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By Electronic Submission to HCA_WA_PDAB@hca.wa.gov

June 18, 2024

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

Re: Washington Prescription Drug Affordability Board May 22, 2024 Meeting: Comments on Draft Eligible Prescription Drugs Policy and Presentations on Preliminary Eligible Prescription Drugs For Affordability Review and Selecting Prescription 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 draft "Eligible Prescription Drug Policy" and the "Preliminary Eligible Prescription Drugs For Affordability Review" and "Selecting Prescription Drugs For Affordability Review, Part 1" presentations (collectively, "Meeting Materials") circulated by the Washington State Health Care Authority ("HCA") in advance of the Prescription Drug Affordability Board's (the "Board's") May 22, 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 HCA's Meeting Materials.[1]

I. Lack of Clear, Specific, and Meaningful Standards and Related Concerns

As detailed in our prior comment letters, PhRMA continues to have significant concerns about the lack of clear and meaningful standards and processes regarding how the Board will conduct the drug selection and affordability review processes, as well as its other activities and decision-making.[2] Although the Meeting Materials provide high level information about certain aspects of how the Board intends to proceed with its preliminary eligibility process and selection for affordability reviews, these materials continue to lack key details with regard to how these processes will be operationalized, which raises procedural and substantive concerns as described below.

[1] PhRMA previously provided comments on various aspects related to HCA's implementation of SSSB 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 Regarding Draft Methodology (Apr. 11, 2024); Letter from PhRMA to Board Regarding Draft Policies and Procedures (Mar. 1, 2024); Letter from PhRMA to Board Regarding Draft Policies and Procedures (Jan. 23, 2024); Letter from PhRMA to HCA Regarding HCA Proposed Regulations (WSR 23-21-082, filed October 16, 2023) (Nov. 20, 2023); Letter from PhRMA to HCA Regarding August 2023 Draft Regulations (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 also reserves all rights to legal arguments with respect to the constitutionality of the Washington PDAB statute and the regulations thereunder.

[2] *See, e.g.*, Letter from PhRMA to HCA Regarding HCA Proposed Regulations (WSR 23-21-082, filed October 16, 2023) (Nov. 20, 2023); Letter from PhRMA to HCA Regarding August 2023 Draft Regulations (Aug. 15, 2023).

PhRMA is concerned that the failure to adopt clear and specific standards risks arbitrary and inconsistent decision-making when the Board begins the selection of drugs for affordability reviews.[3]

PhRMA highlights the following non-exhaustive list of concerns specifically related to the May 22 Meeting Materials:

- Drug Eligibility Standards: Drug Definition. PhRMA remains concerned that the Board has been inconsistent in formulating the process for identifying the drugs that will be eligible for affordability reviews.[4] Because both the Board's drug eligibility and affordability review processes interpret the same statutory term ("prescription drug"), the Board must adopt a single, coherent interpretation of that term in order to be to be consistent with the PDAB Statute and canons of statutory interpretation.[5] As in our prior comments, PhRMA recommends that the Board determine whether a product is a separate "prescription 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"), rather than introducing the vague concept of "drug ingredient."[6] The board should look to an individual NDA or BLA to define a drug regardless of whether there is a shared "drug ingredient" in another NDA or BLA from the same sponsor.

- Drug Eligibility Standards: 7-Year Market Requirement. PhRMA is also concerned that the Board has not aligned its interpretation of the 7-year market requirement with the plain language of the statute.[7] The statute requires that the 7-year eligibility requirement be based on how long a given "prescription drug" has been on the market, rather than how long a "drug ingredient" has been on the market as the Board has previously suggested.[8] To align the Board's policies with the requirements of the statute, PhRMA requests that before it finalizes the Eligible Prescription Drugs Policy, the Board make clear that the 7-year requirement applies to the length of time that the particular prescription drug, as approved under the relevant NDA or BLA, has been on the market.

- Drug Eligibility Standards: Pharmacist Review Standards. The Eligible Prescription Drugs Policy states that a licensed pharmacist will review the "daily high dose and high duration of therapy" for certain brand name drugs and biological products, to "ensure the [Board's] calculations are clinically sound."[9] PhRMA requests additional, more specific information on the guidelines for this process, including what the Board defines as "clinically sound," and safeguards to provide consistent evaluations across

[3] As PhRMA has explained in detail in its prior comments, specific and meaningful standards are a prerequisite to consistent decision-making as required by the Washington Administrative Procedure Act ("APA"), which mandates that agencies' determinations must not impermissibly treat similar products or situations in a dissimilar manner without a reasoned basis for distinction. *See, e.g.*, *Carlson v. Dep't of Soc. & Health Servs.*, 22 Wash. App. 2d 1053 (2022); *see also Relative Motion, LLC v. Dep't of Revenue of the State of Washington*, 19 Wash. App. 2d 1020, at *7 (2021) ("[R]egulation[s] must be sufficiently clear by providing explicit standards to prevent arbitrary enforcement."); Letter from PhRMA to HCA Regarding August 2023 Draft Regulations (Aug. 15, 2023).

[4] PhRMA continues to have concern with the challenge of estimating costs using the high dose and duration of therapy as described in a prior comment letter. *See* Letter from PhRMA to Board Regarding Draft Policies and Procedures 2–5 (Mar. 1, 2024).

[5] PDAB Statute §§ 70.405.010(9) (definition of "prescription drug"), 70.405.030 (drug eligibility), 70.405.040(1) (affordability review process). *See* Letter from PhRMA to Board Regarding Draft Policies and Procedures 2–3 (Mar. 1, 2024).

[6] *Id.*

[7] *Compare* PDAB Statute § 70.405.030 *with* January 31 Meeting Materials, Methodology for Identifying Drugs for Affordability Review at 9.

[8] *Id.*

[9] Board, Eligible Prescription Drugs Policy at 2.

drugs. Further, we ask the Board to specify on what basis the licensed pharmacist will be determining clinical soundness. Additional details are needed to create adequate safeguards so that each drug receives consistent treatment in calculating its high dose and high duration of therapy.

- Choosing Drugs for Affordability Review: Factors for Consideration. PhRMA is also concerned that the Board appears to be contemplating additional factors that it may consider when selecting drugs for affordability review, in addition to the factors enumerated in the statute.[10] Specifically, HCA's slide on what the Board shall consider when deciding whether to conduct an affordability review lists the three statutory factors, then adds "+ ???."[11] To the extent the board intends to consider additional criteria beyond what is enumerated in its statute, PhRMA emphasizes that the Board must adopt those criteria through notice and comment rulemaking, and must clarify how those additional criteria will be considered and weighed in a manner that is consistent with the requirements of the PDAB Statute.[12]

- Choosing Drugs for Affordability Review: Average Out-of-Pocket Cost Methodology. PhRMA requests clarity in how the Board will define "the average patient's out-of-pocket costs" as well as "other cost sharing" as part of the drug selection process.[13]

II. Data-Related Considerations

PhRMA also believes that the Meeting Materials raise a series of data-related questions and concerns, including regarding the data sources that the Board intends to rely upon; how the Board will evaluate the accuracy of the data it relies upon; and how information from various sources will be used and weighed in the drug selection and affordability review processes. PhRMA specifically highlights the following:

- Use of Commercial Databases. Notably, the Board has proposed to rely upon a number commercial data sources as part of its drug identification and affordability review processes, such as First Databank and Medi-Span.[14] The use of commercial databases to determine therapeutic alternatives increases the risk that the data may contain inaccuracies or fail to give the full context of how the therapeutic alternatives were determined for a particular drug. For example, some databases may contain therapeutic alternatives that were chosen due to financial incentives, rather than based on clinical appropriateness. PhRMA requests that the Board clarify how it will ensure that the data it considers is clinically based and accurate.

- Use of All Payer Claims Database ("APCD"). PhRMA urges that the Board's policies regarding the use of the Washington State All Payer Claims Database ("APCD") recognize the inherent limitation of the

[10] The three statutory factors are: "(1) the class of the prescription drug and the availability of any therapeutically equivalent drugs, (2) input from relevant advisory groups, and (3) the average patient's out-of-pocket costs." PDAB Statute § 70.405.040(1). The PDAB Statute does not authorize the Board to consider additional factors in the drug selection process. *Id.*
[11] HCA, Selecting Prescription Drugs For Affordability Review, Part 1 at 7.
[12] *See Mahoney v. Shinpoch*, 732 P.2d 510, 516 (Wash. 1987) (explaining the scope of the notice and comment requirement under the Washington APA).
[13] *See* Letter from PhRMA to HCA Regarding August 2023 Draft Regulations 7 (Aug. 15, 2023); *see also* PDAB Statute § 70.405.040(1)(c).
[14] HCA, Selecting Prescription Drugs For Affordability Review, Part 1 at 9.

APCD data.[15] This will help mitigate the risk that the Board's consideration and use of APCD-based data could otherwise to biased or misleading assessments due to the limitations of such data source.[16]

- Stakeholder Review and Appeal Processes. As described in PhRMA's prior comments, the Board should provide manufacturers an opportunity to review and comment on all data (whether APCD data or otherwise) that the Board intends to rely upon and provide additional data or context for the Board's consideration before the Board renders a final vote on any selection or affordability review decisions.[17] This is especially important as the Board prepares to launch an eligible drug dashboard, which will be populated using a host of disparate data sources. Specifically, PhRMA requests that the Board:

    - Develop an inquiry form on the Board's website that allows manufacturers to submit questions, comments, and objections. The Board and its staff should also commit to responding to any submitted inquiries within a reasonable timeframe;
    - Adopt a process by which the party raising concerns can meet with the Board's staff to discuss that party's questions, comments, or objections;
    - Implement a dispute resolution process to better allow for any disagreements or issues to be mutually resolved by the parties.[18]

  These processes should include mechanisms to protect confidential, proprietary, or trade secret information submitted to the Board against improper disclosure or use, as required consistent with the confidentiality obligations imposed on the Board by federal and state law.[19] PhRMA requests that the Board also defer voting on any selection of drugs for affordability reviews until the relevant data have been provided to the manufacturer and the manufacturer has had adequate time to notify the Board of any discrepancies, errors, or other concerns.

III. Concerns Regarding Public Comment Process

As described in our prior comments, PhRMA remains concerned that the lack of a specified public comment process in the Board's materials could deprive stakeholders of an opportunity to adequately evaluate and respond to the Board's proposals.[20] To date, the Board has posted its meeting materials typically less than a

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[15] *Id.*
The APCD is not truly an "all" payers database, as it only includes data for 70 percent of the total Washington population. Washington State All-Payer Claims Database and Lead Organization biennial report at 5 (available at https://www.hca.wa.gov/assets/program/apcd-lead-organization-biennial-report-2024.pdf). As an example, self-insured plans submit claims data to the APCD on a voluntary basis, which HCA has acknowledged is a challenge. *See id.* at 21. Prior to considering APCD data for any use, we ask that HCA adopt mechanisms to verify APCD-based data points in light of the well-recognized limitations of these databases. The Board should also provide stakeholders an opportunity to review and comment on any APCD data that the Board intends to rely upon and provide additional data for the Board's consideration.
[16] *See, e.g.*, Letter from PhRMA to Board Regarding Draft Policies and Procedures (Jan. 23, 2024); Letter from PhRMA to Board Regarding Draft Policies and Procedures (Mar. 1, 2024) (providing more details on this request); Letter from PhRMA to HCA (Nov. 20, 2023).
[17] *Id.*
[18] *See, e.g.*, Washington Courts, Types of Alternative Dispute Resolution, available at https://www.courts.wa.gov/programs_orgs/pos_adr/?fa=pos_adr.types.
[19] PhRMA also provides more details about the need for more robust confidential protections in its prior comment letters. *See, e.g.*, Letter from PhRMA to Board Regarding Draft Policies and Procedures 6-8 (Jan. 23, 2024).
[20] *See, e.g.*, Letter from PhRMA to Board Regarding Draft Policies and Procedures (Jan. 23, 2024).

week prior to meeting and has separately indicated that written testimony should be submitted at least one week prior to each meeting.[21] Such a timeline does not provide stakeholders sufficient opportunity to review and submit comments on the materials the Board considers at each meeting.[22] PhRMA restates its request that any notice, agenda, and information packets or other meeting materials be provided to interested stakeholders as far in advance of meetings as reasonably possible and sufficiently far in advance to allow stakeholders a meaningful opportunity to comment in both writing and through in-person attendance at meetings.[23]

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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 materials provided by the Board to date, 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,

Dharia McGrew, PhD
Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[21] *See* HCA, Prescription Drug Affordability Board, https://www.hca.wa.gov/about-hca/programs-and-initiatives/clinical-collaboration-and-initiatives/prescription-drug-affordability-board (last visited June 2, 2024).
[22] *Mahoney v. Shinpoch*, 732 P.2d 510, 516 (Wash. 1987) (stating that "[f]ull consideration of public comment prior to agency action is both a statutory and constitutional imperative.").
[23] *Id.* (emphasizing "[t]he opportunity for public comment [as being] essential to agency rulemaking, not because public comment is invariably helpful in discerning legislative intent but because the agency's authority to act is premised on the functioning of such procedural safeguards."). *See* Letter from PhRMA to Board Regarding Draft Policies and Procedures (Jan. 23, 2024).