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September 9, 2024

Lily Sobolik, Senior Policy Advisor
Oregon Department of Consumer and Business Services
Division of Financial Regulation
350 Winter Street NE
Salem, OR 97309-0405

Re: Oregon Prescription Drug Price Transparency Program Proposed Rule Draft

Dear Ms. Sobolik:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to review and comment on the Department's Draft revisions to the Rules for the Oregon Prescription Drug Price Transparency Program ("Draft Revisions"), which were discussed at the Rules Advisory Committee meeting on August 22, 2024 (the "RAC Meeting").[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease.

We provide below our comments, concerns, and recommendations with respect to the Draft Revisions. PhRMA appreciates the Department's work to review the regulations of the Prescription Drug Price Transparency Program ("Program").[2] PhRMA has concerns, however, about several changes proposed by the Draft Revisions, which may create unnecessary ambiguities and may not further the Department's goals of easing administrative burdens for itself and manufacturers or addressing the Program's "misunderstood requirements."[3] We urge the Department to continue refining the ideas in its Draft Revisions in a manner consistent with our below comments and with the requirements of the Drug Price Transparency Program Statute.

I. Expectations of Reporting Manufacturers

PhRMA appreciates the Department's efforts to clarify the reporting requirements, but objects to the proposed removal of the "good faith" standard from the manufacturer requirements.[4] Eliminating the "good faith" language would give the Department virtually unlimited discretion to assess penalties against any manufacturer that it determines to have submitted "inaccurate or incomplete information." We encourage the Department to retain the "good faith" language in these provisions so that its process for reviewing reports must account for manufacturers' efforts when assessing compliance with these requirements.

At the August 22nd meeting, the Department expressed a concern that the phrase "good faith" is currently not defined. However, Oregon law is replete with good faith obligations unaccompanied by specific

[1] *See* Draft Revisions, *available at* https://dfr.oregon.gov/help/committees-workgroups/Documents/RAC/DPT/20240822-drug-price-transparency-rac-rule-draft.pdf.
[2] 2018 Or. Laws ch. 7 (H.B. 4005) (codified as amended at O.R.S. § 646A.689) (the "Drug Price Transparency Program Statute").
[3] Oregon Department of Consumer and Business Services, Division of Financial Regulation, "Drug Price Transparency Rule Advisory Committee Meeting," 7 (Aug. 22, 2024).
[4] Draft Revisions § 836-200-0525(1) and (4).

definitions of the term.[5] Based on its use in those situations, the term "good faith" appears to have a meaning that is sufficiently understood that it does not require a definition.

II. Proposed Definitions

PhRMA is concerned with a number of the changes in definitions. We appreciate the efforts to clarify terminology to properly delineate the scope of the Program. However, some definitions have been expanded inappropriately, and more than necessary to achieve the Program's goals.[6]

A. "New prescription drug"

The Proposed Revisions include a change to the definition of "New prescription drug" that excludes "A product with a change in the national drug code ["NDC"] or labeler name that has been continuously marketed by the same or a different manufacturer."[7] However, the Department staff indicated at the August 22, 2024 RAC Meeting that their intent is to require a manufacturer to file an additional new drug report each time a new NDC code is created for one of their products. The intended approach described by the Department at the RAC Meeting appears to be inconsistent with the Draft Revisions, as it may require additional reports for new NDCs that would not meet the definition of a "New prescription drug". Further, PhRMA has concerns with the Department's indicated approach as described at the RAC Meeting. NDCs are a function of how a product is packaged, repackaged, or labeled and not the drug product itself, and the creation of a new NDC should not automatically be considered a "new drug product" by the Department.

B. "Reporting manufacturer"

PhRMA appreciates the proposed revisions to the definition of "Reporting manufacturer," which appear to clarify the scope of entities that are subject to the Program's reporting obligations.[8] However, PhRMA is concerned that the proposed change to paragraph (c)—specifying that the definition includes an entity that "[s]ets or changes the wholesale acquisition cost of drugs it directly manufactures or indirectly manufactures through, *including but not limited to*, contracts with other entities"—may unintentionally broaden the scope of this definition and may not provide additional clarity.[9] PhRMA asks the Department to adopt language that concretely delineates the scope of this definition, such as by referring to an entity that, "[s]ets or changes the wholesale acquisition cost of drugs it manufactures, directly or through contract manufacturing agreements with other entities."

III. Threshold for Reporting New Prescription Drug

[5] *See, e.g.*, O.R.S. §§ 130.020 (requiring a trustee to "act in good faith and in accordance with the purposes of the trust"); 653.428 (requiring an employer to "provide a new employee with a written good faith estimate of the employee's work schedule"); 676.170 (granting immunity from civil liability to "[a] person who reports or supplies information in good faith to a health professional regulatory board"); 809.450 (requiring the department of transportation to rescind the suspension of a person's driving privileges if the person "reasonably and in good faith believed that the person was in compliance with financial responsibility requirements").

[6] PhRMA has concerns that the Department's interpretation of "Dosage" may overestimate the price of drugs. Drugs may have different courses of treatment, such as when a drug may have both chronic and acute dosing. The Department's use of the highest strength and frequency of administration may not be consistent with the typical course of treatment for the vast majority of patients, and presuming it is could systematically overestimate the cost for certain drugs.

[7] Draft Revisions § 836-200-0505(6)(b).

[8] Draft Revisions § 836-200-0505(11)(c).

[9] *Id* (emphasis added).

A. Introduction of New Drug

The Draft Revisions propose to define the "date of introduction" for a drug product as "the FDA start marketing date or the date the product is first listed for sale in the United States, whichever is later."[10] The FDA start marketing date does not necessarily represent the date a drug is first marketed in the state, and the language, "listed for sale," is ambiguous and diverges from the approach taken by other states which have defined a drug's introduction as the date it is "made available for purchase" within the state.[11] PhRMA suggests that the Department further clarify the Proposed Revisions to refer to the date that a drug is first made available for purchase in Oregon.

B. New Drug Reporting Threshold

PhRMA supports the proposal to update the reporting threshold from $670 to $950 to align with the threshold for Medicare Part D specialty tier eligibility established by the 2024 Final Call Letter from the Centers for Medicare & Medicaid Services ("CMS").[12] PhRMA requests that the Committee adopt language that would update the threshold when the CMS Final Call letter is periodically updated. However, we recognize that the Department staff indicated at the RAC Meeting that automatically incorporating future changes to the Medicare Part D specialty tier threshold into the Proposed Revisions may violate the Oregon Constitution.[13]

* * *

We thank you again for this opportunity to provide comments and feedback, and for your consideration of our concerns. Although PhRMA has concerns about the Draft Revisions to the rules of the Oregon Prescription Drug Price Transparency Program, we stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

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[10] Draft Revisions § 836-200-0520(4).
[11] *See, e.g.*, Cal. Code Regs. tit. 22, § 96060 ("'Introduced to market' means made available for purchase in California."); Washington State Health Care Authority, "Manufacturer Data Submission Guide" (Mar. 1, 2024), *available at* https://www.hca.wa.gov/assets/billers-and-providers/manufacturers-data-submission-guide-4.0.pdf ("'Introduced to market' means marketed in Washington State.'").
[12] Draft Revisions § 836-200-0520(2).
[13] Seale v. McKennon, 215 Or. 562, 572 (1959) (legislation requiring a state agency "to adopt and promulgate as the law of this state future laws of the United States and regulations of the United States … is unconstitutional … Adoption of existing statutes and regulations of the federal government or another state is, however, valid.").