, which is $44.13, while the national commercial average OOP cost of Jardiance® is $44.41[3]. The UPL also does not take into consideration copay assistance available to patients in the state. There is a 47% commercial utilization rate of Boehringer's copay assistance program for Jardiance®, providing reduced copays for Maryland state employees and commercial patients. In these circumstances, instead of improving access

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

[2] American Medical Association. 2022 AMA Prior Authorization Physician Survey. Chicago, IL: AMA; 2022. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

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

to Jardiance®, a UPL could jeopardize that access, discourage life-changing innovation, and cause harmful, unintended consequences.

The proposed framework may impact pharmacies' ability to stock certain medicines, potentially reducing patient access. Per regulation (COMAR 14.01.05.02B), the PDAB is directed to "consider the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs" when setting a UPL, however the staff's recommendation in the methodology to not differentiate UPLs across payors and purchasers effectively turns the UPL into a reimbursement ceiling for all without considering these factors. Due to this, pharmacies may still be reimbursed at levels that do not cover their acquisition costs and associated fees. This may reduce pharmacy margins, an especially serious concern for independent pharmacies that already operate on thin margins. Reimbursement ceilings like UPLs can ultimately make it financially unsustainable for pharmacies to stock certain medications, limiting availability of Jardiance® and other products subject to a UPL and reducing patient access in Maryland.

Additionally, Boehringer is concerned about the reporting requirements included in the draft regulation, COMAR 14.01.06, as they raise significant privacy 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, PBMs 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 is not publicly disseminated.

Boehringer supports the Board's mission to improve affordability for Maryland patients and stands ready to work collaboratively on solutions that support sustainable patient access and medical innovation. 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®. Together, we can build a system that works better for patients and transforms lives, one that balances affordability, access, and innovation for generations to come.

DIABETES PATIENT ADVOCACY COALITION

March 30, 2026
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

RE: Comments on Proposed Changes to COMAR 14.01.06 and COMAR 14.01.07

Dear Members of the Maryland Prescription Drug Affordability Board,

Thank you for the opportunity to comment on the PDAB's proposed changes to regulations governing the implementation and monitoring of upper payment limits (UPLs).

The Diabetes Patient Advocacy Coalition (DPAC) strongly urges the Board to add language that protects patients from unintended harm resulting from UPL implementation. While the proposed regulations reference "monitoring," they do not specify what must be measured, how impacts will be evaluated, or what action the Board should take if a UPL creates access or affordability problems. Without these elements, the monitoring framework risks being largely symbolic rather than a meaningful safeguard for patients.

Our recommended revisions are intended to move the regulations toward clear, patient-centered accountability. Specifically, they would require the Board to track measurable impacts on patient access and affordability, increase transparency to identify emerging problems early and establish defined triggers for corrective action when policies produce harmful real-world consequences. These additions would help ensure the Board can respond promptly if a UPL leads to reduced access, pharmacy shortages, or increased patient costs.

We respectfully suggest the following additions to COMAR 14.01.06 and COMAR 14.01.07.

Suggested Changes to Draft COMAR 14.01.06- Implementation and Monitoring of Upper Payment Limits

Amend Section C and D to .04 UPL Monitoring and Data Reporting

.04 UPL Monitoring and Data Reporting

A. For each prescription drug product for which a UPL has been established and is in effect,an eligible governmental entity subject to that UPL shall report the following data for the prescription drug product:

(1) Total gross spend to the eligible governmental entity;
(2) Final net cost to the eligible governmental entity;
(3) Final net system ingredient cost;
(4) Formulary placement, if applicable, of the drug subject to the UPL before implementation and after
implementation;
(5) Units paid for or purchased in the preceding 12 months; and
(6) For payors,

(a) For each enrollee, calculate and report the GovUPLs in effect during the prior calendar year; and
(b) Calculate and report a weighted average of all GovUPLs for prescription drug products used during the reporting period based on utilization (multiply each GovUPL by its assigned weight (the percent of usage of the GovUPL), sum those products together).

B. The eligible governmental entity shall submit the data report to the Board:

(1) By April 1, following the end of the first calendar year in which the eligible governmental entity is subject to the UPL; and
(2) By April 1, for each subsequent calendar year in which the eligible governmental entity is subject to the UPL.

C. The Board shall monitor the impact of each UPL on patient access and affordability, including for prescription drug products in the same therapeutic class or drugs deemed by the Board to be therapeutic alternatives, using, at a minimum, the following metrics:

(1) Patient out-of-pocket costs;
(2) Prescription abandonment rates;
(3) Formulary placement changes;
(4) Utilization management changes;
(5) Pharmacy stocking and dispensing availability;
(6) Disparities in access across populations.

D. The Board shall publish quarterly public reports summarizing the impact of each UPL on patients, including any identified access issues, including for prescription drug products in the same therapeutic class or drugs deemed by the Board to be therapeutic alternatives.

Explanation: The current draft refers to “monitoring,” but without specifying what must be measured, that requirement may have little practical effect. These revisions define clear metrics and require public reporting, ensuring that patient access concerns are visible early and addressed transparently.

The proposal also expands data reporting to include drugs in the same therapeutic class and those deemed therapeutic alternatives. This would allow the Board to assess whether the

implementation of a UPL shifts utilization or spending to other products. Importantly, this change is limited to follow-up analysis and does not extend the application of UPLs to those additional drugs.

Add New Section .xx - Corrective Action and Suspension.

.xx Corrective Action and Suspension.

A. The Board shall establish thresholds indicating adverse patient impact, including but not limited to:

(1) Increased abandonment rates;
(2) Increased patient cost-sharing;
(3) Reduced pharmacy availability.

B. If the Board determines that a UPL results in adverse patient impact, the Board shall:

(1) Modify the UPL; or
(2) Suspend or terminate the UPL.

C. The Board shall take corrective action within 60 days of identifying such impact.

Explanation: Without enforcement triggers, monitoring doesn't lead to change. This creates a mandatory "fix or stop" mechanism that requires the Board to respond when implementation of UPL harms patients.

Suggested Changes to Draft COMAR 14.01.07- Upper Payment Limit

Add new subsection (6) under .01A and .02A — Patient Cost-Sharing Monitoring.

(6) Patient Cost-Sharing Monitoring
The Board shall monitor whether implementation of the UPL results in changes to patient cost-sharing, including copayments, coinsurance, and deductibles, for the drug.

Explanation: The current draft is entirely payer-facing. This adds a light-touch requirement so the Board can see whether patients actually benefit.

Amend Sections .01B(5) and .02B(5) — Add Transparency if Adjustment Is Not Made

(5) Board staff shall not adjust a UPL if the adjustment would violate the criteria for setting an upper payment limit set forth in COMAR 14.01.05.02D **and shall provide a public explanation for any decision not to adjust the UPL.**

Explanation: The proposed rule allows the Board to forgo an adjustment but does not require any explanation. This revision adds basic transparency and accountability.

Add new Corrective Action and Suspension subsection under both .01 and .02

For .01 (Farxiga)

X. Corrective Action and Suspension.
(1) The Board shall monitor for adverse impacts associated with

implementation of the upper payment limit, including:
(a) Reduced availability of the drug at pharmacies or providers;
(b) Significant changes in utilization patterns; or
(c) Significant changes in patient cost-sharing.
(2) If the Board identifies evidence of adverse impact, the Board shall:
(a) Modify the upper payment limit; or
(b) Suspend the upper payment limit.
(3) The Board shall provide public notice of any modification or suspension under this section.

For .02 (Jardiance)

X. Corrective Action and Suspension.
(1) The Board shall monitor for adverse impacts associated with implementation of the upper payment limit, including:
(a) Reduced availability of the drug at pharmacies or providers;
(b) Significant changes in utilization patterns; or
(c) Significant changes in patient cost-sharing.
(2) If the Board identifies evidence of adverse impact, the Board shall:
(a) Modify the upper payment limit; or
(b) Suspend the upper payment limit.
(3) The Board shall provide public notice of any modification or suspension under this section.

Explanation: This addition would ensure the Board can respond quickly if implementation of a UPL produces unintended consequences, such as reduced access, pharmacy shortages, or higher patient costs. Without a corrective action or suspension mechanism, a policy could remain in effect even if it harms patients in practice.

Taken together, these revisions would create a more practical and accountable framework for the implementation of UPLs. This amended framework would strengthen oversight, improve transparency, and help ensure that affordability policies deliver measurable benefits to patients.
Sincerely,

George Huntley

George Huntley
Chief Executive Officer
Diabetes Patient Advocacy Coalition

Maryland

PDAB Regs <pdab.regs@maryland.gov>

Comment - Draft COMAR 14.01.06

1 message

Grisier, Frances <FGrisier@frederickcountymd.gov> Mon, Mar 30, 2026 at 5:06 PM
To: "pdab.regs@maryland.gov" <pdab.regs@maryland.gov>

Hello,

My name is Fran Grisier. I am the Benefit Supervisor for Frederick County Government.

The idea behind UPLs is good in theory – providing lower costs, in this request for Farxiga and Jardiance. The concern here in Frederick County and I assume for the smaller, more rural Counties in MD is potential access issues. Smaller scale pharmacies are prevalent in these rural areas and by lowering the drug cost, this could mean lowering profits for a family pharmacy, resulting in reduced fulfillment of these drugs.

As for the reporting/monitoring of UPLs, could the language requirement in .02 Contracting and Initial Reporting Requirements (2)B but unfavorable and cause contract issues? Additionally, the reporting requirements sound somewhat burdensome. There may be additional cost associated with providing this information either from a PBM or contractor.

Thank you!

Frances (Fran) Grisier

Human Resources Benefit Supervisor

Pronouns: she/her

Frederick County Government

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PhRMA
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By Electronic Submission

March 30, 2026

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

RE: Draft Regulations – New Regulation COMAR 14.01.06 (Implementation and Monitoring of Upper Payment Limits); New Regulation – COMAR 14.01.07 (Upper Payment Limit)

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 draft regulations regarding Implementation and Monitoring of Upper Payment Limits (COMAR § 14.01.06) and Upper Payment Limits for Jardiance and Farxiga (COMAR § 14.01.07) (collectively, "Draft Regulations").[1] PhRMA represents the country's leading innovative biopharmaceutical research

[1] *See* Draft New Regulation – COMAR 14.01.06 (Implementation and Monitoring of Upper Payment Limits), *available at* https://pdab.maryland.gov/Documents/meetings/2026/March%2023%202026/2016.03.16.DRAFT.14.01.06.Implementation%20and%20Monitoring%20of%20Upper%20Payment%20Limits%20Regs.v.1.0.pdf; *see* Draft New Regulation – COMAR 14.01.07 (Upper Payment Limit), *available at* https://pdab.maryland.gov/Documents/meetings/2026/March%2023%202026/2026.03.16.DRAFT.14.01.07.UPL.Farxiga.Jardiance.v.1.0.pdf. 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 Regarding Draft Cost Review Study Reports for Comment (Mar. 30, 2026); Letter from PhRMA to Board Regarding UPL Amount and Methodology Documents (Mar. 4, 2026); Letter from PhRMA to Board Regarding Cost Review Study Process and Policy Review Process (Feb. 10, 2026); Letter from PhRMA to Board Regarding Proposed Rules – Amendments to COMAR § 14.01.01.01 (Definitions); New Regulation COMAR § 14.01.01.06 (Hearing Procedures); New Chapter COMAR § 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (Feb. 10, 2025); Letter from PhRMA to Board Regarding Proposed Regulation – Amendments to COMAR § 14.01.04.05 (Cost Review Study Process) (Dec. 2, 2024); Letter from PhRMA to Board Regarding Draft Regulations – Amendments to COMAR § 14.01.01.01 (Definitions); New Regulation COMAR § 14.01.01.06 (Hearing Procedures); New Chapter - COMAR § 14.01.05 (Policy Review, Final Action, Upper Payment Limits) (Nov. 8, 2024); Letter from PhRMA to Board Regarding Plan of Action for Implementing the Process for Setting Upper Payment Limits – Draft Working Document (Aug. 26, 2024); Letter from PhRMA to Board Regarding Selected Drug List (July 16, 2024); Letter from PhRMA to Board Regarding Request For Information Draft Forms (July 12, 2024); Letter from PhRMA to Board Regarding List of Proposed Therapeutic Alternatives and Sample Dashboard (May 10, 2024); Letter from PhRMA to Board Regarding Cost Review Study Process (Apr. 24, 2024); Letter from PhRMA to Board Regarding Rules of Construction and Open Meetings Proposed Rule; Confidential, Trade-Secret, and Proprietary Information; Public Comment Procedures; and Cost Study Review Process (Oct. 23, 2023); Letter from PhRMA to Board Regarding Definitions; Rules of Construction and Open Meetings; Confidential, Trade-

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 Draft Regulations and the Board's UPL-setting process in general.

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

A. UPL Reconsideration Process

- **Reconsideration of MFP-Based UPLs.** The Board has proposed using the Medicare Maximum Fair Price ("MFP") as the UPL benchmark. However, a drug for which an MFP has been established may be subject to renegotiation under the Medicare Drug Negotiation Program ("MDPNP") or may cease to be subject to an MFP altogether. Pursuant to its authority to reconsider UPLs, the Board should revise its Draft Regulations to provide for automatic reconsideration of a drug's UPL if its corresponding MFP is revised or rescinded.[4] 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.[5] Adopting clear procedures for reconsidering MFP-based UPLs in the event of change would protect against the perpetuation of UPLs based on outdated information.

- **Reconsideration of UPLs for Drugs in Shortage.** As noted in previous comment letters,[6] 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.[7] Additionally, Board regulations provide that "the Board shall reconsider" a UPL "[i]f the Board

Secret, and Proprietary Information; and Cost Review Study Process (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 Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process (May 1, 2023); Letter from PhRMA to Board Regarding Cost Review: Additional Metrics for Identifying Potential Drugs Presentation (Sept. 12, 2022).

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

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

[4] *See* COMAR § 14.01.05.09.

[5] COMAR § 14.01.05.08(A)(4).

[6] *See* 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.

[7] *See* Md. Code, Health Gen. § 21-2C-13(c)(1)-(2); *see also* COMAR § 14.01.05.09(A)(2).

becomes aware of a shortage . . . in the State."[8] While the Board's regulations require it to "develop a program for monitoring the availability of any prescription drug product for which it sets a UPL," the Board has not yet developed such a process.[9] The Board should revise its regulations to specifically address how the Board will monitor for shortages.

B. **Other Concerns Regarding 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:

- **Patient Access.** PhRMA is concerned that the Draft 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 an UPL, as required in the Board's first annual report on the effects of the UPL for each drug.[10] 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.[11] While formulary placement is an important indicator of coverage, the many other utilization management mandates and benefit design factors can create additional access and affordability issues, as recognized in the PDAB statute.[12] As a result, PhRMA recommends that the Board establish robust measures to monitor benefit design, including utilization management practices, for the impact of UPLs on patient access.

- **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.[13] These concerns are further heightened in light of the reporting requirements contemplated under the Draft Regulations for

[8] COMAR § 14.01.05.09(A)(2).

[9] 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").

[10] *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").

[11] Draft COMAR § 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").

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

[13] Draft COMAR § 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.").

governmental entities.[14] PhRMA urges the Board to amend the Draft Regulations, before finalizing, to include express protections for confidential, proprietary, and trade secret information that may be disclosed to the Board.

- **Net Cost.** Under the Draft Regulations, eligible governmental entities would be required to report a drug's "final net cost to the eligible governmental entity."[15] As PhRMA has previously requested, [16] the Board should clarify the meaning of the term "net cost" as it remains unclear how the Board intends to calculate the metric.

- **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. All documents subject to public comment should be posted on the PDAB website and distributed to stakeholders and distribution lists a minimum of 14 days prior to the comment deadline to allow for meaningful feedback and stakeholder participation. In addition, PhRMA requests details regarding how the Board will incorporate and address all feedback that it receives.[17]

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

PhRMA remains concerned about the Board's contemplated use of MFPs—which apply only to Medicare—as a benchmark for setting Maryland UPLs.[18] MFPs are specifically developed for the Medicare program and patient population under the statutory framework of the Inflation Reduction Act, but the Draft Regulations would apply these prices to an entirely different market and patient population. In doing so, the Board would be disregarding the unique market dynamics and affordability challenges that patients in Maryland may be facing. MFP-based UPLs would raise serious concerns for patient access, particularly if expanded to the commercial market

The Centers for Medicare & Medicaid Services ("CMS") sets its MFPs through the MDPNP, but because the program is still at an early stage, many operational and legal issues remain unresolved. The MFPs for the initial set of drugs only recently went into effect. Although it will be years before the effects of MFPs on patient affordability and access are fully understood, recent evidence shows that out-of-pocket costs for Medicare patients have significantly increased and the number of patients benefiting from MFPs has remained relatively small. Avalere Health's analyses of 2025 and 2026 Part D plan formularies found Part D plans were tightening access to branded medicines, changes that could translate into fewer therapeutic alternatives within classes that contain drugs with an MFP.[19] Avalere's 2026 Part D plan formulary analysis also found Part D plans increased utilization management for some selected drugs along with slight shifts

[14] Draft COMAR §§ 14.01.06.02, 14.01.06.04
[15] Draft COMAR § 14.01.06.04(A)(2).
[16] *See* Letter from PhRMA to Board (Feb. 10, 2025) *supra* note 1 at 3.
[17] *See* 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.
[18] *See* Letter from PhRMA to Board (Mar. 4, 2026) *supra* note 1 at 3-4; Letter from PhRMA to Board (Nov. 8, 2024) *supra* note 1 at 10.
[19] Avalere Health. 2025 Part D Formularies Shift to More Coinsurance and UM. October 2024; Avalere Health. Part D Formulary Management Tightens in 2026. November 2025.

in tier placement.[20] In addition, a 2025 physician survey by Avalere found that nearly all providers (92%) would be somewhat or very likely to stop stocking Part B drugs subject to an MFP.[21] Further, Magnolia Market Access recently reported that, "[i]n 2026, about [66%] of Part D beneficiaries are enrolled in a standalone prescription drug plan (PDP) or Medicare Advantage Prescription Drug (MA-PD) plan that has shifted coverage of IPAY 2026 selected drugs from a fixed copay to coinsurance between 2023 and 2026.[22] Among these beneficiaries, about 60% are projected to face higher cost-sharing after reaching the deductible and before the maximum out-of-pocket cap…than they would have faced in 2023."[23]

The downstream effects of the UPL on patient access are likely to be exacerbated by the use of MFPs in state populations. The use of the MFP as a benchmark is therefore premature, and PhRMA is concerned with the Board moving forward with an MFP-based UPL without fully understanding the patient impact from the MDPNP.

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

* * *

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

Sincerely,

Kristin Parde
Deputy Vice President, State Policy

Alexandra Hussey
Senior Director – Law

[20] *Id.*
[21] Avalere Health. White Paper: Provider Survey on Part B Negotiation. Sept. 2025.
[22] Magnolia Market Access. When Lower Prices Don't Mean Lower Costs: How Part D Benefit Changes Are Shifting Out-of-Pocket Spending in 2026 Under the Inflation Reduction Act. 2026.
[23] *Id.*

March 30, 2026

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

RE: Comments on Draft Regulations to COMAR 14.01.06 and COMAR 14.01.07

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

On behalf of the Value of Care Coalition (VCC), a network of patient, provider, and caregiver organizations, we appreciate the opportunity to submit comments on the Board's draft regulations.

We respectfully offer the following recommended revisions to strengthen the Board's framework for implementing, monitoring, and enforcing upper payment limits (UPLs). These recommendations are designed to ensure that UPL policies achieve their intended goal—improving patient affordability—while safeguarding access to needed therapies in real-world settings.

I. Defining Meaningful Monitoring

The current draft regulations establish a process for applying UPLs but do not provide a sufficiently clear or enforceable framework for evaluating their real-world impact of a UPL once implemented.

To address this gap, we recommend revising COMAR 14.01.06.04 to define "meaningful monitoring" through required tracking of patient-centered indicators, including:

- Patient out-of-pocket costs
- Prescription abandonment rates
- Formulary placement changes
- Utilization management changes
- Pharmacy stocking and dispensing availability
- Disparities in access across populations

These metrics reflect how patients experience the healthcare system in practice.

Patient affordability and access are largely determined by payer benefit design and coverage decisions. Without tracking these dynamics, the Board cannot determine whether a UPL

reduces costs or instead shifts them through higher cost-sharing, tighter utilization management, or changes in coverage.

Evidence from Medicare Part D following federal price-setting policies demonstrates that plan sponsors may respond with increased deductibles, greater reliance on coinsurance, and tighter formulary controls – reinforcing the importance of monitoring downstream patient impact.[1] [2]

II. Capturing Therapeutic Class and Market Dynamics

UPLs do not operate in isolation. Changes in reimbursement for one drug can lead to shifts in utilization, formulary placement, and coverage decisions impacting competing therapies. For this reason, monitoring must extend beyond the individual product subject to a UPL.

We therefore recommend explicitly requiring monitoring across:

- Drugs within the same therapeutic class
- Drugs designated by the Board as therapeutic alternatives

This ensures the Board captures market-wide responses rather than assessing a product in isolation.

Survey research conducted by Avalere on behalf of the Partnership to Fight Chronic Disease indicates that plans anticipate making coverage and formulary changes not only to drugs directly subject to UPLs, but also to other drugs in the same class, including increased utilization management and tier adjustments.[3] Without visibility into these shifts, the Board risks drawing incomplete conclusions about the impact of a UPL on patient access and affordability.

III. Strengthening Reporting and Transparency

We suggest adding quarterly public reporting requirements to ensure timely visibility into patient impact.

Because benefit design and coverage decisions may change throughout the plan year, annual reporting is insufficient. Quarterly reporting enables the Board to identify:

- Mid-year formulary changes
- New utilization management restrictions

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[1] USC Schaeffer Center for Health Policy & Economics, *Most Medicare Beneficiaries May Pay More for Drugs Under the IRA*, June 2025, https://schaeffer.usc.edu/research/medicare-part-d-drug-costs-ira/

[2] Avalere Health, *Part D Formulary Management Tightens in 2026*, November 2025, https://advisory.avalerehealth.com/insights/part-d-formulary-management-tightens-in-2026

[3] Partnership to Fight Chronic Disease, *Payer Perspectives Confirm UPLs Will Likely Raise Costs and Hinder Patient Access*, March 2025, https://b11210f4-9a71-4e4c-a08f-cf43a83bc1df.usrfiles.com/ugd/b11210_1e92735a49744639ac37321c6320e8c8.pdf

- Increases in patient cost-sharing
- Early indicators of access disruption

These reporting requirements are especially important for detecting early signs of access disruption across the delivery system. Pharmacy participation is a key indicator. National survey data indicate that one in five independent pharmacies reports that they may not stock drugs subject to federal price controls due to reimbursement concerns, with many more considering the same.[4] If reimbursement tied to a UPL does not align with acquisition costs or is delayed, patients may face reduced local availability—even when a drug remains covered.

IV. Ensuring Action When Problems Emerge

Monitoring alone is not sufficient without a mechanism to act. We recommend adding a Corrective Action and Suspension Framework requiring the Board to:

1. Establish thresholds for adverse patient impact (e.g., increased cost-sharing, higher abandonment rates, reduced pharmacy availability); and
2. Modify, suspend, or terminate a UPL within a defined timeframe if those thresholds are met.

This creates a necessary "monitor-and-act" structure that ensures policies can be adjusted when unintended consequences arise.

V. Strengthening Transparency and Accountability

We also recommend revisions to COMAR 14.01.07 to:

- Require monitoring of patient cost-sharing (copayments, coinsurance, deductibles)
- Require public explanation when the Board declines to adjust a UPL
- Ensure ongoing evaluation of patient impact beyond initial implementation

These changes will improve transparency and ensure that patient outcomes remain central to regulatory decision-making.

VI. Recommended Regulatory Language

COMAR 14.01.06 Recommended Regulatory Language

Add Sections C & D to COMAR 14.01.06.04 – UPL Monitoring and Data Reporting

.04 UPL Monitoring and Data Reporting

[4] National Community Pharmacists Association, *Independents may opt not to stock MFP drugs*, September 2025, https://ncpa.org/newsroom/qam/2025/09/08/independents-may-opt-not-stock-mdpnp-drugs-ncpa-warns-cms

A. For each prescription drug product for which a UPL has been established and is in effect, an eligible governmental entity subject to that UPL shall report the following data for the prescription drug product:
(1) Total gross spend to the eligible governmental entity;
(2) Final net cost to the eligible governmental entity;
(3) Final net system ingredient cost;
(4) Formulary placement, if applicable, of the drug subject to the UPL before implementation and after
implementation;
(5) Units paid for or purchased in the preceding 12 months; and
(6) For payors,
(a) For each enrollee, calculate and report the GovUPLs in effect during the prior calendar year; and
(b) Calculate and report a weighted average of all GovUPLs for prescription drug products used during the reporting period based on utilization (multiply each GovUPL by its assigned weight (the percent of usage of the GovUPL), sum those products together).
B. The eligible governmental entity shall submit the data report to the Board:
(1) By April 1, following the end of the first calendar year in which the eligible governmental entity is subject to the UPL; and
(2) By April 1, for each subsequent calendar year in which the eligible governmental entity is subject to the UPL.
C. The Board shall monitor the impact of each UPL on patient access and affordability, including for prescription drug products in the same therapeutic class or drugs deemed by the Board to be therapeutic alternatives, using, at a minimum, the following metrics:
(1) Patient out-of-pocket costs;
(2) Prescription abandonment rates;
(3) Formulary placement changes;
(4) Utilization management changes;
(5) Pharmacy stocking and dispensing availability;
(6) Disparities in access across populations.
D. The Board shall publish quarterly public reports summarizing the impact of each UPL on patients, including any identified access issues, including for prescription drug products in the same therapeutic class or drugs deemed by the Board to be therapeutic alternatives.

ADD New Section 14.01.06.xx Corrective Action and Suspension

A. The Board shall establish thresholds indicating adverse patient impact, including but not limited to:

(1) Increased abandonment rates;
(2) Increased patient cost-sharing;
(3) Reduced pharmacy availability.

B. If the Board determines that a UPL results in adverse patient impact, the Board shall:

(1) Modify the UPL; or
(2) Suspend or terminate the UPL.

C. The Board shall take corrective action within 60 days of identifying such impact.

COMAR 14.01.07 Recommended Regulatory Language

Add NEW subsection (6) under .01A and .02A — Patient Cost-Sharing Monitoring

(6) Patient Cost-Sharing Monitoring.
The Board shall monitor whether implementation of the UPL results in changes to patient cost-sharing, including copayments, coinsurance, and deductibles, for the drug.

Sections .01B(5) and .02B(5) — Add Transparency if Adjustment Is Not Made

(5) Board staff shall not adjust a UPL if the adjustment would violate the criteria for setting an upper payment limit set forth in COMAR 14.01.05.02D **and shall provide a public explanation for any decision not to adjust the UPL.**

Add new Corrective Action and Suspension subsection under both .01 and .02

For .01 (Farxiga)

X. Corrective Action and Suspension.
(1) The Board shall monitor for adverse impacts associated with implementation of the upper payment limit, including:
(a) Reduced availability of the drug at pharmacies or providers;
(b) Significant changes in utilization patterns; or
(c) Significant changes in patient cost-sharing.

(2) If the Board identifies evidence of adverse impact, the Board shall:
(a) Modify the upper payment limit; or
(b) Suspend the upper payment limit.

(3) The Board shall provide public notice of any modification or suspension under this section.

For .02 (Jardiance)

X. Corrective Action and Suspension.
(1) The Board shall monitor for adverse impacts associated with implementation of the upper payment limit, including:
(a) Reduced availability of the drug at pharmacies or providers;
(b) Significant changes in utilization patterns; or
(c) Significant changes in patient cost-sharing.

(2) If the Board identifies evidence of adverse impact, the Board shall:
(a) Modify the upper payment limit; or
(b) Suspend the upper payment limit.

(3) The Board shall provide public notice of any modification or suspension under this section.

Conclusion

Taken together, these revisions ensure that the Board's framework better reflects how the prescription drug market functions in practice.

While UPLs may alter reimbursement, patient affordability and access are ultimately determined by how payers, pharmacies, and providers respond. A regulatory structure that measures those responses, captures market-wide effects, and requires corrective action when patients are harmed is essential to achieving the Board's goals.

We appreciate the opportunity to provide input and look forward to continued engagement.

Sincerely,
Derek Flowers
Value of Care Coalition