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By Electronic Submission to HCA_WA_PDAB@hca.wa.gov

July 12, 2024

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

Re: Washington Prescription Drug Affordability Board July 16, 2024 Meeting: Comments on Draft Eligible Prescription Drugs Policy

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 Drugs Policy" (the "Draft Policy") circulated by the Washington State Health Care Authority ("HCA") in advance of the Prescription Drug Affordability Board's ("PDAB's" or "Board's") July 16, 2024 meeting.[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 has previously described at greater length our concerns with the Board's implementation of the PDAB Statute, and we highlight and reiterate below the following non-exhaustive list of comments and concerns of particular importance regarding the Draft Policy: [2]

[1] PhRMA previously provided comments on various aspects related to HCA and the Board's implementation of SSSB 5532, 2022 Sess. Laws ch. 153 (the "PDAB Statute,") including the proposed regulations thereunder, 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 and codified at Wash. Rev. Code §§ 70.405.010 *et seq*. *See also* Letter from PhRMA to Board Regarding Draft Eligible Prescription Drugs Policy and Other Board Materials (June 18, 2024); 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 established thereunder.
As detailed in our prior comment letters, PhRMA also 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. *See, e.g.*, Letter from PhRMA to HCA Regarding HCA Proposed Regulations (WSR 23-21-082, filed October 16, 2023) (Nov. 20, 2023). PhRMA also remains concerned regarding 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. *See, e.g.*, Letter from PhRMA to Board Regarding Draft Policies and Procedures (Jan. 23, 2024). We additionally reiterate our concern that the Board should not formally adopt draft policies implementing its authority under the PDAB Statute without a notice and comment period consistent with the requirements of the Washington Administrative Procedure Act. *See* Letter from PhRMA to Board Regarding Draft Policies and Procedures 2-3 (Jan. 23, 2024); *see also* Mahoney v. Shinpoch, 732 P.2d 510, 516 (Wash. 1987).
[2] *See* Letter from PhRMA to Board Regarding Draft Eligible Prescription Drugs Policy and Other Board Materials 2 (June 18, 2024); Letter from PhRMA to Board Regarding Draft Methodology (Apr. 11, 2024); Letter from PhRMA to Board Regarding Draft Policies and Procedures (Mar. 1, 2024).

- **Drug Definition and 7-Year Market Requirement**. PhRMA remains concerned that the Board proposes to determine whether a drug has "been on the market" for 7 years, and may therefore be eligible for affordability review, based on how long the relevant "drug *ingredient* has been on the market."[3] Entirely distinct products, approved under separate NDAs or licensed under separate BLAs, may have been marketed for varying lengths of time. We emphasize the importance of considering drugs individually to avoid potential errors. In addition, we reiterate that the Board's approach to the 7-year market requirements does not align with the plain language of the PDAB statute.[4] 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 described in the Draft Policy.[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] To conform the Board's policies with the requirements of the statute, the Board should revise the Draft Policy to 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.[7]

- **Pharmacist Review Standards**. The Eligible Prescription Drugs Policy states that a licensed pharmacist will review certain data elements to "ensure the [Board's] calculations are clinically sound."[8] PhRMA reiterates its request that the Board provide additional, more specific information on the guidelines and safeguards for this process, including specifying the basis the licensed pharmacist will use to determine the clinical soundness of a particular calculation.[9]

- **Stakeholder Review and Appeal Processes**. As described in PhRMA's prior comments, we continue to request that the Board provide manufacturers an opportunity to review and comment on the data that the Board intends to rely upon and provide additional data or context for the Board's consideration, including an opportunity to meet with the Board, before the Board renders a final vote on any selection or affordability review decisions.[10] This process 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.[11]

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[3] Draft Policy at 2-3 (emphasis added). *See also* PDAB Statute § 70.405.030.

[4] *Compare* PDAB Statute § 70.405.030 *with* Draft Policy at 2-3. We also reiterate our concern that the process described in the Draft Policy utilizes a separate definition for "prescription drug" for the purposes of drug eligibility determinations and affordability reviews. *See* Letter from PhRMA to Board Regarding Draft Eligible Prescription Drugs Policy and Other Board Materials 2 (June 18, 2024).

[5] *Id.*

[6] *See* Letter from PhRMA to Board Regarding Draft Eligible Prescription Drugs Policy and Other Board Materials 2 (June 18, 2024); Letter from PhRMA to Board Regarding Draft Policies and Procedures 2–3 (Mar. 1, 2024).

[7] *See Potter v. Dep't of Lab. & Indus.*, 101 Wash. App. 399, 408 (2000) (explaining that a statute cannot be given "an interpretation that is inconsistent with its plain language").

[8] Draft Policy at 2-3. PhRMA also continues to have concern with the Board's procedure for 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).

[9] *See* Letter from PhRMA to Board Regarding Draft Eligible Prescription Drugs Policy and Other Board Materials 2-3 (June 18, 2024).

[10] *See, e.g.*, 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).

[11] PhRMA has provided 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) and Letter from PhRMA to Board Regarding Draft Eligible Prescription Drugs Policy and Other Board Materials (June 18, 2024).

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PhRMA thanks the Board again for this opportunity to provide comments and feedback on the Draft Policy 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,

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