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By Electronic Submission to HCA_WA_PDAB@hca.wa.gov

December 9, 2024

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

Re: Washington Prescription Drug Affordability Board: Comments on Draft Eligible Prescription Drugs Policy and Meeting Materials from November 13, 2024 Meeting

Dear Members of the Washington Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to comment on the meeting materials circulated by the Prescription Drug Affordability Board ("Board") for the November 13, 2024 meeting (the "Meeting Materials"). PhRMA represents the country's leading innovative biopharmaceutical research companies, which are laser 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 has previously commented on various aspects related to the administration of the PDAB Statute[1] at Wash. Rev. Code §§ 70.405.010 *et seq*. and its implementing regulations.[2] We highlight below PhRMA's comments and concerns regarding the Meeting Materials.

I. Need for Improvements and Greater Transparency in Draft Methodology

PhRMA appreciates the Board's staff presentation and documents describing the current Draft Methodology for identifying and selecting drugs eligible for affordability reviews.[3] PhRMA supports the Board's discussion to limit the number of drugs it considers for affordability reviews in the first year.[4] in order to provide critical guidelines that safeguard against arbitrary decision-making by the Board, PhRMA stresses that the Board must advance and publish transparent and consistent details of its drug selection methodology before carrying out any drug selection determinations.[5]

PhRMA highlights the following as non-exhaustive examples of areas where increased transparency and detail are needed to understand the methodologies summarized in the Meeting Materials, as well as additional improvements that the Board should establish before it operationalizes this process:

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[1] SB 5532, 2022 Sess. Laws ch. 153 (codified at Wash. Rev. Code §§ 70.405.010 *et seq*.) (the "PDAB Statute").

[2] Codified at Wash. Admin. Code § 182-52-0005 *et seq. See, e.g.*, Letter from PhRMA to Board Oct. 15, 2024); Letter from PhRMA to Board (July 12, 2024); Letter from PhRMA to Board (June 18, 2024); Letter from PhRMA (Apr. 11, 2024); Letter from PhRMA to Board (Mar. 1, 2024); 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 (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 PDAB Statute and its regulations.

[3] Board, Document on Methodology for Selecting Prescription Drugs for Affordability Review ("Methodology Document"); Board, Presentation on Selecting Prescription Drugs for Affordability Review: Methodology and Results ("Methodology Presentation").

[4] *See* Board, Meeting Transcript for Nov. 13, 2024 meeting, at 13, *available at* https://www.hca.wa.gov/assets/program/pdab-meeting-transcript-november-13-2024.pdf.

[5] *See Relative Motion, LLC v. Dep't of Revenue of the State of Washington*, 19 Wash. App. 2d 1020 ("[R]egulation[s] must be sufficiently clear by providing explicit standards to prevent arbitrary enforcement.").

- **Use of Non-Quantifiable Factors.** While the Board has summarized how it intends to determine the Shortlist, there are gaps in the described methodology. In particular, the Board's draft indicates that the Board would determine a subset of drugs eligible for review using the quantifiable data elements identified in the Methodology Document, but does not detail how those quantifiable elements will be considered in conjunction with the statutorily required non-quantifiable data.[6] The absence of these important details raises serious questions about how the Board will consistently consider *all* statutorily required factors—including non-quantifiable ones.[7] While the Board's presentation mentions these factors, it does not explain as to how the Board is proposing to integrate them into the affordability review selection methodology or require that they be given meaningful weight and applied in a consistent manner across all similarly situated products.[8] PhRMA encourages the Board to deliberate and make clear how these non-quantifiable criteria will be incorporated *prior* to moving forward with selecting drugs for affordability review.

- **Selection of "Shortlist" Drugs.** As the Board and staff continue to discuss the criteria and process for how drugs will be selected for review, we request that the Board develop and publish a clear, consistent, and comprehensive methodology for how it intends to make its selections. We note that the November meeting materials introduced an Affordability Review Shortlist ("Shortlist"), but does not provide or build on any previous discussion or policy regarding a Shortlist prior to selecting drugs for review. The meeting included Board member and staff discussions of different methods that might be used to select drugs for affordability review. At this time, however, no substantive detail has been provided as to how the Board will go about making the ultimate determination of the drugs selected for affordability reviews. More granular detail is needed to allow stakeholders to assist the Board in identifying any errors or oversights before it operationalizes an inherently complex and multi-faceted process.[9]

- **Underlying Data**. While, as noted above, the Board has outlined the quantitative data measures that it intends to use to create the Shortlist, PhRMA urges the Board to also make available the underlying data when as it operationalizes the methodology, so stakeholders can review and provide feedback on the measures that are utilized to determine the Shortlist.[10]

- **Notice and Comment Rulemaking.** While PhRMA understands the Board is still developing its draft affordability review selection methodology, we emphasize that the Board should not adopt a final

[6] Methodology Document at 9-13. With respect to the quantifiable data measure "Total Plan Paid amount," PhRMA is also concerned that the Board's formula appears to include the total copay, coinsurance, and deductible amount. But the total plain paid amount should *not* include these items; rather, they should be subtracted from the total plan paid amount—because they are paid by *enrollees*, not the plan. *See* Methodology Document at 4-5. Additionally, PhRMA recommends that the Board consider displaying data in a histogram format. *See* Letter from PhRMA to Board Regarding Comments on Draft Eligible Prescription Drugs Policy and Meeting Materials (Oct. 15, 2024).

[7] For example, when deciding whether to conduct an affordability review, the PDAB statute requires that the Board consider "(a) [t]he class of the prescription drug and whether any therapeutically equivalent prescription drugs are available for sale and (b) [i]nput from relevant advisory groups established pursuant to RCW 70.405.020." Wash. Rev. Code § 70.405.040 (1)(a)-(b).

[8] *See* Board, Methodology Presentation at slide 23 ("Drug class, price, and availability of therapeutic equivalents; Input from relevant advisory groups; Drug meets multiple thresholds of the legislative definition"); *State v. Rushing*, 77 Wash. App. 356, 358, 890 P.2d 1077, 1079 (1995) (Persons and entities "similarly situated with respect to the legitimate purpose of the law must receive like treatment" and cannot be subject to arbitrary legal distinctions).

[9] *See also* the discussion of the need for notice and comment rulemaking consistent with the Washington Administrative Procedure Act, below.

[10] Such data should be made available subject to appropriate protections for confidential, proprietary, and trade secret data. *See* Letter from PhRMA to Board Regarding Draft Policies and Procedures (Jan. 23, 2024). PhRMA also requests that the Board reflect in guidance the most recent data that will be utilized to determine the Board's methodologies for selecting prescription drugs for affordability review.

methodology until after adequate notice and a full comment period that comports with the requirements of the Washington Administrative Procedure Act ("APA"). The methodology for selecting drugs for affordability review will provide binding guidelines for how the Board will ultimately exercise its authority under the PDAB statute. Accordingly, the methodology will establish binding rules carrying the force and effect of law that will impact the substantial rights and obligations of members of the public, including manufacturers impacted by the Board's affordability review decisions. The Washington APA requires that such rules be promulgated through notice and comment rulemaking, not merely issued through informal guidance.[11] Consistent with APA requirements, once the Board has completely developed a draft methodology, it should formally propose that draft in a proposed rule issued in the Washington State Register, and should provide a full and separate opportunity for stakeholders to comment on the proposed rule.[12]

- **Use of All Payers Claim Database ("APCD").** PhRMA recognizes the Board's discussion and acknowledgement that the APCD does not capture data from all payers and the data on prescription drugs does not account for net cost (e.g., after rebates and discounts).[13] Additionally, the reliance on APCD data may skew costs upwards due to hospital markups on drugs. Research shows that spending is higher for medicines administered in hospital outpatient departments relative to non-hospital-owned physician offices because of differences in commercial insurance reimbursement rates, rather than differences in the type or intensity of treatment.[14] On average, hospital outpatient departments markup physician-administrated drugs for commercially insured patients three times the amount received by physician offices.[15] Moreover, a study in the *Journal of the American Medical Association* found that for 25 commonly used oncology medicines, the median mark-up for hospital administered cancer therapies charged to commercial insurers ranged from 118 percent to 634 percent of the acquisition cost.[16]

- **Lack of Consideration of Rebates.** PhRMA is concerned that the Board's use of APCD data to calculate a drug's "Total Paid Amount" does not provide an amount that is net of rebates.[17] In the Board's initial ranking exercise, Total Paid Amount was ranked highly by Board members, and therefore the placement of drugs higher on the Board's ranking may reflect a drug's gross price rather than the actual amount paid by payers.[18] Rebates are essential to the affordability review process as they indicate the actual amount that patients and consumers are paying on prescription drugs.

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[11] "Full consideration of public comment prior to agency action is both a statutory and constitutional imperative. The opportunity for public comment is essential to agency rulemaking ... because the agency's authority to act is premised on the functioning of such procedural safeguards." *Mahoney v. Shinpoch*, 732 P.2d 510, 516 (Wash. 1987) (explaining the purpose and scope of the notice and comment requirement under the Washington APA).

[12] *See* Wash. Rev. Code §§ 34-05-310 – 395.

[13] *See* Board, Methodology Document at 2; Methodology Presentation at slide 29; Meeting Transcript for Nov. 13, 2024 meeting, at 13. For further discussion regarding the limitations of APCD data, *see* Letter from PhRMA to Board Regarding Comments on Draft Eligible Prescription Drugs Policy and Meeting Materials (Oct. 15, 2024); Letter from PhRMA to Board Regarding Draft Eligible Prescription Drugs Policy and Other Board Materials (June 18, 2024); Letter from PhRMA to HCA Regarding August 2023 Draft Regulations (Aug. 15, 2023).

[14] Xiao R, Ross JS, Gross CP, et al. Hospital-Administered Cancer Therapy Prices for Patients With Private Health Insurance. *JAMA Intern Med.* 2022;182(6):603–611. doi:10.1001/jamainternmed.2022.1022.

[15] Employee Benefit Research Institute. Cost Differences for Physician-Administered Outpatient Drugs. 2021. Interactive Web Graphic. https://www.ebri.org/publications/research-publications/ebrinteractive/cost-differences-for-physician-administered-outpatient-drugs. Employee Benefit Research Institute. Shifting From Hospital Outpatient Departments to Physician Offices Equates to Significant Cost Reductions. 2021. https://www.ebri.org/docs/default-source/fast-facts-(public)/ff.405.locationx3.9sep21.pdf?sfvrsn=286a3b2f_4

[16] Xiao R, Ross JS, Gross CP, Dusetzina SB, McWilliams JM, Sethi RKV, Rathi VK. Hospital-Administered Cancer Therapy Prices for Patients With Private Health Insurance. *JAMA Intern Med*. 2022 Jun 1;182(6):603-611. doi: 10.1001/jamainternmed.2022.1022.

[17] *See* Methodology Presentation at Slide 7; Methodology Document at 2.

[18] Methodology Presentation at Slide 13.

- **Comparison to Other States.** PhRMA recommends that the Board refrain from comparing lists of drugs selected in other state PDABs, as each state's PDAB law charges the particular state with an evaluation of affordability challenges based on data and considerations that are particular to that state's population and are structured differently within each state's PDAB statue and regulations.[19] Comparisons across states that ignore differences in those states' context would be inherently misleading. Further, reliance on other states' selections ignores the complexities that these other states are themselves experiencing in implementing their states' PDAB processes. For example, one of the states that the Board references, Oregon, has paused affordability reviews as of June 2024 to "improve both the criteria and methods used to assess and select drugs for potential affordability reviews in 2024, using a refreshed set."[20]

II. Concerns Related to Eligible Prescription Drug Policy

PhRMA reiterates our concerns on the Draft Policy as stated in our previous letter.[21] PhRMA remains particularly concerned with the seven year market requirement, which requires that the Board identify prescription drugs based on if the drug ingredient has been on the market for at least seven years.[22] As previously stated, the PDAB Statute requires that the seven year market requirement be based on how long a "prescription drug" has been on the market, rather than a "drug ingredient."[23] PhRMA reiterates our recommendation that the Board update its Policy to consider drugs that have been on the market for at least seven years individually based on distinct New Drug Applications ("NDAs") and Biologic License Applications ("BLAs").[24] The Board should revise the Draft Policy to clarify that the seven year market requirement applies to the length of time that a particular prescription drug, which is approved under the relevant NDA or BLA, has been on the market.

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PhRMA thanks the PDAB for the opportunity to offer comments and feedback on these Meeting Materials and for your consideration of our concerns. Despite ongoing concerns, PhRMA remains committed to being a constructive partner in this dialogue. If there is additional information or technical assistance that we can provide, please contact dmcgrew@phrma.org.

Sincerely,

Dharia McGrew, PhD
Director, State Policy
Sacramento, CA

Merlin Brittenham
Assistant General Counsel, Law
Washington, DC

[19] *See* Methodology Presentation at Slide 24-25.
[20] *See* Oregon Prescription Drug Affordability Board, PDAB Approved Minutes, *available at* https://dfr.oregon.gov/pdab/Documents/20240626-PDAB-approved-minutes.pdf (July 24, 2024).
[21] *See* Letter from PhRMA to Board Regarding Comments on Draft Eligible Prescription Drugs Policy and Meeting Materials (Oct. 15, 2024).
[22] *See* Board, Draft Policy, at 1.
[23] PDAB Statute § 70.405.030.
[24] *See* Letter from PhRMA to Board Regarding Comments on Draft Eligible Prescription Drugs Policy and Meeting Materials (Oct. 15, 2024); Letter from PhRMA to Board Regarding the Draft Eligible Prescription Drugs Policy (July 12, 2024); Letter from PhRMA to Board Regarding Draft Methodology (Apr. 11, 2024).