SB 793-2
(LC 2867)
4/12/17 (LHF/ps)

Requested by Senator STEINER HAYWARD

PROPOSED AMENDMENTS TO
SENATE BILL 793

On page 1 of the printed bill, delete lines 7 through 9 and insert:

"(A)(i) Greater than 10 percent for a prescription drug:

"(I) For which the active ingredient has been approved by the United States Food and Drug Administration for more than five years; and

"(II) That costs more than $30 and less than $100 for a one-month supply;

"(ii) Greater than five percent for a prescription drug:

"(I) For which the active ingredient has been approved by the United States Food and Drug Administration for more than five years; and

"(II) That costs $100 or more, up to $5,000, for a 12-month supply;

"(iii) Greater than 3.4 percent for a brand name drug that costs more than $5,000 for a 12-month supply; or

"(iv) Greater than 15 percent for a brand name drug for which the active ingredient has been approved by the United States Food and Drug Administration for less than five years.".

On page 2, delete lines 3 through 42 and insert:

"(g) 'Price' means:

"(A) The lowest wholesale acquisition cost for the drug since it has been on the market; or

"(B) For generic drugs, the average wholesale acquisition cost for the previous calendar quarter.

"(h) 'Wholesale acquisition cost' has the meaning given that term in 42

U.S.C. 1395w-3a(c)(6)(B).

"(2) The period for which a prescription drug has been approved by the United States Food and Drug Administration under subsection (1)(b)(A) of this section is the period in which the active ingredient in the drug has been delivered in the same manner, regardless of any changes to the size, shape or color of the drug.

"(3) The Department of Consumer and Business Services shall prescribe the form and manner for a manufacturer to submit annually to the department:

"(a) The prices of the prescription drugs sold in this state by the manufacturer;

"(b) Notice of any excessive price increase that will occur in the next 12 months for prescription drugs sold by the manufacturer in this state;

"(c) The justification for any price increase described in paragraph (b) of this subsection; and

"(d) Any supporting documentation that is required to support the justification described in paragraph (c) of this subsection.

"(4) 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 without the department's prior approval.

"(5) The department shall review a justification provided under subsection (3) 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.

"(6) The department may approve an excessive price increase if the department finds the increase to be justified.

"(7) The department shall post the prices of prescription drugs reported under subsection (3)(a) of this section to a website accessible by the public.

"(8) To the extent that the material described in subsection (3) 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.

"(9) Employees of the department who have responsibilities for evaluating a justification submitted by a manufacturer under subsection (3) 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.

"(10) If a manufacturer increases the price of a prescription drug by an amount that is excessive without the department's prior approval, the department shall order the manufacturer to refund to purchasers of the prescription drug the portion of the price increase that is excessive.

"(11) The department shall have in place a process for consumers to file a complaint, online or by telephone, about an excessive price increase.

"(12) The denial of an excessive price increase or an order under subsection (10) of this section is an order in a contested case subject to appeal and judicial review in accordance with ORS chapter 183.

"(13) The department shall adopt by rule a fee to be imposed on manufacturers to cover the cost of reviewing the justification for excessive price increases and any action taken by the department in response to an excessive

price increase. The fee must consist of a base fee plus a percentage of the wholesale acquisition cost of the drug that is under review.

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

On page 3, after line 11, insert:

"SECTION 3. (1) As used in this section:

"(a) 'Advertise' means to communicate within this state by newspaper, radio, television or other print, broadcast or electronic medium information designed to create public interest in a prescription drug.

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

"(c) '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. '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:

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

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

"(d) 'Manufacturer' means a person that manufactures prescription drugs that are sold or distributed to Oregon residents.

"(e) '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

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

"(2) A manufacturer that advertises a prescription drug shall clearly and conspicuously disclose in the advertisement the wholesale price for the prescription drug paid by pharmacies located in this state and shall include the address for the website described in section 1 (7) of this 2017 Act.

"SECTION 4. (1) In addition to any other liability or penalty provided by law, the Attorney General may impose a civil penalty of up to $5,000 on a manufacturer, as defined in section 3 of this 2017 Act, for each publication or broadcast of an advertisement that fails to disclose the wholesale price of a prescription drug in accordance with section 3 of this 2017 Act.

"(2) A civil penalty imposed under this section may be remitted or reduced upon such terms and conditions as the Attorney General considers proper and consistent with public health and safety.

"(3) All penalties recovered under this section shall be paid into the State Treasury and credited to the General Fund and are available for general governmental expenses.".

In line 12, delete "3" and insert "5" and delete "and 2" and insert "to 4".

After line 12, insert:

"SECTION 6. Section 3 of this 2017 Act applies to a prescription drug advertisement that is published or broadcast on or after the operative date specified in section 5 of this 2017 Act.".

In line 13, delete "4" and insert "7".
