SUBSTITUTE SENATE BILL 6088

AS AMENDED BY THE HOUSE

Passed Legislature - 2020 Regular Session

State of Washington 66th Legislature 2020 Regular Session

By Senate Ways & Means (originally sponsored by Senators Keiser, Conway, Das, Frockt, Hasegawa, Hunt, Kuderer, Pedersen, Randall, Rolfes, Stanford, and Wilson, C.)

READ FIRST TIME 02/11/20.

AN ACT Relating to establishing a prescription drug affordability board; amending RCW 43.71C.100; adding new sections to chapter 70.14 RCW; and adding a new section to chapter 42.56 RCW.

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

NEW SECTION. **Sec. 1.** A new section is added to chapter 70.14 RCW to read as follows:

The definitions in this section apply throughout sections 2 through 5 of this act unless the context clearly requires otherwise.

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

(2) "Biological product" has the meaning provided in 42 U.S.C. Sec. 262(i)(1).

(3) "Biosimilar" has the meaning provided in 42 U.S.C. Sec. 262(i)(2).

(4) "Board" means the prescription drug affordability board.

(5) "Generic drug" has the meaning provided in RCW 69.48.020.

NEW SECTION. **Sec. 2.** A new section is added to chapter 70.14 RCW to read as follows:

(1) Subject to the availability of amounts appropriated for this specific purpose, the prescription drug affordability board is

established, to include five members who have expertise in health care economics or clinical medicine appointed by the governor.

(2) Board members shall serve for a term of five years.

(3) No board member may be an employee of, a board member of, or consultant to, a prescription drug manufacturer, pharmacy benefit manager, health carrier, prescription drug wholesale distributor, or related trade association.

(4) The board may establish advisory groups consisting of relevant stakeholders when the board deems it necessary. Advisory group members are immune from civil liability for any official act performed in good faith as a member of the group.

(5) The authority shall provide administrative support to the board and any advisory group and may adopt rules governing their operation.

(6) Board members shall be compensated for participation in the work of the board in accordance with a personal services contract to be executed after appointment and before commencement of activities related to the work of the board.

(7) A simple majority of the board's membership constitutes a quorum for the purpose of conducting business.

(8) The board must coordinate with and complement the work of the authority, other boards, and work groups related to prescription drug costs and emerging therapies.

(9) All meetings of the board must be open and public, except that the board may hold executive sessions to the extent permitted by chapter 42.30 RCW.

NEW SECTION. **Sec. 3.** A new section is added to chapter 70.14 RCW to read as follows:

(1) By May 1, 2021, the board must provide the health care cost transparency board established in chapter 70.--- RCW (the new chapter created in Second Substitute House Bill No. 2457, Laws of 2020), with recommendations for the means and methodologies to establish a cost growth benchmark related to prescription drugs.

(2) By June 30, 2021, and yearly thereafter, using data collected under chapter 43.71C RCW, or other data deemed relevant by the board, the board must identify:

(a) Brand name prescription drugs and biological products that:

(i) Are introduced to the market with a wholesale acquisition cost of thirty thousand dollars or more per year or course of treatment lasting less than one year; or

(ii) Have a price increase of two thousand dollars or more in any twelve-month period;

(b) Biosimilar products that have a launch wholesale acquisition cost that is not at least fifteen percent lower than the reference brand biological product at the time the biosimilar is launched;

(c) Generic drugs with a wholesale acquisition cost of one hundred dollars or more for a thirty-day supply or less that has increased in price by two hundred percent or more in the preceding twelve months;

(d) Any prescription drug or biological products exceeding the relevant benchmark established by the health care cost transparency board established in chapter 70.--- RCW (the new chapter created in Second Substitute House Bill No. 2457, Laws of 2020); and

(e) Any other prescription drug or biological product the board believes the manufacturer's pricing of may exceed the proposed value of the prescription drug or biological products.

NEW SECTION. **Sec. 4.** A new section is added to chapter 70.14 RCW to read as follows:

(1) The board may choose to conduct a cost review of any prescription drug or biological product identified under section 3 of this act.

(2) For prescription drugs or biological products chosen for a cost review, the board must determine whether the manufacturer's pricing of the prescription drug or biological product substantially exceeds the proposed value of the prescription drug or biological product. The board may examine publicly available information as well as collect information from the drug manufacturer and other relevant sources. When conducting a review, the board may consider:

(a) The relevant factors contributing to the price paid by the state for the prescription drug or biological product, including the wholesale acquisition cost and discounts, rebates, or other price concessions provided by the manufacturer to the state;

(b) The average patient copay or other cost sharing for the drug;

(c) The dollar value of patient assistance programs offered by the manufacturer for the drug;

(d) The price of therapeutic alternatives;

(e) The amount of public funding received or provided for the development of the prescription drug or biological product;

(f) The manufacturer's research and development costs, as indicated on the manufacturer's federal tax filing or information filed with the federal securities and exchange commission for the most recent tax year in proportion to the manufacturer's sales in the state;

(g) The portion of direct-to-consumer marketing costs eligible for favorable federal tax treatment in the most recent tax year that are specific to the prescription drug under review and that are multiplied by the ratio of total manufacturer in-state sales to total manufacturer sales in the United States for the drug under review;

(h) The manufacturer's gross and net revenues for the most recent tax year; and

(i) Any other relevant factors as determined by the board.

(3) All information collected by the board under this section is not subject to public disclosure under chapter 42.56 RCW.

NEW SECTION. **Sec. 5.** A new section is added to chapter 70.14 RCW to read as follows:

(1) If, after the cost review of a prescription drug or biological product the board determines that the manufacturer's pricing of the drug or biological product does not substantially exceed the proposed value of the prescription drug or biological product, the board shall notify the manufacturer, in writing, of its determination and shall evaluate other ways to mitigate the eligible prescription drug or biological product's cost in order to improve patient access to the eligible prescription drug or biological product. The board may engage with the manufacturer and other relevant stakeholders, including, but not limited to, patients, patient advocacy organizations, providers, provider organizations and payers, to explore options for mitigating the cost of the prescription drug or biological product. Upon the conclusion of a stakeholder engagement process under this subsection, the board shall issue recommendations on ways to reduce the cost of the prescription drug or biological product for the purpose of improving patient access to the prescription drug or biological product. Recommendations must be publicly posted on the authority's web site. The recommendations may include, but are not be limited to:

(a) An alternative payment plan or methodology;

(b) A bulk purchasing program;

(c) Copayment, coinsurance, deductible, or other cost-sharing restrictions; and

(d) A reinsurance program to subsidize the cost of the eligible drug.

(2) If, after the cost review of a prescription drug or biological product, the board determines that the manufacturer's pricing of the prescription drug or biological product substantially exceeds the proposed value of the prescription drug or biological product, the board shall request that the manufacturer provide further information related to the pricing of the prescription drug or biological product and the manufacturer's reasons for the pricing not later than sixty days after receiving the request.

(3) No later than ninety days after receiving the additional information from the manufacturer, the board shall confidentially issue a determination on whether the manufacturer's pricing of a prescription drug or biological product still substantially exceeds the board's proposed value of the prescription drug or biological product and request the manufacturer to enter into negotiations to reduce the cost of the prescription drug or biological product. If the manufacturer refuses to enter into negotiations, the authority shall post the board's proposed value on the authority's web site.

(4) Any proprietary information submitted by a prescription drug or biological product manufacturer pursuant to this section or section 4 of this act must be kept confidential.

Sec. 6. RCW 43.71C.100 and 2019 c 334 s 10 are each amended to read as follows:

(1) The authority shall compile and analyze the data submitted by health carriers, pharmacy benefit managers, manufacturers, and pharmacy services administrative organizations pursuant to this chapter and prepare an annual report for the public and the legislature synthesizing the data to demonstrate the overall impact that drug costs, rebates, and other discounts have on health care premiums.

(2) The data in the report must be aggregated and must not reveal information specific to individual health carriers, pharmacy benefit managers, pharmacy services administrative organizations, ((~~individual prescription drugs, individual classes of prescription drugs,~~)) individual manufacturers, except in the case of single

source drugs, or discount amounts paid in connection with individual prescription drugs.

(3) Data received under this section must be used only for the enumerated purposes of this chapter and other statutorily authorized purposes.

(4) Beginning January 1, 2021, and by each January 1st thereafter, the authority must publish the report on its web site.

((~~(4)~~)) (5) Except for the report, and as provided in subsection ((~~(5)~~)) (6) of this section, the authority shall keep confidential all data submitted pursuant to RCW 43.71C.020 through 43.71C.080.

((~~(5)~~)) (6) For purposes of public policy, upon request of ((~~a legislator~~)) the office of the governor, the office of the attorney general, the prescription drug affordability board established in section 2 of this act, or a committee or subcommittee of the legislature with jurisdiction over matters relating to drug transparency, the authority must provide all data provided pursuant to RCW 43.71C.020 through 43.71C.080 and any analysis prepared by the authority. Any information provided pursuant to this subsection must be kept confidential within the ((~~legislature~~)) office of the governor, the office of the attorney general, the prescription drug affordability board established in section 2 of this act, or a committee or subcommittee of the legislature with jurisdiction over matters relating to drug transparency and may not be publicly released.

((~~(6)~~)) (7) The data collected pursuant to this chapter is not subject to public disclosure under chapter 42.56 RCW.

(8) Recipients of data received under subsection (6) of this section must:

(a) Follow all rules adopted by the authority regarding appropriate data use and protection; and

(b) Sign a nondisclosure agreement that includes acknowledgments that the recipient is solely responsible for any liability arising from misuse of the data, that the recipient does not have any conflicts under the ethics in public service act that would prevent the recipient from accessing or using the data, and that any violations of the nondisclosure agreement may result in losing the right to access or use the data.

NEW SECTION. **Sec. 7.** A new section is added to chapter 42.56 RCW to read as follows:

Any data collected by the prescription drug affordability board under section 4 of this act are exempt from disclosure under this chapter.

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