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May 14, 2023

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

Re: Oregon Prescription Drug Prescription Drug Affordability Review Regulations: Selecting Prescription Drugs for Affordability Reviews (925-200-0010) and Conducting an Affordability Reviews (925-200-0020)

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 revised draft regulations titled "Selecting Prescription Drugs for Affordability Reviews" (925-200-0010, "Drug Selection Draft Rule") and "Conducting an Affordability Review" (925-200-0020, "Affordability Review Draft Rule") (collectively, "Draft Rules") published by the Oregon Prescription Drug Affordability Board ("Board") on May 10, 2023 for discussion at the Board's May 17, 2023 meeting.[1] 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 lives.

PhRMA appreciates the Board's consideration of our previous comments. Although the Board has adopted certain revisions to its proposed approach to conducting affordability reviews, PhRMA continues to have concerns about the lack of meaningful standards for and adequate detail on how the Board will use and consider information, which raises concerns about arbitrary and inconsistent decision-making in violation of the Oregon Administrative Procedure Act ("APA").[2] PhRMA incorporates by reference its prior comment letters relating to the selection and affordability review process—including both the above overarching concerns and all other concerns raised in these prior letters.[3]

Below, PhRMA provides additional comments, concerns, and recommendations with respect to the most recent version of the Draft Rules, with emphasis on addressing areas where the Board has proposed new criteria or otherwise refined its prior drafts.[4]

I. AFFORDABILITY REVIEW SELECTION PROCESS

[1] PhRMA also continues to have concerns about the Board's Temporary Procedural Rule OAR 925-100-0003, as described in our letter to the Board, and about the constitutionality of the Oregon PDAB statute. *See* Letter from PhRMA to Board (Oct. 19, 2022). In filing this comment letter requesting changes to the Draft Rules, PhRMA reserves all of its legal arguments with regard to those issues.
[2] As noted in our prior comments, a central tenet of the Oregon APA is that "decisions by administrative agencies be rational, principled, and fair, rather than ad hoc and arbitrary. *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007).
[3] *See, e.g.*, PhRMA, Comment Letter to Or. Prescription Drug Affordability Board ("Board") (Apr. 16, 2023); PhRMA, Comment Letter to Board (Mar. 12, 2023); PhRMA, Comment Letter to Board (Feb. 11, 2023).
[4] PhRMA respectfully requests that the Board consistently redline changes in each draft of its proposed regulations to allow members of the public to more readily determine how the Board is refining its drafts, which will facilitate a more meaningful comment process. *See generally Conn. Light and Power Co. v. NRC*, 673 F.2d 525, 530 (D.C. Cir. 1982) (noting that it subverts the purpose of a comment process if there is not adequate transparency, as this impedes the ability of commenters to make "useful criticism" and to "comment meaningfully upon the agency's proposals").

While reiterating the concerns in PhRMA's previous comment letters,[5] PhRMA raises the following concerns and considerations with respect to the Board's most recent refinements to its Selection Process Draft Rules:

- **Consideration of Wholesale Acquisition Cost ("WAC") Without Net Price Information**. With respect to the Board's proposal to consider historical and current price increases based on WAC information:
    - PhRMA notes that the Board's proposed rule for drug selection considers "[w]hether any prescription drugs are on each of the insurer reported top 25 lists" and includes comparison of "[h]istorical and current manufacturer drug price increases, based on wholesale acquisition cost (WAC) information."[6] PhRMA has previously noted its concerns regarding use of "top 25 list" information without consideration of discounts, rebates, or similar price reductions.[7] ***We strongly encourage the adoption of additional drug selection criteria that take into account information about discounts, rebates, and other price concessions, to the extent available, as this information is critical to ensure that the Board considers the true costs of drugs to payers and patients.*** As PhRMA has explained in more detail in prior comment letters, the impact of these price concessions on actual costs (compared to gross spending) should not be dismissed or minimized. Rebates lower the price that plans are actually paying for medication by an average of 50%.[8] Contrary to claims of rapidly expanding drug prices, data show that spending on medicine remains a small and stable share of total health care spending, accounting for just 14% of total U.S. health care spending.[9]

    - Second, PhRMA requests clarification about how the board intends to compare the "[h]istorical and current manufacturer drug price increases" as described in the Dug Selection Proposed Rule where a prescription drug has multiple national drug codes ("NDCs"). The Drug Selection Draft Rule indicates that a measure of "central tendency" will be used.[10] ***PhRMA requests that the board clarify how it intends to calculate the "central tendency" for changes in prices across multiple NDCs.***

- **New Drug Report or Price Increase Report**.[11] The Drug Selection Draft Rule proposes that the Board will consider "[w]hether the prescription drug is included in the manufacturer launch price or price increase reports . . . for the previous calendar year,"[12] whereas the Board's presentation slides (and prior drafts) indicate that the Board would look to the "same calendar year."[13] In light of the inconsistency between these proposals, ***PhRMA asks the Board to clarify its intended approach.***

- **Accelerated Approval**. PhRMA refers the Board back to the discussion in PhRMA's April 16 comment letter regarding the Board's proposal to consider accelerated approval and other expedited approval pathways as part of its selection process. ***We ask the Board to either clarify why this information should be considered under the Drug Selection Draft Rule or not include this information in its proposed criteria.*** We continue to emphasize that prescription drugs granted accelerated approval

[5] Feb. 11, 2023 PhRMA Letter; Mar. 12, 2023 PhRMA Letter; Apr. 16, 2023 PhRMA Letter.
[6] Drug Selection Draft Rule §§ 1, 3.
[7] *See* April 16 Comment Letter, pp. 3-4.
[8] IQVIA, Use of Medicines in the US.: Spending and Usage Trends and Outlook to 2027 (April 2023).
[9] *See* IQVIA. Use of Medicines in the U.S. 2022: Usage and Spending Trends and Outlook to 2026 (April 2022). *See also* Attachment "The AHIP Premium Dollar: Corrected".
[10] Drug Selection Draft Rule § 3.
[11] Drug Selection Draft Rule § 2.
[12] *Id.* (emphasis added).
[13] *See* PDAB Affordability Review Draft Outline, Presentation Slides at 2.

must adhere to the same statutory standards for safety and effectiveness as medicines receiving a traditional FDA approval, and are critical for the treatment of many diseases.[14]

II. CONDUCTING AN AFFORDABILITY REVIEW

In addition to the concerns previously raised in PhRMA's prior comment letters,[15] PhRMA raises the following concerns and considerations with respect to the Board's most recent refinements to its Affordability Review Draft Rule:

- **Therapeutic Alternatives**.[16] PhRMA appreciated the Board that the Board has revised the Affordability Review Draft Rule to include a definition for "therapeutic alternative" that is consistent with the elements described in PhRMA's April 16, 2023 comments.[17] The proposed definition appropriately requires that, in order for a drug to be considered a therapeutic alternative of a particular product, peer-reviewed clinical studies show that the drug has a similar therapeutic effect, safety profile, and expected outcome when administered to patients in a therapeutically equivalent doses. This definition will help limit comparisons within the affordability review process to those drugs that could safely be considered an alternative to a reference product. ***To further assist the Board in determining where comparisons are clinically appropriate, PhRMA also recommends that the Board incorporate an additional element that requires therapeutic alternatives to be FDA-approved for the same indication as the reference drug*** (recommended changes in bold and underlined emphasis):

  > "Therapeutic alternative is to mean a drug product that contains a different therapeutic agent than the drug in question, but is **FDA-approved for the same indication** with the same pharmacological or therapeutic class and has been shown through peer-reviewed studies to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose or has been recommended as consistent with standard medical practice by medical professional association guidelines."

- **Patient Assistance Program Related Information**.[18] The Board proposes revisions to the Affordability Review Draft Rule to expressly contemplate consideration of information submitted by manufacturers related to patient assistance programs and coupons and the impact of such programs and coupons on copayment and coinsurance.[19] PhRMA asks that the Board carefully weigh and consider such information within the context of how insurance benefit design shifts drug costs onto patients. Over the last several years, commercial health plans have increasingly shifted the burden of prescription drug costs to patients by exposing them to higher deductibles and to coinsurance as opposed to copays. Coinsurance is based on the undiscounted list price of the medicine, which results in higher out-of-pocket costs for patients versus when fixed copays are used. Exacerbating the problem is that the insurance company is paying the negotiated rate, reflecting manufacturer discounts, without passing on those discounts directly to patients. Due to this erosion of insurance coverage, manufacturers have stepped in to fill the void by offering copay assistance to ensure that patients can

[14] FDA, Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics (May 2014), available at https://www.fda.gov/media/86377/download. *See also* Nat'l Org. for Rare Diseases, FDA's Accelerated Approval Pathway: A Rare Disease Perspective (2021), available at NRD-2182-PolicyReport_Accelerated-Approval_FNL.pdf (rarediseases.org).

[15] Apr. 16, 2023 PhRMA Letter; Mar. 12, 2023 PhRMA Letter; Feb. 11, 2023 PhRMA Letter. We also reiterate our concerns regarding the Board's consideration of data collected from safety net providers participating in the federal 340B program. *See* Apr. 16, 2023 PhRMA Letter, at 7.

[16] Affordability Review Draft Rule § 2(c); *see also id.* § 1(f), (g), (j).

[17] *Compare* Affordability Review Draft Rule § 2(c) *with* Apr. 16, 2023 PhRMA Letter, at 5.

[18] Affordability Review Draft Rule § 2(d); *see also id.* § 2(j)(A), 2(k).

[19] *See id.* § 2(j)(A).

afford the medicines they need. In 2021, cost-sharing assistance offset $12 billion in patient out-of-pocket costs, up 50% from $6 billion in 2014.

There are substantial patient benefits associated with these programs. A comprehensive literature review has also found that cost-sharing assistance was associated with improved patient adherence to medicines, with the share of patients staying on treatment for one year increasing by up to 47%.[20] Given the important role of cost-sharing assistance for patients, ***PhRMA believes the Board should further clarify its standards surrounding consideration of information related to such programs as part of the cost review process.***

- **Quality-Adjusted Life Years (QALYs)**.[21] The Board proposes to revise the Affordability Review Draft Rule to remove language that previously required identification of QALY-related sources and that explicitly prohibited use of QALY analyses (or similar analyses).[22] PhRMA has serious concerns about this proposed removal. The PDAB statute expressly bars use of QALYs or "similar formulas that take into account a patient's age or severity of illness or disability" for purposes of evaluating a drug's cost-effectiveness.[23] We strongly urge the Board to expressly adopt this prohibition in its regulations and provide clear safeguards that restrict it from directly or indirectly considering QALYs and similar measures.[24]

- **Input from Payers**.[25] As part of conducting an affordability review, the Board proposes to solicit certain information from payers—including their total cost of care for disease(s), the costs of the prescription drug for the payer, the availability of therapeutic alternatives on formulary, coverage mandates and impacts to per member per month or premiums, information about affordability concerns and other costs information.[26] It is not clear whether the information provided by payers regarding the "[c]ost of the prescription drug" will be net of rebates or other discounts; as above, we strongly recommend the Board consider cost and price information net of rebates, discounts, and other prices concessions.

  We also urge the Board to consider the broader context of factors that drive patient affordability and out-of-pocket costs, including benefit design (e.g., cost-sharing requirements such as coinsurance and deductibles, and copay accumulator adjustment[27] and maximizer programs[28]) and fees, rebates, and other price concessions paid by drug manufacturers to PBMs and health insurance plans that the PBMs and plans are not sharing directly with patients at the point of sale. These factors, which are determined by plans and PBMs, are contributing to the inability of Oregonians to afford their health care.

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[20] Hung, A. B., D.V.; Miller, J.; McDermott, J.; Wessler, H.; Oakes, M.M.; Reed, S.D.; Bosworth, H.B.; Zullig, L.L. (2021). Impact of Financial Medication Assistance on Medication Adherence: A Systematic Review. In Journal of Managed Care & Specialty Pharmacy (Vol. 27, pp. 924-935).

[21] Affordability Review Draft Rule § 2(i).

[22] *Compare id. with* Draft Affordability Review Outline from April 19, 2023 Meeting § 4(b)(G)(ii), *available at* https://dfr.oregon.gov/pdab/Documents/20230419-PDAB-document-package.pdf.

[23] 2021 Or. Laws ch. 589, § 2(4)(a) (codified at ORS 646A.694).

[24] *See* further discussion regarding the PDAB Statute's restriction on the use of QALYs, evLYGs, or similar measures in PhRMA's April 16, 2023 PDAB Letter, pp. 7-8.

[25] Affordability Review Draft Rule § 2(k)(D).

[26] *See id.* We also note that, for consistency, consideration of therapeutic alternatives for this purpose should be limited to the same definition for "therapeutic alternative" that the Board has proposed in section 2(c) of the Affordability Review Draft Rule.

[27] Accumulator adjustment programs are insurance benefit designs that exclude the value of manufacturer-sponsored cost-sharing assistance from a patient's accrual of out-of-pocket expenses toward out-of-pocket limits through a plan benefit year.

[28] Copay maximizer programs are insurance benefit designs that generally restructure patients' cost sharing obligations for a particular drug to equal the full value of manufacturer cost sharing assistance available for that drug. Such programs skirt the protection of the Affordable Care Act's annual limit on cost sharing for some plans by designating medications as non-Essential Health Benefits.

III. CONFIDENTIALITY

PhRMA reiterates its concerns that the Draft Rules do not address how the Board will ensure the confidentiality of the materials it reviews in accordance with PDAB Statute.[29] State and federal law protect manufacturers' confidential, proprietary, and trade secret information from disclosure; such information cannot be publicly disclosed without violating state and federal prohibitions against the misappropriation of trade secrets. In addition, the Fifth Amendment's prohibition against taking private property without just compensation similarly prohibits the uncompensated disclosure of trade secrets. Courts have made clear that "when disclosure [of pricing information] is compelled by the government," even the "failure to provide adequate protection to assure its confidentiality ... can amount to an unconstitutional 'taking' of property."[30] Consistent with these state and federal requirements, the Legislature incorporated into the PDAB Statute an independent obligation on the PDAB to "keep strictly confidential any information" that is "[c]onfidential, proprietary or a trade secret," including "[i]nformation submitted to the department by a manufacturer under ORS 646A.689."[31] ***In order to effectuate these requirements and sufficiently protect against disclosure of this information, the Board should revise its Draft Rules to incorporate clear standards addressing how it will maintain the confidentiality of relevant information consistent with state and federal law.***

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We thank you again for this opportunity to provide comments and feedback on the Draft Rules and for your consideration of our concerns and requests for revisions. Although PhRMA has concerns with the Draft Rules, we remain committed to engaging in a productive conversation and are eager to contribute positively to the 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,

Dharia McGrew, PhD
Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[29] Or. Rev. Stat. § 646A.694(7) (enacted as § 2(7) of the PDAB Statute). We also reiterate our concerns regarding potential disclosure of sensitive information related to the federal 340B program. *See* Apr. 16, 2023 PhRMA Letter, at 7.
[30] *St. Michael's Convalescent Hosp. v. California*, 643 F.3d 1369, 1374 (9th Cir. 1981) (brackets and quotation marks omitted).
[31] Or. Rev. Stat. § 646A.694(7).

The AHIP Premium Dollar: Corrected

America's Health Insurance Plans (AHIP) would have you believe that brand medicines are the primary driver of insurance premium costs. But AHIP's own data show that this simply isn't true. A recent AHIP infographic, "Where Does Your Premium Dollar Go?," gives the misleading impression that prescription medicines account for the largest share of insurance premiums. However, when you properly account for the share of spending that goes to brand biopharmaceutical companies vs. generic manufacturers and supply chain intermediaries, **brand medicines comprise less than 11 cents of the premium dollar, or about 50% less than what is spent on insurer administrative costs and profit.**[1, 2]

48.4% Hospital Costs

17.5% Insurer Admin Costs & Profit

11.8% Doctor Visits

10.8% Brand Medicines

6.9% Medicine Supply Chain

4.5% Generic Medicines

Furthermore, by breaking hospital inpatient, hospital outpatient, and emergency room spending into separate categories, AHIP's original infographic obscures the fact that hospital spending is by far the largest contributor to insurance premium costs. Combined, hospital costs account for nearly half (48%) of the insurance premium dollar, more than four times as much as brand medicines.

Both the original and corrected AHIP infographics also highlight an often overlooked fact about health care spending: **nearly 20 cents of every premium dollar is not spent on medical care, but instead goes towards administrative costs or is retained by the health plan as profit.**

1 Berkeley Research Group. "The Pharmaceutical Supply Chain; Addendum," 2020. Available at: https://www.thinkbrg.com/insights/publications/the-pharmaceutical-supply-chain/

2 This corrected infographic conservatively assumes that AHIP's original premium spending distribution was accurate. AHIP restricts its sample to patients younger than 65 years of age, who are younger and healthier than the population as a whole, and for whom spending on prescription medicines constitutes a proportionally higher percentage of total health expenditures. Spending captured in AHIP's premium dollar also excludes a significant share of health care spending, including long-term care and investments in public health. More comprehensive analysis shows that retail and non-retail prescription medicines (including brand, generic, and supply chain costs) account for just 14% of total U.S. health care spending.