Leading the Fight for Insulin Affordability

Insulin saves lives. That's why we're fight to make it more affordable. Through tireless advocacy and powerful partnerships with health organizations and insulin manufacturers, we're breaking down barriers to affordable care. Together, we can ensure all of the 8.4 million Americans who rely on insulin can access and afford it.

Burden of Diabetes in Oregon[1]

- Approximately 306,000 people in Oregon, or 9.5% of the adult population, have diagnosed diabetes.
- An additional 93,000 people in Oregon have diabetes but don't know it, greatly increasing their health risk.
- There are 1,097,000 people in Oregon, 33.5% of the adult population, who have prediabetes.
- Every year an estimated 20,000 people in Oregon are diagnosed with diabetes.

The problem

In 2021, the Oregon legislature passed House Bill 2623 to cap copayments for insulin. At the time, the legislation capped copayments at $75 for a one-month supply of insulin for people on state-regulated plans. At the time, Oregon was the 18th state to address cost-sharing for insulin. Today, 25 states plus the District of Columbia have passed similar legislation. We applaud Oregon's steps to address insulin, but we can do better:

1. Remove the requirement that the copay cap on insulin be adjusted with the consumer price index. Since 2021, the copay cap has increased and will now be $85. People are having to make difficult choices between paying their bills, rent, and paying for their prescription medication. When the cost-of-living increases, it makes it more challenging for people to afford their medication and tying the copay cap to the CPI only puts the life-saving medication further out of reach. **The ADA supports legislation to remove this requirement**.
2. Lower the copay amount to $35 in line with Medicare and other states across the country. **The ADA supports legislation to lower the copay cap amount**.

If you have questions please contact Carissa Kemp, Director of State Government Affairs, ckemp@diabetes.org.

[1] http://main.diabetes.org/dorg/docs/state-fact-sheets/ADV_2020_State_Fact_sheets_OR.pdf

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September 16, 2023

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

Re: Oregon Prescription Drug Affordability Review: PDAB Affordability Review Proposed Timeline, Potential Data Integrity Issues, and Media in Executive Sessions

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to review and comment on the Board's discussion draft of its PDAB Affordability Review Proposed Timeline ("Proposed Timeline")[1] and draft policies and other agenda materials ("Draft Policies"),[2] which are scheduled for discussion at the Oregon Prescription Drug Affordability Board's ("Board's") September 23, 2023 meeting.[3] PhRMA is a voluntary nonprofit organization representing 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 selection process described in the Proposed Timeline, as well as with respect to certain potential data integrity issues and media attendance at executive session meeting policies described in the Board's Meeting Materials. PhRMA appreciates the Board's work to develop potential policies and materials with respect to implementation of its responsibilities under Oregon Senate Bill 844 (2021), as amended by Oregon Senate Bill 192 (2023) (collectively, the "PDAB Statute"). However, PhRMA has concerns on these topics, as outlined in greater detail below.

I. TIMELINE FOR AFFORDABILITY REVIEW

In the Proposed Timeline, the Board indicates that it will select "some subset" of drugs for which it will conduct affordability reviews, based on which it will "select 9 unaffordable drugs + 1 insulin product." The process described in the PDAB Statute requires the Board to "conduct an affordability review," including consideration of the full complement of data it receives for each drug, and ultimately to "determine [whether the drug in question] may create affordability challenges."[4] However the Proposed Timeline appears to envision a *result* rather than a *process*, specifically that nine drugs and one insulin product will be unaffordable out of the

[1] *See* Board Meeting Agenda 35–36 (Sept. 20, 2023).
[2] *See id.* at
[3] Collectively, PhRMA refers to the Proposed Timeline and Draft Policies as "Meeting Materials."
[4] Ore. Rev. Stat. §§ 646A.694(1) ("[T]he board shall identify nine drugs and at least one insulin product from the lists provided under this subsection *that the board determines* may create affordability challenges for health care systems or high out-of-pocket costs for patients in this state *based on criteria adopted by the board by rule* …"), 646A.694(6); *see also* § 646A.694 (1)(d)-(e), (2), (3), (7) (five additional references to the Board's "review" of information relating to a particular drug subject toi affordability review, e.g., "The estimated average monetary price concession, discount or rebate the manufacturer provides … *for the prescription drug under review*").

Board's chosen subset, irrespective of the evidence presented as part of the review process. As the Board moves forward in conducting affordability reviews, we remind the Board of its obligation to review the available evidence for a drug's affordability on a drug-by-drug basis that carefully considers the full and individual scope of data available for that particular drug. Just as a hearing violates due process if it is not before an impartial decisionmaker who "does not prejudge the evidence and who cannot say with [] utter certainty ... how he would assess the evidence he has not yet seen," so too does due process dictate that the Board's review process should not pre-judge the outcome by deeming a certain number of products to be categorically unaffordable, before any evidence is considered.[5]

II. PROCESS TO ADDRESS DATA ISSUES

As the Board continues to implement a complex methodology for conducting affordability reviews that involves compiling and analyzing data from a broad set of data sources, it should be cognizant of the potential for errors and discrepancies that may exist in that data.[6] Use of erroneous data in the Board's processes risks making irrational or ad hoc comparisons that are inconsistent with the requirements of the Oregon Administrative Procedure Act ("APA").[7] To manage this risk, and to provide manufacturers with transparency into the data that may be used to determine the affordability of their drugs, the Board should establish a process for manufacturers to review the Board's data and raise any concerns with the Board before it moves forward with the affordability review process. To facilitate this process, and ensure data accuracy from 3rd party sources, the Board should supply to manufacturers upon request all data and information necessary for their review.[8] PhRMA recommends the following specific processes to help ensure that this process is robust and meaningful:

- The Board should develop an inquiry form on the Board's website that allows manufacturers to submit questions, comments, and objections. The Board and its staff should also commit to responding to any submitted inquiries within a reasonable timeframe;
- The Board should implement a dispute resolution process to better allow for any disagreements or issues to be mutually resolved by the parties. Where appropriate, this could be modeled on established dispute resolution mechanisms, such as the collaborative dispute resolution model rules used by Oregon agencies.[9] To allow for a more fulsome discussion of issues or concerns, the Board could also include a process by which the party raising concerns can request a virtual meeting with the Board's staff for discussion.

PhRMA also requests that the Board defer selection of drugs for affordability reviews until a verification process has been established that allows the manufacturer of a drug adequate time to verify the data and notify the Board of any discrepancies or other concerns. These changes would help the Board identify and correct errors and inaccuracies in its data. Ultimately, Board decision-making is only as reliable as the information that the

[5] *Patterson v. Coughlin*, 905 F.2d 564, 570 (2d Cir. 1990).
[6] *See, e.g.*, discussion of procedures for evaluating the reliability of information in Letter from Pharmaceutical Research and Manufacturers of America ("PhRMA") to Or. Prescription Drug Affordability Board ("Board") (Feb. 11, 2023).
[7] Ore. Rev. Stat., ch. 183; *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007).
[8] The Board should, however, ensure that any disclosures are consistent with the confidentiality requirements imposed by federal and state law, as further discussed in Section III, below.
[9] *See* Ore. Rev. Stat. § 183.502(3); Ore. Admin. R. 137-005-0010 *et seq*. (providing collaborative dispute resolution model rules for Oregon state agencies); *see also* Ore. Rev. Stat. §§ 36.185 to .210 (discussing mediation available in local Oregon courts)..

Board uses as part of its review process. As such, it is critical that the Board take steps to help the board provide a transparent process and reduce the risk that the Board might inadvertently rely upon erroneous data, especially given that the affordability review process will entail collating large volumes of information from a range of different data sources.[10]

III. MEDIA IN EXECUTIVE SESSION

In addition, PhRMA is concerned that the Board has not adopted explicit protections for any confidential, trade secret, or proprietary information discussed at executive sessions at which members of the media may be present. While the Board is required to allow representatives of the news media to attend executive sessions, it also "may require that specified information be undisclosed."[11] As PhRMA has previously explained, federal and state law forbid the involuntary public disclosure of manufacturers' confidential, proprietary, and trade secret information.[12] The Board therefore must make clear that members of the media are *not* allowed to disclose such information. In addition, before non-public information about a manufacturer is disclosed, the manufacturer must be given the opportunity to review such information to determine whether it contains confidential, proprietary, or trade secret material. Failure to afford a manufacturer such an opportunity creates a significant risk that protected information will be disclosed inappropriately or by mistake, and as the Ninth Circuit has held, even "exposing [a company] to the risk of destruction [of confidentiality] by public disclosure or by disclosure to competitors ... can amount to an unconstitutional taking of property."[13]

* * *

We thank you again for this opportunity to provide comments and feedback, and for your consideration of our concerns. Although PhRMA has concerns with the Meeting Materials, we stand ready to be a constructive partner in this dialogue. Additionally, PhRMA would like to formally requesting a meeting with the Executive Director and Board Chair to discuss these concerns and others prior to any selection of drugs for affordability review. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[10] *See, e.g.*, *Conn. Light and Power Co. v. NRC*, 673 F.2d 525, 530–31 (D.C. Cir. 1982) (explaining that it is critical to provide the full technical information that an agency relies upon to reach its decision-making, especially when, as under the Oregon PDAB Statute, the statutory regime contemplates the opportunity for stakeholder comment as part of the agency's decision-making process).
[11] Ore. Rev. Stat. § 192.660(4).
[12] *See, e.g.,* Letter from PhRMA to Board (June 23, 2023); Letter from PhRMA to Board (Oct. 19. 2023). *See also* Letter from PhRMA to Board (June 20, 2022) (discussing PhRMA's concerns regarding the discussion of confidential, proprietary, or trade secret information in executive session).
[13] *St. Michael's Convalescent Hosp. v. State of Cal.*, 643 F.2d 1369, 1374 (9th Cir. 1981) (cleaned up).