MARYLAND HEALTH BENEFIT EXCHANGE

750 E. Pratt St., 6th floor
Baltimore, MD 21202
marylandhbe.com

Mach 23, 2026

Re: MHBE Comment – Cost Review Study Report – JARDIANCE (empaglifozin)

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

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, Jardiance accounted for a significant portion of total drug claims costs in the individual market **- 1,967 enrollees received at least one prescription of various formulations of Jardiance** [2], accounting for 1.5% ($5.04M) alone of brand name prescription drug claims costs in the individual market. Further, Jardiance accounted for a significant portion of individual market drug claims costs by enrollees in the SRP as well. Just **571 enrollees who received at least one prescription of various formulations of Jardiance** accounted for **0.8% ($2.21M)** 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 2025),[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] JARDIANCE 10 MG, 25 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
16900 Science Drive, Suite 112-114
Bowie, MD 20715
comments.pdab@maryland.gov

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.