NOTICE OF PROPOSED RULEMAKING
STATEMENT OF NEED AND FISCAL IMPACT

Filing caption: Drug Manufacturers Annual Fee Assessment
Public comment deadline: 3/15/2024
Effective Date: 8/1/2024

HEARING

Date: **TBD**
Time: **TBD**
Officer: **Cortnee Whitlock**

Location: Labor & Industries Building
350 Winter St. NE
Basement, Conf Rm E
Salem, OR 97301

This is an online meeting only via Microsoft Teams.

Join on your computer, mobile app or room device
Click here to join the meeting
Meeting ID: **TBD**
Passcode: **TBD**
Or call in (audio only)
503-446-4951 United States, Portland
Phone Conference ID: **TBD**

NEED FOR RULE(S)

Provide background on why the rule is needed, including a short summary of the rulemaking authority and statutes implemented. Provide a summary of what the rule does. Describe the involvement of the RAC, including the types of stakeholders that were invited to and did participate. Specify if any of the stakeholders were small businesses.

The Prescription Drug Affordability Board (PDAB) was created as a part of Senate Bill 844 in 2021, which falls under the Department of Consumer and Business Services (DCBS). Its primary objective is to safeguard Oregon consumers and other entities from the high costs of prescription drugs. The law grants the PDAB the power to adopt necessary regulations for the functioning of the board.

Senate Bill 192 passed in 2023, amends ORS 646A.695 and requires DCBS to adopt by rule, in consultation with the PDAB, annual fees to be paid by manufacturers of prescription drugs that are sold in Oregon. The fees are calculated to cover the expenses incurred by the Division of Financial Regulation (DFR) for running the Drug Price Transparency (DPT) program and the PDAB. ORS 646A.680 to 646A.697.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Draft rules are available from Karen Winkel, Rules Coordinator, Division of Financial Regulation located at 350 Winter St. NE, Salem, OR 97301 and are available on the division's website: https://dfr.oregon.gov/laws-rules/Pages/proposed-rules.aspx

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT EQUITY IN THIS STATE:

(*Who is this going to impact and how might it impact one group of people differently than others?)*

Collecting the necessary fees to support the work of PDAB and the DPT program helps ensure that individuals with limited access to healthcare and underserved communities are not disproportionately burdened by high drug costs. The PDAB and the DPT program promote equity regarding access to necessary medications.

FISCAL AND ECONOMIC IMPACT:

Based on information available to DCBS, briefly discuss the cost of compliance for businesses, generally. State whether there are compliance costs for small businesses (independently owned and operated with fewer than 50 employees).

The implementation of this rulemaking will not result in significant compliance costs for businesses, as most of the compliance standards are already regulated through the Drug Price Transparency Program. The program collects the necessary data as required by ORS 646A.689 (2), (5), and (6) and ORS 743.025, and shares it with the PDAB to identify the nine drugs and insulin products. There is no expected impact on the compliance costs for small businesses as a result of this rule.

COST OF COMPLIANCE FOR SMALL BUSINESSES

(1) Identify any state agencies, units of local government, and members of the public (including specific interest groups) likely to be economically affected by the rulemaking.

Based on the information currently available, it is expected that the proposed rule will not have any significant fiscal or economic impact on state agencies, local government units, or the general public, beyond what is already required by law. However, the rule does include a requirement for manufacturers who sell drugs in Oregon to pay fees, which will have a fiscal impact on the Department of Consumer and Business Services, due to the additional staffing and resources required to perform this work. Nevertheless, the rules provide detailed information about this requirement and do not have any fiscal impact beyond what is already mandated by the underlying statute.

(2)(a) Estimate the number and type of small businesses subject to the rule(s).

The proposed rule outlines the criteria for collecting fees to support the work of the PDAB and the DPT program and does not impose any additional requirements on businesses.

According to ORS 646A.695, drug manufacturers are required to provide payments that cover the cost of departments in administering the law. The proposed rule outlines additional uses for this requirement but does not impose any additional burdens on manufacturers.

The RAC had representatives from prescription drug manufacturers, health insurers, pharmacy benefit managers, and consumer and patient advocates.

(2)(b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s).
Based on the available information, the proposed rule does not impose additional compliance costs beyond the underlying statutory requirements.

(2)(c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).
Based on the available information, the proposed rule does not impose additional costs for professional services, equipment supplies, labor, and increased administration beyond the underlying statutory requirements.

How were small businesses involved in the development of the rule?
The rulemaking advisory committee includes stakeholders within the pharmaceutical supply chain that included representation of some pharmacies are small businesses.

Was an administrative rule advisory committee consulted?

Yes. A rulemaking advisory committee, which included representatives of prescription drug manufacturers, health insurers, pharmacy benefit managers, and consumer and patient advocates, has been encouraged to provide feedback on the rule development process.

Did membership of the RAC represent the interests of persons and communities likely to be affected by the rule?

Yes. RAC members include professionals from prescription drug manufacturers, health insurers, pharmacy benefit managers, and consumer groups. Consumer groups represent the interests of Oregonians impacted by prescription drug costs.

RULE NUMBER AND SUMMARY

List each rule number and a short summary of what the rule does.

TBD

STATUTORY REFERENCE

Statutory authority: ORS 646A.693; ORS 646A.695
Statutes implemented: ORS 646A.695

Signature Printed name Date

LEGISLATOR NOTICE

If the rulemaking results from legislation passed within two years of this notice of proposed rulemaking, the agency must give notice to: 1) the legislator(s) who introduced the bill; and 2) the chair or co-chairs of all committees that reported the bill out. (Does not include referrals to other committees).

If the rule does not result from legislation within the last two years, notice shall be given to the chair or cochairs of any interim or session committee with authority over the subject matter of the rule. If notice cannot be given to these individuals, notice shall be given to the Speaker of the House and the President of the Senate.

Name	Committee or Title	Email

RULEMAKING ADVISORY COMMITTEE

Name	Organization	Email