



Hearing Officer's Report to Agency on Rulemaking Hearing

Date: 9/14/2026

To: Department of Consumer and Business Services

From: Lily Sobolik, Hearing Officer

Subject: Drug Price Transparency program updates

Hearing Date: August 26, 2026

Hearing Location: Hybrid hearing conducted in-person at Labor and Industries Building and virtually on Microsoft Teams.

Comment Period End: September 2, 2026

Background

The Oregon Prescription Drug Price Transparency (DPT) program, housed in the Department of Consumer and Business Services (DCBS), was established under the Prescription Drug Price Transparency Act (2018 Oregon House Bill 4005). The DPT program collects and reports information from prescription drug manufacturers, health insurance carriers and consumers to increase the transparency of prescription drug pricing in Oregon. The law directs DCBS to engage in rulemaking to define key terms and timelines, and empowers DCBS to establish fees, adopt a schedule of civil penalties for violations, and adopt any other rules necessary for carrying out the provisions of Section 2 of the law.

Due to an August 2025 opinion issued by the Ninth Circuit (*Pharmaceutical Research and Manufacturers of America v. Stolfi*, No. 24-1570 (9th Cir. Aug. 26, 2025)), that took effect on October 31, 2025, the department was required to resume collection of mandatory price increase reports from manufacturers in 2026. In February 2026, the department undertook temporary rulemaking to reflect this court decision and provide accurate and timely rules for reporting manufacturers. While updating the permanent rules to reflect the recent court decision, the department also took the opportunity to make other needed administrative updates.

In addition to updating the rules to reflect the 2025 court decision, the department also clarified requirements, updated a reporting threshold, and added minor data collection points to allow program staff to verify accurate reporting. The proposed changes to the rules include:

- Adding a clarifying definition for “drug;”
- Correction of internal references;
- Reverting annual price increase reporting from voluntary to mandatory per court judgment;
- Clarifying language about the timing of data reporting;
- Adding examples of factors that may contribute to price increases;
- Updating the threshold for reporting new prescription drugs; and,
- Adding minor data collection points to allow for DPT program staff verification.

The proposed rule changes are necessary to ensure that the program is administered in a fair and equal manner for all participating drug manufacturers, to minimize the administrative burden and cost of the program for the state and the industry, and to achieve the program’s purpose of providing notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability for prescription drug pricing.

Hearing

A public hearing to receive testimony was held on August 26, 2026, at 9:30 am. Notice for the hearing was published in the Oregon Bulletin on August 3, 2026. Public testimony was accepted until 5:00 p.m. on September 2, 2026. Representing DCBS at the public hearing were Lily Sobolik and Karen Winkel.

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

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

Summary of Testimony

The written and verbal testimony during the public hearing and Rulemaking Advisory Committee processes covered perspectives on both technical and substantive concepts regarding the adoption of the proposed rules. Main themes included:

- **First Amendment and trade secret concerns**
 - Comments included concerns that information collected through the required DPT reporting could be disclosed to the public, potentially violating trade secret protections, due process, and constitutional law.
 - Comments also stated the ongoing belief that DPT statute and regulations are unconstitutional.
- **Concerns about the scope of reporting requirements**
 - Comments expressed concerns regarding the statutory requirement for DPT to collect reporting on certain international drug prices. Concerns

- include special confidentiality protections and that comparisons are inappropriate given the different structures of health care systems, pricing, and reimbursement between the United States and other countries.
- Comments expressed concerns regarding the statutory requirement for DPT to collect detailed reporting on manufacturer patient assistance programs as it is operationally burdensome, may not be readily available, and may undermine patient access to these programs.
 - Comments expressed concerns about reporting a drug's initial launch price and about reporting the date of every price change during the previous two calendar years for annual price increase reporting because it would be overly burdensome and not useful.
 - Comments expressed concerns on overburdensome and subjective requirements regarding reporting on "all factors" related to annual price increases, particularly the potential for manufacturers to report on products other than their own. Comments state that requiring reporting on the products of other manufacturers may raise legal issues.
 - **Clarity of definitions**
 - Comments expressed confusion regarding the meaning of the terms "price," "drug," "reporting year," and "net profit."
 - **Threshold for reporting new specialty drugs**
 - Comments recommended updating the threshold for reporting new prescription drugs to align with the current Centers for Medicare and Medicaid Service (CMS) Part D specialty-tier eligibility amount.

Public Comment Discussion

- **First amendment and trade secret protections:**
 - The primary reason to conduct rulemaking was to reinstate required reporting based on the Ninth Circuit opinion in the PhRMA v. Stolfi case that found the DPT program constitutional and took effect October 31, 2025.
 - This rulemaking does not contain any changes to the rules regarding trade secrets. The DPT program continues to provide a trade secret determination appeal process that is required by its underlying statute and set out in the 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)).
- **Concerns about the scope of reporting requirements:**
 - Reporting on international drug pricing and patient assistance programs is required in statute (ORS 646A.689(3)(j) and 646A.689(5)) and has been included in DPT rules since they were first adopted. This rulemaking did not include any changes to the rules for either type of mandated data collection.

- As discussed during the RAC, the information collected regarding the date of every price change during the calendar year preceding the report for annual price increase reporting is necessary for the program to verify the reported net price increase and to ensure proper reporting as required by statute. At times manufacturers have submitted price increase reports that were not required; this information will allow program staff to more easily verify the net price increase and confirm that reports are appropriately submitted. The initial launch price and the yearly increases for the previous five years are required by statute (ORS 646A.689(3)(i)). The required information is widely available and so is readily accessible by the manufacturers.
- As discussed with the RAC, reporting on “all factors” contributing to an annual price increase aligns with reporting requirements for new prescription drugs. More importantly, it aligns with the underlying statute, ORS 646A.689(3)(c), which requires reporting on “*the* factors...” meaning “*all* factors” in plain language as described in the rules [emphasis added].
- **Updating the threshold for reporting new specialty drugs:**
 - The final rules adopted this recommended change and updated the threshold for reporting new specialty drugs to align with the most current reporting threshold set by CMS for Medicare Part D.
- **Clarifying definitions:**
 - After discussion with the RAC, the proposed language to clarify the term “reporting year” was removed from the rules to retain the original language.
 - As requested by the RAC, a definition for “drug” was included for clarity even though inconsistencies in the usage of ‘drug’ and ‘prescription drug’ were not identified.
 - Similarly, the term “price” was changed to “wholesale acquisition cost” for clarity and ease of reading (OAR 836-200-0531(4)(a) and 836-200-0533(9)(a)) even though “price” had been defined as “wholesale acquisition cost”.
 - Draft rules for the first RAC meeting added ‘loss’ to the term “net profit” to clarify the concept as some reporting manufacturers reported negative amounts of net profit. After RAC discussion, the addition of ‘loss’ was removed from the draft rules and the underlying description remains.

Recommendation

Having considered fully the testimony presented at the hearing and the written comments, I recommend adopting the rules as proposed.

Lily Sobolik
Hearing Officer
Division of Financial Regulation

This Summary and Recommendation are reviewed and adopted.

Signed on September 22, 2026.



TK Keen, Administrator
Insurance Commissioner
Division of Financial Regulation
Department of Consumer and Business Services