Hearing Officer's Report to Agency on Rulemaking Hearing

Date: 3/12/2025

To: Department of Consumer and Business Services

From: Lily Sobolik, Hearing Officer

Subject: Oregon Prescription Drug Price Transparency Rulemaking

Hearing Date/Time:	February 24, 2025
Hearing Location:	Hybrid meeting conducted in person at Labor and Industries Building and virtually on Microsoft Teams
Comment Period End:	March 3, 2025

Background

The Oregon Prescription Drug Price Transparency (DPT) program, housed in the Department of Consumer and Business Services (DCBS), was established five years ago under the Prescription Drug Price Transparency Act (2018 Oregon House Bill 4005, Oregon Revised Statutes 646A.680 et seq.). A five year review of the rules pursuant to ORS 183.405 revealed areas to clarify requirements, increase efficiency, and more accurately reflect the existing DPT program processes and procedures.

A Rulemaking Advisory Committee (RAC) included nine stakeholders representing a range of industries and perspectives. The RAC members represented consumer advocates and coalitions, large and small pharmaceutical manufacturers, trade associations, third party compliance partners, and insurance carriers. The RAC met four times between August and November, 2024. Each meeting included draft changes to the rules, member comments, questions and discussion, and public comments. The changes to the proposed rules include:

- Clarifying existing definitions of key terms including "new prescription drug," "one-month supply," and "reporting manufacturer;"
- Correction of internal references;
- Changing annual price increase reporting from mandatory to voluntary per a recent court judgment;
- Specifying requirements of a designated contact person for a reporting manufacturer;
- Updating the threshold for reporting new prescription drugs;

- Adding clarification about the reported data elements for new prescription drugs;
- Adding automatic approval of appropriately submitted requests for additional time; and,
- Removing rules no longer necessary for program implementation.

Hearing

A public hearing to receive testimony was held on February 24, 2025. Notice for the hearing was published in the Oregon Bulletin on January 27, 2025. Public testimony was accepted until 5:00 p.m. on March 3, 2025. Representing DCBS at the public hearing were Lily Sobolik and Karen Winkel.

21 members of the public attended the hearing in person or remotely, and one provided verbal testimony.

Three public comments were received in writing after the Notice of Proposed Rulemaking was published and before the comment deadline.

Summary of Testimony

The written and verbal testimony covered perspectives on both technical and substantive concepts regarding the adoption of the proposed rules. Main themes included:

1. **First amendment concerns:**
   - Comments express concern that certain reporting requirements, particularly regarding new drugs, are highly burdensome, significantly overbroad, and not adequately tailored to serve valid governmental interests. Comments state that these requirements violate reporting manufacturer's First Amendment rights as was decided in the *PhRMA v. Stolfi* judgment for price-increase reporting.

2. **Clarity on new and revised definitions:**
   - Comments express confusion regarding the newly added definition of the term "dosage" as the 'highest amount, strength, and frequency' of a medication may not correlate with each other.
   - Comments express concern and confusion regarding certain revisions to the definition of "new prescription drug" particularly that some additions would making reporting unnecessarily expansive and burdensome.
   - Comments noted conflicting definitions of the concept of a drug's 'date of introduction.'

3. **Clarity on the threshold for reporting new drugs**
   - Comments request that the threshold for reporting new drugs automatically align with the federal reference point or clarify that it will be updated.

4. **Alignment with statutory authority**
   - Comments express concerns that the language proposed to clarify the reporting requirements for new drugs exceeds or conflicts with DPT's statutory authority.
   - Comments also request clarity on a change in language from 'cost' to 'spend' following the proposed rules presented at the final RAC meeting.
   - Comments request that reporting requirements on independent patient assistance programs be removed because it exceeds DPT's statutory authority to collect information on patient assistance programs "offered by" the manufacturer.
   - Comments request reverting to the current rule's language about submitting "a written request for supporting documentation…" instead of the revised language of "one or more" requests.

5. **Trade Secret Concerns**
   - Comments expressed concerns that revised and current trade secret provisions are insufficient and may compromise the confidential and proprietary nature of trade secret information submitted to the DPT program. Concerns were also raised about the lack of an appeal process after a departmental determination that submitted information is not exempt from public disclosure.

Discussion

- **First amendment protections:** The *PhRMA v. Stolfi* judgement, which is under appeal, is applicable to the DPT's price-increase reporting and is not applicable to other aspects of the program's reporting requirements.

- **Definition clarity:**
  - The current definition of "dosage" has been in every draft of the proposed rule since the initial Rulemaking Advisory Committee (RAC) meeting. Written and verbal comments expressing concerns that the definition would overestimate the price of drugs were discussed during the RAC process. The department clarified that the goal of the term 'dosage' and its definition is to provide a consistent standard for determining drugs' reporting threshold. Additionally, the department noted the existing, aligned explanation of 'dosage' in the definition of "course of treatment." Following this explanation, no written comments were provided by the RAC on this topic.
  - The proposed changes to the definition of 'new prescription drug' are clarifications of current DPT program practice. As discussed during the RAC process, the DPT's current reporting system is NDC-11 (package NDC) based, which necessitates reporting at the package NDC level. Furthermore, as manufacturers regularly release new variations (e.g., changes in strength, dosage form, formulation, package type, or package size) of the same product after its initial release the program currently

expects reporting whenever a new package NDC is available and meets the threshold, even if there were related package NDCs already on the market.

- The department agrees that the language regarding a drug's 'date of introduction' should be clarified and aligned across the proposed rules. To that end, the department will revise the proposed new drug definition in OAR 836-200-0505(6) to read:
  - **"… A new prescription drug's introduction date is the FDA start marketing date or the date the product is first available for purchase in the United States, whichever is later."**

- **New drug reporting threshold:**
  - As discussed during the RAC process, the Oregon Constitution prohibits delegating authority of public bodies exercising governmental power granted by the legislature. The DPT statute (ORS 646A.689(6)) references the reporting threshold set by the Centers for Medicare and Medicaid Services for specialty drugs in Medicare Part D program so it is not appropriate to remove that reference from the rule.

- **New drug reporting requirements**:
  - The RAC discussed this section of the proposed rule in detail across multiple meetings. In response to RAC feedback, the department made changes to more narrowly tailor the rule to the program's statutory authority.

    The purpose of adding clarifying language to the new drug reporting requirements is to provide an illustrative description of the categories of required information. The proposed rule clarifies two types of spending that are part of the marketing description: "associated spending … prior to launch" and "planned costs … following launch." The proposed rule also includes additional examples of types of marketing and target audiences so reporting manufacturers can better understand the reporting requirements and the two types of spending to report for each type of marketing. The DPT program does not expect every example to apply to every report, an expectation which is expressed by the phrase "with any associated explanation."

    Similarly, the proposed rule provides additional details for reporting "the methodology used to establish the price of the new prescription drug." The proposed rule provides a non-exhaustive list of potential factors impacting the pricing methodology.

    By providing more details about the types of information required, depending on each manufacturer's marketing spending and pricing methodology, the data will be collected in a more uniform manner while also allowing for individualized explanation as needed. This will allow DPT

to conduct deeper analysis on its collected data, thus, improving the program's ability to accomplish its charge of providing accountability for prescription drug pricing through transparency of specific cost and price information.

- The change in language from "associated actual costs" to "associated spending" is not a substantive change but rather represents an effort to align language in the rule.

- **Independent patient assistance program reporting:**
  - The DPT rules have included reporting requirements on independent patient assistance programs since the beginning of the DPT program. The proposed rules do not include substantive changes to this reporting requirement.

    As discussed during the RAC process, the department continues to include independent patient assistance programs in the broad statutory requirement for reporting on patient assistance programs that manufacturers 'offer.' The department interprets this requirement to include patient assistance programs supported, maintained, or administered by the manufacturer. During the RAC process, the department solicited feedback to clarify rule language but none was received.

    Additionally, the rule contains language regarding information ("available to the manufacturer at the time of the report") that reflects the department's understanding that access to information may differ for a program the manufacturer does not directly administer.

- **Additional information requests:**
  - The clarifying change from "a written request" to "one or more written requests" was discussed during the RAC process. As explained, the use of the article "a" in statute ("the department may make a written request…") grants the department permission to request information as needed instead of limiting it to a single request as the use of the article 'the' would have indicated. In practice, the DPT program typically only makes multiple requests when a manufacturer does not fully understand or comply with the original request.

- **Trade secrets**
  - The DPT program continues to provide a trade secret determination appeal process in its current rules. The existing appeal process requires the department to notify the manufacturer of an adverse trade secret determination and provides 15 days for a department appeal and request for redetermination (OAR 836-200-0540(3)). After an adverse appeal determination, the department is not permitted to disclose information

claimed to be trade secret for at least 21 days giving a manufacturer sufficient time to file a legal appeal if desired (OAR 836-200-0540(4)).

Recommendation

Having considered fully the testimony presented at the hearing and the written comments, I recommend that the division adopt the proposed rules with the change noted above in bold on page 4.

Lily Sobolik
Hearing Officer
Division of Financial Regulation

This Summary and Recommendation are reviewed and adopted.

Signed this 25 day of March, 2025.

Andrew R. Stolfi
Insurance Commissioner and Director
Department of Consumer and Business Services