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August 1, 2023

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

Re: Oregon Prescription Drug Affordability Review: Data Collection Template for Health Insurance Companies in Oregon

Dear Members of the Oregon Prescription Drug Affordability Board ("Board"):

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the Board's publication for review of its draft data collection template for health insurance companies in Oregon and associated draft instructions (the "Draft Carrier Data Template"),[1] which were released July 17, 2023 and discussed at the Board's July 19th meeting.

We provide below our comments and concerns with respect to the Draft Carrier Data Template. PhRMA has concerns about the current Draft Carrier Data Template. Specifically, PhRMA is concerned about the lack of adequate processes in place for identifying and safeguarding confidential information collected using the Draft Template. In addition, we believe that there should be clearer definitions surrounding key data elements related to rebates and discounts.[2]

I. ESSENTIAL PROTECTIONS FOR CONFIDENTIAL INFORMATION SHOULD EXTEND TO CONTRACTORS AND SUB-CONTRACTORS

PhRMA appreciates the Board's recognition that rebate information will likely include proprietary information and must be kept confidential and only be used in aggregate form.[3] Consistent with our prior comment letters, PhRMA reiterates the importance of maintaining the confidentiality of all sensitive, proprietary, trade secret, and otherwise confidential information (collectively, "confidential information") submitted to the Board.[4]

[1] *See* Board Meeting Agenda 50–60 (July 19, 2023).

[2] As described in our prior letters to the Board, PhRMA also continues to have concerns about the Board's broader implementation of the PDAB Statute, including about the Board's Temporary Procedural Rule OAR 925-100-0003, as well as about the constitutionality of the Oregon PDAB statute more generally. *See, e.g.*, Letter from PhRMA to Board (Oct. 19, 2022). In filing this comment letter requesting changes to the Draft Carrier Data Template, PhRMA reserves all of the legal arguments related to the PDAB Statute and its implementation that have been raised in all of PhRMA's prior comments submitted to the Board.

[3] Board Meeting Agenda at 54.

[4] *See*, e.g., Letter from PhRMA to Board (June 23, 2023), at 3; Letter from PhRMA to Board (May 14, 2023), at 5; Letter from PhRMA to Board (Apr. 16, 2023), at 8. State and federal law protect confidential, trade secret, and proprietary 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." St. Michael's Convalescent Hosp. v. California, 643 F.3d 1369, 1374 (9th Cir. 1981) (brackets and quotation marks omitted).

In order to provide adequate protections against disclosure of confidential information, PhRMA urges the Board to adopt clear and concrete standards and processes in regulations addressing how the Board will maintain the confidentiality of information collected from health insurance companies in this manner, consistent with state and federal law. As appropriate, these standards and processes should also be incorporated into any future Draft Carrier Data Templates. ***We also urge the Board to clarify that it will extend its confidentiality requirements to any contractors or sub-contractors with which the Board directly or indirectly works—including by requiring these persons or entities to enter into binding nondisclosure agreements before they have access to any confidential information.***[5]

II. THE BOARD SHOULD ADOPT CLEAR DEFINITIONS FOR KEY TERMS, PARTICULARLY "REBATE" AND "DISCOUNT"

PhRMA urges the board to adopt clear and consistent definitions of the data elements referred to in the Draft Carrier Data Template, specifically those related to rebates and discounts.

As noted by industry analysts, contracts between PBMs and health insurers (and other entities) often utilize flexible and inconsistent terminology to describe fees, rebates, and other negotiated terms; for example, "rebates" tallied under one PBM contract may be considered "service fees" under another.[6] Because of these PBM contract practices, without clear definitions for its data elements, the Board may receive data from health insurers that is inconsistent and incomplete.[7] PhRMA recommends that the Board adopt the following definitions, which provide a consistent and comprehensive basis for health plans to report these data:

- "Rebate" means "(i) negotiated price concessions including but not limited to base price concessions (whether described as a "rebate" or otherwise) and reasonable estimates of any price protection rebates and performance-based price concessions that may accrue directly or indirectly to the insurer during the coverage year from a manufacturer, dispensing pharmacy, or other party in connection with the dispensing or administration of a prescription drug, and (ii) reasonable estimates of any negotiated price concessions, fees and other administrative costs

[5] For further discussion of the elements that should be included in these nondisclosure agreements, *see* Letter from PhRMA to Board (June 20, 2022), at 3-4.

[6] PBM Accountability Project. "Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers," December 2021. https://www.pbmaccountability.org/_files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf ("PBMs' ability to optimize their revenue model on an ongoing basis through formulary management, specialty designations, brand/generic designations, and other means creates complexity in understanding PBM contracting costs and monitoring contract performance. Such flexibility, protected in provisions of PBM contracts with public sector and commercial plans, prevents market forces from acting efficiently to drive down costs for all stakeholders. It also allows PBMs to continuously make adjustments in real time to maximize the revenue they collect, a benefit that can be to the detriment of prescription drug payers. These practices can prevent both payers and patients from realizing the full benefits of cost reductions."). This inconsistency provides PBMs a great deal of flexibility to interpret contract terms in their favor and further contribute to the unequal bargaining power in contract negotiations between PBMs and pharmacies, as well as with employers and other payers. *See also* Herman B. "The biggest PBMs are handling more and more of the country's drug price negotiations. *STAT+.* March 22, 2021. https://www.statnews.com/2022/03/22/pharmacy-benefit-managers-revenue-contracts/.

[7] Furthermore, lack of clarity surrounding these data elements risks undermining the ability of the Board to conduct its work in a manner that is "rational, principled, and fair, rather than ad hoc and arbitrary," as required under the Oregon Administrative Procedures Act ("APA"). *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007).

that are passed through, or are reasonably anticipated to be passed through, to the insurer and serve to reduce the insurer's liabilities for a prescription drug."

- "Discount" means "a reduction in the price, whether direct or indirect, that would otherwise be paid by an insurer for a prescription drug, including any negotiated price reductions that may accrue directly or indirectly to an insurer in connection with the dispensing or administration of a prescription drug that serve to reduce the insurer's or insurer's agent's liabilities for a prescription drug."

III. OTHER ISSUES

In addition, PhRMA believes other refinements and clarifications to the Draft Carrier Data Template are necessary to improve clarity, enhance reliability of the information collected, or otherwise reduce the risk of erroneous data being submitted. PhRMA highlights the following specific areas for recommended refinement:

- ***"Other Discounts and Rebates (including (PAPs)" Data Element***. PhRMA is concerned that the Board's proposal to collect Patient Assistance Program ("PAP") information from health insurance plans under the Draft Carrier Data Template reflects a significant misunderstanding of the function of PAPs. Assistance that manufacturers provide to patients (for example, cost-sharing assistance) is separate and distinct from commercially negotiated price concessions, discounts, or rebates provided to a payer or their plans. In fact, industry analysts consider manufacturer copay assistance data separately from rebates and discounts.[8] Rather, manufacturer PAPs help support *patients*—i.e., they facilitate patient access by helping patients afford their out-of-pocket costs for medicines, which can be significant and are directly impacted by structure of their health plans' benefit designs (e.g., if they have a deductible or pay coinsurance).

  The Board's affordability review rule includes consideration of PAP data in the Board's identification of drugs that "may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon."[9] Nevertheless, it is inaccurate to characterize such support as a rebate or discount to the plan because it is intended to help patients with out-of-pocket costs and does not impact the cost to the plan. Additionally, health insurance plans 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.[10] ***We urge the Board to remove this data element from future versions of the Draft Carrier Data Template.***

[8] IQVIA, "The Use of Medicines in the U.S. 2023: Usage and Spending Trends and Outlook to 2027", May 2, 2023
[9] OAR 925-200-0020(2)(j)(A)(i).
[10] 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."). PhRMA also remains concerned that the Board has not provided a principled and specific methodology for how the affordability review process will be operationalized, including how PAP information will be considered within that process. *See* Letter from PhRMA to Board (Feb. 11, 2023), at 1-3; Letter from PhRMA to Board (Apr. 16, 2023), at 1-2.

- ***"Is 3rd Party Payment Allowed for the Drug" Data Element***. PhRMA requests clarification about what data the Board intends to collect from its "Is 3rd party payment allowed" data element. If the Board intends this data element to capture information about Accumulator Adjustment Programs ("AAPs"), ***we recommend the Board revise this data element to ask whether the plan restricts third party payments from applying toward patient out-of-pocket requirements (e.g., deductible or cost-sharing obligations).***

  As the Board is aware, commercial health plans and PBMs have increasingly shifted costs for prescription medicines to patients in recent years through increased use of deductibles and coinsurance. To help patients better afford their medications in the face of eroding health insurance coverage, biopharmaceutical manufacturers offer cost-sharing assistance to help patients overcome financial barriers to access and stay adherent to treatment. In recent years PBMs and other vendors have devised schemes, such as AAPs and other programs that siphon patient assistance from the patients for whom it is intended.[11] AAPs can substantially increase patients' out-of-pocket costs and increase financial burden and health risk, especially for those with serious and chronic illnesses.

* * *

We thank you again for this opportunity to provide comments and feedback on the Draft Carrier Data Template and for your consideration of our concerns and requests for revisions. We stand ready to be a constructive partner with the Board and can offer technical insight in this field for the Board's consideration. If there is additional information 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

[11] https://www.iqvia.com/locations/united-states/blogs/2022/03/trends-copay-accumulator-adjuster-programs