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March 12, 2023

Oregon Prescription Drug Affordability Board
350 Winter Street NE
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Re: Oregon Prescription Drug Affordability Board Draft Outlines: Fee Structure and Affordability Reviews for Eligible Prescription Drugs

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 draft outlines on fee structure and affordability reviews for eligible prescription drugs ("Draft Outlines") issued by the Oregon Prescription Drug Affordability Board ("Board"), which are scheduled to be discussed at the March 15, 2023, 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 Outlines. PhRMA appreciates the Board's work to establish rules that implement its responsibilities under Oregon Senate Bill 844 (2021) (the "PDAB Statute").[1] PhRMA has concerns, however, about the approach contemplated by the Draft Outlines. As detailed below, the Fee Structure Draft Outline lacks important safeguards and processes. In addition, as with the draft issued in February, the Affordability Review Draft Outline continues to lack clear standards for selection and affordability reviews and adequate safeguards to ensure the confidentiality of all trade secret, confidential, or proprietary information used in the affordability review process.[2] We also note some important considerations with respect to the data in the "Quarterly Drug Lists" included in the Board's March meeting materials.

I. Fee Structure Draft Outline

A. Lack of Clear and Meaningful Fee Structure Standards

The PDAB Statute requires the Department of Consumer Business Services ("Department"), in consultation with the Board, to adopt a rule for establishing annual fees to be paid by drug manufacturers.[3] By statute, such fees must be calculated in amounts "necessary to meet the costs of the Department and Board" (collectively, "Board")[4] in administering sections (1) through (3) the PDAB statute,[5] and such fees must be based on "a manufacturer's share of gross revenue from sales of prescription drugs" in Oregon.[6]

[1] 2021 Or. Laws ch. 844 (codified at ORS 646A.693-.697).
[2] PhRMA also continues to have concerns about the Board's Temporary Procedural Rule OAR 925-100-0003, as described in a prior letter to the Board, and about the constitutionality of the Oregon PDAB Statute more generally. *See* Letter from Pharmaceutical Research and Manufacturers of America to Or. Prescription Drug Affordability Board (Oct. 19, 2022). In filing this comment letter requesting changes to the Fee Structure and Affordability Review Draft Outlines, PhRMA reserves all of its legal arguments with regard to those issues.
[3] ORS 646A.695(1).
[4] *Id.* (emphasis added).
[5] ORS 646A.693 through ORS 646A.695.
[6] ORS 646A.695(1).

By specifically requiring the adoption of a rule governing fee assessments, the PDAB statute directs the Board to establish meaningful processes to fairly and accurately calculate fees consistent with the statutory text. To do so, the Board needs to establish specific procedures to accurately and reliably calculate and fairly assess fees in amounts no greater than that "necessary" to meet the costs incurred by the Board in administering sections (1) to (3) of the PDAB Statute.

PhRMA is concerned that the Fee Structure Draft Outline does not provide these specific procedures. The Board's proposal does not provide certain details about how the fee assessment process will be implemented. Among other things, the Fee Structure Draft Outline does not explain how the Board proposes to calculate fee amounts. Further, the Board's proposal lacks important operational particulars that will be necessary to implement the proposed fee process in a fair, accurate, and transparent manner.

PhRMA provides the following as examples of the need for clearer and more detailed standards and specifications governing the proposed fee process:

- ***Determination of Necessary Board Costs***. As noted, the PDAB statute requires that fees be no more than "necessary" to cover the Board's costs in administering sections (1) through (3).[7] However, the Fee Structure Draft Outline does not explain how the Board will implement this requirement.[8] Nor does it provide for stakeholder input in that process, including from manufacturers against whom these costs will be assessed. PhRMA requests that the Board adopt an open and transparent budgeting process that demonstrates how the Board will assess these fees in a manner consistent with the PDAB Statute.

- ***Calculation of "Gross Revenue***." Because manufacturers' fees will be "based on [their] share of gross revenue from sales of prescription drugs" in Oregon, a single, consistent definition for "gross revenue" is important for implementing a fair and transparent process for fee assessment. The Board should adopt a definition of "gross revenue" that clarifies how it intends to define and calculate gross revenue from sales of prescription drug in the state.[9]

- ***Identification of Manufacturers Subject to Fee Assessments***. The Fee Structure Draft Outline does not describe how the Board will identify manufacturers that will be subject to fee assessments. The PDAB Statute contemplates assessing fees on manufacturers that "sell prescription drugs" in Oregon, and the draft rule defines "manufacturers" to be entities that are required to be registered with the Oregon Board of Pharmacy ("BOP") and that set or change the wholesale acquisition costs of the drugs they manufacture.[10] However, unlike the PDAB statute, the BOP registration requirement applies to entities that are "engaged in dispensing, delivery or distribution of drugs within this state."[11] It is not clear how the Board will determine which manufacturers that are registered with the BOP will satisfy the characteristics of entities eligible for fee assessment by the PDAB, or what sources of information the PDAB will draw on to make those determinations.

- ***Invoicing of Fee Amounts***. The Fee Structure Draft Outline states that fees imposed on manufacturers must be paid by October 1 of each year, but does not provide details about when the

[7] *Id.*
[8] Fee Structure Draft Outline § 1(a) (draft language for annual fees to be paid by manufacturers that sell prescription drugs in this state).
[9] ORS 646A.695(1).
[10] *Id.*
[11] ORS 689.005(13).

Board will invoice manufacturers or what information it will provide in the invoices.[12] PhRMA requests that the Board specify that written invoices be sent to manufacturers before July 3 of each year (i.e., at least 90 days before the October 1 deadline).[13] This will give manufacturers time to review and potentially appeal their assessment in advance of the deadline for payment.[14] Written invoices should include sufficient details for manufacturers to understand the basis of their assessment, including the Board's total costs, the manufacturer's attributed gross revenue from sales of prescription drugs in Oregon (including the sources relied upon to calculate it), and the percentage of and explanation for the total costs that are being assessed to the manufacturer.

- ***Appeals of Fee Assessments***. The Fee Structure Draft Outline does not incorporate an express mechanism for disputing fee assessments that a manufacturer believes to be erroneous. An inability by manufacturers to meaningfully challenge erroneous fees raises significant due process concerns.[15] Accordingly, PhRMA urges the Board to modify its Draft Outline to incorporate an appeals mechanism for manufacturer fee assessments, consistent with basic standards of due process. Such a mechanism should provide manufacturers an opportunity to obtain a full accounting of how their fee was calculated and an opportunity to rebut or correct that calculation with additional information. The manufacturer's fee assessment should be suspended, without the accumulation of interest, while the appeal is reviewed, and manufacturers should be given adequate time to pay any applicable fee assessment after final resolution of the appeal.

Any new processes established by the Board should be set forth in proposed rules and finalized after notice-and-comment rulemaking that provides stakeholders with full and fair opportunity for feedback.

B. Data Sources Used in Fee Assessments

The Fee Structure Draft Outline currently permits the Board to "use any prescription drug price information it deems appropriate to assess a fee based on a manufacturer's share of gross revenue from sales of prescription drugs in this state."[16] We reiterate to the Board that any confidential, trade secret, or proprietary information relied upon by it must be protected from public disclosure, as required by state and federal law, even if the Board deems such information "appropriate" for use in fee assessments.[17] It is not clear from the Fee Structure Draft Outline how the Board would determine that information is "appropriate" for assessing fees or how it will ensure that the information is accurate, reliable, and considered in a consistent manner. Erroneous and inconsistent fee assessments would violate the rights of manufacturers to be free from "ad hoc and arbitrary" agency decision-making.[18] PhRMA therefore recommends that the Board amend this rule to provide for transparency and consistency in the data used by the Board for fee assessments, and to make clear that manufacturers' confidential, trade secret, or proprietary information will be protected from disclosure in violation of state and federal law.

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[12] Fee Structure Draft Outline § 2(a) (draft language for annual fees to be paid by manufacturers that sell prescription drugs in this state).
[13] The Board should also specify a mechanism for manufacturers to designate an appropriate mailing address and point-of-contact for receipt of such invoices.
[14] See below for the need for formal appeal.
[15] *See generally* U.S. Const. amend. XIV.
[16] Fee Structure Draft Outline § 3 (draft language for annual fees to be paid by manufacturers that sell prescription drugs in this state).
[17] *See, e.g.*, Letter from Pharmaceutical Research and Manufacturers of America to Or. Prescription Drug Affordability Board, Sec. VII (Feb. 11, 2022).
[18] *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007).

II. Affordability Review Draft Outline

In addition to its concerns about the Fee Structure Draft Outline, PhRMA continues to have serious concerns about the proposed affordability review process. The Board's Affordability Review Draft Outline for its March meeting is unchanged from the draft outline that the Board previously issued in advance of its February meeting. PhRMA therefore refers the Board to its February comment letter for a description of PhRMA's concerns related to the Affordability Review Draft Outline, and PhRMA incorporates by reference all comments, concerns, and objections that it has previously raised about the proposed affordability review process.[19]

III. March Meeting Agenda Quarterly Drug Lists

The Board's March meeting materials include "Quarterly Drug Lists" provided by the Drug Price Transparency program containing information from manufacturers, wholesale acquisition cost (WAC), and health plan-reported spending data.[20] PhRMA is concerned that these data provide the Board members with incomplete information about the costs of prescription drugs and cost-drivers in the health care system. We therefore recommend that the Board consider the following points when reviewing these lists:

- It is not clear whether these data include the impact of rebates on plans' drug spending. Without data on the rebates, discounts, and other price concessions that are provided by manufacturers to health plans and pharmacy benefit managers ("PBMs"), the data drastically overestimate the amount that plans are spending on medicine. The impact of these price concessions on actual costs (compared to gross spending) should not be dismissed or minimized. In 2021, rebates, discounts, and other payments made by manufacturers of prescription drugs to PBMs reached $236 billion.[21] Rebates lower the price that plans are actually paying for medication by an average of 49%.[22]

- For example, the Board's table of "most expensive" drugs appears to be based upon carrier-reimbursed amounts (drug spend) and not net prices paid or net costs incurred by carriers, but rebates and discounts bear directly on the true price of medicines. For instance, in 2021 the net price for the most common insulins dropped 84% with rebates and discounts.[23] Due to misaligned incentives in the system, middlemen—not patients—have been the primary beneficiaries of the deep discounts and rebates that have lowered the cost of insulins. In fact, between 2014 and 2018, the share of total spending on insulins received by PBMs increased 155%.

- Where the data in the charts reflect plan-reported drug spend, a clear definition is needed for what "costs" are included. For example, the "2022 Top 25 Most Costly Prescription Drugs Reported by Oregon

[19] *See* PhRMA, Letter Regarding Oregon Prescription Drug Affordability Board Draft Outline: Affordability Reviews for Eligible Prescription Drugs (Feb. 11, 2023).
[20] Tables titled 2022 Quarter 4 Specialty Drugs by Drug Name, 2022 Top 25 Greatest Price Increase Prescription Drugs Reported by Oregon Carriers, 2022 Most Expensive Prescription Drugs Reported by Oregon Carriers, and Insulin Marketed in Oregon in 2022 (collectively, "Quarterly Drug Lists")
[21] Drug Channels Institute. The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. March 2022.
[22] IQVIA. Use of Medicines in the US.: Spending and Usage Trends and Outlook to 2026, April 2022.
[23] Partnership to Fight Chronic Disease, *Sharing Rebates on Diabetes Medicines Could Save Patients $3.7 Billion a Year* 1, *available at* https://www.fightchronicdisease.org/sites/default/files/PFCD-Diabetes%20Rebates-USA-Final%20%281%29.pdf.

Carriers" lists spending on COVID-19 vaccines as the 5th highest for plans.[24] However, the cost of COVID-19 vaccines was covered by the federal government, while health plans were responsible for the cost of administration of a significant number of vaccines.[25] If the cost of administration for drugs is being reported as total drug spend, that should be reflected in the Board's consideration.

PhRMA recommends that, in evaluating prices and costs, the Board should carefully weigh the data sources it relies upon and any limitations of that data, and clearly define the types of costs or spend accounted for in those sources. Moreover, the Board should be consistently factoring in the net effect of rebates or other price concessions when evaluating prices and costs. Otherwise, the Board's assessments will be inherently unreliable because the Board will not be considering the true prices paid and costs accrued.

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We thank you again for this opportunity to provide comments and feedback on the March 15th meeting materials and for your consideration of our concerns and requests for revisions. Although PhRMA has concerns with the Draft Outlines and Quarterly Drug Lists, 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 with any questions.

Sincerely,

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Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[24] March 15 meeting materials, page 25, $20.6 million is reported for COVID-19 vaccines.
[25] California Department of Managed Health Care. "Prescription Drug Cost Transparency Report. Measurement Year 2021". https://www.dmhc.ca.gov/Portals/0/Docs/DO/SB172021Report.pdf.