March 30, 2026

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VIA ELECTRONIC MAIL TO COMMENTS.PDAB@MARYLAND.GOV

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

RE: Comments on the Draft FARXIGA® Cost Review Study Report

Dear Members of the Maryland Prescription Drug Affordability Board:

AstraZeneca appreciates the opportunity to provide comments on the draft FARXIGA® Cost Review Study Report from the July 28, 2025 PDAB meeting. We share the Board's goal of supporting Maryland patients while ensuring responsible stewardship of public resources.

EXECUTIVE SUMMARY

The Board's preliminary determination that FARXIGA® creates affordability challenges is flawed and unsupported by evidence. The three identified circumstances either do not represent actual affordability challenges, reflect supply chain issues unrelated to manufacturer pricing, or are based on incomplete and misleading data. Most critically:

- **The 1% gross spending threshold uses list prices bearing no relationship to actual state expenditures.** The Board acknowledges "rebates substantially reduced the average net price of the drug" (p. 38), yet ignores these reductions entirely, violating requirements to consider price concessions.
- **The Board provides no transparency about whether confidential net cost data was considered in the 1% calculation,** making the determination unreviewable and potentially based on inflated figures overstating actual costs.
- **Recent market changes render the analysis obsolete.** Effective January 1, 2026, AstraZeneca reduced FARXIGA®'s list price by 30%, and primary patent expiration in April 2026 will bring robust generic competition.
- **The Board's analysis violates multiple statutory and regulatory requirements,** including failure to quantify cost offsets, failure to obtain actual net acquisition costs from Maryland

governmental entities, and failure to analyze whether intervention is in the state's best interest.

AstraZeneca respectfully requests that the Board finalize a determination that FARXIGA® does not create affordability challenges and decline to pursue any upper payment limit or other price control mechanisms for FARXIGA®.

I. THE THREE IDENTIFIED CIRCUMSTANCES DO NOT SUPPORT AN UNAFFORDABILITY DETERMINATION

The Board identified three circumstances to support its preliminary determination:

> (1) the percentage change in WAC over time is substantially larger than the percentage change in inflation (closed session); (2) at 90th percentile, patient out of pocket (OOP) cost in certain markets is disproportionate to the net cost paid by payors (closed session); and (3) total gross spending for Farxiga for state and local governments exceeds 1% of gross prescription drug spend for state and local governments (public session).

Each circumstance is fundamentally flawed and is not an authorized basis for an affordability determination under Health General §21 2C 09 and related regulations, and that reliance on any of them exceeds the scope of the Board's authority.

A. Circumstance #1: WAC Increase vs. Inflation Is Irrelevant to Actual Affordability

The Board provides no evidence that WAC changes impact total drug spending in state and local government programs or what patients pay. WAC analysis in isolation reveals nothing about a drug's affordability.

1. WAC Is Not What Maryland Pays. Wholesale Acquisition Cost is a list price no purchaser pays. The Board acknowledges "rebates substantially reduced the average net price of the drug" (p. 38), yet analyzes only list price changes without considering net price trends. In heavily rebated pharmaceutical markets, net prices often remain stable or decline even as list prices rise due to competitive rebating. The Board's failure to analyze net price trends makes the WAC-to-inflation comparison not useful to cost review process.

2. Closed Session Analysis Lacks Disclosed Methodology. While protecting AstraZeneca's confidential pricing data is appropriate, the Board's own analytical methodology should be transparent and publicly reviewable. The closed-session analysis prevents verification of time periods analyzed, inflation index used, adjustments made, or whether net price trends were considered.

3. Recent Price Reduction Renders Finding Obsolete. Effective January 1, 2026, AstraZeneca reduced FARXIGA®'s list price by 30%. Any inflation comparison using pre-2026 pricing data is obsolete and cannot support current policy decisions.
Any determination of unaffordability from WAC analysis requires thorough analysis of supply chain mechanics and net costs, which the Board has failed to conduct.

B. Circumstance #2: Patient OOP Disproportionality Reflects Benefit Design, Not Drug Pricing
This finding signals a potential affordability challenge driven by health plan benefit design, not manufacturer pricing decisions. The current emphasis on manufacturers may be misaligned with the primary drivers of cost, and using this rationale to pursue an upper payment limit is unlikely to achieve the intended objectives.

1. 90th Percentile Represents Extreme Outliers. The Board bases its finding on the worst 10% of cases while ignoring that average annual out-of-pocket costs are $123 for state and local government employees and $334 for commercial patients (Table 23, p. 66). These modest costs demonstrate FARXIGA® is generally affordable for Maryland patients. Focusing on extreme outliers rather than typical experience is statistical manipulation manufacturing an affordability crisis where none exists.

2. Cost-Sharing Is Determined by Benefit Design, Not Drug Price. Out-of-pocket costs are a function of plan design decisions including deductible levels, coinsurance rates, copayment structures, and formulary tier placement. Manufacturers have no control over how health plans structure cost-sharing or whether pharmacy benefit managers (PBMs) pass rebates through to patients. Federal laws prohibit manufacturers from providing copay assistance to patients enrolled in government programs, meaning any remaining out-of-pocket issues for state and local government employees are regulatory problems, not pricing problems. The Board blames manufacturers for insurer and PBM decisions driving patient costs.

3. Closed Session Analysis Lacks Disclosed Methodology. The Board provides no public explanation of what "certain markets" means, how "disproportionate" was defined, whether the comparison adjusted for different benefit structures, or why 90th percentile is appropriate. While protecting confidential manufacturer data is appropriate, the Board's analytical methodology should be disclosed in the cost review report.

C. Circumstance #3: The 1% Gross Spending Threshold Uses Misleading Data Overstating Actual State Costs

This is the most problematic finding and warrants detailed examination.

1. The Finding Explicitly Uses Gross Spending, Not Actual State Costs

The Board's Resolution 2025-01 states:

> "**total gross spending for Farxiga for state and local governments exceeds 1% of gross prescription drug spend for state and local governments** (public session)." (Resolution 2025-01, p. 13)

The public deliberation record confirms:

> "Another member pointed to the data in the dossier showing **gross** noted that (when rounded) state and local government spending on Farxiga NDCs were .09%, .and. 02% of **total gross spending**, adding to up 1.1% **(Table 10b)**." (p. 12)

Table 10b (p. 33) contains columns labeled "**State Local Gov. Emp. (2023) Gross Spending**" and "**State Local Gov. Emp. (2023) Pct Total Gross Spend**." The percentages cited (0.87% and 0.21% aggregating to 1.1%) match exactly the gross spending percentages in Table 10b.

Board members were reading gross spending percentages from Table 10b during deliberations and using these figures as the basis for the 1% threshold determination.

2. Gross Spending Bears No Relationship with Actual State Expenditures

The Board's own analysis acknowledges:

"On a list price basis, the data suggested that Farxiga had prices (not including rebates) in excess of $5,000 per year. **However, rebates substantially reduced the average net price of the drug.**" (p. 38)

The phrase "**substantially reduced**" describes significant discounts. In pharmaceutical markets, "substantial" rebates for heavily rebated drug classes like SGLT2 inhibitors typically range from 40-70% off list prices in commercial markets, with required statutory and supplemental rebates in Medicaid.

If rebates "substantially reduce" net prices by 50%, then $1 million in gross spending represents only $500,000 in actual state expenditure.

3. The Board Provides No Transparency About Whether Net Costs Were Considered

AstraZeneca submitted detailed confidential data on actual rebates, discounts, and net pricing (Exhibit 2). The Board appropriately reviewed this information in closed session (p. 11). However, **the Board provides no explanation for the methodology used with this confidential net cost information. In fact, there is no indication it was incorporated into the 1% threshold calculation at all.**

This creates an impossible verification problem:

- **If the Board used gross spending:** This violates COMAR 14.01.04.05C(1)(b)(i), which requires consideration of "average price concession, discount, and rebate provided by the manufacturer...expressed as a number and as a percent of the WAC."
- **If the Board used net spending:** The Board provides no transparency about this analysis, making it impossible for AstraZeneca to verify whether the arbitrary threshold was exceeded using real-world costs.

The Board cannot shield its own analytical methodology behind closed-session confidentiality. While AstraZeneca's proprietary pricing data warrants confidential treatment, the Board's decision-making process must be transparent and reviewable. The Board should disclose:

1. Whether the 1% threshold was calculated using gross spending, net spending, or both

2. If net spending was used, what the actual percentage was
3. If gross spending was used, why the Board ignored rebates analysis required under regulation

Without this transparency, the determination is unreviewable and potentially based on inflated list prices significantly overstating actual state costs. The Board's failure to disclose whether, how, or to what extent confidential net cost data was incorporated into the 1% threshold determination also deprives AstraZeneca and the public of fair notice of the standards governing an affordability determination, and thus this preliminary determination is arbitrary, capricious, and inconsistent with due process principles under Maryland law.

4. The 1% Threshold Is Arbitrary and Lacks Justification

The Board provides no explanation for why 1% of gross drug spending indicates unaffordability. This threshold has no statutory or regulatory basis and no economic rationale. The Board simply declares this threshold without explanation, making it arbitrary and legally vulnerable under administrative law principles prohibiting arbitrary and capricious agency action.
Moreover, FARXIGA® barely exceeds this arbitrary threshold (if gross sales are used). Table 10b shows 0.8660% + 0.2137% = 1.0797%, rounding to 1.1%. This razor-thin exceedance of an unjustified threshold cannot support consequential price controls, especially when the underlying metric overstates actual costs.

5. The Analysis Ignores Critical Context About Disease Burden

The Board's disease burden analysis documents that diabetes costs Maryland $6.5 billion annually in direct medical costs (p. 12), and heart failure and chronic kidney disease impose additional multi-billion dollar burdens (pp. 14-20).

FARXIGA®'s $20-30 million annual cost represents less than 0.5% of the state's diabetes burden alone. The Board frames this tiny fraction as unaffordable without perspective on the massive disease costs FARXIGA® helps prevent. A drug costing 0.5% of a disease's total burden while preventing expensive complications like dialysis, heart failure hospitalizations, and cardiovascular death is not unaffordable. It is cost-effective.

6. Recent Market Changes Render the Analysis Obsolete

The Board's analysis uses 2023 data. Two major market changes have occurred:

First, effective January 1, 2026, AstraZeneca reduced FARXIGA®'s list price by 30%. Even if the Board's gross spending analysis was appropriate (which it is not), the figures are outdated. A 30% price reduction would reduce gross spending percentages from 1.1% to approximately 0.77%, falling well below the Board's arbitrary 1% threshold.

Second, FARXIGA®'s primary patent expires in April 2026, with 18 generic applications tentatively approved by the FDA (p. 21). Generic competition typically reduces costs by 80-90% within 6-12 months. The affordability landscape will fundamentally change within months, making price control intervention obsolete before implementation.

The Board is proceeding with price controls based on a market reality that will cease to exist in 2026, violating requirements that intervention be in the state's best interest.

II. THE BOARD'S MEDICAID UTILIZATION CONCERN REFLECTS PROPER MARKET DYNAMICS

The draft report mentions an "observation and concern regarding the limited utilization of Farxiga among Medicaid patients in the public data" (p. 12). One Board member asserted, without evidence, that utilization is low because physicians perceive FARXIGA® as unaffordable, creating an affordability challenge.

This concern is unfounded and reflects misunderstanding of Maryland's Medicaid market dynamics.

While FARXIGA® is on Maryland's Medicaid preferred drug list, Medicaid managed care plans (covering 85-90% of Medicaid lives) prefer the authorized generic of FARXIGA®. The authorized generic contains the identical active ingredient (dapagliflozin) at the same strength and is therapeutically equivalent to branded FARXIGA®, but a lower list price.

This demonstrates the pharmaceutical market working as intended. Managed care plans negotiated access to a lower-cost version of the same medication, and physicians appropriately

prescribe the authorized generic to Medicaid patients. This is not evidence of an affordability problem but evidence of a functioning market.

The Board's concern about Medicaid utilization should be an additional reason why the Board does NOT deem FARXIGA® creates an affordability challenge. The availability of an authorized generic at lower price, combined with managed care plans' preference for this option, demonstrates Maryland Medicaid beneficiaries have affordable access to dapagliflozin therapy without Board intervention.

III. THE BOARD'S ANALYSIS VIOLATES MULTIPLE STATUTORY AND REGULATORY REQUIREMENTS

Beyond the specific flaws in each identified circumstance, the Board's overall analytical approach violates numerous statutory and regulatory requirements that govern the cost review process.

Failure to Quantify Cost Offsets. COMAR 14.01.04.05C(1)(e)(i) explicitly requires analysis of "incremental costs associated with a prescription drug product, including financial impacts to health, medical, or social services as can be quantified and compared to baseline effects of existing therapeutic alternatives." The Board documents that FARXIGA® reduces heart failure hospitalizations ($15,000+ per admission), delays progression to dialysis ($90,000 per patient-year), and decreases cardiovascular events (tens of thousands per event), yet provides zero quantification of these savings. This one-sided cost analysis ignoring billions in potential offsets violates explicit regulatory requirements and renders the affordability determination incomplete and misleading. This also violates COMAR 14.01.05.02B(3) requirements to minimize adverse outcomes, as the Board cannot assess whether a UPL's harms outweigh benefits without quantifying the healthcare costs FARXIGA® prevents.

Failure to Obtain Actual Net Acquisition Costs. COMAR 14.01.05.06C(2) requires "Net costs for: (a) State health plan; (b) County, bicounty, and municipal health plans; (c) Direct government purchases; and (d) Medicaid." The study provides none of this required information, instead relying on third-party national rebate estimates from SSR Health that may not reflect Maryland-specific rebate agreements, manufacturer-state contracts, or supplemental rebates. Making affordability determinations without actual Maryland net cost data violates explicit regulatory requirements and systematically overstates state expenditures.

Failure to Analyze Whether Intervention Is in State's Best Interest. Health-General § 21-2C-14(c) requires the Board to determine if any upper payment limit "is in the best interest of the State" before implementation. The Board provides no analysis of patient access impact, innovation effects, administrative costs, or whether benefits outweigh harms. The Board's own Draft UPL Framework admits a UPL "may not result in additional discounts" and "may not yield significant savings" for Maryland programs, undermining any claim that intervention is in the state's best interest.

Incomplete Factor Analysis. Health-General § 21-2C-09(b) requires the Board to consider numerous specified factors before making an affordability determination. The Board admits inability to complete analysis of Factor 7.6 (equity impact - MCDB lacks demographic data for "vast majority of patients," p. 67), Factor 4.3 (local government budget impact - non-uniform data, p. 38), and Factor 8.3 (governmental entity input - none received, p. 74). Making affordability determinations with incomplete regulatory analysis violates statutory requirements to consider all enumerated factors.

Lack of Transparent Decision-Making Methodology. COMAR 14.01.01.05 requires transparent public decision-making processes. The Board provides no clear decision framework, factor weighting, or threshold criteria explaining why the three identified circumstances (out of dozens analyzed) constitute dispositive evidence, how the Board weighted different factors, or why 1% of gross spending and 90th percentile OOP are appropriate metrics. The Board's failure to explain its decision-making methodology makes findings appear arbitrary and unreviewable, violating basic administrative law principles.

IV. THE BOARD'S DETERMINATION CONTRADICTS CLINICAL EVIDENCE

FARXIGA® is first-line therapy per major clinical guidelines from the American Diabetes Association, American College of Cardiology/American Heart Association, and Kidney Disease: Improving Global Outcomes (KDIGO) for multiple conditions (pp. 7-11). The drug is proven to reduce heart failure hospitalizations, slow chronic kidney disease progression, and decrease cardiovascular death in large-scale randomized controlled trials. The Board's own analysis acknowledges FARXIGA® is "an effective drug and clear from clinical practice that Farxiga should

be used" (p. 12), yet proceeds to recommend policies that could restrict access through formulary removal, step therapy requirements, or prior authorization.

This creates a fundamental contradiction: if use is appropriate and clinically indicated, high utilization reflects therapeutic necessity, not overuse. Any policy restricting access to guideline-recommended therapy forces physicians to deviate from evidence-based medicine, potentially leading to worse outcomes and higher downstream costs, from preventable hospitalizations and disease progression. This contradicts the Board's purpose to "protect State residents" from high prescription drug costs. Restricting access to effective therapy harms patients rather than protecting them.

V. CONCLUSION

The Board's preliminary determination is fundamentally flawed, unsupported by evidence, and violates multiple statutory and regulatory requirements. The three identified circumstances do not support an unaffordability determination. After expending significant taxpayer resources on this multi-year cost review process, the Board now risks implementing a flawed system that will not benefit the patient or lead to significant savings by the State.

AstraZeneca respectfully requests that the Board:

1. **Finalize a determination that FARXIGA® does not create affordability challenges** for Maryland's state and local government health care system
2. **Decline to pursue any upper payment limit or other price control mechanisms** for FARXIGA®

Rather than pursuing UPLs, the Board should redirect efforts toward alternative solutions that address actual drivers of patient out-of-pocket costs, such as benefit design reforms and PBM rebate retention practices, without undermining innovation or restricting access to effective therapies.

While AstraZeneca has focused these comments to address the specific analytical and evidentiary deficiencies in the draft Cost Review Study Report, 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,

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Head of Corporate & State Government Affairs

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Mach 23, 2026

Re: MHBE Comment – Cost Review Study Report – FARXIGA (dapagliflozin)

The Maryland Health Benefit Exchange (MHBE) respectfully submits this comment letter for the cost review study report for Farxiga (dapagliflozin).

MHBE recognizes the importance of state-wide efforts to address high costs of prescription drug products and health care costs generally. We know that prescription drugs, in particular brand name drugs, are a significant driver of premium costs in the individual market and state costs via the state reinsurance program. A report from the Maryland Health Care Commission determined that **prescription drugs accounted for almost a third (30%) of total per capita spending** for privately insured markets in Maryland in 2020.[1] In an MHBE analysis of 2022 Maryland individual market claims, **brand name drugs accounted for** 21% ($343M) of all claims costs by all enrollees and **27% ($279M) of all claims costs by enrollees in the state reinsurance program (SRP)**.

In the 2022 MHBE analysis, Farxiga accounted for a significant portion of total drug claims costs in the individual market - **930 enrollees received at least one prescription of various formulations of Farxiga** [2], accounting for 1.05% ($3.59M) alone of brand name prescription drug claims costs in the individual market. Further, Farxiga accounted for a significant portion of individual market drug claims costs by enrollees in the SRP as well. Just **325 enrollees who received at least one prescription of various formulations of Farxiga** accounted for **0.5% ($1.37M)** alone of brand name prescription drug claims costs by SRP enrollees.

Lower prices for higher-cost prescription drugs could reduce commercial insurers' per capita spending, putting downward pressure on average monthly premiums, along with out-of-pocket drug costs for consumers. Recent polling by the Kaiser Family Foundation found that more than a quarter of adults taking prescription drugs report difficulty affording their medication, including 40% of those with annual household incomes below $40,000.[3]

Lowering certain prescription drug costs would also potentially decrease costs associated with the reinsurance program, which works to mitigate the impact of high-cost enrollees on premium rate increases in the individual market. Specifically, lower prescription drug costs could reduce the number of individuals whose annual costs exceed the threshold at which reinsurance payments made by the State to an individual's insurer kicks in ($24,000 for plan year 2026),[4] and, for those individuals who reach the threshold, reduce the claims costs that the reinsurance program reimburses.

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[1] Maryland Health Care Commission: Spending and Use Among Maryland's Privately Insured Report, 2020 (2022).

[2] FARXIGA 5 MG, 10 MG.

[3] Kaiser Family Foundation: Public Opinion on Prescription Drugs and Their Prices (August 2023).

[4] Maryland Health Benefit Exchange: 2026 Reinsurance Parameters (August 18, 2025 MHBE Board Meeting).

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For further discussions or questions, please contact Johanna Fabian-Marks, Deputy Executive Director at johanna.fabian-marks@maryland.gov.

Sincerely,

Michele Eberle
Executive Director

PhRMA
RESEARCH • PROGRESS • HOPE

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By Electronic Submission

March 30, 2026

Maryland Prescription Drug Affordability Board
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RE: Draft Cost Review Study Reports for Comment

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 Cost Review Study Reports for Jardiance and Farxiga (collectively, "Draft Reports").[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.

[1] *See* Jardiance (empagliflozin) – Draft Cost Review Study Report (Mar. 16, 2026), *available at* https://pdab.maryland.gov/Documents/meetings/2026/March%2023%202026/2026.03.16.DRAFT.Jardiance%20Cost%20Review%20Study%20Report.v.1.0.Final.pdf; Farxiga (dapagliflozin) – Draft Cost Review Study Report (Mar. 16, 2026), *available at* https://pdab.maryland.gov/Documents/meetings/2026/March%2023%202026/2026.03.16.DRAFT.Farxiga%20Cost%20Review%20Study%20Report.v.1.0.Final.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 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- 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).

PhRMA recognizes the Board's ongoing work to implement and carry out its responsibilities under the Maryland PDAB Statute ("PDAB Statute").[2] PhRMA has expressed in detail our concerns regarding the cost review study process, and we encourage the Board to consider these previously submitted comments.[3] In addition, we provide below select comments and concerns in response to this request for comment.

I. Clear, Specific, and Meaningful Standards

Consistent with our prior comments, PhRMA remains concerned about the lack of sufficiently clear, specific, and meaningful standards provided by the Board to govern its cost review process.[4] To avoid arbitrary and inconsistent decision making, the Board should adopt, publish, and consistently apply clear and meaningful standards for conducting cost reviews and considering all cost review criteria..[5]

Below are examples of areas for which the Board should develop clearer standards:

- **"Affordability Challenge" Definition.** As noted in prior comment letters, the definition of "affordability challenge" is circular, as it refers in part to "*an affordability challenge* for the State health care system," but does not identify specific criteria or a methodology for making an affordability determination.[6] Without concrete criteria, the Board risks inconsistently evaluating different drugs, which may impact the Board's cost reviews and Draft Reports. PhRMA continues to urge the Board to adopt clear, workable standards to guide the cost review study process and limit the risk of arbitrary decision-making.

- **Use of Public Input**. PhRMA reiterates its request that the Board provide further detail about when and how public comment informs specific decisions in the cost review process.[7] The PDAB Statute and Board regulations require public notice and an opportunity to comment on each meeting and pending decision of the Board.[8] Further, the Board's regulations provide for consideration of public comments in the Board's cost reviews.[9] However, the Board has not meaningfully explained in the Draft Reports how public comments were considered and how they impacted its decision-making. For example, the Board has yet to meaningfully address and account for the clinical and economic benefits of a drug, including by considering the overall disease burden.[10] For these reasons, PhRMA asks the Board to provide additional transparency into its decision-making process and establish clear standards regarding how public comments are considered and how they impact the Board's decisions.[11]

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[2] *See* Md. Code, Health Gen. §§ 21-2C-01–16.
[3] *See supra* note 1.
[4] *See* Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 5-6; Letter from PhRMA to Board (April 24, 2024) *supra* note 1 at 4-5.
[5] *See* Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 5-6; Letter from PhRMA to Board (April 24, 2024) *supra* note 1 at 4-5.
[6] COMAR § 14.01.05.01C (emphasis added). *See* Letter from PhRMA to Board (Feb. 10, 2026) *supra* note 1 at 4; Letter from PhRMA to Board (Nov. 8, 2024) *supra* note 1 at 5.
[7] *See* Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 6; Letter from PhRMA to Board (April 24, 2024) *supra* note 1 at 5.
[8] *See* Md. Code Ann., Health-Gen. § 21-2C-03 (e)(2), (4)–(5); COMAR §§ 14.01.01.03(B), 14.01.01.05; 14.01.04.03(D)(4).
[9] *See* COMAR § 14.01.05(C)(1)(g)(xvi)-(xvii), (C)(2), (D)(1)-(2).
[10] *See* Jardiance (empaglifozin) – Draft Cost Review Study Report (Mar. 16, 2026) at 136, 156-57, 165; Farxiga (dapagliflozin) – Draft Cost Review Study Report (Mar. 16, 2026) at 133, 151-59, 165.
[11] *See* Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 6; Letter from PhRMA to Board (April 24, 2024) *supra* note 1 at 5.

- **Cost Review Study Process.** The Board has not provided clarity into the specific data and standards used in its cost review process.[12] The Board only provides a summary of the various factors involved in its decision-making, without explaining how it weighs or balances those factors. As a result, stakeholders lack meaningful insight into the Board's process and decision-making. The Board also has not developed an adequate record of the reasoning supporting its decision-making, including how it evaluated the statutory and regulatory factors for each specific drug. The Maryland Administrative Procedure Act (APA) requires the Board to provide a "reasoned analysis" that shows the "basis of the agency's action" and adequate "factual findings ... to support the agency's conclusions."[13] Accordingly, PhRMA requests that the Board adopt a systematic, reasoned, and unbiased review methodology to comply with the Maryland APA and ensure the Board transparently and consistently applies review criteria in the PDAB Statute and the Board's regulations.[14]

II. Transparency Concerns

PhRMA requests that the Board provide additional insight into the Board's cost review process, including by revising the non-exhaustive list of processes below:

- **Data Review Process.** As discussed above, PhRMA is concerned about the data review process that informs the Board's cost reviews.[15] The Board's processes involve compiling and considering voluminous data from diverse sources, which inherently risks inclusion of data that may be inaccurate, incomplete, or misleading. PhRMA therefore reiterates its request that the Board establish processes that provide manufacturers an opportunity to review, evaluate, confirm, and meet with the Board about the data it is relying on prior to the Board rendering any final decisions.[16] This process should also ensure confidential, proprietary, and trade secret information is protected from disclosure.[17] We ask that the Board provide this opportunity to manufacturers before conducting any further cost reviews.

- **Process for Identifying Therapeutic Alternatives.** PhRMA reiterates its concerns regarding the Board's consideration of therapeutic alternatives in its cost review process, including the Board's definition of "therapeutic alternative" and how it determines which drugs meet that definition for a particular drug under review.[18] As expressed in prior letters, PhRMA requests that the Board engage with manufacturers regarding potential therapeutic alternatives and publish criteria for identifying therapeutic alternatives to ensure the Board's decisions are consistent with clinical

[12] *See* Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 5-6.
[13] *Elbert v. Charles Cnty. Plan. Comm'n*, 259 Md. App. 499, 509 (2023); *see also, e.g., Mortimer v. Howard Research and Development Corp.,* 83 Md. App. 432, 442 (1990).
[14] *See* Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 5-6.
[15] *See* Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 4; Letter from PhRMA to Board (April 24, 2024) *supra* note 1 at 5.
[16] *See* Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 4; Letter from PhRMA to Board (April 24, 2024) *supra* note 1 at 5.
[17] *See* Md. Code, Health Gen. § 21-2C-10 (statutory protections for confidential, proprietary, and trade secret information). For additional discussion of confidentiality issues, *see, e.g.*, Letter from PhRMA to Board (May 1, 2023) *supra* note 1 at 18-19.
[18] *See* COMAR § 14.01.01.01(B)(61) (defining "[t]herapeutic alternative" as "a drug product that has the same or similar indications for use as a particular drug but is not a therapeutic equivalent to that drug"); Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 4-5; Letter from PhRMA to Board (April 24, 2024) *supra* note 1 at 3.

evidence.[19] Some therapies that could be identified as therapeutic alternatives under the Board's definitions are not appropriate for all patients using the therapy. PhRMA continues to urge caution in how the Board defines therapeutic alternatives for a particular drug.

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On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA has concerns with the cost review study process, 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

[19] *See* Letter from PhRMA to Board (July 16, 2024) *supra* note 1 at 4-5; Letter from PhRMA to Board (April 24, 2024) *supra* note 1 at 3.