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November 4, 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 October 2024 Revisions to Draft Rule

Dear Ms. Sobolik:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to review and comment on the third round of the Oregon Department of Consumer and Business Services' ("Department's") draft revisions to the Rules for the Oregon Prescription Drug Price Transparency Program ("DPT" or "Program"), which were discussed at the Rules Advisory Committee ("RAC") meeting on October 17, 2024 ("Draft Revisions").[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.

As described in our prior comments, PhRMA appreciates the Department's ongoing work to review the regulations of the Program and supports the Department's decision to make the price-increase reporting requirements voluntary as an appropriate implementation of the Court's judgment in *PhRMA v. Stolfi*.[2] However, PhRMA remains concerned with several changes in the Draft Revisions that appear to conflict with the DPT Statute, and which would create additional and undue burdens on manufacturers.[3] We provide below our comments, concerns, and recommendations with respect to the third set of Draft Revisions. We urge the Department to continue refining the ideas in its Draft Revisions in a manner consistent with our below comments and the requirements of the DPT Statute.

I. Manufacturer Certification, draft OAR 836-200-0540

PhRMA objects to the language in subsection (1)(d) of draft OAR 836-200-0540, which would seek to force an officer or other employee of a manufacturer to certify, under penalty, that the officer or employee has taken steps to ensure that submitted information is accurate and to certify, under penalty, that information subject to a trade secret claim is not publicly available. This provision appears aimed at manufacturers' attempts to exercise their right to protect trade secrets. But the DPT Statute expressly protects manufacturers' trade secrets, forbidding their disclosure except under limited circumstances.[4] The DPT Statute provision on civil penalties also expressly limits the circumstances under which penalties may be

[1] *See* Draft Revisions, *available at* https://dfr.oregon.gov/help/committees-workgroups/Documents/RAC/DPT/20241017-drug-price-transparency-rac-rule-draft.pdf.
[2] No. 19-cv-01996, 2024 WL 1177999 (D. Or. March 19, 2024).
[3] 2018 Or. Laws ch. 7 (H.B. 4005) (codified as amended at O.R.S. § 646A.689) (the "DPT Statute"). PhRMA also incorporates by reference all prior comment letters to the extent applicable. *See* Letter from PhRMA to the Department regarding Oregon Prescription Drug Price Transparency Program Proposed Rule Draft (Sept. 9, 2024) (hereinafter "September Letter from PhRMA to the Department"); Letter from PhRMA to the Department regarding Oregon Prescription Drug Price Transparency Program September 2024 Revisions to Draft Rule (Oct. 3, 2024) (hereinafter "October Letter from PhRMA to the Department").
[4] DPT Statute § 646A.689(10)(a)(A).

levied by the Department,[5] and does not authorize DCBS to mandate certification as a new substantive requirement, above and beyond a manufacturers' enumerated obligations. We accordingly ask that subsection (1)(d) be removed from the Draft Revisions.

II. New Prescription Drug Reporting Requirements, draft OAR 836-200-0531

PhRMA welcomes changes in the most recent Draft Revisions that would delete the previous version's language requiring reporting of detailed information describing the sources and use of public funds for research and development.[6] As we stated in our October comments, the reporting of particular details on the use of public funds for research and development would not be consistent with the DPT Statute.[7]

However, PhRMA continues to have concerns with the proposed amendments to the new prescription drug reporting requirements regarding the reporting of marketing costs and pricing methodology. As explained in the October Letter from PhRMA to the Department, the proposals go beyond what is required under the DPT Statute.[8] We request that the Department withdraw these proposals consistent with our prior comments.

III. New Drug Definition, draft OAR 836-200-0505

PhRMA requests that the Department clarify the proposed revisions to the "new prescription drug" definition. The Draft Revisions would revise the term to state, in relevant part, that "[i]n cases where multiple products are included on an application or approved later, each product *with a unique national drug code [("NDC")]* will be considered a new prescription drug."[9] It is not clear whether the reference to an NDC is to a drug's NDC-11 or NDC-9. PhRMA requests that the Department clarify the intended meaning. We note that products reported at the NDC-11 level relative to NDC-9 do not represent meaningful differences that indicate different drug products in a way that is relevant to operating the Program. A drug's NDC-11 includes information down to the size of the package, such as the volume size of a suspension or how many bottles/packages of a drug are contained in a carton. For example, the listing of a common allergy medication FDA's NDC directory shows distinct NDC-11s for one blister pack in one carton or for three blister packs in one carton.[10] These are simply differences in packaging, not distinct drugs. Reporting at the NDC-11 level does not serve a meaningful purpose and reporting with this level of granularity may be more administratively burdensome for manufacturers looking to report under the Program.

IV. Expectations of Reporting Manufacturers, draft OAR 836-200-0525

The Department has proposed to change the "good faith" standard in the Draft Revisions from the current "*make a good faith effort*" language to new "*act in good faith*" language.[11] As we stated when the Department proposed to remove the "good faith" standard entirely in the previous version of the draft revisions, the DPT Program requires manufacturers to submit voluminous information as part of the

[5] The Department may impose a civil penalty for: "(a) Failing to submit timely reports or notices as required by [the DPT Statute]; (b) Failing to provide information required under [the DPT Statute]; (c) Failing to respond in a timely manner to a written request by the department for additional information under subsection (7) of [the DPT Statute]; or (d) Providing inaccurate or incomplete information under [the DPT Statute]." DPT Statute § 646A.689(8).

[6] Draft Revisions § 836-200-0531(1)(h).

[7] Letter from PhRMA to the Department (Oct. 3, 2024), 3.

[8] Letter from PhRMA to the Department (Oct. 3, 2024), 2.

[9] Draft Revisions § 836-200-0505(6) (emphasis added).

[10] https://dps.fda.gov/ndc

[11] *Id.* (emphasis added).

reporting requirements and there may be cases where the reporting requirements are unclear.[12] The "good faith effort" standard allows the Department to account for a manufacturer's efforts when assessing compliance with these requirements. Focusing on whether a manufacturer has "act[ed] in good faith" rather than on the manufacturer's "effort" appears to substantively change the nature of this requirement, and absent a clear explanation from the Department for this change, we ask that the Department maintain the existing standard.

V. Reporting on Patient Assistance Programs, draft OAR 836-200-0532

The DPT Statute requires manufacturers to report certain information related to patient assistance programs "offered by the manufacturer."[13] Despite this clear statutory language, the Draft Revisions would restate in section 836-200-0532 a requirement for manufacturers to provide information on "independent patient assistance programs."[14] When the Department initially proposed this language in regulation in 2018, PhRMA provided comments to the Department that this requirement is inconsistent with the plain text of the DPT Statute, and would require reporting of information to which manufacturers do not have access.[15] PhRMA reiterates our prior concerns with respect to this language and requests that the Department instead adopt rules that are consistent with the requirements of the DPT Statute.

VI. Additional Information Requests, draft OAR 836-200-0535

PhRMA recognizes the Department's clarification that it will automatically grant manufacturers additional time requests for responses to additional information requests.[16] This will better provide manufacturers with necessary time to prepare and submit responses to additional information requests in a predictable manner.

* * *

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 Program rules, we stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

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[12] September Letter from PhRMA to the Department at 2.
[13] DPT Statute § 646A.689(5).
[14] Draft Revisions § 836-200-0532(2). Substantially similar language is currently included under § 836-200-0530(3).
[15] *See* Letter from PhRMA on Preliminary Draft House Bill 4005 Rules Distributed on September 24, 2018 at 5 (Oct. 15, 2018); Letter from PhRMA on the Second Draft HB 4005 Rules Distributed on October 19, 2018 at 3-4 (Nov. 1, 2018); Letter from PhRMA on the Third Draft HB 4005 Rules at 3-4 (Nov. 29, 2018); Letter from PhRMA on Final Rule at 6-7 (Feb. 1, 2019).
[16] Draft Revisions § 836-200-0535(4).