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December 7, 2023

Numi Rehfield-Griffith, Senior Policy Advisor
Oregon Department of Consumer and Business Services
350 Winter St NE 2nd floor
Salem, OR 97301

Re: Comments on OAR 836-053-0473, OAR 836-053-XXX, and OAR 836-200-04XX

Dear Ms. Rehfield-Griffith:

On behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), I am writing to offer comments and seek clarification on draft revisions to OAR 836-053-0473, and draft rules OAR 836-053-XXX, and OAR 836-200-04XX, released on November 9, 2023 and implementing 2023 Senate Bill 192. 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.

PhRMA appreciates the conversation in the RAC panel for this rule and offers the following comments regarding the current draft.

1) Definition of Rebates

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.[1] Because of these PBM contract practices, without clear definitions for its data elements, the Department may receive data from health insurers and PBMs that is inconsistent and incomplete. For clarity and consistency in how the term is applied, PhRMA requests that the Draft Regulations be revised to include a definition of "rebate" for both OAR 836-053-XXXX and OAR 836-200-04XX. We suggest the following definition:

> "Rebate" means
> (a) 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 an insurer, health

[1] 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/.

plan, or PBM during the coverage year from a manufacturer, dispensing pharmacy, or other party in connection with the dispensing or administration of a prescription drug, and
(b) reasonable estimates of any negotiated price concessions, fees and other administrative costs that are passed through, or are reasonably anticipated to be passed through, to an insurer or health plan and serve to reduce the insurer or health plan's liabilities for a prescription drug.

2) Capturing the full range of business entities under PBMs

Effective implementation of SB 192's PBM transparency and reporting requirements is critical because opaque PBMs have concentrated their market power, hiding dollars from insurers, employers, and patients. PBMs are operating in ways that enrich themselves to the detriment of those who rely on their negotiating power and expertise, creating and profiting from misaligned incentives and raising clear conflicts of interest. This has raised the attention of states, Congress, and the Federal Trade Commission. Because PBMs operate almost entirely in a black box, health plans, employers, and patients often do not know about the conflicts of interest that riddle PBM decision-making. And when policymakers do get close to reigning in unfair practices, that black box allows them to "shape-shift" into other entities in order to evade regulation (e.g., creating foreign-based rebate management organizations or group purchasing organizations).

For example, despite the already considerable market power of their respective PBMs, vertically integrated organizations[2] have recently created a separate "rebate contracting entity" that is responsible for negotiating, collecting, and disbursing manufacturer rebates for their commercial book of business. Rebate contracting entities combine the purchasing power of large PBMs, smaller PBMs, and health insurers, significantly increasing their leverage in negotiations with manufacturers.[3] To date, very limited information about these rebate contracting entities, including their financial relationships with PBMs and insurers, has been made publicly available. The three entities and their associated PBMs / health insurers are:

- Ascent Health Services: Express Scripts / Cigna, launched in 2019
- Zinc: CVS Health / Aetna, launched in 2020
- Emisar Pharma Services: OptumRx / UnitedHealthcare, launched in 2021

In addition to increased negotiating leverage, market analysts and industry experts suggest that rebate contracting entities may create other advantages for PBMs. First, two of the three rebate contracting entities of these U.S.-based corporations are headquartered overseas (Ascent Health Solutions in Switzerland and Emisar Pharma Services in Ireland), allowing them to take advantage of lower foreign corporate tax rates and more restrictive privacy laws. Second, PBMs are consolidating market power through these entities to create new revenue streams via additional administrative service fees charged to manufacturers.[4] Growth of administrative service fees is consistent with research showing that PBMs are increasingly shifting away from a compensation model based on retained commercial rebates – perhaps in response to increased public and employer scrutiny – in favor of revenues collected from spread pricing and administrative service fees assessed on manufacturers, payers, and pharmacies.[5]

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[2] In recent years, the three largest PBMs – CVS Caremark, Express Scripts, and OptumRx – have also combined with health insurers, specialty and mail order pharmacies, and provider groups to form large vertically integrated organizations. Source: Fein, AJ. The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute. March 2022.
[3] Nephron. "Optum Launches 'Emisar' Contracting Entity; Navtius Aligns with Ascent via Prime." July 26, 2021.
[4] Ibid.
[5] 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

We recognize the intent of drafting this section to attempt to capture new rebate contracting entities, GPOs, and other PBM subsidiaries within the scope of reporting under this section. Further, based on the discussion at the Rules Advisory Committee meeting on November 13, 2023, we understand that draft rule OAR 836-200-04XX is intended to read and will be revised as follows:

> *(3) The amounts described in section (1) of this rule must include all payments that the pharmacy benefit manager received from manufacturers directly and any payments the pharmacy benefit manager received from ~~manufacturers'~~ pharmacy benefit managers' subsidiaries or otherwise affiliated entities.*

For clarity, the Department should consider providing a definition for "Otherwise Affiliated Entities." PhRMA suggests the following definition:

> "Otherwise Affiliated Entity" means:
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> (a) any entity, whether foreign or domestic, that is a member of any controlled group of corporations (as defined in section 1563(a) of the Internal Revenue Code, except that "50 percent" shall be substituted for "80 percent" wherever the latter percentage appears in such code) of which a pharmacy benefit manager is a member; or
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> (b) any of the following persons or entities that are treated as a related entity to the extent provided in rules adopted by the Director:
>
> (i) a person other than a corporation that is treated under such rules as a related entity of a pharmacy benefit manager, or
>
> (ii) a person or entity that is treated under such rules as affiliated with a pharmacy benefit manager in cases where the pharmacy benefit manager is a person other than a corporation.

Sincerely,

Dharia McGrew, PhD
Director, State Policy