AN ACT Relating to establishing a prescription drug affordability board; and adding new sections to chapter 70.14 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 this act unless the context clearly requires otherwise.

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

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

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

(4) "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 ten-year time frame.

(5) "Generic drug" has the same meaning as 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 health care 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) 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:

By June 30, 2021, and yearly thereafter, utilizing data collected pursuant to chapter 43.71C RCW, or other data deemed relevant by the board, the board must identify:

(1) Brand name prescription drugs and biologic products that:
   (a) 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
   (b) Have a price increase of three thousand dollars or more in any twelve-month period or for a course of treatment lasting less than twelve months;
(2) Biosimilar products with a wholesale acquisition cost less than fifteen percent below the reference brand biologic product;

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

(4) Any other prescription drug product the board determines may create excess costs for the state and patients.

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 identified pursuant to section 3 of this act.

(2) For drugs chosen for a cost review, the board must determine whether the drug has led or will lead to excess costs to the state or patients. 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 should consider:

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

(b) The average patient co-pay 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; and

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

(3) If, after considering the factors listed in subsection (2) of this section, the board is unable to determine if the drug will lead to excess costs for the state or patients, the board may consider the following factors:

(a) 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;

(b) The portion of direct-to-consumer marketing costs eligible for favorable federal tax treatment in the most recent tax year that

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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;

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

(d) Any additional factors identified by the board.

(4) All information collected by the board pursuant to 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) The board must establish a process for setting upper payment limits for prescription drugs the board has determined have led or will lead to excess costs to the state or patients.

(2) Any state agency administering a state purchased health care program shall not pay an amount above the upper payment limit set by the board for a prescription drug.

(3) The process must take into consideration:

(a) The cost of administering the drug;

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

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

(4) The process must provide for the suspension of an upper payment limit if a drug is placed on the food and drug administration shortage list.

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

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