***By Electronic Submission***

May 10, 2024

Maryland Prescription Drug Affordability Board
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Dear Members of the Maryland Prescription Drug Affordability Board ("Board"):

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on the list of proposed therapeutic alternatives and sample dashboard (the "Sample Dashboard") of drugs identified for referral to the Stakeholder Council.[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

PhRMA recognizes the Board's ongoing work to implement and carry out its responsibilities under the Maryland PDAB Statute ("PDAB Statute").[2] Consistent with our prior comment letters, however, PhRMA has concerns about the Board's implementation of the PDAB Statute, including a lack of adequate transparency and lack of sufficiently clear and meaningful standards.[3] As described below, these concerns pertain to both the Board's determination of therapeutic alternatives and the Sample Dashboard data relied upon by the Board for its ongoing drug selection and cost review processes.

## I. TRANSPARENCY

PhRMA remains concerned that the Board's approach to implementing the PDAB Statute provides insufficient transparency with respect to the data and considerations that inform the Board's decision-making. Below, PhRMA highlights examples of the lack of transparency with respect to the Board's proposed list of therapeutic alternatives and the Board's Sample Dashboard of certain eligible drugs.

[1] *See* Board, Therapeutic Alternatives (for Drugs Referred to the Stakeholder Council), *available at* https://pdab.maryland.gov/Pages/cost_review_process.aspx#Therapeutic; Drugs Referred to the Stakeholder Council - Dashboard, *available at* https://pdab.maryland.gov/documents/comments/drugs_referred_stakeholder_council_dashboard_2024.xlsx.

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

[3] *See* Letter from PhRMA to Board Regarding Maryland Prescription Drug Affordability Board: 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 General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process (May 1, 2023). PhRMA incorporates by reference all comments, concerns, and objections that it has previously raised regarding the Board's implementation of the PDAB Statute.

### A. Process for Identifying Therapeutic Alternatives

While the Board has published a list of proposed "therapeutic alternatives" for the eight drug products referred to the Stakeholder Council (the "Proposed List"), to date it has not provided a detailed description of how those proposed therapeutic alternatives were identified or how therapeutic alternatives will be identified for other drug products in the future. The Board staff's February 26, 2023 presentation on the process for selecting therapeutic alternatives includes an example of a selected drug's purported therapeutic alternatives that provided some details, such as whether a product was a biosimilar or generic, the therapeutic class, and indications for each of the purported therapeutic alternatives.[4] However, the Proposed List does not contain even these limited details. Rather, the only information that it provides is the names of the proposed therapeutic alternatives. This lack of information prevents the public from understanding the rationale that went into the selection of proposed therapeutic alternatives and impedes the ability of stakeholders to meaningfully comment on the Board's Proposed List or the Board's process for determining therapeutic alternatives.

The purpose of a comment period is to "give the agency free-flowing information from a broad range of interests."[5] Accordingly, the comment process is only meaningful to the extent proposals include adequate details and technical information to allow stakeholders to provide substantive feedback on the agency's proposals. Administrative law recognizes both the centrality of the comment process to an agency's activities and the necessity of providing members of the public with the information they need to meaningfully comment.[6]

In order to provide members of the public with a meaningful opportunity to review the Proposed List and provide substantive comments, PhRMA requests that the Board publicly release the information that informed the Board's creation of the list, subject to appropriate protections against the disclosure of confidential, proprietary, or trade secret information.[7] Following such publication, the Board should provide members of the public with a new opportunity to comment on the Proposed List.

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[4] *See* Board, Cost Review: Selection of Therapeutic Alternatives (Feb. 26, 2023), *available at* https://pdab.maryland.gov/documents/stakeholders/2024/pdasc_therapeutic_alternatives_02262024.pdf.

[5] *Adventist Healthcare Midatlantic, Inc. v. Suburban Hosp., Inc.*, 350 Md. 104, 123 (1998).

[6] *See* 75 Op. Atty Gen. Md. at 43 (Jan. 23, 1990) ("[T]he heart of an APA's rulemaking requirements is its public notice and comment procedures. Designed to assure fairness and mature consideration of rules of general application, these significant provisions serve the important twin functions of safeguarding public rights and educating the administrative lawmakers."), available at https://www.marylandattorneygeneral.gov/Opinions%20Documents/Volume75_1990.pdf. *See also Conn. Light and Power Co. v. Nuclear Reg. Com'n*, 673 F. 2d 525, 530–31 (D.C. Cir. 1982) (construing the federal Administrative Procedure Act, 5 U.S.C. § 553(b)(3)) ("An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary."); Md. Bar Ass'n, Practice Manual for the Maryland Lawyer, ch. 3, Administrative Law § 5 (6th Ed. 2023) (Maryland courts generally "seek to harmonize Maryland common administrative law and Maryland APA interpretation with federal administrative law").

[7] *See, e.g.*, Letter from PhRMA to Board Regarding Confidential, Trade-Secret, and Proprietary Information Proposed Rule (May 4, 2023).

### B. Sample Dashboard and Other Data Considerations

PhRMA is also concerned about lack of transparency with respect to other data elements that the Board is relying on to carry out its responsibilities under the PDAB statute, including the data used to compile the Board's Sample Dashboard.[8] While the Board has published a Sample Dashboard containing data elements for the eight drug products referred to the Stakeholder Council for review, it has not made the data underlying the Sample Dashboard public, so stakeholders are unable to verify the data's accuracy or confirm how Board staff calculated various metrics. Notably, data in the Sample Dashboard contain several apparent limitations. For example, the Sample Dashboard does not state where cost information for each drug product was drawn from, and pricing data is from different years depending on the payer (2022 for commercial payers and 2020 for Medicare).[9] Because of the limited quantity and quality of data in the Sample Dashboards stakeholders will be unable to comprehensively review and determine whether the Board based its selection of drugs for referral to the Stakeholder Council on erroneous data.

To provide greater transparency with respect to the data being relied on by the Board for when performing its functions, PhRMA asks that the Board take the following additional steps:

- **Release of Full Dashboard**. PhRMA asks that the Board clarify the extent to which a comprehensive dashboard exists for all drugs determined to be eligible for cost reviews. To the extent more complete dashboard is available, we ask the Board to make public the full dashboards, subject to appropriate confidentiality and trade secret protections.[10] This would allow the stakeholders to review the data relied upon by the Board and provide information regarding any issues with the data used by the Board in its drug selection process. To the extent the Board does not have more complete dashboards, we ask that the Board provide more information about how it determined which products to refer for Stakeholder Council review and specifically, how it selected those drug products from among others it determined to be eligible for cost review.

- **Data Review Process**. PhRMA reiterates its prior requests that the Board establish a data review process for stakeholders to review and comment on potential errors in the data that the Board uses in its decision-making, including the data used as part of the dashboard and to select therapeutic alternatives.[11] The Board's activities rely on voluminous data from diverse sources. This creates an inherent risk that some data may be inaccurate, incomplete, or misleading. We ask that the Board provide manufacturers an opportunity to review, evaluate, confirm and meet with the Board about the data it is relying on before the Board decides on potential medicines to evaluate for affordability and before the Board decides on and publishes a list of medicines for affordability review. To provide protection for confidential, proprietary, and trade secret information as required under the PDAB Statute, the data review process should also include a confidential method for stakeholders to submit data regarding any issues found in the data that

[8] *See* Board, Drugs Referred to the Stakeholder Council- Dashboard, available at https://pdab.maryland.gov/documents/comments/drugs_referred_stakeholder_council_dashboard_2024.xlsx.
[9] *Id*. (eligible drug statistics worksheet).
[10] *See* Letter from PhRMA to Board (June 30, 2023), 4.
[11] *See* Letter from PhRMA to Board Regarding Maryland Prescription Drug Affordability Board: Cost Review Study Process (Apr. 24, 2024), 5; Letter from PhRMA to Board (May 1, 2023), 7.

the Board has relied on.[12] We ask that the Board not finalize any list of therapeutic alternatives or otherwise use therapeutic alternatives in its decision-making until this process is established and completed.

## II. LACK OF CLEAR AND MEANINGFUL STANDARDS

### A. Use of Therapeutic Alternatives

In addition to the issues described above, PhRMA continues to have concerns with the Board's consideration of therapeutic alternatives in its drug selection and cost review processes, including how it determines which drugs are a "therapeutic alternative" for drugs under consideration. The broad regulatory definition for "therapeutic alternative" could lead to certain therapies being identified as therapeutic alternatives that are not appropriate for all patients using the therapy.[13] In order to guide the Board's consideration of therapeutic alternatives in a manner that is consistent with clinical evidence, PhRMA recommends that the Board adopt a standard of "clinical appropriateness" for its identification of therapeutic alternatives for a selected drug. Specifically, when identifying the therapeutic alternatives for a drug subject to cost review, we ask that the Board do the following:

- Engage meaningfully with the manufacturer on potential therapeutic alternative(s);
- Look to clinician guidance, including physician-driven evidence-based clinical guidelines, as a resource; and
- Reference other widely recognized, scientifically rigorous, evidence-driven resources to identify therapeutic alternative(s).

We ask that, prior to publishing its proposed list of therapeutic alternatives in the future and prior to finalizing its current proposed list of therapeutic alternatives, the Board provide manufacturers an opportunity to review, provide feedback, and meet with the Board about the data it is relying on to select therapeutic alternatives and the therapeutic alternatives it has identified for the list.

Tailoring the therapeutic alternatives for drugs under consideration in this manner would help the Board avoid making comparisons between drugs in the drug selection and cost review process that may not be appropriate. As PhRMA has previously explained, not every drug product that has the same or a similar indication as a particular drug can be considered to be a therapeutic alternative.[14] A patient who can safely and effectively use one drug may experience increased risk of negative outcomes (e.g., drug

[12] *See* Md. Code Ann., Health-Gen. § 21-2C-10; *see also* Letter from PhRMA to Board Regarding Confidential, Trade-Secret, and Proprietary Information Proposed Rule (May 4, 2023).
[13] *See* Md. Code Regs. 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"); *see also* Md. Code Regs. 14.01.04.03(H), (I)(8), 14.01.04.05(C)(1)(c). For additional discussion regarding PhRMA's concerns with the consideration of therapeutic alternatives, *see, e.g.*, Letter from PhRMA to Board Regarding General Provisions; Fee Assessment, Exemption, Waiver, and Collection Amendments; and Cost Review Process (May 1, 2023).
[14] *See* Letter from PhRMA to Board (June 30, 2023), 6.

interactions, side effects, treatment failures) with another drug with a similar indication.[15] An approach to therapeutic alternatives that is targeted in this manner would reduce the risk of misleading comparisons that could skew the PDAB's consideration in a manner that has ramifications on the clinical choices of the prescribing health care provider and that interfere with the relationship between the patient and their health care provider.

Further, such an approach would better account for patients who rely on specific drug therapies to treat their conditions, such as those who are immune-compromised, pediatric patients, and women — particularly those who are pregnant — and the elderly. Patients in these groups in particular may respond differently to treatments and be limited to one specific drug therapy for their condition. In addition, patients also respond differently to treatment because of a number of factors, such as genetics, age, sex, socioeconomic status, drug-drug interactions, diet, environment, and co-morbidities. Specifically in the situation of co-morbidities that are managed effectively by a specific prescription drug regimen, switching to another medication could upset the stability of their ongoing treatment plan. Because the treatments that are the best option for some individuals are not as effective or safe for others, we ask that the Board carefully take these considerations into account in determining which drugs to compare as "therapeutic alternatives."

In addition to identifying therapeutic alternative(s) for a selected drug that are clinically appropriate, PhRMA strongly cautions the Board that drug cost should not play a role in determining of a selected drug's therapeutic alternative.

### B. Consideration of Public Comments

PhRMA reiterates its request that the Board adopt additional procedures regarding how it will consider public comment in each step throughout the drug selection and cost review process, including in its deliberations on therapeutic alternatives.[16] The PDAB statute requires public notice and opportunity to comment on each meeting and pending decision of the Board; these requirements are further elaborated on in the Board's regulations.[17] In order to effectively implement these requirement, we ask that the Board provide additional transparency regarding how public comments are considered and how they impact the Board's decisions.[18] Greater transparency will give the public and stakeholders an understanding of how their concerns are being considered by the Board and how they are weighed in the Board's decision-making.

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We thank you again for this opportunity to provide comments and feedback on the Board's drug selection and cost review processes and for your consideration of our concerns and requests for clarifications. Although PhRMA has concerns with the use of therapeutic alternatives in the Board's processes, we are

[15] McRae, J., Onukwugha, E. Why the Gap in Evaluating the Social Constructs and the Value of Medicines? PharmacoEconomics (2021), *available at* https://doi.org/10.1007/s40273-021-01075-w.
[16] *See e.g.*, Letter from PhRMA to Board Regarding Maryland Prescription Drug Affordability Board: Cost Review Study Process (Apr. 24, 2024), 5.
[17] *See* Md. Code Ann., Health-Gen. § 21-2C-03 (e)(2), (4)–(5); Md. Code Regs. 14.01.01.03(B), 14.01.01.05; 14.01.04.03(D)(4).
[18] This process should include protections for confidential, proprietary, or trade secret information received by the Board from stakeholders or other sources from inappropriate disclosure. *See* Letter from PhRMA to Board (June 30, 2023), 4.s

ready to be a constructive partner in this dialogue. If there is additional information or technical assistance that we can provide as therapeutic alternatives are considered and their use is deliberated, please contact Kristin Parde at Kparde@phrma.org.

Sincerely,

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