OFFICE OF THE SECRETARY OF STATE
LAVONNE GRIFFIN-VALADE
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

PERMANENT ADMINISTRATIVE ORDER

FILED
07/31/2024 1:16 PM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

ID 14-2024

CHAPTER 836
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
INSURANCE REGULATION

FILING CAPTION: Drug Manufacturers Annual Fee Assessment

EFFECTIVE DATE: 08/01/2024

AGENCY APPROVED DATE: 07/31/2024

CONTACT: Karen Winkel
503-947-7694
karen.j.winkel@dcbs.oregon.gov

350 Winter St. NE
Salem,OR 97301

Filed By:
Karen Winkel
Rules Coordinator

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

ADOPT: 836-200-0553

NOTICE FILED DATE: 05/29/2024

RULE SUMMARY: Adopted 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 and FDA market category of the National Drug Code package codes (NDCs) for U.S. Food and Drug Administration (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 size categories shall be delineated as follows: ¶
(A) For all reporting manufacturers not subject to paragraph (3)(c)(B), there are three size categories: large (40 or more NDCs), medium (11 to 39 NDCs), and small (10 or fewer NDCs). ¶
(B) For reporting manufacturers where every NDC used for billing purposes under this section (3), has an FDA market category of ANDA (abbreviated new drug application) or NDA authorized generic (new drug application for an authorized generic of a brand name drug) or is a biosimilar product where the proprietary and nonproprietary name are the same that is approved under a biologics license application (BLA), there are two size categories: medium (40 or more NDCs) and small (39 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. If a manufacturer does not submit a request to change within 30 days, the assigned size category for the billing period is final.¶
(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 62 percent of the total revenue needed.¶
(b) Manufacturers classified as medium shall collectively be apportioned 31 percent of the total revenue needed. ¶
(c) Manufacturers classified as small shall collectively be apportioned seven 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 $6,200 ($1,000,000 x 0.62/100 = $6,200). ¶
(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 rule no later than 30 days after the date of the assessment by the department. A manufacturer shall pay interest at nine 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 sections (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

NOTICE FILED DATE: 05/29/2024

RULE SUMMARY: Amended 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 ~~sub~~section (2), the director shall determine the amount of the assessment by subtracting the revenue collected under ~~sub~~section (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 ~~sub~~sections (1) and (2) of this ~~section~~rule 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 sections (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
Statutes/Other Implemented: Or Laws 2018, ch 7