Department of Consumer and Business Services
Insurance Regulation - Chapter 836, Division 200
Department Regulatory Programs

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 through 646A.697. The fee shall be based on the manufacturer's size as set forth in sections (3) and (4) 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) 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 seventy percent of the total revenue needed.

(b) Manufacturers classified as medium shall collectively be apportioned twenty-five percent of the total revenue needed.

(c) Manufacturers classified as small shall collectively be apportioned five 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)

(5) The revenue collected under this rule shall be deposited in the Prescription Drug Affordability Account established in ORS 705.146.

(6) 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 nine percent per annum on any assessment that is not paid when due.