S-0879.2

SUBSTITUTE SENATE BILL 5020

State of Washington 67th Legislature 2021 Regular Session

By Senate Health & Long Term Care (originally sponsored by Senators Keiser, Robinson, Conway, Das, Hasegawa, Kuderer, Lovelett, Rolfes, Stanford, Van De Wege, and Wilson, C.)

READ FIRST TIME 02/15/21.

AN ACT Relating to assessing a penalty on unsupported prescription drug price increases to protect the safety, health, and economic well-being of Washington residents; amending RCW 43.71C.010; adding new sections to chapter 43.71C RCW; creating new sections; prescribing penalties; and providing an effective date.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec. 1.** (1) The legislature recognizes a need to protect the safety, health, and economic well-being of Washington residents by guarding them from the negative and harmful impact of unsupported price increases for prescription drugs.

(2) The legislature finds that:

(a) Access to prescription drugs is necessary for people to maintain or acquire good health;

(b) Unsupported price increases negatively impact the ability of people to obtain prescription drugs and thereby endanger the health and safety of such people by making it difficult for them to maintain or acquire good health;

(c) Unsupported price increases for prescription drugs threaten the economic well-being of Washington residents and endanger their ability to pay for other necessary and essential goods and services, including housing, food, and utilities;

(d) Unsupported price increases for prescription drugs contribute significantly to a dramatic and unsustainable rise in health care costs and health insurance, which threatens the overall ability of people to obtain health coverage and maintain or acquire good health; and

(e) Unsupported price increases for prescription drugs contribute significantly to rising state costs for health care provided and paid for through state-funded medical assistance programs for Washington residents who are older, are living with disabilities, or have low incomes; and health insurance programs for public employees, including employees of the state, municipalities and counties, school districts, institutions of higher education, and retirees whose health care costs are funded by public programs, thereby threatening the ability of the state to fund those programs adequately and further threatening the ability of the state to fund other programs necessary for the public good and safety, such as public education and public safety.

(3) Analysis of the increase in prices charged by manufacturers of prescription drugs demonstrates that many price increases for high-cost and high-volume prescription drugs are not supported by adequate evidence of improved clinical benefit or by significant increase in costs to the manufacturer related to the production or sale of the product.

(4) Based on the findings contained in this section, the legislature intends to pass this act as an essential means to protect the health and well-being of Washington residents from the negative impacts of unsupported price increases.

Sec. 2. RCW 43.71C.010 and 2019 c 334 s 2 are each amended to read as follows:

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Authority" means the health care authority.

(2) "Covered drug" means any prescription drug that:

(a) A covered manufacturer intends to introduce to the market at a wholesale acquisition cost of ten thousand dollars or more for a course of treatment lasting less than one month or a thirty-day supply, whichever period is longer; or

(b) Is currently on the market, is manufactured by a covered manufacturer, and has a wholesale acquisition cost of more than one

hundred dollars for a course of treatment lasting less than one month or a thirty-day supply, and, taking into account only price increases that take effect after July 28, 2019, the manufacturer increases the wholesale acquisition cost at least:

(i) Twenty percent, including the proposed increase and the cumulative increase over one calendar year prior to the date of the proposed increase; or

(ii) Fifty percent, including the proposed increase and the cumulative increase over three calendar years prior to the date of the proposed increase.

(3) "Covered manufacturer" means a person, corporation, or other entity engaged in the manufacture of prescription drugs sold in or into Washington state. "Covered manufacturer" does not include a private label distributor or retail pharmacy that sells a drug under the retail pharmacy's store, or a prescription drug repackager.

(4) "Department" means the department of revenue.

(5) "Health care provider," "health plan," "health carrier," and "carrier" mean the same as in RCW 48.43.005.

((~~(5)~~)) (6) "Identified drug" means any legend drug that is newly identified to have an unsupported price increase in the unsupported price increase report published on or after October 1, 2021.

(7) "Legend drug" has the same meaning as in RCW 69.41.010.

(8) "Pharmacy benefit manager" means the same as in RCW 19.340.010.

((~~(6)~~)) (9) "Pharmacy services administrative organization" means an entity that contracts with a pharmacy to act as the pharmacy's agent with respect to matters involving a pharmacy benefit manager, third-party payor, or other entities, including negotiating, executing, or administering contracts with the pharmacy benefit manager, third-party payor, or other entities and provides administrative services to pharmacies.

((~~(7)~~)) (10) "Prescription drug" means a drug regulated under chapter 69.41 or 69.50 RCW, including generic, brand name, specialty drugs, and biological products that are prescribed for outpatient use and distributed in a retail setting.

((~~(8)~~)) (11) "Qualifying price increase" means a price increase described in subsection (2)(b) of this section.

((~~(9)~~)) (12) "Sales" means legend drug sales into the state directly by the manufacturer, or indirectly through a private label

distributor, wholesaler, or other distributor as defined in RCW 69.41.010.

(13) "Unsupported price increase" means an increase in price for a legend drug for which there was no, or inadequate, new clinical evidence to support the price increase. In order to determine whether a price increase for a legend drug is unsupported by new clinical evidence, the state must utilize the analyses of legend drugs in the unsupported price increase report.

(14) "Unsupported price increase report" means the analyses of legend drugs prepared annually by the institute for clinical and economic review and published in its annual unsupported price increase report or similar analysis created by another third party. "Unsupported price increase report" does not include reports that use analyses that use the cost-per-quality adjusted life year or similar measure to identify subpopulations for which a treatment would be less cost-effective due to severity of illness, age, or preexisting disability.

(15) "Wholesale acquisition cost" or "price" means, with respect to a prescription or legend drug, the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, excluding any discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of prescription or legend drug pricing.

NEW SECTION. **Sec. 3.** A new section is added to chapter 43.71C RCW to read as follows:

(1) Manufacturers may be assessed a penalty on identified drug sales, for identified drugs sold within the state, directly by the manufacturer or indirectly through a private label distributor, wholesaler, or other distributor as defined in chapter 69.41 RCW. The penalty must be imposed and calculated as described in this section.

(2) The penalty in any calendar year must equal 80 percent of the difference between the revenue generated by sales within the state, either directly or indirectly, of the identified drugs and the revenue that would have been generated if the manufacturer had maintained the wholesale acquisition cost from the previous calendar year, adjusted for inflation using the consumer price index.

(3) A manufacturer is subject to the penalty if the manufacturer has at least $250,000 in total annual sales, either directly or

indirectly, within the state in the calendar year for which the penalty is assessed.

(4) Within 60 days of the publication of the unsupported price increase report, the authority must identify the manufacturers of identified drugs and notify the department and each manufacturer with at least $250,000 in total annual sales in the state that sales within the state of identified drugs are subject to the penalty assessed under this section for a period of two calendar years following the identified drug's appearance in the unsupported price increase report.

(5)(a) The penalty described under this section must be collected annually.

(b) Any manufacturer notified by the authority pursuant to subsection (4) of this section must submit information to the department, in the time frame, form, and manner as prescribed by the department, and pay the penalty within the time frame determined by the department.

(c) The department will notify manufacturers of the amount of the penalty within 90 days of receiving the information described in subsection (6) of this section.

(6) The information described in subsection (5) of this section must contain the following:

(a) The total amount of sales of the identified drug within the state;

(b) The total number of units sold of the identified drug within the state;

(c) The wholesale acquisition cost of the identified drug during the reporting period and any changes in the wholesale acquisition cost during the calendar year;

(d) The wholesale acquisition cost during the previous calendar year; and

(e) Any other information the department deems necessary to calculate the correct amount of the penalty owed.

(7) Failure by any manufacturer to file the information required in subsection (6) of this section, by the time frames determined by the department under subsection (5) of this section, must result in an additional penalty in an amount equal to the greater of 10 percent of the assessed fine as described in subsection (2) of this section or $50,000.

(8) All revenues collected from the penalty under this section must be deposited into the foundational public health services account created in RCW 82.25.015.

NEW SECTION. **Sec. 4.** A new section is added to chapter 43.71C RCW to read as follows:

(1) A manufacturer of an identified drug must not withdraw that drug from sale or distribution, either directly or indirectly, within this state in order to avoid the penalty set forth in section 3 of this act.

(2) Any manufacturer who intends to withdraw an identified drug from sale or distribution from within the state in order to avoid a penalty described in section 3 of this act must provide a notice of withdrawal in writing to the authority and department at least 180 days before such withdrawal. Notification must include the reason for withdrawal in the state. Notification of withdrawal does not exempt the manufacturer from the penalties under subsection (3) of this section.

(3) The department must assess a penalty of $500,000 per identified drug on any manufacturer of an identified drug, that it determines has withdrawn an identified drug from distribution or sale in the state in violation of this section.

(4) All revenues collected from the penalty under this section must be deposited into the foundational public health services account created in RCW 82.25.015.

NEW SECTION. **Sec. 5.** A new section is added to chapter 43.71C RCW to read as follows:

The authority and department may adopt rules necessary to implement this act.

NEW SECTION. **Sec. 6.** If the reliance on an unsupported price increase report to identify drugs subject to the penalties prescribed in this act is found to be invalid, the remainder of the act or the application of the provision to other persons or circumstances is terminated.

NEW SECTION. **Sec. 7.** This act takes effect January 1, 2023.

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