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***By Electronic Submission to HCA_WA_PDAB@hca.wa.gov***

March 1, 2024

Washington Prescription Drug Affordability Board
Washington Health Care Authority
PO Box 42716
Olympia, Washington 98504-2716

**Re: January 31, 2024 Meeting Materials: Advisory Group Proposal and Draft Methodology For Identifying Drugs for Affordability Review**

Dear Members of the Washington Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on the "Advisory Group Proposal" and "Methodology for Identifying Drugs for Affordability Review" presentations (collectively, the "Meeting Materials") circulated by the Prescription Drug Affordability Board ("Board") in advance of its January 31, 2024 meeting. 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. We provide below our comments and concerns with respect to the Board's Meeting Materials.[1]

## I. Transparency and Need for Clear, Specific, and Meaningful Standards

PhRMA is concerned that the information provided to date by the Board and the Washington Health Care Authority ("HCA") regarding the Board's drug selection and affordability review processes continues to lack adequate detail with respect to a number of important areas. PhRMA emphasizes the need for clear, meaningful, and specific standards and processes governing how the Board will conduct its activities and decision-making. PhRMA requests that, as it continues to work toward implementing the PDAB Statute, the Board provide specific and detailed policies and processes for its proposed activities.[2]

[1] PhRMA previously provided comments on various aspects related to HCA's implementation of SB 5532, 2022 Sess. Laws ch. 153 (the "PDAB Statute"), including the proposed regulations, Wash. Admin. Code § 182-52-0005 et seq. (the "Proposed Regulations") filed with the Washington Office of the Code Reviser by HCA on October 16, 2023. Codified at Wash. Rev. Code §§ 70.405.010 *et seq*.; *see also* Letter from PhRMA to Board (Jan. 23, 2024); Letter from PhRMA to HCA (Nov. 20, 2023); Letter from PhRMA to HCA (Aug. 15, 2023); Letter from PhRMA to HCA Regarding HCA Advance Notice (Aug. 25, 2020). In filing this comment letter, PhRMA reserves all rights associated with its prior comment letters and, to the extent applicable, incorporates by reference all comments, concerns, and objections that it has raised in its previous comments. PhRMA reserves all rights to legal arguments with respect to the constitutionality of the Washington PDAB statute and the regulations thereunder.

[2] We reiterate our concerns that the lack of clear and meaningful standards for the Board's processes creates a risk of inconsistent and arbitrary decision-making. *See* Letter from PhRMA to HCA (Aug. 15, 2023), 2. In the sections below, PhRMA provides more details about its specific concerns regarding the Board's advisory group proposal and draft methodology for identifying drugs for affordability review.

PhRMA also requests that the Board's draft methodologies and other proposals be provided for discussion in a fully documented form—including the draft methodology for identifying drugs for affordability reviews, which the Board has so far provided only in a summary slide deck. It is difficult for stakeholders to fully understand the proposals and provide meaningful feedback if these materials are not presented in a complete and comprehensive format. Further, we note that the Board has not clearly articulated a formal process for stakeholders to meaningfully review and comment on its activities in advance of the Board's discussions, including the affordability review methodologies described in the Meeting Materials.[3] We ask that the Board not formally adopt any final policies (including interpretive policies) before the public is given an opportunity to participate in a notice-and-comment process consistent with the Washington Administrative Procedure Act ("APA"), including adequate time periods for stakeholder to review its materials and provide feedback.[4]

## II. Draft Methodology for Identifying Drugs for Affordability Review

In addition to the broader concerns described above, PhRMA has a number of specific concerns regarding the summary of the draft methodology set forth in the January Meeting Materials. PhRMA provides the following as a non-exhaustive list of examples of the lack of clear standards with respect to the summary of the draft methodology:

- Drug Definition. PhRMA is concerned that the Board is proposing to interpret the term "drug" in an inconsistent manner for its drug selection and affordability review procedures. In the Meeting Materials, the Board appears to interpret each distinct National Drug Code ("NDC") as a separate drug for purposes of affordability review eligibility.[5] However, the Meeting Materials also state that, for the affordability review process, "NDCs from a single labeler or branded product[], with the same drug ingredient" will be treated as a single drug and reviewed in aggregate.[6]

  A single, coherent interpretation of a statutory term is needed to be consistent with the PDAB Statute and canons of statutory interpretation.[7] The PDAB Statute enumerates specific considerations for the affordability review process, which would not be consistently comparable for a single drug ingredient that is common across multiple separate NDAs or BLAs.[8] A consistent definition should apply across all applicable processes under the PDAB Statute.

[3] *See also* Letter from PhRMA to Board (Jan. 23, 2024), 2.
[4] Notice and comment is an "essential" procedural safeguard under the APA and is "both a statutory and constitutional imperative" even for interpretive rules. *Mahoney v. Shinpoch*, 732 P.2d 510, 516 (Wash. 1987) (explaining the scope of the notice and comment requirement under the Washington APA).
[5] *See* Meeting Materials, Methodology for Identifying Drugs for Affordability Review at 9.
[6] *Id.*
[7] *See Samish Indian Nation v. Wash. Dep't of Licensing*, 14 Wash. App. 2d 437, 443 (2020) ("Where the identical word or phrase is used more than once in the same act, there is a presumption that they have the same meaning") (internal citations omitted).
[8] *See* PDAB Statute § 70.405.040(5). For example, different products may share active ingredients but have significantly different characteristics and routes of administration that result in different units of measurement (e.g., mg versus mL). In such circumstance, it is unclear how the Board could group the two products together in a coherent fashion to determine per unit costs, which is a necessary pre-requisite to evaluating affordability.

Further, PhRMA is concerned that treating all products with the same active ingredient under the same labeler or branded product as a single drug would ignore the significant benefits that flow from new innovations involving distinct products that share an active ingredient. For example, fixed-dose combination products combine two or more drugs. These products can revolutionize treatment options for patients by achieving breakthroughs that eliminate substantial technological and practical challenges. It would devalue the immense benefits and vast investment associated with creating such products if the Board grouped the products with one of the individual counterpart drugs simply because they share an active ingredient.

In order to provide a consistent definition, PhRMA recommends that the Board determine whether a product is a separate "drug" based on whether the product is approved under a distinct Food and Drug Administration ("FDA") New Drug Application ("NDA") or Biologics License Application ("BLA"), regardless of whether there is shared drug ingredient with another NDA or BLA.

- 7-Year Market Requirement. PhRMA is similarly concerned about the Board's proposed interpretation of whether a drug has "been on the market for at least seven years" based on how long "[t]he drug *ingredient* has been on the market."[9] This plainly contradicts the statute, which establishes the 7-year period based on how long a given *prescription drug* has been on the market. Multiple products, approved under separate NDAs or licensed under separate BLAs, may have been marketed for varying lengths of time. By grouping those products together, the approach described in the Meeting Materials risks contravening the text of the statute by subjecting drugs to affordability review that may not have "been on the market for at least seven years."[10]

- Institutional Product Definition. PhRMA requests that the Board clarify how it will determine which "institutional products" are excluded from affordability review and provide greater detail on its specific methodology for identifying drugs as "institutional products." Specifically, PhRMA requests that the Board clarify the exact methodology for how it intends to use the "First Databank (FDB) provided indicators" to consistently exclude "institutional products and products likely to be used by home healthcare providers," and should explain how those indicators will consistently denote non-pharmacy-dispensed products and therefore determine which products are eligible for affordability review.[11]

[9] PDAB Statute § 70.405.030; Meeting Materials, Methodology for Identifying Drugs for Affordability Review at 9.
[10] PDAB Statute § 70.405.030.
[11] Meeting Materials, Methodology for Identifying Drugs for Affordability Review at 10; *see also* PDAB Statute § 70.405.030 (limiting eligibility to drugs that are "dispensed at retail, specialty, or mail-order pharmacy").

- Cost Estimation Methodology. PhRMA is concerned that the draft methodology considered by the Board for estimating the cost of a drug's course of treatment would significantly bias its determinations of which drugs are eligible for affordability review.[12] As described in the Meeting Materials, the draft methodology's "de-duplication algorithm" multiplies an NDC's "high dose by high duration of therapy" to determine a course of treatment, which is then used to calculate the cost of a course of treatment for one year to compare against the PDAB's statute's eligibility threshold.[13] The Board's slides do not explain why its proposed "high dose by high duration" methodology is a reasonable and clinically appropriate approach for estimating each drug's course of treatment.[14] As the Meeting Materials describe, drugs may have different courses of treatment, such as when a drug may have both chronic and acute dosing. The "high dose by high duration" approach may not be consistent with the typical course of treatment for the vast majority of patients, and presuming it is could systematically overestimate the cost for certain drugs. The Board itself acknowledges that its approach "may not always reflect the amount that most people are prescribed."[15] For example, for products with weight-based dosing, calculating cost based on the highest dose would systematically shift affordability evaluation toward medications that treat conditions that disproportionately impact communities of color and other vulnerable populations. Not only do Black and Hispanic adults have higher rates of obesity and secondary comorbid conditions such as diabetes and cardiovascular disease, research shows that these populations also experience inequitable access and quality of obesity care.[16] The proposed approach may inadvertently exacerbate health disparities within those communities.

  As discussed above, the Board's summary slides do not provide adequate detail for stakeholders to fully evaluate the Board's intended approach. We ask that, prior to adopting any particular approach, the Board provide a fully documented form of its proposed methodology so that stakeholders have an opportunity to review and provide comments.

- Transparency in Data Sources and Reliability Safeguards. It remains critical that the Board be transparent with respect to its data sources and cognizant of the potential for errors and discrepancies that may exist in the data and information that it relies upon. Consistent with our requests in prior comment letters, PhRMA urges the Board to establish a process for

[12] *See* Meeting Materials, Methodology for Identifying Drugs for Affordability Review at 20–22.
[13] *See* Meeting Materials, Methodology for Identifying Drugs for Affordability Review at 20, 22, 24; PDAB Statute § 70.405.030(1)(a).
[14] Specifically, as the Board continues to develop its methodology, we ask that it provide an explanation for why it believes its contemplated use of FDB data in this manner will provide a consistent and clinically appropriate estimate for a drug's course of treatment, as well as how it intends to evaluate whether the FDB data itself is consistent with the label information for each drug that it evaluates. Similarly, the Board's proposed methodology requires it to use "dosing data for the highest age range" listed for a particular drug, but it is not clear how those age ranges are derived nor why the highest age range would automatically be appropriate for the Board's calculation. The Board should clarify why it considers the "highest age range" approach to be an appropriate method for determining each drug's course of treatment, and how it intends to evaluate whether the age range indicated in its data source is clinically appropriate for each drug.
[15] Meeting Materials, Methodology for Identifying Drugs for Affordability Review at 39.
[16] Washington TB, Johnson VR, Kendrick K, Ibrahim AA, Tu L, Sun K, Stanford FC. Disparities in Access and Quality of Obesity Care. Gastroenterol Clin North Am. 2023 Jun;52(2):429-441.

manufacturers to review the Board's data and raise any technical questions or concerns before the Board moves forward with its affordability review.[17] Such process should include protections for confidential, proprietary, or trade secret information against improper disclosure or use, as required by federal and state law.[18]

## III. Advisory Group Proposal

PhRMA reiterates its request that the Board clarify its conflict of interest procedures, including what constitutes a "competitor" relationship. As described below, the proposal discussed in the Meeting Materials appears inconsistent with statutory requirements for advisory group membership criteria and the timeline for when the Board must consider advisory group input.

- Conflict of Interest Procedures. PhRMA continues to be concerned by the lack of express definition for what constitutes a "conflict of interest," and particularly which situations would require recusal or may disqualify an individual from serving as a member of an advisory group.[19] As requested in PhRMA's January 23, 2024 comment letter, the Board should adopt a clear and reasonable definition for what constitutes a "competitor" relationship that would disqualify a member of the advisory group from giving input on eligible drugs and participating in the affordability review process.[20]

- Advisory Group Membership Criteria and Input Process. The PDAB Statute requires that the Board "shall consider ... [i]nput from relevant advisory groups established pursuant to RCW 70.405.020" prior to deciding whether to conduct an affordability review for a particular drug.[21] Further, each advisory group must include "patients and patient advocates" and "one member who is a representative of the prescription drug industry."[22] However, the proposed advisory group structure described in the Meeting Materials limits the participation of patients, patient advocates, and "representative[s] of the prescription drug industry" to a "Supplemental Advisory Group," which would only be formed and for which members would be selected only after a drug is selected for affordability review.[23] To comply with the requirements of the PDAB Statute, the Board should revise its proposed advisory group structure to include patients, patient advocates, and prescription drug industry representatives in the advisory group that provides input on whether an affordability review should be conducted for the relevant prescription drug.[24]

[17] *See, e.g.*, Letter from PhRMA to HCA (Nov. 20, 2023), 3; Letter from PhRMA to Board (Jan. 23, 2024), 5.
[18] *See generally* Letter from PhRMA to Board (Jan. 23, 2024), 5 (providing more details on these requests).
[19] *See* Meeting Materials, Advisory Group Proposal 4.
[20] *See* Letter from PhRMA to Board (Jan. 23, 2024), 4 (requesting clarity in the Board's conflict of interest provisions).
[21] PDAB Statute § 70.405.040(1)(b).
[22] PDAB Statute § 70.405.020(5).
[23] *See* Meeting Materials, Advisory Group Proposal 8, 10 ("As drugs are selected for Affordability Review, open applications and select supplementary advisors").
[24] *See* PDAB Statute § 70.405.020(5).

- Recruiting Outreach: PhRMA is concerned that the limited scope of proposed sources that the Board has identified for candidate outreach will fail to reach candidates of diverse backgrounds with relevant experience for each prescription drug, as contemplated by the statute.[25] PhRMA urges the board to broaden its recruiting process in order to reach a diverse set of "relevant stakeholders."

* * *

PhRMA thanks the Board again for this opportunity to provide comments and feedback on the Meeting Materials and for your consideration of our concerns and requests for revisions. Although PhRMA continues to have concerns with the Board's proposals, we stand ready to be a constructive partner in this dialogue. If there is additional information that we can provide, please contact dmcgrew@phrma.org.

Sincerely,

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[25] *See* Meeting Materials, Advisory Group Proposal 13; PDAB Statute § 70.405.020(5).