
SECOND SUBSTITUTE SENATE BILL 5532

State of Washington

67th Legislature

2022 Regular Session

By Senate Ways & Means (originally sponsored by Senators Keiser, Robinson, Conway, Hasegawa, Nobles, Pedersen, Randall, Stanford, and C. Wilson)

READ FIRST TIME 02/07/22.

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

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

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

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

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

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

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

14 (5) "Excess costs" means:

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

18 (b) Costs of appropriate utilization of a prescription drug that
19 are not sustainable to public and private health care systems over a
20 10-year time frame.

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

1 (7) "Health carrier" or "carrier" has the same meaning as in RCW
2 48.43.005.

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

8 NEW SECTION. **Sec. 2.** PRESCRIPTION DRUG AFFORDABILITY BOARD. (1)
9 The prescription drug affordability board is established, to include
10 five members who have expertise in health care economics or clinical
11 medicine appointed by the governor.

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

14 (3) No board member or advisory group member may be an employee
15 of, a board member of, or consultant to a prescription drug
16 manufacturer, pharmacy benefit manager, health carrier, prescription
17 drug wholesale distributor, or related trade association, except that
18 a representative from the prescription drug industry serving on an
19 advisory group may be an employee, consultant, or board member of a
20 prescription drug manufacturer or related trade association and shall
21 not be deemed to have a conflict of interest pursuant to subsection
22 (4) of this section.

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

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

32 (5) The board shall establish advisory groups consisting of
33 relevant stakeholders, including but not limited to patients and
34 patient advocates for the condition treated by the drug and one
35 member who is a representative of the prescription drug industry, for
36 each drug affordability review conducted by the board pursuant to
37 section 4 of this act. Advisory group members are immune from civil
38 liability for any official act performed in good faith as a member of
39 the group.

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

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

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

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

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

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

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

25 NEW SECTION. **Sec. 3.** AUTHORITY TO REVIEW DRUG PRICES. By June
26 30, 2023, and annually thereafter, utilizing data collected pursuant
27 to chapter 43.71C RCW, the all-payer health care claims database, or
28 other data deemed relevant by the board, the board must identify
29 drugs that have been on the market for at least 10 years, are
30 dispensed at a retail pharmacy, are not designated by the United
31 States food and drug administration under 21 U.S.C. Sec. 360bb as a
32 drug for a rare disease or condition, and meet the following
33 thresholds:

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

35 (a) Have a wholesale acquisition cost of \$60,000 or more per year
36 or course of treatment lasting less than one year; or

37 (b) Have a price increase of 15 percent or more in any 12-month
38 period or for a course of treatment lasting less than 12 months, or a
39 50 percent cumulative increase over three years;

1 (2) A biosimilar product with an initial wholesale acquisition
2 cost that is not at least 15 percent lower than the reference
3 biological product; and

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

7 NEW SECTION. **Sec. 4.** AFFORDABILITY REVIEWS. (1) The board may
8 choose to conduct an affordability review of up to 24 prescription
9 drugs per year identified pursuant to section 3 of this act. When
10 deciding whether to conduct a review, the board shall consider:

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

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

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

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

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

23 (4) The authority may assess a fine of up to \$100,000 against a
24 manufacturer for each failure to comply with an information request
25 from the board. The assessment of a fine under this subsection is
26 subject to review under the administrative procedure act, chapter
27 34.05 RCW.

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

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

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

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

35 (d) Orphan drug status;

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

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

39 (g) Input from:

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

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

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

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

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

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

12 (a) Life-cycle management;

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

14 (c) Market competition and context;

15 (d) Projected revenue;

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

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

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

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

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

27 (2) The methodology must take into consideration:

28 (a) The cost of administering the drug;

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

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

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

34 (3) The methodology determined by the board must not use quality-
35 adjusted life years that take into account a patient's age or
36 severity of illness or disability to identify subpopulations for
37 which a prescription drug would be less cost-effective. For any
38 prescription drug that extends life, the board's analysis of cost-
39 effectiveness may not employ a measure or metric which assigns a

1 reduced value to the life extension provided by a treatment based on
2 a preexisting disability or chronic health condition of the
3 individuals whom the treatment would benefit.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 (1) Any manufacturer that intends to withdraw a prescription drug
25 from sale or distribution within the state because the board has
26 established an upper payment limit for that drug shall provide a
27 notice of withdrawal in writing indicating the drug will be withdrawn
28 because of the establishment of the upper payment limit at least 180
29 days before the withdrawal to the office of the insurance
30 commissioner, the authority, and any entity in the state with which
31 the manufacturer has a contract for the sale or distribution of the
32 drug.

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

36 (3) A manufacturer that has withdrawn a drug from the market may
37 petition the authority, in a form and manner determined by the
38 authority in rule, to reenter the market before the expiration of the

1 five-year ban if it agrees to make the drug available for sale in
2 compliance with the upper payment limit.

3 NEW SECTION. **Sec. 8.** RULE MAKING. The authority may adopt any
4 rules necessary to implement this chapter.

5 NEW SECTION. **Sec. 9.** A new section is added to chapter 48.43
6 RCW to read as follows:

7 (1) For health plans issued or renewed on or after January 1,
8 2024, if the prescription drug affordability board, as established in
9 chapter 70.--- RCW (the new chapter created in section 11 of this
10 act), establishes an upper payment limit for a prescription drug
11 pursuant to section 5 of this act, a carrier's compensation
12 agreements must provide sufficient information, as determined by the
13 commissioner, to indicate that reimbursement for a claim for that
14 prescription drug will not exceed the upper payment limit for the
15 drug established by the board.

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

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

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

27 (2) The data in the report must be aggregated and must not reveal
28 information specific to individual health carriers, pharmacy benefit
29 managers, pharmacy services administrative organizations, individual
30 prescription drugs, individual classes of prescription drugs,
31 individual manufacturers, or discount amounts paid in connection with
32 individual prescription drugs.

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

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

1 (5) For purposes of public policy, upon request of a legislator,
2 the authority must provide all data provided pursuant to RCW
3 43.71C.020 through 43.71C.080 and any analysis prepared by the
4 authority. Any information provided pursuant to this subsection must
5 be kept confidential within the legislature and may not be publicly
6 released.

7 (6) For the purpose of reviewing drug prices and conducting
8 affordability reviews, the prescription drug affordability board, as
9 established in chapter 70.--- RCW (the new chapter created in section
10 11 of this act), and the health care cost transparency board,
11 established in chapter 70.390 RCW, may access all data collected
12 pursuant to RCW 43.71C.020 through 43.71C.080 and any analysis
13 prepared by the authority.

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

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

21 (b) Acknowledge that the recipient is responsible for any
22 liability arising from misuse of the data and that the recipient does
23 not have any conflicts under the ethics in public service act that
24 would prevent the recipient from accessing or using the data.

25 NEW SECTION. Sec. 11. Sections 1 through 8 of this act
26 constitute a new chapter in Title 70 RCW.

--- END ---