PhRMA
RESEARCH • PROGRESS • HOPE
950 F STREET, NW, SUITE 300 • WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

By Electronic Submission to HCA_WA_PDAB@hca.wa.gov

January 23, 2024

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

Re: Washington Prescription Drug Affordability Board: Draft Policies and Procedures

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 policies and procedures ("Draft Policies") circulated by the Washington State Health Care Authority ("HCA") on December 8, 2023 in advance of the Board's December 11, 2023 Prescription Drug Affordability Board ("PDAB" or "Board") 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 Draft Policies.[1]

I. Lack of Full and Fair Opportunity for Public Comment

PhRMA is concerned that the PDAB's practices do not provide adequate opportunity for public comment on its agenda and meeting materials or on the Draft Policies.

A. *Public Comment on the Draft Policies*

HCA has not expressly solicited comment on the Draft Policies and, accordingly, did not articulate a clear process for stakeholders to provide feedback on them. As PhRMA has explained in more detail in its prior comment letters, the Washington Administrative Procedure Act ("APA") requires a full and fair opportunity for public comment on any proposed rule, including any interpretive rule.[2] The Draft Policies

[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 HCA Regarding Health Care Authority 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 (August 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] *See* Letter from PhRMA to HCA Regarding HCA Advance Notice 2 (August 25. 2020); *see also Ass'n of Washington Bus. v. State of Washington, Dep't of Revenue*, 439, 120 P.3d 46, 53 n.16 (Wash. 2005) ("[U]nlike Washington state agencies, federal agencies can adopt interpretive rules without using the notice-and-comment process."); *see also* RCW 34.05.230 (providing for "advisory only" interpretive and policy statements, for which an agency must provide a notice for publication in the state

interpret and specifically define the contours of the Board's (and Advisory Group's) meetings, the affordability review process, and procedures for maintaining the confidentiality of confidential, proprietary, and trade secret information. These contours provide critical guidance as to how the Board will ultimately implement and operate its authority under the PDAB Statute. Interpretive guidance like the Draft Policies should only be adopted after adequate notice and a full comment period that comports with the requirements of the Washington APA. As the Supreme Court of Washington has explained:

> "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."[3]

We ask the Board not to formally adopt the Draft Policies until HCA has provided an APA-compliant notice-and-comment process to allow for public comment on them. The public should be given clear advance notice and opportunity to meaningfully comment on these types of interpretive guidance given their sheer importance to ensuring fair, reliable, and consistent implementation of the PDAB Statute. Accordingly, PhRMA urges HCA to submit its Draft Policies to the APA's notice-and-comment rulemaking process, consistent with the "statutory and constitutional imperative" of "[f]ull consideration of public comment prior to agency action."[4]

B. Public Comment on Board Meeting Proceedings

PhRMA is also concerned that the Draft Policies do not provide adequate opportunity for written feedback from interested members of the public as part of the Board meeting process. Notably, the Draft Policies state that the Board "may" provide opportunity for public comment at each meeting or in writing.[5] And the Board's website indicates that written testimony is limited to a "one page maximum" due at least one week before the meeting.[6] An arbitrary page limit, as well as lack of clarity as to whether comments will be received and reviewed by the Board, could prevent stakeholders from having a full or fair opportunity to voice their specific concerns in a detailed manner. We urge the Board to clarify that it "will" accept <u>all</u> public comments in written form and that it will not unduly limit the length or scope of written comments that it considers.

Further, PhRMA is concerned that the meeting procedures described in the Draft Policies fail to provide an opportunity for full and fair comment by stakeholders. For example, to date HCA has only provided a short timeline (less than a week) for meeting materials to be reviewed prior to both of its meetings, a timeline which is inconsistent with the Board's Draft Policies.[7] As a result, written testimony for PDAB meetings has been due <u>before</u> HCA announces the topics at issue for discussion, provides an agenda, or

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register to describe the statement, with express legislative encouragement to convert longstanding statements into rules "[t]o better inform and involve the public").

[3] *Mahoney v. Shinpoch*, 732 P.2d 510, 516 (Wash. 1987).

[4] *Id.*

[5] *See* Draft Policies § 3(D).

[6] 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 Jan. 10, 2024).

[7] Draft Policies § 3(D) ("The agenda will be posted on the Board's website no less than 24 hours prior to the Board meeting.").

publishes its meeting packet. Reasonable standards must give the public notice of the topics for consideration sufficiently far in advance to prepare meaningful written testimony for the Board's consideration. Pre-meeting disclosures should also not be limited only to the Board's agenda. The Draft Policies should also require the Board to disclose any other notices or non-confidential information under consideration at the meeting so that members of the public can adequately review and provide meaningful comment at meetings or through written submissions.[8] As such, PhRMA requests that any notice, agenda, and similar information packets be provided to interested stakeholders as far in advance of meetings as reasonably possible and always sufficiently far in advance to allow stakeholders a meaningful opportunity to comment in both writing and through in-person attendance at the meetings.

II. Lack of Clear and Meaningful Standards and Processes

As described in our prior comments on HCA's proposed rules,[9] PhRMA continues to have significant concerns regarding the lack of clear and meaningful standards and processes in the Draft Policies for the how the Board will conduct its activities and decision-making. In particular, the Draft Policies lack sufficient specificity and clarity, both in substance and procedure, to adequately guide the Board's work in administering the PDAB Statute. The current Draft Policies, as written, would not adequately guard against the risk of arbitrary and inconsistent decision-making and raise fundamental questions about the adequacy of the draft procedures.[10]

Because they lack critical details about important Board processes, the Draft Policies raise significant concerns regarding whether the Board will operate in a consistent and non-arbitrary manner. PhRMA highlights the following as a non-exhaustive list of examples of the lack of clear standards within the Draft Policies:

- Meeting Procedures (Voting).[11] The Draft Policies do not address whether the Board will vote at each meeting after discussing a specific drug or after reviewing a slate of multiple drugs. HCA should clarify its intended timing and process to ensure that stakeholders understand the procedures associated with the Board's votes and that such procedures are implemented by the Board in a consistent fashion.

- Recusal Procedures. The Draft Policies only appear to require recusal for Board members with a conflict of interest with a pharmaceutical company or drug.[12] This is inconsistent with the PDAB Statute, which is clear that recusal is required for all conflicts of interest and is not limited to

[8] *See* Section IV, below, for a more detailed discussion of confidentiality issues.
[9] Letter from PhRMA to HCA Regarding Health Care Authority 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 reiterates its concerns that HCA and the Board have not provided specific, concrete, and meaningful details for how the Board will conduct its processes for identifying eligible drugs and conducting affordability reviews and standards that explain how the Board will make use of the information it obtains from various disparate sources, including how information will be weighed, compared, and considered both independently and relative to other information and factors considered by the Board.
[10] *See, e.g.*, *Silverstreak, Inc. v. Washington State Dep't of Lab. & Indus.*, 159 Wash. 2d 868, 890 (2007) ("Regulations are unconstitutionally vague if they allow an administrative agency to make arbitrary discretionary decisions.").
[11] *Id.*
[12] *See* Draft Policies § 3(E)(iv) (only expressly referencing "pharmaceutical companies").

conflicts involving pharmaceutical manufacturers.[13] Even further, the statute specifically prohibits Board and Advisory Group members from being an employee, board member, or consultant of a *pharmacy benefit manager ("PBM"), health carrier, wholesale distributor, drug manufacturer, or associated trade association*.[14] The Draft Policies should be revised to be consistent with the statute; specifically, the Draft Policies should be updated to clarify that conflicts of interest requiring recusal are not limited to individuals who have an employment or other relationship with a manufacturer, but also situations where individuals have disqualifying relationships with other entities in the prescription drug supply chain (e.g., payers, distributors, PBMs, and associated trade associations). In addition, HCA should revise its Draft Policies to state that Board staff "shall" (rather than "may") recuse themselves in the case of conflicts of interest. Such recusal is required under the PDAB Statute.[15]

- Conflict of Interest Procedures. HCA should adopt an express definition of "conflict of interest" in its Draft Policies and clarify the difference between "conflict[s] of interest," "actual conflict[s] of interest," and the "appearance of impropriety." Each of these terms is used in the Draft Policies, but without a clear definition or procedures for how such conflicts are to be distinguished. The Draft Policies should be revised clarify how recusal requirements apply to "appearances of impropriety" versus "actual" conflicts of interest.

  In addition, HCA should clarify which entities constitute "competitors" for purposes of the Board's conflict of interest procedures. The Draft Policies' conflict of interest procedures prohibit an Advisory Group member who is a representative from the prescription drug industry from being an employee, consultant, or board member of the manufacturer whose drug is being reviewed, "or a competitor" of that manufacturer.[16] PhRMA urges HCA to adopt a clear and reasonable definition of "competitor," as it is currently unclear what would constitute a disqualifying competitor relationship.

- Coordination with Other Entities. HCA should update its Draft Policies to require transparency in the information and analyses that the Board is obtaining through coordination with other entities. There can be notable differences in the reliability and comparability of different data sources, and the Board should be transparent to the public about where different information and analyses are being obtained, such that interested members of the public can meaningfully provide feedback on such data sources.

- Interaction with Media and Lobbyists. HCA should provide clarity regarding the definition of a "lobbyist" for purposes of the Board policy on interaction with the media and lobbyists. Lack of clarity about who constitutes a lobbyist could inhibit substantive participation during Board meetings by members of the public.

[13] PDAB Statue § 70.405.020(3).
[14] *Id.* (a statutory exception also exists for a representative from the prescription drug industry serving on an advisory group).
[15] *Id*.
[16] Draft Policies § 3(E).

- Identifying Prescription Drugs for Affordability Reviews.

    - PhRMA urges HCA and the Board to be cognizant of the potential for errors and discrepancies that may exist in the data and information that the Board relies upon, especially given that HCA's regulations and Draft Policies contemplate application of a complex methodology that involves compiling and analyzing data from a potentially broad and diverse set of data sources.

      Given this potential for errors and discrepancies, PhRMA urges HCA to establish a process for manufacturers to review the Board's data and raise any technical questions or concerns with the Board before it moves forward with the affordability review process. This process should include a mechanism 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.[17]

    - The Draft Policy states that "methodologies used to extract data" to identify eligible drugs will be "publicly presented to the Board, or presented in executive session, as applicable."[18] PhRMA urges HCA to clarify that the Board will allow for public discussion of all non-confidential components of its extraction methodologies. Given the important role of data extraction in the Board's affordability review process, it is important that all non-confidential aspects of the Board's methodologies be discussed in a public forum to allow manufacturers and other stakeholders the opportunity to fully weigh in and provide meaningful comment on the specific technical details of the Board's methodological approaches.[19]

    - HCA should also revise its Draft Policies to require that the list of eligible prescription drugs is published at least sixty days prior to conducting any review. This will give interested members of the public an opportunity to review the list in advance. Among other things, this will better allow members of the public to help the Board identify any inadvertent errors or inaccuracies in the list of eligible drugs before any review is initiated.

III. Use of International Pricing Information

PhRMA is also concerned by the Draft Policies' statement that Board staff will compile information from other states "or other countries as appropriate."[20] Before it considers any such information as part of an affordability review, the Board should carefully evaluate whether any international pricing information obtained by its staff members provides a meaningful comparison to drug prices in Washington state.

[17] *See* Section IV, below.
[18] Draft Policies § 6(A).
[19] *See* Section IV, below, for a more detailed discussion of confidentiality issues.
[20] Draft Policies § 6(A)(i).

International pricing information is often subject to significant confidentiality requirements and may be confidential by law. Manufacturer agreements with sovereign entities like England, for example, include strict requirements of confidentiality. Contracts are often executed nationally with PBMs, and in most cases, the manufacturer would not know PBMs' contract terms with various in-state insurers. Moreover, there are likely to be challenges in obtaining international pricing information across a consistent standard (e.g., based on a WAC equivalent standard). As a result, it is imperative that HCA and the Board recognize the legal and practical barriers associated with the use of such international pricing information, especially when dealing with jurisdictions that have stringent regulations regarding government pricing data.

Additionally, comparing drug prices in the United States to prices in other countries is an apples-to-oranges comparison because it involves comparing list, or gross, domestic prices to the government-set net prices in foreign countries. These misleading comparisons ignore the hundreds of billions of dollars – $256 billion in 2022[21] – in rebates and discounts manufacturers provide that lower the price of medicines in the United States. In many countries, governments are the primary or only payer of health care and in effect dictate the prices of medicines as a condition of market access. Practices like these force artificially low prices, delay patient access to new medicines, and keep some innovative treatments off the market entirely.

IV. Confidentiality

PhRMA also continues to have serious concerns about the lack of sufficient protections for confidential, proprietary, and trade secret information in the Draft Policies. Consistent with the concerns raised in PhRMA's August and November 2023 comments regarding the Board's proposed regulations, the Draft Policies do not implement adequate safeguards for manufacturers' (and other stakeholders') confidential, proprietary, and trade secret information, and they thereby create a serious risk of unlawful disclosures.

Under the PDAB statute, the Legislature has provided that "[*a*]*ll* information collected by the board" during the affordability review process "is confidential and not subject to public disclosure."[22] The Draft Policies are inconsistent with the plain language of the statute because they narrow the definition of "confidential information" to "(a) [s]pecific information collected by the authority that is not publicly available for the purposes of 'Chapter'; or (b) [information that] [i]s proprietary data provided by manufacturers in accordance with 'Chapter' that is not subject to public disclosure."[23] But the PDAB statute is clear that *all* collected information is confidential and must be treated as such. The Draft Policies should be modified to conform to the full scope of the statute's confidentiality mandate.

In addition, HCA should modify its Draft Policies to state that the Board will individually evaluate all information received from all parties—not merely manufacturer-provided information—to identify potential confidential, proprietary, and trade secret information. As PhRMA has previously explained in detail, the Board may solicit information from multiple stakeholders that possess relevant information obtained from other entities. There is a significant risk that the submitter may not appropriately label the

[21] Fein, A. "The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute. March 2023

[22] PDAB Statute § 70.405.040(7) (emphasis added).

[23] Draft Policies § 6(C)(iii).

confidential, proprietary, or trade secret information of another entity, including because the submitter may not recognize that the information is treated as such by the other entity.[24]

Moreover, the Draft Policies do not explain how the Board will determine if other information is confidential. The current process outlined in the Draft Policies appears to only contemplate an evaluation of whether information designated as "confidential" by manufacturers is "confidential pursuant to state and federal law."[25] It is crucial that HCA establish a more comprehensive process to adequately protect the confidentiality of the sensitive information that the Board obtains as part of the affordability review process.

In addition, to guard against inadvertent disclosure of protected information, HCA should establish a mechanism for advance judicial review of the PDAB's determination that any information is subject to public release and should afford affected stakeholder the opportunity to appeal any such determination. Without such an opportunity, the statute's protection for confidential, proprietary, and trade secret information would be illusory—raising serious due process, takings, and other constitutional concerns.

PhRMA is also concerned about the continued lack of detail regarding how confidential information will be stored and safeguarded. The Draft Policies describe the involvement of other entities in addition to the Board, but they fail to provide specific and meaningful rules, policies, or procedures for how confidential information should be stored or handled within HCA, including rules about who will have access to confidential information.[26]

The Draft Policies similarly fail to provide adequate processes to safeguard information accessible by third-party contractors. The Draft Policies state that "[t]he Authority may enter into contracts with qualified, independent third-parties for services necessary to carry out the powers and duties of the Board. All third-party contractors are required to enter into a nondisclosure agreement to protect trade-secret, confidential, or proprietary information."[27] But there is no detail regarding which contractors will have access to such information or how access will be governed or controlled, such as limiting contractor access to the minimum level necessary for the contractor to fulfill its obligations. Further, the Draft Policies allow the Board to "coordinate" with other entities whose "responsibilities and interests overlap in creating transparency for the cost of prescription drugs and determining the affordability of prescription drugs for Washington consumers,"[28] but the Draft Policies do not provide procedures for limiting these entities' access to confidential, proprietary, and trade secret information. The Board should revise its Draft Policies to include specific rules on who will be permitted access to such data; how it will be stored; and how access to the data will be governed, including the consequences for any impermissible disclosure of confidential, proprietary, and trade secret information.

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[24] *See* Letter from PhRMA to HCA Regarding August 2023 Draft Regulations 10 (Aug. 15, 2023).
[25] *Id.*
[26] *See* Draft Policies § 6(C)(iii) (merely providing that "[i]f confidential information has been submitted for the Board's consideration, Staff will separately distribute a confidential Board meeting packet containing materials identified as having confidential information," without detailing the process for who will have access to the confidential information, including which "staff" will have access).
[27] Draft Policies § 4.
[28] Draft Policies § 3(H).

Finally, HCA should clarify that the Board will discuss confidential information only in executive session.[29] The Draft Policies state that "[t]o the extent the Board deliberates [on] such confidential information, the deliberations may take place in executive session."[30] Consistent with the Board's constitutional and statutory obligations, PhRMA requests that the language be changed to state that "the deliberations *must* take place in executive session."

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PhRMA thanks HCA again for this opportunity to provide comments and feedback on the Draft Policies and for your consideration of our concerns and requests for revisions. Although PhRMA continues to have concerns with the Draft Policies, we stand ready to be a constructive partner in this dialogue. If there is additional information or technical assistance that we can provide as these regulations are further developed, please contact dmcgrew@phrma.org.

Sincerely,

Dharia McGrew, PhD
Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[29] As explained above, it is, however, also crucial that discussion of *non*-confidential information (including substantive discussion of eligible drug selection and drug affordability) occur in open meetings and not in closed executive sessions, so that members of the public can be fully apprised of such non-confidential proceedings.
[30] Draft Policies § 6(C)(iii).