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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 836
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
INSURANCE REGULATION

FILED
05/29/2024 1:49 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Drug Manufacturers Annual Fee Assessment

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 07/02/2024 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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Salem,OR 97301

Filed By:
Karen Winkel
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 06/25/2024
TIME: 11:00 AM - 11:45 AM
OFFICER: Cortnee Whitlock

IN-PERSON HEARING DETAILS
ADDRESS: Labor and Industries Building, 350 Winter St NE, Basement, Conf Rm E, Salem, OR 97301

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 1-503-446-4951
CONFERENCE ID: 863932832
SPECIAL INSTRUCTIONS:
This is a hybrid meeting conducted in-person and virtually via Microsoft Teams:

Meeting ID: 260 381 698 658
Passcode: pebgZg

NEED FOR THE RULE(S)

The Prescription Drug Affordability Board (PDAB) was created in the Department of Consumer and Business Services (DCBS) by Senate Bill 844 in 2021. 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 administrative rules necessary for the functioning of the board.

Senate Bill 192 (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 administering the Drug Price Transparency (DPT) program and the PDAB under ORS 646A.680 to 646A.697. Reporting manufacturers shall be subject to the assessment requirements set forth in subsections (1) to (5) of OAR 836-200-0555 for billing periods through July 31, 2023. For billing periods on or after August 1, 2023, reporting manufacturers shall be subject to the annual fee set forth in OAR 836-200-0553.

Reporting manufacturers shall submit annual fees based on the number of National Drug Codes (NDCs) for U.S. Food and Drug Administration (FDA) approved prescription drugs in the manufacturer's portfolio during the annual billing period. The department shall determine the number of NDCs for a manufacturer by referencing the FDA National Drug Code directory to calculate the number of unique NDCs for the manufacturer and any known labeler the manufacturer uses.

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 RACIAL EQUITY IN THIS STATE

The fees are paid by manufacturers of prescription drugs and do not have a disproportionate impact on any specific individuals or communities in Oregon. 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:

The annual fees paid by reporting manufacturers will provide a positive economic impact with supporting the work of the PDAB and the DPT program. The fees will ensure that the programs are integrating compliance infrastructure, policies, and regulations that improve or sustain the affordability of prescription drugs in Oregon.

The more extensive annual assessment may have an economic impact on small to medium-sized manufacturers, subject to the rule. The division does not have enough information about the quantity of small or medium-sized manufacturing businesses. However, the impact of the fee is estimated to be relatively insignificant compared to the overall revenue of pharmaceutical manufacturers.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) 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 or local government units. The public may be economically affected to the extent that manufacturers that did not submit reports to the Drug Price Transparency program in the past will now be subject to a larger annual assessment fee.

(2)(a) The department solicited feedback on small business impact from the RAC but did not receive specific information

about how many pharmaceutical manufacturers subject to the rule are small businesses, and the department is unaware of any other sources for this information.

(2)(b) Based on the available information, the proposed rule does not impose additional compliance costs beyond the underlying statutory requirements.

(2)(c) 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.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

The rulemaking advisory committee (RAC) included stakeholders within the pharmaceutical supply chain that had representation of some pharmacies that are small businesses.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:
836-200-0553, 836-200-0555

ADOPT: 836-200-0553

RULE SUMMARY: Adopting annual fees paid by drug manufacturers.

CHANGES TO RULE:

836-200-0553
Annual Fees Paid by Drug Manufacturers
(1) Each reporting manufacturer, as defined under OAR 836-200-0505, shall pay an annual fee to the Department of Consumer and Business Services to meet the costs of the department in administering ORS 646A.680 to 646A.697. The fee shall be based on the manufacturer's size as set forth in sections (3) and (5) of this rule.¶
(2) For purposes of section (1), the director shall determine the amount of revenue needed by considering expenditures in administering ORS 646A.680 to 646A.697 and cash reserves.¶
(3) Each reporting manufacturer shall be assigned to one of three size categories based on the number of National Drug Code package codes (NDCs) for FDA approved prescription drugs in the manufacturer's portfolio during the annual billing period. ¶
(a) The annual billing period is the calendar year prior to the year the annual fee is imposed.¶
(b) The department shall determine the number of NDCs for a manufacturer by referencing the FDA National Drug Code directory to calculate the number of unique NDCs for the manufacturer and any known labeler the manufacturer uses.¶
(c) The three size categories are: large (40 or more NDCs), medium (11 to 39 NDCs), and small (10 or fewer NDCs). ¶
(4) The department shall inform manufacturers of their assigned size category and provide manufacturers the opportunity to request a change to their assigned size category prior to assessment. Manufacturers will have 30 days to submit the request, which must include information to demonstrate why their size category is not correct.¶
(5) At the end of the annual billing period each manufacturer's annual fee will be calculated based on its size category, the amount of total revenue needed apportioned to its size category, and the number of reporting manufacturers in its size category. ¶
(a) Manufacturers classified as large shall collectively be apportioned 70 percent of the total revenue needed.¶
(b) Manufacturers classified as medium shall collectively be apportioned 25 percent of the total revenue needed. ¶
(c) Manufacturers classified as small shall collectively be apportioned 5 percent of the total revenue needed.¶
Example: Total revenue needed for the year is $1,000,000. There are 100 manufacturers categorized as large. Each large manufacturer's fee will be $7,000 ($1,000,000 x 0.7 / 100 = $7,000).¶
(6) The revenue collected under this rule shall be deposited in the Prescription Drug Affordability Account established in ORS 705.146.¶

(7) A manufacturer shall pay its annual fee imposed under this section no later than 30 days after the date of the assessment by the department. A manufacturer shall pay interest at 9 percent per annum on any assessment that is not paid when due.¶
(8) Reporting manufacturers shall be subject to the assessment requirements set forth under OAR 836-200-0555 in subsections (1) to (5) for billing periods through July 31, 2023. For billing periods on or after August 1, 2023, reporting manufacturers shall be subject to the annual fee set forth under this rule.
Statutory/Other Authority: ORS 646A.693, ORS 646A.695
Statutes/Other Implemented: ORS 646A.695

AMEND: 836-200-0555

RULE SUMMARY: Adopting assessments against prescription drug manufacturers for 2023 and prior.

CHANGES TO RULE:

836-200-0555
Assessments Against Prescription Drug Manufacturers for 2023 and Prior
(1) Once annually, no later than October 1, all reporting manufacturers will pay an assessment of $400. The director may by order reduce the fees assessed for any specific year.¶
(2) Once annually, no later than October 1, reporting manufacturers that have filed one or more reports under OAR 836-200-0515 to 836-200-0530 between August 1 of the previous year and July 31 of the current year must pay an additional assessment for each report filed.¶
(3) For the purposes of subsection (2), the director shall determine the amount of the assessment by subtracting the revenue collected under subsection (1) from the amount of revenue needed to cover the department's estimated expenses in administering Oregon Laws 2018, chapter 7, section 2 and OAR 836-200-0500 to 836-200-0550, and dividing the resulting amount by the total number of filings subject to assessment between August 1 of the previous year and July 31 of the current year. The director shall determine the amount of revenue needed by considering the legislatively approved expenditures for administration of Oregon Laws 2018, chapter 7, section 2 and OAR 836-200-0500 to 836-200-0555, as well as the timing of cash revenues and expenditures.¶
(4) The revenue collected under subsections (1) and (2) of this section must be used solely for expenses incurred in the administration of Oregon Laws 2018, chapter 7, section 2 and OAR 836-200-0500 to 836-200-0555.¶
(5) A manufacturer must pay each assessment imposed under this rule no later than 30 days after the date of the assessment by the department. A manufacturer must pay interest at nine percent per annum on any assessment that is not paid when due.¶
(6) Reporting manufacturers shall be subject to the assessment requirements set forth in subsections (1) to (5) of this rule for billing periods through July 31, 2023. For billing periods on or after August 1, 2023, reporting manufacturers shall be subject to the annual fee set forth in OAR 836-200-0553.
Statutory/Other Authority: Or Laws 2018, ch 7, ORS 646A.693, ORS 646A.695
Statutes/Other Implemented: Or Laws 2018, ch 7, ORS 646A.695