One Park Place | Suite 475 | Annapolis, MD 21401-3475
1-866-542-8163 | Fax: 410-837-0269
aarp.org/md | md@aarp.org | twitter: @aarpmd
facebook.com/aarpmd

Prescription Drug Affordability Board
Comment on the Proposed UPL Methodology for Jardiance and Farxiga
March 4, 2026

The Maryland Prescription Drug Affordability Board's (PDAB) Upper Payment Limit Methodology documents for Jardiance and Farxiga are thoroughly researched and explained. They provide a very sound, balanced approach to advancing Upper Payment Limits (UPLs) for these major drugs. AARP Maryland, which has 850,000 members in the state, therefore asks the PDAB to promptly adopt this methodology for state- and local-government purchasers and complete action on the UPLs for these first two drugs under consideration.

Using the Medicare Maximum Fair Price (MFP) as a base standard for developing UPLs makes a lot of sense. The work by Medicare that went into that included detailed discussions and negotiations with the drug producers, and it led to the establishment of prices already being used in that market. Similarly, excluding dispensing and administration fees, as well as direct and indirect payments to pharmacies, is a sound approach for determining the prices of the drugs themselves.

The methodology for calculating UPLs for subsequent years is also appropriate and well thought out. The annual inflation assumption of 2.7 percent fits with inflation in the most recent year.

The PDAB is also right to note that, under the MFP rules the board proposes to use to determine prices for these two drugs, pharmacies can be reimbursed a dispensing fee in addition to the MFP. Furthermore, the board's staff is correct in its recommendation that "no adjustments be made to ensure the UPL based on MFP excludes dispensing fees."

Those statements and the rationale leading up to them aim to protect pharmacies from any negative effects that could affect those important businesses as a result of these initial UPLs. AARP appreciates PDAB's attention to that issue as well.

For all of these reasons, AARP Maryland congratulates the PDAB on developing a sound methodology for determining UPLs for Jardiance and Farxiga and urges the board to adopt it promptly. By taking that action, it will begin to make these key drugs more affordable for state and local government agencies and their employees. That, in turn, will start the clock on using the 2025 PDAB expansion law to bring much-needed prescription-drug price relief to all Marylanders one year after the initial step on these important two drugs takes effect.

March 4, 2025

Via Electronic Correspondence

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

RE: COMAR 14.01.05.06D(4) – Farxiga: Upper Payment Limit Methodology

Dear Chair Mitchell:

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's Prescription Drug Affordability Board's ("PDAB" or "Board") commitment to addressing the rising cost of prescription drugs for Maryland patients. As the Board continues to move forward with the upper payment limit (UPL) rulemaking process for Farxiga, Aimed Alliance urges it to proceed with caution, carefully monitoring potential unintended consequences and ensuring that patient feedback is meaningfully prioritized during the process.

I. Exercise Caution as the Board Proceeds with the UPL Rulemaking Process and Consider Unintended Consequences

Aimed Alliance recognizes the inherent challenges and complexity of conducting affordability reviews and setting UPLs. For this reason, we urge the Board to move forward with caution and diligence as it continues the rulemaking process for Farxiga. We are particularly concerned about possible unintended consequences. Recent data indicate that 57 percent of surveyed health plans expect both UPL-targeted drugs and their therapeutic alternatives to face formulary changes, while half anticipate increased utilization management.[1] These findings suggest a strong likelihood that pharmacy benefit managers (PBMs) may exclude Farxiga from formularies or impose more aggressive non-medical switching once a UPL is implemented.

Such practices can be incredibly harmful to patients who have spent months or years cycling through alternative treatments before finding one that is effective. Non-medical switching jeopardizes these patients' stability and undermines patient progress. For patients who are stable on their current therapy, being forced to switch medications due to a UPL may trigger disease flares, or accelerate disease progression, potentially erasing any potential short-term savings the UPL might produce.

II. Intentionally Monitor the UPL's Effects on Patients and Establish Clear Safeguards

If the Board decides to move forward with setting a UPL, it is essential that it closely and intentionally monitor its effects on patients. Because the Board's mission includes protecting state residents from high prescription drug costs, it should ensure not only that a UPL lowers

[1] Avalere Health, *Update: Health Plans' Perceptions of PDABs and UPLs* (Mar. 28, 2025), https://advisory.avalerehealth.com/insights/update-health-plans-perceptions-of-pdabs-and-upls.

costs for consumers, but also that it does not inadvertently harm patients by reducing access to medically necessary therapies. This requires ongoing monitoring of utilization management practices adopted by health plans following implementation, for both Farxiga and for its therapeutic alternatives. Without this oversight, patient access issues may go undetected, and the Board will not have the information needed to correct such unintended consequences.

These considerations raise several important process questions regarding implementation. For example:

- What will constitute sufficient harm to warrant withdrawal of a UPL?
- Will the threshold apply only to patient harm, or also to harm experienced by providers?
- What data sources will be used to assess impact, and how will data be collected and measured?

Without a transparent and enforceable mechanism to monitor patient impact, it is unclear how the Board would effectively and swiftly identify and address unintended consequences. We therefore urge the Board to develop a deliberate process that meaningfully tracks UPL impacts and provides patients with opportunities to engage the Board when access challenges arise.

III. Prioritize the Patient Voice During the UPL Rulemaking Process

Aimed Alliance appreciates the Board's commitment to considering the patient voice throughout the affordability review and UPL-setting process. However, because patients are the individuals most directly affected by affordability decisions, their experiences and perspectives should serve as essential evidence rather than commentary that is acknowledged but not acted upon.

One way to do this is by drawing on international actors with extensive experience implementing drug-pricing mechanisms comparable to UPLs.[2] Across health technology assessment systems globally, widely recognized best practices highlight the importance of embedding patient perspectives directly into affordability and reimbursement decisions. These practices include establishing consumer-engagement frameworks that prioritize transparent communication and timely notification; expanding centralized consumer support; elevating consumer evidence and input; maintaining a structured feedback loop following committee recommendations; and offering user-friendly tools, such as a digital consumer portal, that enable ongoing patient participation and accountability.[3]

Integrating patient feedback in this manner can also help the Board and legislators determine whether supplemental reforms may be more appropriate than setting a UPL. For example, if patients report that a drug is unaffordable primarily due to payer policies rather than the drug's actual price, it is critical for the Board to reconcile this information before moving forward.

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[2] Australian Government Department of Health and Aged Care, Enhance HTA: An Enhanced Consumer Engagement Process in Australian Health Technology Assessment A Report of Recommendations (June 2024), https://www.health.gov.au/sites/default/files/2024-09/enhance-hta-an-enhanced-consumer-engagement-process-in-australian-health-technology-assessment-a-report-of-recommendations.pdf.

[3] *Id*.

Implementing a UPL for a drug whose affordability issues are not price-driven could lead to ineffective policy choices and increased time and spending on solutions that fail to address the underlying problem.

For these reasons, Aimed Alliance urges the Board to meaningfully center patient experience as it considers whether to set a UPL for Farxiga. We encourage the Board to closely evaluate and reconcile the feedback it has gathered with its ultimate decisions, ensuring that patient input is treated as a formal data source.

IV. Conclusion

In conclusion, Aimed Alliance commends the Board for its commitment to addressing the rising cost of prescription drugs for Maryland patients. However, we urge the Board to proceed with caution, carefully evaluating potential unintended consequences and ensuring that patient feedback is meaningfully prioritized during the process. If you have any questions or wish to discuss these matters further, please contact us at policy@aimedalliance.org.

Sincerely,

Olivia Backhaus
Staff Attorney

AstraZeneca
1800 Concord Pike
Wilmington, DE 19850
astrazeneca.com

March 4, 2026

VIA ELECTRONIC MAIL TO COMMENTS.PDAB@MARYLAND.GOV
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Draft Upper Payment Limit Regulations

Dear Members of the Maryland Prescription Drug Affordability Board:

AstraZeneca appreciates the opportunity to provide comments on the February 17, 2026, proposed Upper Payment Limit (UPL) Methodology for FARXIGA® (dapagliflozin) (the "Draft UPL Methodology"). We share the Board's goal of supporting Maryland patients while ensuring responsible stewardship of public resources. AstraZeneca is a global, science-led biopharmaceutical company committed to developing innovative, lifesaving medicines and making them accessible. FARXIGA® is a first-in-class SGLT2 inhibitor with indications for chronic kidney disease, heart failure, and type 2 diabetes. It provides substantial clinical benefits including reduced hospitalizations and disease progression.

We incorporate by reference our prior submissions to the Board, including comments on the FARXIGA® Dossier (July 3, 2025), Draft UPL Regulations (November 8, 2024), Draft UPL Action Plan (October 18, 2024), and Draft UPL Framework (November 12, 2025). These highlight ongoing concerns with the Board's process for FARXIGA®, including its inappropriate selection for cost review and failure to demonstrate affordability challenges under COMAR 14.01.05. Proceeding with a UPL would be arbitrary and capricious. We urge the Board to not make a final determination that FARXIGA® is unaffordable and discontinue the UPL process. The Draft UPL Methodology amplifies these issues and contains significant flaws, as detailed below.

EXECUTIVE SUMMARY

- The Draft UPL Methodology notes that a UPL set at the Medicare Maximum Fair Price (MFP) "may not result in additional discounts" and "may not yield significant savings for State and local government health plans." This admission undermines the rationale for including FARXIGA® in the Board's cost review, preliminary determination of unaffordability, and implementation of a UPL.
- The Draft UPL Methodology is incomplete and insufficient. It fails to address COMAR requirements for determining whether a UPL is appropriate, including affordability drivers, adverse outcomes, administrative costs, and out-of-pocket prioritization. It also does not provide clear, objective standards or factor weighting sufficient to support reasoned decision-making and policy/legal review.
- It is not a true methodology. It lacks details on implementation or enforcement, which will have a large effect on the supply chain and drug coverage within the State. It also prevents substantive feedback. Without the

operational assumptions needed to evaluate real-world impact, stakeholders lack meaningful notice and opportunity to comment on the policy being proposed.

- Reliance on Medicare MFP is inappropriate for Maryland's populations and admits limited savings, undermining the rationale. In addition, the Methodology does not adequately assess interactions with, and potential downstream impacts on, federal pricing and access frameworks.
- The Board must freshly analyze recent FARXIGA® price reductions effective January 1, 2026, and imminent generic entry.
- The comment timeline of March 4, 2026, is too short and limits input from supply chain actors and, most importantly, Patient Advocacy Groups and the patients themselves.

IMMINENT LOSS OF PATENT EXCLUSIVITY

The Board Staff has recently admitted that FARXIGA®'s primary patent exclusivity is expected to expire in April 2026. The FDA has tentatively approved 18 Abbreviated New Drug Applications (ANDAs) with the expectation that many of them will launch in early April. This is expected to lead to increased competition and price erosion within months of generic availability. The Board should discontinue the UPL process to avoid the unnecessary burden of implementing the UPL that will not have an impact on the cost to patients or payors within Maryland. If the Board is inclined to continue to evaluate FARXIGA®, we request that the Board pause the UPL evaluation of FARXIGA® for 60 days to avoid a costly implementation of a UPL on a drug category that is likely to see significant cost reduction through market events.

ASTRAZENECA'S VOLUNTARY PRICE REDUCTION EFFORTS

Market conditions have changed, and The Board is proceeding on a stale record. Publicly available information shows Farxiga price reductions of 37% effective January 1, 2026. In addition, AstraZeneca has voluntarily begun participation in several programs that are targeted to decrease the cost of drugs for patients within the State. These include publicly reported Most Favored Nation drug price discussions with the Federal Government and the direct-to-patient assistance programs.

The Board must conduct a fresh, Maryland-specific analysis incorporating the impact on cost from these engagements. A new analysis would allow the Board to address the recent cost changes as well as the Maryland specific analysis on net acquisition costs, and clinical cost offsets (e.g., avoided hospitalizations for heart failure and kidney failure), as required under COMAR 14.01.05.02B(1) and COMAR 14.01.05.02B(2). The omission of these issues in a Maryland specific analysis risks an outdated and incorrect UPL.

INADEQUACY OF MEDICARE MFP AS BASIS FOR STATE UPL

Medicare's MFP prices are inappropriate as the basis for state UPLs because Medicare serves different patient populations than those affected by state UPLs. In addition, the Board's own staff has admitted a UPL at MFP "may not result in additional discounts" or "yield significant savings." This undermines COMAR 14.01.05.02B(2)'s requirement to confirm a UPL addresses affordability drivers.

Moreover, the methodology's reliance on MFP is flawed because it does not fully reflect all discounts, rebates, and price concessions, such as those from the Medicare Inflation Rebate Program or supplemental rebates negotiated in the commercial business. This creates inherent incompleteness. The UPL may overstate net costs to other payors, leading to an artificially low cap. This violates COMAR 14.01.05.06D's requirement to "reflect all" such elements. Without

adjustments or alternative data sources (e.g., real-world net pricing data beyond MFP), the framework risks inaccuracy and fails to provide a holistic view.

FAILURE TO ADDRESS COMAR REQUIREMENTS FOR UPL DETERMINATION

The Draft UPL Methodology skips foundational COMAR steps and focuses on calculation without justifying a UPL's need.

- **Affordability Drivers and Appropriateness (COMAR 14.01.05.02B(2))**: No analysis of underlying challenges or why a UPL is the best tool. It ignores alternatives like benefit design reforms or PBM practices that drive patient costs.
- **Adverse Outcomes and Unintended Consequences (COMAR 14.01.05.02B(3))**: No evaluation of risks like supply disruptions, reduced innovation, or access barriers. It fails to minimize adverse outcomes and the risk of unintended consequences.
- **Administrative Costs vs. Spending (COMAR 14.01.05.02C(1))**: No assessment if governmental spending on Farxiga exceeds implementation costs. This potentially prohibits a UPL.
- **Out-of-Pocket Prioritization (COMAR 14.01.05.02B(4))**: No data showing high out-of-pocket proportions relative to net costs. Patient barriers stem from plan design and federal rules, not pricing.
- **Statutory Impacts (COMAR 14.01.05.02D(1))**: No discussion of effects on Medicaid Best Price or other benchmarks. This risks indirect violations.

These omissions render the methodology incomplete and non-compliant. COMAR 14.01.05.02A requires applying all criteria before setting a UPL.

ADDITIONAL METHODOLOGICAL FLAWS

The Draft UPL Methodology contains further weaknesses that undermine its validity:

- **Insufficient Consideration of Supply Chain Differences**: It briefly considers but dismisses setting different UPLs for payors versus purchasers, citing the MFP as the maximum net cost. This is insufficient, as it overlooks nuanced supply chain markups (e.g., wholesalers' roles for purchasers), which could justify tiered UPLs. Without empirical data or modeling, this one-size-fits-all approach may be incorrect for entities at varying supply chain levels, potentially leading to inequitable application and reduced access.
- **Lack of Health Outcome or Threshold Integration**: COMAR 14.01.05.06D requires analyses to include "health outcome or threshold" assumptions, yet the document provides no explicit integration of FARXIGA's® clinical value. This is incomplete, as the UPL framework focuses narrowly on MFP without linking to value-based metrics, potentially undervaluing the drug's therapeutic benefits and innovation.
- **Reliance on CMS Guidance Without Independent Verification**: The analysis heavily cites CMS documents but includes no independent data or audits to verify assumptions. This is insufficient, especially if CMS guidance evolves. This leads to an incomplete methodology that doesn't account for discrepancies in state contexts.

LACK OF IMPLEMENTATION AND ENFORCEMENT DETAILS

The Draft UPL Methodology provides no specifics on how a UPL would be implemented or enforced in the supply chain. This includes interactions with wholesalers, pharmacies, or existing contracts. Without this, manufacturers like AstraZeneca cannot provide substantive feedback. The document fails as a true methodology. It also overlooks administrative/delivery costs (COMAR 14.01.05.02B(1)) and potential unintended consequences (COMAR 14.01.05.02B(3)). The lack of specificity creates uncertainty for patients and other stakeholders who will be directly and significantly impacted by a potential UPL.

CONCLUSION

Given these flaws, imminent generics, limited savings, and COMAR non-compliance, the Board should not make a final determination that FARXIGA® is unaffordable and discontinue the UPL process for FARXIGA®. The Board should instead prioritize systemic reforms like PBM transparency. We urge a Maryland-specific analysis incorporating clinical value, net costs, and recent price changes. AstraZeneca remains committed to collaboration.

Sincerely,

Geoffrey A Gallo
Head of Corporate & State Government Affairs
(603) 770-9000
geoffrey.gallo@astrazeneca.com

EACH PIC COALITION

March 4, 2026

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

RE: Public Comments on UPL Framework for Farxiga

Dear Members and Staff of the Maryland Prescription Drug Affordability Board:

The Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC) is a two-part coalition that unites patient organizations and allied groups (EACH), as well as patients and caregivers (PIC), to advocate for drug affordability policies that benefit patients.

We appreciate the opportunity to comment on the board's proposed upper payment limit (UPL) framework for Farxiga.

UPLs Do Not Guarantee Savings for Patients

We continue to underscore the limitations of a UPL in addressing patient affordability. UPLs may change what insurers or the state pay for a medication, but they do not cap or guarantee reductions in patient out-of-pocket costs. As our coalition has cautioned before, these policies can introduce new incentives for insurers and pharmacy benefit managers (PBMs) that may ultimately restrict access to needed treatments through greater utilization management, formulary reshuffling, or adverse tiering. These shifts risk delaying or disrupting care, and as our Patient Experience Study has demonstrated, insurance barriers, not price alone, are often the real drivers of patient hardship and perceived "unaffordability."

Furthermore, patients reported that treatments are not interchangeable and that accessing the correct medication is critically important for patients with chronic conditions. Therefore, while intended to reduce costs, implementing a UPL without complementary patient protections could worsen the very challenges patients already face.

We urge the board to establish clear safeguards before advancing any UPL frameworks and to continue exploring its policy alternatives, including reforms that directly address PBM and insurance practices that most influence patient costs.

Limitations of Applying Medicare MFP

Maryland's proposal to apply the "maximum fair price" (MFP) established by the Medicare Drug Price Negotiation Program (MDPNP) to state programs is concerning because those prices were negotiated specifically for the Medicare population and benefit design. Those rates reflect the structure and cost-sharing rules of Medicare, which are not the same as those that apply in state-regulated coverage. Applying those prices outside of Medicare assumes the markets function the same way, and they do not.

Further, the establishment of UPLs at MFP rates does not guarantee any savings for patients. Patients could instead face higher copay or coinsurance rates to retain access to that drug or

alternatively be forced to switch to a more expensive drug, which results in higher profits for their PBM. Recent research from the Pioneer Institute has shown that patient OOP costs have increased by an average of 32 percent under the MDPNP even before the maximum fair price caps for the first round of drugs went into effect on January 1st.

Simply importing Medicare pricing may create disruption without meaningfully improving what patients actually pay or experience.

Delinking PBM Compensation Is a More Effective Path Forward

We strongly support the board's consideration of non-UPL alternatives and endorse the proposal to delink PBM compensation from drug prices. The current rebate-driven PBM model creates perverse incentives to favor higher-priced drugs, as PBMs profit from larger rebates tied to inflated list prices. Delinking PBM compensation from drug prices and rebates is critical to realigning incentives toward lower costs and improved access for patients.

This approach offers a more targeted and sustainable solution to affordability challenges and addresses the mechanics of the drug supply chain rather than imposing blunt payment caps that may shift costs and restrict access. States such as Colorado have already taken steps in this direction, and similar reforms are being actively considered at both the state and federal levels.

As the board continues its deliberations, we urge it to establish a clear and transparent framework for evaluating non-UPL policy options and to ensure these alternatives are given equal weight alongside UPL proposals. Based on available evidence and lived patient experience, PBM delinking and related insurance reforms are far more likely to reduce patient costs without introducing new access barriers or disrupting care.

Conclusion

We appreciate the board's willingness to consider alternatives to UPLs and its ongoing engagement with patient stakeholders. We stand ready to work collaboratively with the board to advance policies that address the real drivers of patient affordability while preserving timely access to the treatments patients rely on.

Sincerely,

Tiffany Westrich-Robertson
tiffany@aiarthritis.org
Ensuring Access through Collaborative Health (EACH) Coalition Lead

Vanessa Lathan
vanessa@aiarthritis.org

EACH PIC COALITION

Patient Inclusion Council (PIC) Coalition Lead

March 4, 2026

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

VIA email: christina.shaklee1@maryland.gov

Supply Chain Coalition Comments
Farxiga Upper Payment Limits Methodology

Dear Chair Mitchell, Members of the Board, and Staff:

On behalf of the undersigned organizations representing diverse stakeholders in the healthcare supply chain who work to ensure access to critical medications in Maryland, we would like to express our collective feedback and concerns regarding the Maryland PDAB's proposed Upper Payment Limits (UPL) Methodology for Farxiga.

The Healthcare Distribution Alliance (HDA) and the National Community Pharmacy Association (NCPA) support the state's goal of addressing the affordability of prescription drugs. Although our members do not set the prices for drugs, supply chain resiliency is top of mind for our members. Accordingly, we would like to continue to express concerns regarding the significant impact that using Domestic Reference UPL proposals could have on the availability and accessibility of identified prescription drugs, especially when using limits based on Medicare's Maximum Fair Price (MFP).

Simply put, state-level UPLs do not align with how prescription drugs are bought and paid for in the United States. If the Maryland PDAB chooses to move forward with establishing a price cap on the price for these identified prescription drugs, the prices at which these drugs are bought and sold for nationally will remain unchanged. Because many Maryland providers purchase drugs in out-of-state transactions that would not be subject to the limitations of a state-level UPL, our in-state distributors and providers will purchase drugs at a national price and then be subject to in-state price caps. Providers will then have to choose whether to purchase drugs for more than they can be reimbursed or to stop purchasing some drugs altogether. This, in turn, could drive some patients to out-of-state retail and mail order pharmacies, further deepening the impact on our healthcare infrastructure.

The proposed UPL methodology which seeks to apply Medicare's Maximum Fair Price (MFP) prices to drugs bought and sold in Maryland does not fully take into account the fact while MFP represents the most that Medicare will pay for a drug, again the national list price of the drugs remains unchanged. This methodology also does not take into account the operational models that Medicare is still working to effectuate to protect efficiency, accuracy, and program integrity- for example, creating an entirely new supply chain entity called a Medicare Transaction Facilitator (MFT). Such operationalization complexities likely cannot be replicated at the state level- and in fact, are difficult to implement even at the national level. For example, a recent NCPA survey of pharmacies showed that the majority of respondents are minimizing their MFP inventory due to the inefficiencies associated with the MFP program, such as waiting more than 22 days for MFP reimbursement.[1] Adding the additional complexities of a state-level MFP UPL for certain products would further burden Maryland pharmacies and would likely harm patient access.

As you likely know, a provider such as a pharmacy, hospital, or clinic that dispenses or administers drugs to

[1] https://www.ncpa.co/pdf/2026/advocacy/mtfsurveyletter.pdf

patients must first purchase the physical product and float the cost until after they dispense the product and receive subsequent reimbursement from the insurer. The complex drug purchasing and distribution system — from manufacturer to wholesaler, then to the pharmacy or healthcare provider, and, finally, to the patient — involves numerous data and financial transactions between each entity. In addition, there are parallel and simultaneous permissions and transactions with insurance companies, pharmacy benefit managers, and government payers. At each step along the way, transactions are subject to private negotiations and involve complicated discount and rebate arrangements that often take place at the national level and are not state specific, thus leaving pharmacies, hospitals, and clinics often reimbursed below their costs to acquire and subsequently dispense drugs.

For example, have recognized, pharmacy reimbursement should be comprised of two parts: 1) the product cost; and 2) a professional dispensing fee across payer markets (e.g., Medicaid, Medicare, commercial) to help ensure reasonable reimbursement at a level that allows pharmacies to serve patients. The dispensing fee is typically calculated to incorporate the costs of a pharmacist's time reviewing the patient's medication history/coverage, filling the container, performing a drug utilization review, overhead expenses (rent, heat, etc.), labor expenses, patient counseling, and other cost elements necessary to provide quality patient care. Maryland Medicaid performed a cost of dispensing (COD) study in 2020 that found it costs $$13.72 for pharmacies in Maryland to dispense most medications. In the Maryland PDAB plan of action, staff are 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. In order to maintain pharmacy availability and access for Marylanders, it is imperative that the PDAB account for both the product cost of the drug and a professional dispensing fee.

In conclusion, we encourage the PDAB to strongly consider the other methods currently under discussion to reduce drug costs outside of setting a UPL. As has been raised by multiple patient groups, moving forward with the UPL methodologies proposed for Jardiance, Farxiga, or in the future other drugs could inadvertently threaten Marylanders' access to those medications.

Sincerely,

Healthcare Distribution Alliance (HDA)

National Community Pharmacists Association (NCPA)

March 4, 2026

Chair Mitchell, Members of the Prescription Drug Affordability Board, and Staff;

The Maryland Health Care for All Coalition would like to thank you for the opportunity to provide comment on Jardiance and Farxiga Upper Payment Limit Methodology. We appreciate the dedicated work that the Board and its Staff has done to reach this point and are pleased to see a proposed number for an upper payment limit for both prescription drug products. Since both methodologies utilize the Medicare Maximum Fair Price set by CMS, we have no suggested alterations to these calculations, but would like to acknowledge our appreciation of the Staff's consideration and efforts to mitigate potential negative impacts to supply chain members like pharmacies.

We again urge the Board to act swiftly to enact this first step so that the one-year countdown toward statewide upper payment limits can begin, and Marylanders can see relief from the skyrocketing costs of prescription drugs.

PhRMA
RESEARCH • PROGRESS • HOPE

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

By Electronic Submission

March 4, 2026

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

RE: UPL Amount and Methodology Documents

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 Jardiance UPL Amount and Methodology Document and Farxiga UPL Amount and Methodology Document (collectively, "UPL Methodology Documents").[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 detailed our concerns regarding the

[1] Farxiga UPL Amount and Methodology Document (Feb. 13, 2026), *available at* https://pdab.maryland.gov/Documents/Cost%20Review/2026/Farxiga.Upper%20Payment%20Limit.METHODOLOGY.v1.0.pdf; Jardiance UPL Amount and Methodology Document (Feb. 17, 2026), *available at* https://pdab.maryland.gov/Documents/Cost%20Review/2026/Jardiance.Upper%20Payment%20Limit.METHODOLOGY.v.1.0.pdf. In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to the constitutionality of Md. Code Ann., Health-Gen. §§ 21-2C-01–16 (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 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- 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.

Board's upper payment limit ("UPL")-setting activities and the policy review process 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 approaches reflected in the UPL Methodology Documents and the Board's UPL-setting process in general.

I. Lack of Meaningful Standards and Processes for Developing Proposed UPLs

PhRMA remains concerned by the lack of clear standards and processes governing the Board's development of proposed UPLs, without which the Board has unduly broad discretion with respect to, among other things, selecting the information to be considered, choosing UPL framework parameters and amounts, and determining in the first instance whether a UPL "is an appropriate tool to address the drivers of the affordability challenge identified for [a given] prescription drug product."[4] This broad discretion creates a risk of inconsistent and ad hoc application of the process for evaluating drugs, resulting in arbitrary and capricious reviews. These concerns are heightened now that the Board is contemplating setting UPLs for two drugs—without first addressing these fundamental procedural issues.[5] PhRMA again urges the Board to establish meaningful standards to guide its actions and avoid arbitrary decision-making.[6]

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

- **UPL Criteria.** The Board's regulations do not establish concrete, workable standards for deciding when to set a UPL.[7] One criterion, for instance, instructs the Board to "[s]et an upper payment limit in a way to minimize *adverse outcomes* and minimize the risk of unintended consequences."[8] But the regulations do not define "adverse outcomes," and the Board has not provided objective metrics for identifying when an adverse outcome would cause it to not establish a UPL.[9] This lack of meaningful standards lays the groundwork for arbitrary UPL determinations. PhRMA continues to ask the Board to adopt clearly defined criteria to facilitate consistent decisions on whether to establish UPLs.[10]

- **UPL Framework Selection.** The Board's current regulations fail to provide meaningful guidance on how to determine which UPL "framework" the Board should apply for a particular drug.[11] The regulations provide that "Board staff shall recommend at least one framework . . . for use in developing a UPL for the subject prescription drug product," and then describe eight frameworks from which the Board may choose.[12] There is no guidance, however, on how to choose among the frameworks, and the regulations do not require a consistent framework selection process across drugs. Thus far, the Board has proposed UPLs using the "Domestic Reference Upper Payment Limit" framework, under which it proposes using Medicare Maximum Fair Prices ("MFPs")—prices established under a separate, federal statutory regime and that are the product of different considerations—as UPL benchmarks.[13] Reliance on available benchmarks is not a substitute for engaging in meaningful consideration of a product's characteristics and the ability of a given

[3] *See* comments cited *supra* note 1.
[4] COMAR § 14.01.05.02B; *see, e.g.*, Letter from PhRMA to Board (Feb. 10, 2025) at 2-3; Letter from PhRMA to Board (Nov. 8, 2024) at 5-9; Letter from PhRMA to Board (Aug. 26, 2024) at 3-6.
[5] The Board even appears to be aware of potential problems with its cost review and policy review processes, having recently held informational hearings to solicit feedback on these procedures. The Board nevertheless forges ahead with setting UPLs, rather than pausing its UPL-setting activities while these processes are under review.
[6] *See* Letter from PhRMA to Board (Feb. 10, 2026) at 4; Letter from PhRMA to Board (Nov. 8, 2024) at 6.
[7] *See* COMAR § 14.01.05.02B; Letter from PhRMA to Board (Feb. 10, 2026) at 2-3; Letter from PhRMA to Board (Aug. 26, 2024) at 6.
[8] COMAR § 14.01.05.02B(3) (emphasis added).
[9] *See* Letter from PhRMA to Board (Nov. 8, 2024) at 6.
[10] *See* Letter from PhRMA to Board (Feb. 10, 2026) at 3; Letter from PhRMA to Board (Nov. 8, 2024) at 7-8.
[11] Letter from PhRMA to Board (Nov. 8, 2024) at 8.
[12] COMAR § 14.01.05.06A(1), B.
[13] *See* COMAR § 14.01.05.06B(5); Farxiga UPL Amount and Methodology Document at 1; Jardiance UPL Amount and Methodology Document at 1.

framework to address affordability challenges to the state health care system and patients.[14] Without clearer standards for framework selection, the Board risks making arbitrary and inconsistent decisions across different drugs. PhRMA asks that the Board revise its regulations to provide specific criteria for how Board staff will make their recommendations and how the Board will render an ultimate determination as to the UPL framework applied to a particular drug.

As illustrated by the above examples and others described in PhRMA's previous comments, the lack of meaningful standards for UPL-setting creates a significant risk of inconsistent determinations.[15] Maryland courts consistently invalidate agency actions as arbitrary and capricious where they treat similarly situated entities or products differently without providing a reasonable justification for such differential treatment.[16] Agency decisions that exhibit unexplained inconsistencies similarly do not survive judicial review.[17] PhRMA continues to advocate for the establishment of clear and specific standards as necessary safeguards against arbitrary and inconsistent decision-making.

II. Improper Characterization of Medicare Maximum Fair Prices ("MFPs") as "Negotiated"

The UPL Methodology Documents misrepresent the MFP-setting process by describing MFPs as "negotiated."[18] Under the Inflation Reduction Act ("IRA") and Centers for Medicare & Medicaid Services ("CMS") implementing guidance, the process for establishing an MFP is far from a "negotiation," as that word is customarily used.[19] CMS has unilateral and virtually unconstrained discretion to set any price it wishes (below a statutory ceiling) and impose severe penalties on manufacturers that do not agree to CMS's prices or refuse to engage in the process. A manufacturer that does not agree to "negotiate" or does not agree to the MFP that CMS sets must withdraw *all* of its products from Medicare and Medicaid—which account for approximately 45 percent of nationwide retail prescription drug spending.[20] Manufacturers' only alternative is to accept an excise tax of up to 1,900 percent and, in some circumstances, civil monetary penalties. These penalties and taxes command acquiescence, not true negotiation.[21] Furthermore, CMS dictates MFP terms through a rigid, non-negotiable framework. Manufacturers must sign the agreement with CMS before knowing the final price, they cannot revise the terms, and they are denied legal recourse or transparency into CMS's decision-making process.[22]

III. MFP is an Inherently Flawed Metric for State Use and Could Create Access Challenges for Patients

We also remain concerned about the repercussions of any attempt to apply the MFP to fundamentally different markets. MFPs apply only to Medicare. A Maryland MFP-based UPL, particularly if expanded to the commercial market per statute, will create significant complexity by attempting to impose a price control developed for

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[14] *See* Md. Code, Health-Gen.§§ 21-2C-08–09.

[15] *See, e.g.*, Letter from PhRMA to Board (Nov. 8, 2024) at 8; Letter from PhRMA to Board (Aug. 26, 2024) at 3.

[16] *Maryland State Bd. of Soc. Work Examiners v. Chertkov,* 121 Md. App. 574, 588 (1998); *see* Letter from PhRMA to Board (Aug. 26, 2024) at 3.

[17] *See, e.g., Christopher v. Montgomery Cnty. Dep't of Health & Human Servs.,* 381 Md. 188, 215 (2004); *see also* Letter from PhRMA to Board (Aug. 26, 2024) at 3.

[18] Farxiga UPL Amount and Methodology Document at 1; Jardiance UPL Amount and Methodology Document at 1.

[19] *See, e.g.*, Decl. of P. Costello, *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 1:23-cv-00707-DII (W.D. Tex. Aug. 10, 2023), ECF No. 35-6 at ¶¶ 12-14, 20 (describing the MFP-setting process and indicating that, "[a]bsent a legal compulsion to do so, Amgen would not agree to these prices").

[20] Congressional Budget Office ("CBO"), Prescription Drugs: Spending, Use, and Prices (Jan. 2022), *available at* https://www.cbo.gov/publication/57050.

[21] In fact, the CBO score for the IRA presumes that the excise tax will not generate any revenue independent of its effects on drug pricing through imposition of the government's MFP. *See* CBO, Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14 at 5 (Sept. 7, 2022), *available at* https://www.cbo.gov/publication/58455.

[22] *See* Inflation Reduction Act of 2022, Pub. L. 117-168, §§ 11001(c), 11002(c) (lack of notice-and-comment rulemaking); 42 U.S.C. § 1320f–7, Social Security Act § 1198 (lack of judicial review).

Medicare and its patient population on a different market and patient population.[23] This raises serious concerns, as adopting an unworkable approach could lead to access challenges for patients.

Additionally, the Medicare Drug Negotiation Program ("MDPNP"), through which CMS sets MFPs, is still at an early stage, and many operational and legal issues remain unresolved. It will be years before the effects of MFPs on patient affordability and access can be fully understood. However, there is mounting evidence that the number of patients benefiting from MFPs is relatively small while the increase in out-of-pocket costs for Medicare patients is significant. DLA Piper estimates that only about 11% of Medicare beneficiaries using the Part D benefit are likely to experience direct cost savings from the 2026 MFPs.[24] Meanwhile, average out-of-pocket costs have increased by 32% for nine of the first 10 drugs selected for price setting as insurers and PBMs respond to the MDPNP, meaning the vast majority of patients are paying more for their drugs than they did before the MDPNP.[25] Pushing forward with an MFP-based UPL approach before fully evaluating patient impact from the MDPNP is concerning.

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On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA remains concerned about the UPL Methodology Documents, 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

[23] Md. Code, Health Gen. §§ 21-2C-01–16.
[24] DLA Piper. Keeping Watch on Medicare: 2026 Maximum Fair Prices for Ten Selected Drugs. January 2026, available here.
[25] Pioneer Institute. Pioneer Institute Launches Tracker Showing Drug Price Controls Are Raising Out of Pocket Costs for Medicare Patients. May 2025, available here.

Unitarian Universalist Legislative Ministry of Maryland

TO: Chair Mitchell, Members of the Prescription Drug Affordability Board, and Staff
FROM: Betty McGarvie Crowley, Lead Advocate for Health Care
Unitarian Universalist Legislative Ministry of Maryland (UULM-MD)
SUBJECT: Comments on UPL Amount and Methodology Documents

The UULM-MD appreciates the opportunity to review and comment on these long-awaited documents on Jardiance and Farxiga. We agree with the methods you used to calculate Upper Payment Levels and feel they will more than likely withstand challenges.

We are concerned as to what the meaning of your sentence is: "For Jardiance, the Baseline UPL reflects the amount that would be paid in 2026 if a UPL were implemented in that year." Are you expecting to implement the adoption of this in the near future in 2026? The expansion cannot begin until you finish the process for these two medications.

We appreciate your hard work on complicated changes to long established unfair prices for patients for expensive medications. However, is there a way you can now move more quickly to implementation?

UULM-MD c/o UU Church of Annapolis 333 Dubois Road Annapolis, MD 21401 410-266-8044,

www.uulmmd.org info@uulmmd.org www.facebook.com/uulmmd www.Twitter.com/uulmmd