724 Columbia St. NW, Ste. 310 • Olympia, WA 98501 • PHRMA.ORG

January 7, 2025

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

Re: Oregon Prescription Drug Affordability Board: December 18, 2024 Agenda and Meeting Materials

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing in response to the Oregon Prescription Drug Affordability Board's (the "Board's") agenda packet for its December 18, 2024 meeting, including the Board's draft proposed policy recommendations, draft 2024 Annual Report for the Oregon Legislature, and affordability review presentation documents (collectively, the "Meeting Materials").[1] 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.

Since 2022, PhRMA has raised significant administrative and operational concerns about the process and work of the Board, including with respect to implementation of affordability reviews and the Board's development of its Upper Payment Limit ("UPL") plan.[2] The Board itself has recognized issues with respect to its processes, as evident by its decision on June 26, 2024 to postpone further affordability reviews until 2025 while it reviews and improves its affordability review criteria and methods. Despite these concerns, the Meeting Materials fail to meaningfully address the concerns that led to the halting of affordability reviews. PhRMA is also concerned that the presentation to the Interim Senate Health Care Committee on December 11, 2024 provided an overly simplified view of the complexity of matters before the PDAB and underplayed the multitude of stakeholder concerns that have been raised throughout the process.[3] As detailed further herein, we ask that the Board continue to develop its policy recommendations and affordability review procedures to provide much needed clarity and sound and consistent decision-making.

[1] Meeting Materials (Dec. 18, 2024), *available at* https://dfr.oregon.gov/pdab/Documents/20241218-PDAB-document-package.pdf.

[2] PhRMA has filed 32 comment letters to date with the Oregon PDAB, detailing, among other things, our ongoing concerns with the Board's affordability review process and procedures, as well the Board's UPL Study process. In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to the Oregon PDAB statute and the Board's implementation thereof. PhRMA also incorporates by reference all prior comment letters to the extent applicable. *See, e.g.*, Letter from PhRMA to Board (Nov. 26, 2024) (commenting on Draft UPL Study); Letter from PhRMA to Board (Sept. 15, 2024) (commenting on draft UPL approaches and draft policy recommendations); Letter from PhRMA to Board (June 28, 2024) (commenting on manufacturer survey); Letter from PhRMA to Board (Apr. 13, 2024) (commenting on draft revisions to affordability review template and generic drug report); Letter from PhRMA to Board (Mar. 15, 2024) (commenting on annual fees paid by drug manufacturers); Letter from PhRMA to Board (Feb. 17, 2024) (commenting on affordability reviews); Letter from PhRMA to Board (Oct. 15, 2023) (commenting on affordability review rule OAR 925-200-0010); Letter from PhRMA to Board (Sept. 16, 2023) (commenting on affordability review proposed timeline and data integrity issues).

[3] *See* https://olis.oregonlegislature.gov/liz/2023I1/Committees/SHC/2024-12-11-08-30/Agenda (testimony of Ralph Magrish, Executive Director, Oregon Prescription Drug Affordability Board).

I. Draft 2024 Annual Report[4]

PhRMA is concerned that the Draft Annual Report downplays the obstacles that the Board has encountered with respect to its affordability reviews and other processes and fails to meaningfully grapple with the ongoing and necessary changes to the Board's processes. The Draft Annual Report exemplifies PhRMA's overarching concerns with the lack of context and transparency in the information disseminated by the Board.

PhRMA continues to have serious concerns about the Board's processes for drug selection and affordability reviews. PhRMA and other stakeholders previously warned of the problems inherent in the Board's failure to set forth clear and adequate criteria and methods in its processes.[5] While the Board's Meeting Materials outline potential updates to the process, PhRMA asks the Board to clarify how the affordability review process has been improved from the process that was suspended in 2024. The Board's draft 2024 Annual Report states that "[f]or the affordability reviews starting in 2025," the Board "has initiated a five-phase strategy to evaluate the cost of prescription medications in Oregon."[6] But these five phases appear to be substantially similar to the steps set forth in the prior iteration of the Board's affordability review process.[7] Although the report states that "[t]he information provided by the DPT has been enhanced through improved data cleaning, verification, and source validation," and that Board staff will use Medi-Span to source certain product data, the selection process outlined in the December Meeting Materials largely mirrors the previous process.[8]

Further, the details of the phases described in the Draft Annual Report are largely limited to the drug selection process and, and do not provide detail regarding changes the Board intends to implement in its affordability reviews.[9] While the Meeting Materials note that "[r]ecent enhancements to the affordability review process also included a comprehensive restructuring of the organizational headings and sections of the drug material packet," to align more "closely with statutory and regulatory requirements,"[10] it is not

[4] Consistent with our prior comment letters, PhRMA also reiterates the importance of maintaining the confidentiality of all sensitive, proprietary, trade secret, and otherwise confidential information submitted to the Board and asks that the Board adopt further guidelines for how this information will be protected from unlawful disclosure. *See, e.g.*, Letter from PhRMA to Board 7–8 (Feb. 11, 2023) (outlining PhRMA's confidentiality concerns in detail, and explaining the confidentiality obligations of the Board under state and federal law); *see also* Letter from PhRMA to Board 3 (Oct. 15, 2023); Letter from PhRMA to Board 3 (June 23, 2023); Letter from PhRMA to Board 1 (Aug. 1, 2023).

[5] *See, e.g.*, Letter from PhRMA to Board (Feb. 17, 2024); Letter from PhRMA to Board (Oct. 15, 2023).

[6] Meeting Materials 16.

[7] *Compare id.* at 32–33, *with* Meeting Materials 42–48 (Nov. 15, 2023), *available at* https://dfr.oregon.gov/pdab/Documents/20231115-PDAB-document-package.pdf.

[8] *See* Meeting Materials 32.

[9] For example, the Board has not explained how it will assess the "[f]inancial impacts to health, medical or social services costs compared to therapeutic alternative[s]," even though this data gap was apparent in the prior attempts to conduct affordability reviews. Meeting Materials 35 (citing OAR 925-200-0020); *see also, e.g.*, Humulin R U-500 KwikPen Affordability Review - Version 2, at 9–10 (Jan. 26, 2024), *available at* https://dfr.oregon.gov/pdab/Documents/Affordability-Review-Humulin-R-U-500-v2.pdf (acknowledging drawbacks of using package wholesale acquisition cost (WAC) as an indicator of historic price trends for the drug and noting that "[n]o additional data or information was found or provided to reflect the relative financial effects of the prescription drug on broader health, medical, or social services costs, compared with therapeutic alternatives or no treatment" and "[n]o additional data or information was found or provided to quantify the total cost of the disease and the drug price offset"); Ozempic Affordability Review Updated 12 (May 15, 2024), *available at* https://dfr.oregon.gov/pdab/Documents/20240515-PDAB-document-package.pdf#page=5 (explaining that estimated net price for therapeutic alternatives "is not included due to lack of information in discounts, rebates, and other price adjustments"); Trulicity Affordability Review Updated 9 (May 15, 2024), *available at* https://dfr.oregon.gov/pdab/Documents/20240515-PDAB-document-package.pdf (same).

[10] *Id.* at 17.

clear what material changes the Board has considered or implemented for the process of conducting affordability reviews of selected drugs.[11]

The Board's Draft Annual Report additionally states that some elements, including the affordability review template, will be updated in the future, while also discussing "recent enhancements" to the template. The most recent template was published in April 2024, *prior to suspension of affordability reviews*.[12] PhRMA raised continuing concerns with the April 2024 draft revised template that appear to remain unaddressed.[13] The Meeting Materials indicate that "[t]he updated material review packet *will* also include indicators about data sourcing, limitations in scope, and available resources," but the specifics of these changes have yet to be provided to the public.[14] Without providing stakeholders with information regarding what additional data or information sources may be included in additional template revisions, it is unclear how these changes will address the concerns raised by Board members and stakeholders.

The absence of clear and consistent standards, for example in the definition of affordability, was an important part of the decision to pause affordability reviews in June 2024.[15] The Board has yet to have public discussions and revisit this issue. Despite the obvious importance of such standards, the Draft Annual Report does not provide any new information nor has the Board yet at any discussions of how these factors will be addressed in a concrete and comprehensive manner.[16]

II. Initial, Preliminary List of Prescription Drugs

It is unclear how these preliminary published data have been compiled and arranged.[17] PhRMA highlights the following non-exhaustive examples of the lack of clear standards and processes within the drug eligibility and affordability review procedures:

- **Drug Eligibility:** Although the file "Carrier_2023_Preliminary aggregated_information_v01" appears

[11] *See* Meeting Materials 17 (describing "Phase 4: Conducting the affordability review" by referring to "OAR 925-200-0020" and "Affordability review material packet").
[12] *See* Meeting Materials 11–28 (Apr. 17, 2024) [hereinafter "April Meeting Materials"], *available at* https://dfr.oregon.gov/pdab/Documents/20240417-PDAB-document-package.pdf. The Board reports that it "took proactive steps to redesign the affordability review template" in the spring of this year, publishing a revised template in advance of the Board's April 17, 2024 meeting prior to suspension of affordability reviews in June 2024. Meeting Materials 15; *see also* April Meeting Materials 11–36. It is unclear whether the Board has taken any additional steps to revise the packet since this time.
[13] *See* Letter from PhRMA to Board 1–3 (Apr. 13, 2024) (discussing April Meeting Materials 18–35). For example, PhRMA noted that several fields lacked clarity as to the information the Board intends to consider, such as reporting of a "PBM Concession" as an element of the "[b]reakdown of ... gross to net costs" for each drug under review, as well as the "input from specified stakeholders." *Id.*
[14] Meeting Materials 17 (emphasis added).
[15] Meeting Recording (June 26, 2024), *available at* https://youtu.be/9z2VkDiR_XA?si=pu2JpLRrtj9nZloe&t=1860 (statement of Board member John Murray: "What does 'affordability' mean to this Board? .. That's the kind of discussion I need to hear and have to end up with a concept that I can work off of to make decisions …."); Meeting Recording (June 26, 2024), *available at* https://youtu.be/9z2VkDiR_XA?si=PLikEaOvFpuZPSRS&t=1380 (statement of Board member Daniel Hartung: "I also support this pause and reset … I think we can get maybe back to first principles … really thinking about what affordability means as others have indicated ….").
[16] *See* Meeting Materials 37-38 (reciting statutory and regulatory criteria without elaboration); *cf.* Letter from PhRMA to Board 2 (Feb. 11, 2023) (noting that the Board's affordability review "enumerates factors as varied as '[t]he number of residents in th[e] state prescribed the prescription drug' and '[t]he relative financial impacts to health, medical or social services costs as can be quantified and compared to the costs of existing therapeutic alternatives'" and explaining that "[w]ithout some specific and principled methodology for how the Board will be using such information, it is impossible to ensure that these data sources will be evaluated in a fair, even-handed, and statutorily permissible manner").
[17] *See* Meeting Materials 39 (linking to spreadsheets of preliminary aggregated information).

to compile drugs reported to the Board by carriers, it also contains twenty-nine drugs that are not on any of the four "Top 25 list(s)" without explanation for why those additional drugs may be eligible for review. The Board should clarify its processes that determine inclusion on its drug lists and explain why each metric is relevant to the Board's prioritization process, and provide stakeholders adequate time to review and comment on the data.

- **Orphan Indications:** PhRMA urges the Board to clarify how it intends to use this information regarding orphan designations.[18] The PDAB Statute prohibits the Board from conducting an affordability review on drugs designated for the treatment of rare diseases.[19] In 2024 reviews, the Board ultimately decided to exclude drugs with any Orphan designations due to inability to differentiate data from orphan and non-orphan indications; however, the preliminary list of drugs for affordability review includes drugs that it notes have "orphan designation(s) per FDA."[20] It is unclear whether this inclusion in the data indicates any changes in the available data that will be evaluated by the Board, which creates significant uncertainty regarding the Board's process.

- **Stakeholder Input:** PhRMA reiterates its concerns regarding the lack of explicit procedures to provide for meaningful stakeholder input, as well as the lack of clear and consistent standards for the Board's consideration of such input.[21] PhRMA urges the Board to adopt stronger procedural protections that allow impacted stakeholders to provide material feedback on the Board's affordability reviews and recommendations before they are finalized. Among other things, responses received from stakeholders should be included in reports that the Board presents or shares so that they can be considered by the relevant government bodies.[22]

PhRMA urges the Board to continue to address these issues in an open and transparent manner before resuming the affordability review process.

III. Draft Policy Recommendations for Legislative Changes

The Meeting Materials include a series of draft Policy Recommendations (the "Draft Policy Recommendations"). However, without additional details or specific legislative language to respond to, PhRMA is only able to provide high-level comments on several of the Draft Policy Recommendations outlined in the Board's Meeting Materials, as follows:

- **"Nine Drugs Per Year" Requirement:** PhRMA supports the recommended language change from "nine drugs a year" for affordability reviews to "up to nine" drugs per year.[23] This change would

[18] *See* Letter from PhRMA to Board 3–4 (Oct. 15, 2023) (advancing this same request with additional discussion of the acute need for such stakeholder protections).
[19] Or. Rev. Stat. § 646A.694(2).
[20] *See* Meeting Materials 39 (linked file "Carrier_2023_Preliminary_aggregated_information_v01"); *see also* Letter from PhRMA to Board 3 (Oct. 15, 2023) (noting that in August 2023, "the Board stated it would remove drugs with orphan-only designations, yet these orphan-only designated drugs appear to have been re-included on the October Drug List without explanation").
[21] *See, e.g.*, Letter from PhRMA to Board 4 (Feb. 11, 2023) (discussing the importance of procedural protections for stakeholders).
[22] Any confidential or otherwise sensitive information in stakeholder opposition statements should (and must) also be fully redacted in accordance with the statute's confidentiality requirements before being provided to the legislature or any other person or entity. Or. Rev. Stat. § 646A.694(7).
[23] Meeting Materials 6.

provide additional flexibility for the Board's affordability review process.[24]

- **Patient Assistance Program Reporting Expansion:** Both the basis and scope of the Board's recommendation to require reporting on "manufacturer coupons and any other payment that reduces a patient's out-of-pocket cost" are unclear.[25] As PhRMA has stated in prior comment letters, requiring manufacturers to submit additional confidential and proprietary information, including data on all PAPs that a manufacturer has offered or funded for any drug, exacerbates existing concerns with the Oregon transparency laws.[26]

- **PBM and Insurer Reporting on Accumulators and Maximizers:** The Board recommends that the legislature "[i]mplement mandatory reporting on copay accumulator and maximizer programs to ensure equitable access to essential medications and prioritize transparency."[27] PhRMA shares the Board's concerns with the lack of transparency for copay accumulator and maximizer programs and recognizes this effort to gather additional information. As the Board knows, these programs can unfairly increase patient cost-sharing burdens by not counting assistance towards a patient's cost-sharing and target patient assistance, and may impact a patient's ability to use these programs as intended.

* * *

On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA has concerns about the Meeting Materials, we stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Director, State Policy
Sacramento, CA

Merlin Brittenham
Assistant General Counsel, Law
Washington, DC

[24] PhRMA remains concerned, however, about the Board's language indicating that the reason for this recommendation is to "ensure that the board focuses on reviewing drugs that are known to cause affordability challenges." *See* Letter from PhRMA to Board 8 (Sept. 15, 2024). In contrast to the statutory directive to identify nine drugs that "*may* create affordability challenges," the Board's language risks presupposing or biasing the outcome of its affordability review process before the review has been conducted. Or. Rev. Stat. § 646A.694(1) (emphasis added).
[25] Meeting Materials 7 (emphasis added).
[26] *See* Letter from PhRMA to Board 9 (Sept. 15, 2024); PhRMA v. Stolfi, --- F. Supp. 3d ----, 2024 WL 1177999 (D. Or. Mar. 19, 2024), *appeal pending*, No. 24-1570 (9th Cir. filed Mar. 15, 2024).
[27] *Id.*

COMMUNITY ACCESS NATIONAL NETWORK

Mailing Address:

Attn: Jen Laws
PO Box 3009
Slidell, LA 70459

Chief Executive Officer:

Jen Laws
Phone: (313) 333-8534
Fax: (646) 786-3825
Email: jen@tiicann.org

January 10, 2025

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

RE: Clarification and Conflict of Interest Concerns

Dear Honorable Members of the Oregon Prescription Drug Affordability Board,

The Community Access National Network (CANN) is a 501(c)(3) national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and support for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

While CANN is primarily focused on policy matters affecting access to care for people living with and affected by HIV, we stand in firm support of all people living with chronic and rare diseases and recognize the very reality of those living with multiple health conditions and the necessity of timely, personalized care for every one of those health conditions. State Prescription Drug Affordability Boards are of profound importance to our community.

Today, we write with exceptional concern regarding conflicts of interest and clarifying points from the December 2024 meeting.

More Focused Awareness of Conflicts of Interest is Needed

During the last meeting, the conflicts of interest of board member Robert Judge were concerning, if not alarming. Mr. Judge recused himself, due to conflicts of interest, on voting on policy recommendation number five. Yet, he actively contributed input and commentary to the discourse that led up to the vote. We feel that he also should have recused himself from participating regarding policy recommendation number 9 regarding the dispensing fees and pharmacy reimbursements. Unfortunately, he adamantly contributed his commentary against the measure, participated in the discussion about the measure, and ultimately voted on it. This vote was highly related to profits associated with his employer.

Conflicts of interest should preclude a member not only from voting on an issue but also from contributing to the discourse of an issue, which can erroneously

influence the decision-making. Inappropriate actions of board members risk the public trust of the board and should result in censure or removal.

Copay Accumulators and Maximizers are Theft in Action

In the last meeting, there were several points of confusion, as well as misleading information presented concerning copay accumulators and copay maximizers. We would like to clear the informational palate and present clarity.

Copay accumulators and copay maximizers do not have any value in the marketplace for consumers. They do not establish the payment obligations of enrollees with their insurers. They only financially benefit the profit margins of insurers and cause financial harm to enrollees. Operationally, these programs border on theft.

Copay accumulators and copay maximizers result in insurers 'double-dipping' padding their profit margins while causing patients financial harm and access challenges. It should not matter where funds originate as long as a patient's copay and deductible obligations are met. If a family member or friend paid a patient's copays, those payments would be applied to contractually required cost-sharing. The same should apply to payments made via copay assistance programs.

Copay accumulators redirect manufacturer copay assistance from the patient to the insurer. Many manufacturers provide copay assistance programs to individuals utilizing commercial insurance. The programs offer copay cards that patients use to pay their contractually obligated copay for their medications based on their plan design. However, under copay accumulators, insurers do not apply the paid copayments to enrollees' deductibles or out-of-pocket maximums, as they would any other third-party payment.

Once the copay assistance funds are depleted, patients are still responsible for the entirety of their deductibles and other cost-sharing amounting to their out-of-pocket maximums. Copay accumulators effectively pay insurers twice for the same thing.

After copay cards are depleted, patients must pay the full price of their medications out of pocket until they reach their deductibles and out-of-pocket maximums. This can equate to thousands of dollars per month.

Copay maximizer programs manipulate the system, taking advantage of manufacturer copay assistance. With copay maximizers, insurers use third-party vendors to research the maximum copay assistance allowed by a manufacturer's copay assistance program for a particular drug. They then set a patient's copay to equal the maximum permitted copay assistance. Insurers spread the amounts out evenly to receive the entire allowed amount throughout the year or institute higher initial copays to max out the copay assistance early. They then adjust the copay down to zero after all of the funds are depleted.

Problems with copay maximizers also arise because delays occur as patients are required to enroll in third-party maximizer programs. Additionally, there are issues when the third-party vendors do not communicate properly to downwardly adjust patient copays after manufacturer assistance funds are depleted. Patients can be saddled with exorbitant copay costs or forego medication entirely if they can't afford it in the interim of third-party vendors correcting the issue.

We applaud the discussion surrounding pharmacy protection

We would like to thank Mr. John Murray for emphasizing the importance of protecting pharmacies and keeping them in business as a part of ensuring affordability and access for Oregonians. He stated that it doesn't matter how affordable a medication is if a patient can't access it. His highlight of the billions of dollars of healthcare costs incurred as a result of medication non-adherence was very poignant, as part of non-adherence is due to lack of access to pharmacies.

These statements reflect CANN's ongoing concern regarding the establishment of an Upper Payment Limit, particularly as it relates to the sustainability of safety-net providers, like Federally Qualified Health Centers and Ryan White-funded HIV clinics. As previously stated and shared as a matter of fact in the Meyer-Stauffer report, the reduction of 340B revenues as a result of a UPL dramatically impacts a safety net provider's ability to reach and serve highly vulnerable populations. The financial harm caused to safety net providers under a UPL threatens ready access to prescribing providers – if a patient cannot meaningfully and readily access their provider, they cannot acquire necessary prescriptions in order to acquire medications, regardless of how "affordable" those medications might be on paper.

In a related matter, we would also like to thank Chair Bailey and Mr. Dan Kennedy for emphasizing the existence of documented data on significant losses for pharmacies in the adjudicated claim amount versus acquisition costs. The example presented by Mr. Kennedy of the pharmacist who lost over $27K in 2024 from being reimbursed below cost for filling Ozempic prescriptions is not an isolated incident.

Respectfully submitted,

Ranier Simons
Director of State Policy, PDABs
Community Access National Network (CANN)

On behalf of
Jen Laws
President & CEO
Community Access National Network

724 Columbia St. NW, Ste. 310 • Olympia, WA 98501 • PHRMA.ORG

January 11, 2025

Oregon Prescription Drug Affordability Board 350
Winter Street NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

Re: Oregon Prescription Drug Affordability Board: January 15, 2025 Agenda and Meeting Materials

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing in response to the Oregon Prescription Drug Affordability Board's (the "PDAB's" or "Board's") meeting materials for its January 15, 2025 meeting, including draft changes to the Board's policy documents ("Board Policies"), carrier data call template ("Carrier Data Call Template"), and "Board review of technical data sets and OAR 925-200-0010 criteria for upcoming affordability reviews" ("Affordability Review Data Sets") (collectively, the "Meeting Materials").[1] 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.

We provide below our comments and concerns with respect to the Meeting Materials. Among other things, PhRMA continues to be concerned with the limited time to comment provided by the Board and in the Board's Policy on Public Comment.[2] PhRMA is also concerned with various aspects of the Carrier Data Call Template[3] and the Affordability Review Data Sets.[4]

I. Board Policy Annual Review and Proposed Changes

a. Lack of Opportunity for Meaningful Comment

PhRMA remains concerned with the Board's process for publicly posting meeting materials, and its timeframe for soliciting comments as provided in the Board's Policies,[5] including with respect to the upcoming January 15, 2025 meeting. As PhRMA has previously explained, the limited timeframe that the Board has given stakeholders to review and comment on materials in advance of meetings does not allow a full and adequate opportunity for meaningful participation by stakeholders on the important and complex issues before the Board and raises significant legal concerns.[6]

As stated in the Public Comment Policy, the Board requires that all written comments "be submitted no later

[1] Meeting Materials (Jan. 15, 2025), *available at* https://dfr.oregon.gov/pdab/Documents/20250115-PDAB-document-package.pdf. In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to Oregon Senate Bill 844 (2021), as amended by Oregon Senate Bill 192 (2023) (collectively, the "PDAB statute"), and the Board's implementation of the PDAB Statute. PhRMA also incorporates by reference all prior comment letters to the extent applicable.
[2] *See* Board, Policy Number: 04, Public Comment 3.
[3] *See* Board, Carrier Data Call Template.
[4] *See* Board, Affordability Review Data Sets.
[5] Board Policy Number: 04, Public Comment 1-2.
[6] *See* Letter from PhRMA to Board 1-2 (Oct. 12, 2024); *see also* Letter from PhRMA to Board 2-3 (July 31, 2022).

than 72 hours before the PDAB meeting."[7] The Board's standard practice since 2022 has been to post meeting materials one week prior to its meetings. Because Board meetings are currently scheduled for Wednesdays at 9:30 a.m. PT, PhRMA, and all other stakeholders who intend on submitting comments, have been given approximately two business days, and about four calendar days overall, to review these materials and respond substantively via written comments for the Board's consideration.

PhRMA notes that while the Board has proposed changes to its procedures for public comment at meetings, it has not taken any steps to address PhRMA's prior-stated concerns about the limited timeframe that the Board affords for review of and comment on materials in advance of meetings. As PhRMA has explained, the current timeframe does now allow a full and adequate opportunity for meaningful participation by stakeholders on the important and complex issues before the Board. The Board's extremely short timeframe for comments does not comply with the PDAB Statute, the APA, and due process because it does not afford stakeholders the opportunity to *meaningfully* comment.[8] The Board's continued failure to address this problem violates constitutional and statutory requirements and threatens the quality of the Board's decision-making. The matters before the Board are highly complex, and the Board's work would benefit from thoughtful input from all impacted stakeholders. **PhRMA requests that the Board amend "Policy Number: 01, Policies and Procedures" to require Board meeting materials be posted at least two weeks prior to the Board meetings.**

b. Confidentiality in Executive Session

PhRMA is concerned by the Board's proposed removal of language in the Policies that previously stated that the Board was required to "ensure that electronic recordings of executive sessions are securely stored and will only be disclosed if required under the Oregon Public Records Law."[9] It is unclear what the Board intended by deleting this language. Section 11 of the Board's Policies and Procedures requires "all members [to] maintain the confidentiality of the information discussed and/or legal advice provided in executive session." However, the Board generally permits attendance at executive sessions by *non*-Board members, including members of the media, who are not directly bound by this confidentiality requirement. Absent further protection, there exists a substantial risk that confidential, proprietary, or trade secret information may be disclosed during executive session to persons who are not entitled to receive it and who may publish or otherwise misuse it. As PhRMA has previously explained, the Board "may require that specified information be undisclosed."[10] **The Board therefore should amend Section 11 to make clear that when confidential, proprietary, or trade secret information may be disclosed or discussed during executive session, *only* members of the Board – who are bound to maintain the confidentiality of such information – and permitted members of the media may be present, and further, that members of the media who are permitted to attend executive sessions must not disclose any confidential, proprietary, or trade secret information that is discussed.**

[7] Board, Policy Number: 04, Public Comment 1.

[8] As courts have recognized, even a 10-day comment period is generally not "adequate." *N.C. Growers' Ass'n v. UFW*, 702 F.3d 755,770 (4th Cir. 2012). Courts have also opined that even a comment period of 30-days is remarkably "short" if a rule is significant. *Pangea Legal Servs. V. U.S. Dep't of Homeland Sec'y*, 501 F. Supp. 3d 792 (N.D. Cal. 2020); *see, e.g.*, *N.C. Growers' Ass'n*, 702 F.3d at 770; *California v. U.S. Dep't of Interior*, 381 F. Supp. 1153, 1176-77 (N.D. Cal. 2019). Here, the Board is providing significantly less than a 10-day comment period by requiring that the public submit written comments within two business days. Additionally, as described in prior comment letters, many of the decisions set forth by the Board through informal policy guidance constitute rules that must be adopted through a formal rulemaking process under the APA, and the Board's procedures fail to comply with these APA requirements. *See* Letter from PhRMA to Board 2-3 (July 31, 2022); Letter from PhRMA to Board 1-2 (Oct. 12, 2024).

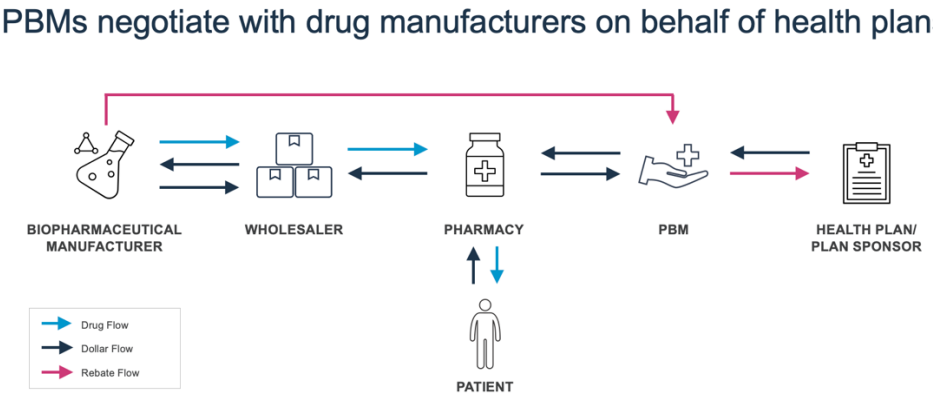
[9] Board, Policy Number: 01, Policies and Procedures 4.

[10] ORS § 192.660(4).

II. Carrier Data Call Template

PhRMA reiterates its previously expressed concerns with the Carrier Data Call Template.[11] First, PhRMA is concerned that the Carrier Data Call Template draws a distinction between "price concessions from manufacturers" and "price concessions from … pharmacy benefit managers" ("PBMs").[12] This distinction incorrectly characterizes how rebates and other price concessions flow across the supply chain and risks inaccurate or misleading reporting.

PBMs contract with pharmaceutical manufacturers to negotiate rebates on behalf of the PBMs' health plan clients. Manufacturers generally pay rebates directly to PBMs, which then pass them on, in whole or in part, to health plans or employers according to the terms of the client's agreement with the PBM.[13] Confusions about this distinction and lack of clarity may have been a factor in problems that arose during the Board's 2024 Affordability Reviews.[14] Due to this, **PhRMA requests clarification on what the Board intends to distinguish between price concessions from manufacturers and price concessions from PBMs**.



Second, as explained in prior comment letters, PhRMA remains concerned that the Board characterizes cost-sharing assistance provided by manufacturers ("Patient Assistance Programs," or "PAPs") as "other rebates and price concessions."[15] Assistance provided to patients by manufacturers is separate and distinct from commercially negotiated price concessions, discounts, or rebates provided to a payer or its plans. In part, this is because payers and their PBMs control how rebates and discounts are used and often refuse to pass the benefits of such price concessions on to their enrollees. By contrast, manufacturer PAPs directly help support patients by, for example, facilitating patient access by helping patients afford their out-of-pocket costs for medicines, which are impacted by the structure of the patient's health plans' benefit designs.

PhRMA acknowledges the Board's regulations require it to consider, "to the extent practicable, "PAP data in the Board's identification of drugs that "may create affordability challenges for health care systems or high

[11] *See* Letter from PhRMA to Board 1-2 (Apr. 13, 2023).
[12] Board, Carrier Data Call Template 35.
[13] PhRMA, Follow the Dollar: Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines, *available at* https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Follow-the-Dollar-Report.pdf.
[14] Board, Meeting Recording (June 26, 2024), available at https://youtu.be/9z2VkDiR_XA?si=UKkzHB3VlrCfdSGw&t=1637 (statement of Board member Robert Judge: "We know we have the data issues … we know we have issues related meaning to net cost …").
[15] *See* Letter from PhRMA to Board 3 (Aug. 1, 2023).

out-of-pocket costs for patients in Oregon."[16] However, it is critical that PAP information be accurate and used appropriately. Payers are generally not directly involved in patient assistance programs and will have no direct basis for providing accurate and comprehensive data on the types and amount of patient support that is provided to patients.[17] For all these reasons, **PhRMA requests that the Board remove this data element from future versions of the Carrier Data Call Template**.[18]

III. Affordability Review Data Sets and Related Materials

PhRMA appreciates the Board's efforts in developing new methodology documents regarding the Preliminary Drug List Data Process[19] and Insulin Data Process.[20] PhRMA has consistently stated the need for transparency in the Board's methodology, and the publication of these process documents is a meaningful first step toward providing that transparency.[21]

PhRMA remains concerned though with the use of therapeutic alternatives in the data sets and, in particular, the Board's definition of "therapeutic alternative."[22] Experts, including manufacturers and clinicians, should be the primary resources for determining therapeutic alternatives, and it is therefore critical to engage key stakeholders in the identification of therapeutic alternatives. PhRMA recommends that the Board use "clinical appropriateness" as the standard for decision-making when determining the therapeutic alternative for a selected drug. In order to determine the clinical appropriateness of a therapeutic alternative, the Board should: (1) engage in meaningful conversation with the manufacturer on potential therapeutic alternatives and comparators; (2) look to clinician guidance, including physician-driven evidence-based guidelines as a resource; and (3) reference other widely recognized and scientifically rigorous, evidence-driven resources to identify therapeutic alternatives. As the Board's current definition of "therapeutic alternative" fails to systematically address whether a particular comparator meets this standard, **PhRMA asks that the Board amend its definition to apply the standard of "clinical appropriateness" in determining therapeutic alternatives**.[23]

Additionally, we note that the basis for several of the specific calculations described in this process document is unclear. For example, while the Preliminary Drug List Data Process document states that "[i]f a drug was reported by 5 or more carriers for the Greatest Increase and Most Costly lists they were included in the preliminary drug list," the published preliminary data table contains a number of drugs that did not meet the

[16] OAR 925-200-0020(2)(j)(A)(i).
[17] National Council for Prescription Drug Programs, "Upstream Reporting of Copay Assistance Issues Brief," June 2018. https://www.ncpdp.org/NCPDP/media/pdf/20180604_Upstream_Reporting_of_Copay_Assistance_Issues_Brief.pdf ("Prescription assistance programs are not linked with commercial health insurance plans ... There is currently no standard mechanism to share transaction data between prescription assistance programs and commercial health insurance programs.").
[18] Consistent with our prior comment letters, PhRMA also reiterates the importance of maintaining the confidentiality of all sensitive, proprietary, trade secret, and otherwise confidential information submitted to the Board by all stakeholders, including health insurance companies, consistent with federal and state law. *See* Letter from PhRMA to Board 1-2 (Aug. 1, 2023). PhRMA requests that the Board adopt clear and concrete processes and standards in regulations addressing how the Board will maintain the confidentiality of information. These processes and standards should also be incorporated in the Carrier Data Template. Additionally, PhRMA requests that the Board clarify how it intends to extend confidentiality requirements to others that the Board works with, such as contractors and sub-contractors. PhRMA recommends that these contracted members be required to enter into binding nondisclosure agreements before having access or knowledge of any confidential information.
[19] *See* Board, Affordability Review Data Sets on Preliminary Drug List Data Process 1-9.
[20] *See* Board, Affordability Review Data Sets on Insulin Data Process 1-11.
[21] *See, e.g.*, Letter from PhRMA to Board 1-2 (Nov. 11, 2023); Letter from PhRMA to Oregon Department of Business and Consumer Services ("DCBS") 1-2 (June 23, 2023); Letter from PhRMA to Board 1-3 (Feb. 11, 2023).
[22] OAR 925-200-0020(2)(c); Board, Affordability Review Data Sets on Preliminary Drug List Data Process 8-9.
[23] OAR 925-200-0020; *see* Letter from PhRMA to Board (May 14, 2023).

5-carrier threshold.[24] Similarly, the calculations for creating the 2023 preliminary drug list create a "Most Expensive (ME) Rank," or the drugs with the highest cost per prescription; however, that metric is not required in the carrier reporting, nor is it included in the criteria on which the Board is required to prioritize drugs for affordability review under OAR 925-200-0010.[25] **PhRMA requests greater explanation of how the Board developed and is implementing these calculations in order for stakeholders to fully and properly evaluate them and provide full and comprehensive feedback**.

PhRMA also notes that some of the calculation metrics (e.g., greatest increase) can be greatly impacted by factors other than the list price of the drug, such as changes in utilization or formulary status.[26] Illustrative of this point, out of the 72 drugs on the "Greatest Increase" drug list, 38 (52.7%) had either zero or negative percent WAC price increases in the prior year according to the Board's preliminary aggregated data.[27] **PhRMA requests information on how the Board will address these factors and if it will create processes to collect information on other changes that could result in increased costs, such as utilization or formulary changes from the prior plan year.**

* * *

On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA has concerns about the Meeting Materials, we stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Director, State Policy
Sacramento, CA

Merlin Brittenham
Assistant General Counsel, Law
Washington, DC

[24] *See* Board, Affordability Review Data Sets on Preliminary Drug List Data Process 3-4. PhRMA analysis of Board's published data shows 40 of 158 drugs on the eligible drug list do not meet the stated criteria for inclusion.
[25] ORS § 743.025. PhRMA also notes inconsistency in the "Terms" tab, stating that "Most Expensive" is calculated on a per prescription basis, and the Process document which states that it is based on "cost per enrollee," and we ask that the Board clarify the basis for this calculation.
[26] *See* Board, Affordability Review Data Sets on Preliminary Drug List Data Process 6.
[27] PhRMA analysis of Preliminary data file published by the Board.

ENSURING ACCESS THROUGH COLLABORATIVE HEALTH

January 12, 2024

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

RE: Public Comments on Board Annual Policies

Dear Members and Staff of the Oregon Prescription Drug Affordability Board:

The Ensuring Access through Collaborative Health (EACH) Coalition is a network of national and state patient organizations and allied groups that advocate for treatment affordability policies that consider patient needs first.

On behalf of our coalition, we appreciate the opportunity to engage with the board and offer the following recommendations to improve transparency, accountability, and public participation in your important work.

Policy 1 Item 9: Meeting Agenda, Materials, and Recordings

We urge the board to adopt a policy requiring agendas and materials for board meetings be posted two weeks before each meeting. While we appreciate the board's current practice of posting materials approximately a week in advance, this timeline is insufficient. Under the current policy, stakeholders have as little as two business days to review materials and submit written responses to meet the 72-hour deadline for public comments.

This limited time frame creates barriers to meaningful participation in board meetings. Instead, we urge the board to establish a minimum standard of 10-14 days for posting meeting materials to ensure stakeholders have adequate time to analyze and provide meaningful input to the board. This improvement will enhance transparency, facilitate informed input, and ensure diverse perspectives are considered in board deliberations.

Policy 3: Conflict of Interest

We applaud the board for having a robust conflict of interest policy for its board members; however, the policy is ineffective if it is not enforced as outlined. We urge the board to ensure that members with actual conflicts of interest abstain from not only voting but also participating in deliberations related to the issue in question.

This conforms to the policy outlined by the board: "Except as provided in subparagraph (B) of this paragraph, refrain from participating as a board member in any discussion or debate on the issue out of which the actual conflict arises or from voting on the issue."

Policy 4: Public Comment

Public input is vital to the board's mission of addressing drug affordability while protecting patient access. To this end, we recommend allowing opportunities for longer and more meaningful interactions between board members and stakeholders. This could be through quarterly forums, office hours, or opportunities at existing meetings. During these sessions, we

also urge the board to adopt a more conversational style that allows for back and forth with stakeholders to receive more robust and meaningful input.

Additionally, we recommend slightly lengthening timeframes for public comments during board meetings and holding comment opportunities both at the beginning and end of meetings. This ensures participants can respond to issues raised during the meeting. Taking these steps will provide stakeholders, including patients, more opportunities to contribute.

We appreciate your laudable efforts to improve our health system and your steadfast commitment to protecting patients. We look forward to working together to achieve these goals.

Sincerely,

Tiffany Westrich-Robertson
Ensuring Access through Collaborative Health (EACH) Coalition

January 10, 2025

Oregon Prescription Drug Affordability Board
c/o Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

TO: Members of Oregon Prescription Drug Affordability Board

I am writing to share my concerns regarding the Oregon Prescription Drug Affordability Board's process for selecting medications and conducting affordability reviews. As a physician, my primary focus is the well-being of my patients, and I am deeply troubled that the current approach to affordability reviews may jeopardize access to essential medications.

As a board-certified pediatrician and rheumatologist, I have spent my career caring for children and young people with chronic or disabling conditions. Many of my patients, including those with juvenile idiopathic arthritis and lupus, rely on specialized, innovative, yet often expensive therapies.

One key issue is the absence of a clear, consistent definition of "affordability." The 2024 Annual Report, included in the meeting materials, outlines a five-phase strategy for evaluating drug costs but lacks detailed guidance on how affordability will be assessed.

The agenda for the upcoming January 15th meeting indicates that the Board will review data sets and criteria under OAR 925-200-0010 for future affordability reviews. However, the ongoing reliance on Wholesale Acquisition Cost (WAC) as a primary metric is problematic. The two data sets under review are heavily dependent on WAC, which represents a starting point but fails to reflect the actual costs to payers and patients. Rebates, discounts, and other pricing adjustments significantly affect net costs, and the Board's methods should account for these factors comprehensively.

While I understand and support the need to address prescription drug costs, the proposed process could inadvertently restrict access to vital medications for those who need them most. The current approach lacks adequate safeguards to ensure that affordability measures do not compromise the availability of critical treatments.

Physicians and patients are ready and willing to collaborate with the Board to make medications more affordable for all Oregonians, but achieving this goal requires a more thorough, thoughtful, and patient-centered approach.

Thank you for your attention to this critical issue.
Sincerely,

Harry L. Gewanter, MD, FAAP, MACR
President, Virginia Society of Rheumatology
Board Member, Let My Doctors Decide Action Network

From: Tony Coelho <tony@pipcpatients.org>
Sent: Monday, January 13, 2025 8:34 AM
To: PDAB * DCBS <pdab@dcbs.oregon.gov>
Subject: Discriminatory value assessments

Board Members:

As the author of the Americans with Disabilities Act (ADA) and a lifelong disability advocate, I remain very concerned about the influence of entities that strongly support the use of discriminatory value assessments on the Oregon PDAB.

PIPC and other representatives of patients and people with disabilities have consistently provided information highlighting the discriminatory implications of cost effectiveness studies that are inherently biased against people living with disabilities and chronic conditions. Yet, the Oregon PDAB continues to argue for their use. Whether the QALY or the evLYG, these measures are not allowable nor appropriate for use in making decisions that affect reimbursement and access to care. As CMS stated in the final rule for Section 504 of the Rehabilitation Act, "Methods of utility weight generation are subject to section 504 when they are used in a way that discriminates. They are subject to § 84.57 and other provisions within the rule, such as § 84.56's prohibition of discrimination based on biases or stereotypes about a patient's disability, among others." Therefore, it will be critical for compliance with these rules that the Board understand the methods for generating the utility weights in any clinical and cost effectiveness studies that it may be using to make decisions to ensure they do not devalue people with disabilities. The PDAB has been unresponsive to the concerns from patients and people with disabilities that QALYs and similar measures such as evLYG rely on utility weights and surveys that are over-generalized and/or involve significant public bias against disability. All cost effectiveness measures involve tradeoffs that the board has not addressed or highlighted for the public to respond.

Since passage of SB 1508 by the Oregon legislature barring use of generalized measures of quality of life, the HERC has been involved in a very engaged process with the disability community related to its efforts to shift away from the use of measures now barred by state and federal law. As I understand, the HERC is not considering use of evLYG as the commission has heard from and listened to the disability community as part of an engaged process. The efforts of the PDAB to rely on discriminatory value assessments are by contrast dismissive of the concerns of patients and people with disabilities impacted by the PDAB's decisions.

I urge the PDAB to pause and provide opportunities for meaningful engagement with patients and people with disabilities.

Tony Coelho

Chairman

Partnership to Improve Patient Care

100 M Street SE - Suite 750

Washington, DC 20003

www.pipcpatients.org