Senate Bill 793

Sponsored by Senator STEINER HAYWARD, Representative NOSSE

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure **as introduced.**

Requires prescription drug manufacturer to report to Department of Consumer and Business Services prices and increases in prices of manufacturer's prescription drugs sold in Oregon. Requires manufacturer to provide justification for increase in price greater than 3.4 percent for prescription drugs sold in Oregon longer than 36 months. Requires department to order manufacturer to refund excessive price increases to purchasers of prescription drugs.

Declares emergency, effective on passage.

A BILL FOR AN ACT

Relating to the price of prescription drugs; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. (1) As used in this section:

(a) "Drug" has the meaning given that term in ORS 689.005.

(b) "Excessive" means an increase in the price of a prescription drug that is:

(A) Greater than 3.4 percent during a 12-month period; and

(B) Not justified based on rules adopted by the Department of Consumer and Business Services under subsection (4) of this section.

(c) "Health care practitioner" means an individual who is licensed, certified or registered in this state to furnish prescription drugs.

(d)(A) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

(B) "Manufacture" includes packaging or repackaging of the substances or labeling or relabeling of the container, but does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug:

(i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice; or

(ii) By a health care practitioner or at the practitioner's authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale.

(e) "Manufacturer" means a person that manufactures prescription drugs that are sold or distributed to residents of this state.

(f) "Prescription drug" means a drug that must:

(A) Under federal law, be labeled "Caution: Federal law prohibits dispensing without prescription" prior to being dispensed or delivered; or

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

(B) Under any applicable federal or state law or regulation, be dispensed only by prescription or that is restricted to use only by health care practitioners.

(g) "Price" means the average manufacturer price as defined in 42 C.F.R. 447.504.

(2) The department shall prescribe the form and manner for a manufacturer to submit annually to the department:

(a) The prices of the prescription drugs sold by the manufacturer;

(b) A report of any increase by a manufacturer in the price of a prescription drug if the prescription drug has been sold in this state for a total of at least 36 months;

(c) The justification for any price increase described in paragraph (b) of this subsection that is greater than 3.4 percent; and

(d) Any supporting documentation that must be submitted to the department by a manufacturer to support the justification described in paragraph (c) of this subsection.

(3) A manufacturer may not increase the price of a prescription drug that is sold to residents of this state by an amount that is excessive.

(4) The department shall review a justification provided under subsection (2) of this section to determine if the price increase is excessive based upon criteria adopted by the department by rule that take into account:

(a) The direct costs incurred by the manufacturer:

(A) In the research and development of the prescription drug;

(B) To obtain approval of the prescription drug by the United States Food and Drug Administration; and

(C) In marketing the prescription drug during the 12-month period following approval by the United States Food and Drug Administration;

(b) The manufacturer's financial position, including but not limited to profitability, surplus, reserves and investments;

(c) The manufacturer's historical and projected administrative expenses; and

(d) Expected sales based on market demand for the prescription drug.

(5) If the department finds a price increase to be excessive, the department's final order shall require the manufacturer to refund to purchasers of the prescription drug the portion of the price increase that the department finds to be excessive.

(6) An order under subsection (5) of this section is an order in a contested case subject to appeal and judicial review in accordance with ORS chapter 183.

(7) To the extent that the material described in subsection (2) of this section, or any portion of the material, would otherwise qualify as a trade secret under ORS 192.501, the action taken by the department or any expert or consultant employed by the department in reviewing the material does not affect the status of the material as a trade secret.

(8) Employees of the department who have responsibilities for evaluating a justification submitted by a manufacturer under subsection (2) of this section may not have a direct or indirect financial interest or involvement, or have a family member with a direct or indirect financial interest or involvement, in a manufacturer, other than an incidental interest.

(9) The department may adopt rules as necessary for carrying out the provisions of this section.

SECTION 2. (1) The Department of Consumer and Business Services, in carrying out the provisions of section 1 of this 2017 Act, shall have the power to:

(a) Administer oaths and affirmations;

(b) Subpoena witnesses;

(c) Compel witnesses to testify under oath; and

(d) Subpoena the production of books, papers, correspondence, memoranda, agreements or other documents or records that the department considers relevant or material to the inquiry.

(2) Each witness who appears before the department under a subpoena shall receive the fees and mileage provided for witnesses under ORS 44.415 (2).

(3) If a person fails to comply with a subpoena or a party or witness refuses to testify on any matters, the judge of the circuit court for any county, on the application of the department, shall compel obedience by proceedings for contempt as in the case of disobedience of the requirements of a subpoena issued from the court or a refusal to testify in the court.

SECTION 3. Sections 1 and 2 of this 2017 Act become operative on January 1, 2018.

SECTION 4. This 2017 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2017 Act takes effect on its passage.