S-4113.1

SUBSTITUTE SENATE BILL 5532

State of Washington 67th Legislature 2022 Regular Session

By Senate Health & Long Term Care (originally sponsored by Senators Keiser, Robinson, Conway, Hasegawa, Nobles, Pedersen, Randall, Stanford, and C. Wilson)

READ FIRST TIME 01/31/22.

AN ACT Relating to establishing a prescription drug affordability board; amending RCW 43.71C.100 and 43.71.130; adding a new section to chapter 48.43 RCW; adding a new chapter to Title 70 RCW; and prescribing penalties.

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

NEW SECTION. **Sec. 1.** DEFINITIONS. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

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

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

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

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

(5) "Excess costs" means:

(a) Costs of appropriate utilization of a prescription drug that exceed the therapeutic benefit relative to other alternative treatments; or

(b) Costs of appropriate utilization of a prescription drug that are not sustainable to public and private health care systems over a 10-year time frame.

(6) "Generic drug" has the same meaning as in RCW 69.48.020.

(7) "Health carrier" or "carrier" has the same meaning as in RCW 48.43.005.

(8) "Manufacturer" means a person, corporation, or other entity engaged in the manufacture of prescription drugs sold in or into Washington state. "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.

NEW SECTION. **Sec. 2.** PRESCRIPTION DRUG AFFORDABILITY BOARD. (1) 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 and members may be reappointed by the governor for additional terms.

(3) No board member or advisory group 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)(a) Board members, advisory group members, staff members, and contractors providing services on behalf of the board shall recuse themselves from any board activity in any case in which they have a conflict of interest.

(b) For the purposes of this section, a conflict of interest means an association, including a financial or personal association, that has the potential to bias or appear to bias an individual's decisions in matters related to the board or the activities of the board.

(5) The board shall establish advisory groups consisting of relevant stakeholders, including but not limited to patients and patient advocates for the condition treated by the drug, for each drug affordability review conducted by the board pursuant to section 4 of the act. Advisory group members are immune from civil liability for any official act performed in good faith as a member of the group.

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

(7) 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.

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

(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.

(10) The board may not hold its first meeting until at least one year after the authority publishes its first report on the impact that drug costs, rebates, and other discounts have on health care premiums pursuant to RCW 43.71C.100.

(11) The board must coordinate and collaborate with the authority, other boards, work groups, and commissions related to prescription drug costs and emerging therapies, including but not limited to the health care cost transparency board established in chapter 70.390 RCW, and the universal health care commission established in RCW 41.05.840.

(12) The board may collaborate with prescription drug affordability boards established in other states.

NEW SECTION. **Sec. 3.** AUTHORITY TO REVIEW DRUG PRICES. By June 30, 2023, and annually thereafter, utilizing data collected pursuant to chapter 43.71C RCW, the all-payer health care claims database, or other data deemed relevant by the board, the board must identify drugs that have been on the market for at least 10 years, are dispensed at a retail pharmacy, are not designated by the United States food and drug administration under 21 U.S.C. Sec. 360bb as a drug for a rare disease or condition, and meet the following thresholds:

(1) Brand name prescription drugs and biologic products that:

(a) Have a wholesale acquisition cost of $25,000 or more per year or course of treatment lasting less than one year; or

(b) Have a price increase of $3,000 or more in any 12-month period or for a course of treatment lasting less than 12 months;

(2) Biosimilar products with a wholesale acquisition cost less than 15 percent below the reference brand biologic product; and

(3) Generic drugs with a wholesale acquisition cost of $100 or more for a 30-day supply or less that has increased in price by 200 percent or more in the preceding 12 months.

NEW SECTION. **Sec. 4.** AFFORDABILITY REVIEWS. (1) The board may choose to conduct an affordability review of any prescription drug identified pursuant to section 3 of this act. When deciding whether to conduct a review, the board shall consider:

(a) The class of the prescription drug and whether any therapeutically equivalent prescription drugs are available for sale;

(b) Input from relevant advisory groups established pursuant to section 2 of this act; and

(c) The average patient's out-of-pocket cost for the drug.

(2) For drugs chosen for an affordability review, the board must determine whether the drug has led or will lead to excess costs to patients. The board may examine publicly available information as well as collect confidential and proprietary information from the drug manufacturer and other relevant sources.

(3) A manufacturer must submit all requested information to the board within 30 days of the request.

(4) The authority may assess a fine of up to $100,000 against a manufacturer for each failure to comply with an information request from the board. The assessment of a fine under this subsection is subject to review under the administrative procedure act, chapter 34.05 RCW.

(5) When conducting a review, the board shall consider:

(a) The relevant factors contributing to the price paid for the prescription drug, including the wholesale acquisition cost, discounts, rebates, or other price concessions;

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

(c) The effect of the price on consumers' access to the drug in the state;

(d) Orphan drug status;

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

(f) The price and availability of therapeutic alternatives;

(g) Input from:

(i) Patients affected by the condition or disease treated by the drug; and

(ii) Individuals with medical or scientific expertise related to the condition or disease treated by the drug;

(h) Any other information the drug manufacturer or other relevant entity chooses to provide;

(i) The impact of pharmacy benefit manager policies on the price consumers pay for the drug; and

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

(6) In performing an affordability review of a drug the board may consider the following factors:

(a) Life-cycle management;

(b) The average cost of the drug in the state;

(c) Market competition and context;

(d) Projected revenue;

(e) Off-label usage of the drug; and

(f) Any additional factors identified by the board.

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

(8) The board shall publicize which drugs are subject to an affordability review before the review begins.

NEW SECTION. **Sec. 5.** UPPER PAYMENT LIMITS. (1) The board must establish a methodology in rule for setting upper payment limits for prescription drugs the board has determined have led or will lead to excess costs based on its affordability review. Each year, the board may set an upper payment limit for up to 12 prescription drugs.

(2) The methodology must take into consideration:

(a) The cost of administering the drug;

(b) The cost of delivering the drug to patients;

(c) The status of the drug on the drug shortage list published by the United States food and drug administration; and

(d) Other relevant administrative costs related to the production and delivery of the drug.

(3) The methodology determined by the board must not use quality-adjusted life years, or similar formulas that take into account a patient's age or severity of illness or disability, to identify subpopulations for which a prescription drug would be less cost-effective. For any prescription drug that extends life, the board's analysis of cost-effectiveness must weigh the value of the quality of life equally for all patients, regardless of the patients' age or severity of illness or disability.

(4) Before setting an upper payment limit for a drug, the board must post notice of the proposed upper payment limit on the authority's website, including an explanation of the factors considered when setting the proposed limit and instructions to submit

written comment. The board must provide 30 days to submit public comment.

(5) The board must monitor the supply of drugs for which it sets an upper payment limit and may suspend that limit if there is a shortage of the drug in the state.

(6) An upper payment limit for a prescription drug established by the board applies to all purchases of the drug by any entity and reimbursements for a claim for the drug by a health carrier, or a health plan offered under chapter 41.05 RCW, when the drug is dispensed or administered to an individual in the state in person, by mail, or by other means.

(7) An employer-sponsored self-funded plan may elect to be subject to the upper payment limits as established by the board.

(8) The board must establish an effective date for each upper payment limit, provided that the date is at least six months after the adoption of the upper payment limit and applies only to purchases, contracts, and plans that are issued on or renewed after the effective date.

(9) Any entity affected by a decision of the board may request an appeal within 30 days of the board's decision, and the board must rule on the appeal within 60 days. Board rulings are subject to judicial review pursuant to chapter 34.05 RCW.

(10) For any upper payment limit set by the board, the board must notify the manufacturer of the drug and the manufacturer must inform the board if it is able to make the drug available for sale in the state and include a rationale for its decision. The board must annually report to the relevant committees of the legislature detailing the manufacturers' responses.

(11) The board may reassess the upper payment limit for any drug annually based on current economic factors.

(12) The board may not establish an upper payment limit for any prescription drug before January 1, 2027.

(13)(a) Any individual denied coverage by a health carrier for a prescription drug because the drug was unavailable due to an upper payment limit established by the board, may seek review of the denial pursuant to RCW 48.43.530 and 48.43.535.

(b) If it is determined that the prescription drug should be covered based on medical necessity, the carrier may disregard the upper payment limit and must provide coverage for the drug.

NEW SECTION. **Sec. 6.** USE OF SAVINGS. (1) Any savings generated for a health plan, as defined in RCW 48.43.005, or a health plan offered under chapter 41.05 RCW that are attributable to the establishment of an upper payment limit established by the board must be used to reduce costs to consumers, prioritizing the reduction of out-of-pocket costs for prescription drugs.

(2) By January 1, 2024, the board must establish a formula for calculating savings for the purpose of complying with this section.

(3) By March 1st of the year following the effective date of the first upper payment limit, and annually thereafter, each state agency and health carrier issuing a health plan in the state must submit a report to the board describing the savings in the previous calendar year that were attributable to upper payment limits set by the board and how the savings were used to satisfy the requirements of subsection (1) of this section.

NEW SECTION. **Sec. 7.** MANUFACTURER WITHDRAWAL FROM THE MARKET. (1) Any manufacturer that intends to withdraw a prescription drug from sale or distribution within the state because the board has established an upper payment limit for that drug shall provide a notice of withdrawal in writing indicating the drug will be withdrawn because of the establishment of the upper payment limit at least 180 days before the withdrawal to the office of the insurance commissioner, the authority, and any entity in the state with which the manufacturer has a contract for the sale or distribution of the drug.

(2) If a manufacturer chooses to withdraw the prescription drug from the state, it shall be prohibited from selling that drug in the state for a period of five years.

(3) A manufacturer that has withdrawn a drug from the market may petition the authority, in a form and manner determined by the authority in rule, to reenter the market before the expiration of the five-year ban if it agrees to make the drug available for sale in compliance with the upper payment limit.

NEW SECTION. **Sec. 8.** PRESCRIPTION DRUG PRICE INCREASE PENALTY. (1) If the board determines, after an affordability review, that a prescription drug will result in excess costs for patients, but does not impose an upper payment limit on the drug, the board may impose a

penalty on the manufacturer based on the increased revenue resulting from the price increase on the drug.

(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) Before imposing a penalty, the board must notify the drug manufacturer within 60 days of its decision not to impose an upper payment limit.

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

(b) Any manufacturer notified by the board pursuant to subsection (3) of this section must submit information to the board, in the time frame, form, and manner as prescribed by the board, and pay the penalty within the time frame determined by the board.

(c) The board will notify manufacturers of the amount of the penalty within 90 days of receiving the information described in subsection (5) of this section.

(5) The information described in subsection (4)(b) 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 board deems necessary to calculate the correct amount of the penalty owed.

(6) Failure by any manufacturer to file the information required in subsection (5) of this section, by the time frames determined by the board under subsection (4) of this section, must result in an additional penalty of $50,000.

(7) All revenue collected pursuant to this section must be deposited into the state health care affordability account created in RCW 43.71.130.

NEW SECTION. **Sec. 9.** RULE MAKING. The authority may adopt any rules necessary to implement this chapter.

NEW SECTION. **Sec. 10.** A new section is added to chapter 48.43 RCW to read as follows:

(1) For health plans issued or renewed on or after January 1, 2024, if the prescription drug affordability board, as established in chapter 70.--- RCW (the new chapter created in section 13 of this act), establishes an upper payment limit for a prescription drug pursuant to section 5 of this act, a carrier's compensation agreements must provide sufficient information, as determined by the commissioner, to indicate that reimbursement for a claim for that prescription drug will not exceed the upper payment limit for the drug established by the board.

(2) The commissioner may adopt any rules necessary to implement this section.

Sec. 11. 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, or discount amounts paid in connection with individual prescription drugs.

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

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

(5) For purposes of public policy, upon request of a legislator, 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 and may not be publicly released.

(6) For the purpose of reviewing drug prices and conducting affordability reviews, the prescription drug affordability board, as established in chapter 70.--- RCW (the new chapter created in section 13 of this act), and the health care cost transparency board, established in chapter 70.390 RCW, may access all data collected pursuant to RCW 43.71C.020 through 43.71C.080 and any analysis prepared by the authority.

(7) The data collected pursuant to this chapter is not subject to public disclosure under chapter 42.56 RCW. Any information provided pursuant to this section must be kept confidential and may not be publicly released. Recipients of data under subsection (6) of this section shall:

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

(b) Acknowledge that the recipient is responsible for any liability arising from misuse of the data and 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.

Sec. 12. RCW 43.71.130 and 2021 c 246 s 3 are each amended to read as follows:

(1) The state health care affordability account is created in the state treasury. Expenditures from the account may only be used for premium and cost-sharing assistance programs established in RCW 43.71.110.

(2) The following funds must be deposited in the account:

(a) Any grants, donations, or contributions of money collected for purposes of the premium assistance or cost-sharing reduction programs established in RCW 48.43.795;

(b) Any federal funds received by the health benefit exchange pursuant to RCW 43.71.120; ((~~and~~))

(c) Any funds collected pursuant to section 8 of this act; and

(d) Any additional funding specifically appropriated to the account.

NEW SECTION. **Sec. 13.** Sections 1 through 9 of this act constitute a new chapter in Title 70 RCW.

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