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**SENATE BILL 5532**

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**State of Washington**

**67th Legislature**

**2022 Regular Session**

**By** Senators Keiser, Robinson, Conway, Hasegawa, Nobles, Pedersen, Randall, Stanford, and C. Wilson

Prefiled 12/10/21. Read first time 01/10/22. Referred to Committee on Health & Long Term Care.

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

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

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

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

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

12 (3) "Biosimilar" has the same meaning as in 42 U.S.C. Sec.  
13 262(i)(2).

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

15 (5) "Department" means the department of revenue.

16 (6) "Excess costs" means:

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

1 (b) Costs of appropriate utilization of a prescription drug that  
2 are not sustainable to public and private health care systems over a  
3 10-year time frame.

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

5 (8) "Health carrier" or "carrier" has the same meaning as in RCW  
6 48.43.005.

7 NEW SECTION. **Sec. 2.** PRESCRIPTION DRUG AFFORDABILITY BOARD. (1)

8 The prescription drug affordability board is established, to include  
9 five members who have expertise in health care economics or clinical  
10 medicine appointed by the governor.

11 (2) Board members shall serve for a term of five years and  
12 members may be reappointed by the governor for additional terms.

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

17 (4) (a) Board members, advisory group members, staff members, and  
18 contractors providing services on behalf of the board shall recuse  
19 themselves from any board activity in any case in which they have a  
20 conflict of interest.

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

26 (5) The board shall establish advisory groups consisting of  
27 relevant stakeholders, including but not limited to patients and  
28 patient advocates for the condition treated by the drug, for each  
29 drug affordability review conducted by the board pursuant to section  
30 4 of the act. Advisory group members are immune from civil liability  
31 for any official act performed in good faith as a member of the  
32 group.

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

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

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

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

6 (10) The board must hold its first meeting by March 1, 2023.

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

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

15 NEW SECTION. **Sec. 3.** AUTHORITY TO REVIEW DRUG PRICES. By June  
16 30, 2023, and annually thereafter, utilizing data collected pursuant  
17 to chapter 43.71C RCW, the all-payer health care claims database, or  
18 other data deemed relevant by the board, the board must identify:

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

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

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

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

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

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

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

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

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

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

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

8 (4) The authority may assess a fine of up to \$100,000 against a  
9 manufacturer for each failure to comply with an information request  
10 from the board. The assessment of a fine under this subsection is  
11 subject to review under the administrative procedure act, chapter  
12 34.05 RCW.

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

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

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

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

20 (d) Orphan drug status;

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

23 (f) The price and availability of therapeutic alternatives;

24 (g) Input from:

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

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

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

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

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

34 (a) Life-cycle management;

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

36 (c) Market competition and context;

37 (d) Projected revenue;

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

39 (f) Any additional factors identified by the board.

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

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

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

10 (2) The methodology must take into consideration:

11 (a) The cost of administering the drug;

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

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

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

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

25 (4) Before setting an upper payment limit for a drug, the board  
26 must post notice of the proposed upper payment limit on the  
27 authority's website, including an explanation of the factors  
28 considered when setting the proposed limit and instructions to submit  
29 written comment. The board must provide 30 days to submit public  
30 comment.

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

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

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

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

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

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

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

20 (12) The board may not establish an upper payment limit for any  
21 prescription drug before January 1, 2024.

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

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

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

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

37 (3) By March 1st of the year following the effective date of the  
38 first upper payment limit, and annually thereafter, each state agency  
39 and health carrier issuing a health plan in the state must submit a

1 report to the board describing the savings in the previous calendar  
2 year that were attributable to upper payment limits set by the board  
3 and how the savings were used to satisfy the requirements of  
4 subsection (1) of this section.

5 NEW SECTION. **Sec. 7.** MANUFACTURER WITHDRAWAL FROM THE MARKET.

6 (1) Any manufacturer that intends to withdraw from sale or  
7 distribution within the state a prescription drug for which the board  
8 has established an upper payment limit shall provide a notice of  
9 withdrawal in writing at least 180 days before the withdrawal to the  
10 office of the insurance commissioner, the authority, and any entity  
11 in the state with which the manufacturer has a contract for the sale  
12 or distribution of the drug.

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

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

21 NEW SECTION. **Sec. 8.** PRESCRIPTION DRUG PRICE INCREASE PENALTY.

22 (1) If the board determines, after an affordability review, that a  
23 prescription drug will result in excess costs for patients, but does  
24 not impose an upper payment limit on the drug, the department must  
25 impose a penalty on the increased revenue resulting from the price  
26 increase on the drug.

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

33 (3) The board must notify the drug manufacturer and the  
34 department within 60 days of its decision not to impose an upper  
35 payment limit.

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

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

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

8 (5) The information described in subsection (4)(b) of this  
9 section must contain the following:

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

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

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

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

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

21 (6) Failure by any manufacturer to file the information required  
22 in subsection (5) of this section, by the time frames determined by  
23 the department under subsection (4) of this section, must result in  
24 an additional penalty in an amount equal to the greater of 10 percent  
25 of the assessed fine as described in subsection (2) of this section  
26 or \$50,000.

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

30 NEW SECTION. **Sec. 9.** RULE MAKING. The authority and the  
31 department may adopt any rules necessary to implement this chapter.

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

34 (1) For health plans issued or renewed on or after January 1,  
35 2024, if the prescription drug affordability board, as established in  
36 chapter 70.--- RCW (the new chapter created in section 13 of this  
37 act), establishes an upper payment limit for a prescription drug  
38 pursuant to section 5 of this act, a carrier's compensation



1 agreements must provide sufficient information, as determined by the  
2 commissioner, to indicate that reimbursement for a claim for that  
3 prescription drug will not exceed the upper payment limit for the  
4 drug established by the board.

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

7 **Sec. 11.** RCW 43.71C.100 and 2019 c 334 s 10 are each amended to  
8 read as follows:

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

16 (2) The data in the report must be aggregated and must not reveal  
17 information specific to individual health carriers, pharmacy benefit  
18 managers, pharmacy services administrative organizations, individual  
19 prescription drugs, individual classes of prescription drugs,  
20 individual manufacturers, or discount amounts paid in connection with  
21 individual prescription drugs.

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

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

27 (5) For purposes of public policy, upon request of a legislator,  
28 the authority must provide all data provided pursuant to RCW  
29 43.71C.020 through 43.71C.080 and any analysis prepared by the  
30 authority. Any information provided pursuant to this subsection must  
31 be kept confidential within the legislature and may not be publicly  
32 released.

33 (6) For the purpose of reviewing drug prices and conducting  
34 affordability reviews, the prescription drug affordability board, as  
35 established in chapter 70.--- RCW (the new chapter created in section  
36 13 of this act), and the health care cost transparency board,  
37 established in chapter 70.390 RCW, may access all data collected  
38 pursuant to RCW 43.71C.020 through 43.71C.080 and any analysis  
39 prepared by the authority.

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

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

5        (1) The state health care affordability account is created in the  
6 state treasury. Expenditures from the account may only be used for  
7 premium and cost-sharing assistance programs established in RCW  
8 43.71.110.

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

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

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

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

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

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

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