

2SSB 5532 - H COMM AMD
By Committee on Appropriations

ADOPTED 03/02/2022

1 Strike everything after the enacting clause and insert the
2 following:

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

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

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

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

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

12 (5) "Excess costs" means:

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

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

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

20 (7) "Health carrier" or "carrier" has the same meaning as in RCW
21 48.43.005.

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

27 (9) "Prescription drug" means a drug regulated under chapter
28 69.41 or 69.50 RCW, including generic, brand name, specialty drugs,
29 and biological products.

30 NEW SECTION. **Sec. 2.** PRESCRIPTION DRUG AFFORDABILITY BOARD. (1)
31 The prescription drug affordability board is established, to include

1 five members who have expertise in health care economics or clinical
2 medicine appointed by the governor.

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

5 (3) No board member or advisory group member may be an employee
6 of, a board member of, or consultant to a prescription drug
7 manufacturer, pharmacy benefit manager, health carrier, prescription
8 drug wholesale distributor, or related trade association, except that
9 a representative from the prescription drug industry serving on an
10 advisory group may be an employee, consultant, or board member of a
11 prescription drug manufacturer or related trade association and shall
12 not be deemed to have a conflict of interest pursuant to subsection
13 (4) of this section.

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

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

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

31 (6) The authority shall provide administrative support to the
32 board and any advisory group of the board and shall adopt rules
33 governing their operation that shall include how and when the board
34 will use and discuss confidential information that is exempt from
35 public disclosure. The rules adopted under this subsection may not go
36 into effect until at least 90 days after the next regular legislative
37 session.

38 (7) Board members shall be compensated for participation in the
39 work of the board in accordance with a personal services contract to

1 be executed after appointment and before commencement of activities
2 related to the work of the board.

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

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

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

12 (11) The board must coordinate and collaborate with the
13 authority, other boards, work groups, and commissions related to
14 prescription drug costs and emerging therapies, including but not
15 limited to the health care cost transparency board established in
16 chapter 70.390 RCW, and the universal health care commission
17 established in RCW 41.05.840. All coordination and collaboration by
18 the board pursuant to this subsection must comply with chapter 42.30
19 RCW, the open public meetings act.

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

22 NEW SECTION. **Sec. 3.** AUTHORITY TO REVIEW DRUG PRICES. By June
23 30, 2023, and annually thereafter, utilizing data collected pursuant
24 to chapter 43.71C RCW, the all-payer health care claims database, or
25 other data deemed relevant by the board, the board must identify
26 prescription drugs that have been on the market for at least seven
27 years, are dispensed at a retail, specialty, or mail-order pharmacy,
28 are not designated by the United States food and drug administration
29 under 21 U.S.C. Sec. 360bb as a drug solely for the treatment of a
30 rare disease or condition, and meet the following thresholds:

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

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

34 (b) Have a price increase of 15 percent or more in any 12-month
35 period or for a course of treatment lasting less than 12 months, or a
36 50 percent cumulative increase over three years;

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

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

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

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

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

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

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

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

21 (4) The authority may assess a fine of up to \$100,000 against a
22 manufacturer for each failure to comply with an information request
23 from the board. The process for the assessment of a fine under this
24 subsection shall be established by the authority in rule and is
25 subject to review under the administrative procedure act, chapter
26 34.05 RCW. The rules adopted under this subsection may not go into
27 effect until at least 90 days after the next regular legislative
28 session.

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

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

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

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

36 (d) Orphan drug status;

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

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

- 1 (g) Input from:
- 2 (i) Patients affected by the condition or disease treated by the
3 drug; and
- 4 (ii) Individuals with medical or scientific expertise related to
5 the condition or disease treated by the drug;
- 6 (h) Any other information the drug manufacturer or other relevant
7 entity chooses to provide;
- 8 (i) The impact of pharmacy benefit manager policies on the price
9 consumers pay for the drug; and
- 10 (j) Any other relevant factors as determined by the board.
- 11 (6) In performing an affordability review of a drug the board may
12 consider the following factors:
- 13 (a) Life-cycle management;
- 14 (b) The average cost of the drug in the state;
- 15 (c) Market competition and context;
- 16 (d) Projected revenue;
- 17 (e) Off-label usage of the drug; and
- 18 (f) Any additional factors identified by the board.
- 19 (7) All information collected by the board pursuant to this
20 section is confidential and not subject to public disclosure under
21 chapter 42.56 RCW.
- 22 (8) The board shall publicize which prescription drugs are
23 subject to an affordability review before the review begins.

24 NEW SECTION. **Sec. 5.** UPPER PAYMENT LIMITS. (1) The authority
25 must adopt rules setting forth a methodology established by the board
26 for setting upper payment limits for prescription drugs the board has
27 determined have led or will lead to excess costs based on its
28 affordability review. The rules adopted under this subsection may not
29 go into effect until at least 90 days after the next regular
30 legislative session. Each year, the board may set an upper payment
31 limit for up to 12 prescription drugs.

- 32 (2) The methodology must take into consideration:
- 33 (a) The cost of administering the drug;
- 34 (b) The cost of delivering the drug to patients;
- 35 (c) The status of the drug on the drug shortage list published by
36 the United States food and drug administration; and
- 37 (d) Other relevant administrative costs related to the production
38 and delivery of the drug.

1 (3) The methodology determined by the board must not use quality-
2 adjusted life years that take into account a patient's age or
3 severity of illness or disability to identify subpopulations for
4 which a prescription drug would be less cost-effective. For any
5 prescription drug that extends life, the board's analysis of cost-
6 effectiveness may not employ a measure or metric which assigns a
7 reduced value to the life extension provided by a treatment based on
8 a preexisting disability or chronic health condition of the
9 individuals whom the treatment would benefit.

10 (4) Before setting an upper payment limit for a drug, the board
11 must post notice of the proposed upper payment limit on the
12 authority's website, including an explanation of the factors
13 considered when setting the proposed limit and instructions to submit
14 written comment. The board must provide 30 days to submit public
15 comment.

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

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

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

27 (8) The board must establish an effective date for each upper
28 payment limit, provided that the upper payment limit may not go into
29 effect until at least 90 days after the next regular legislative
30 session and that the date is at least six months after the adoption
31 of the upper payment limit and applies only to purchases, contracts,
32 and plans that are issued on or renewed after the effective date.

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

37 (10) For any upper payment limit set by the board, the board must
38 notify the manufacturer of the drug and the manufacturer must inform
39 the board if it is able to make the drug available for sale in the
40 state and include a rationale for its decision. The board must

1 annually report to the relevant committees of the legislature
2 detailing the manufacturers' responses.

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

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

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

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

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

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

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

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

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

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

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

9 (4) The rules adopted under this section may not go into effect
10 until at least 90 days after the next regular legislative session.

11 NEW SECTION. **Sec. 8.** By December 15, 2022, and annually
12 thereafter, the board shall provide a comprehensive report to the
13 legislature detailing all actions the board has taken in the past
14 year, including any rules adopted by the authority pursuant to this
15 act, establishing any processes, such as the methodology for the
16 upper payment limit, the list of drugs identified in section 3 of
17 this act, the drugs the board completed an affordability review of
18 and any determinations of whether the drug had led or will lead to
19 excess costs, and the establishment of any upper payment limits.

20 NEW SECTION. **Sec. 9.** RULE MAKING. The authority may adopt any
21 rules necessary to implement this chapter. The rules adopted under
22 this section may not go into effect until at least 90 days after the
23 next regular legislative session.

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

26 (1) For health plans issued or renewed on or after January 1,
27 2024, if the prescription drug affordability board, as established in
28 chapter 70.--- RCW (the new chapter created in section 12 of this
29 act), establishes an upper payment limit for a prescription drug
30 pursuant to section 5 of this act, a carrier must provide sufficient
31 information, as determined by the commissioner, to indicate that
32 reimbursement for a claim for that prescription drug will not exceed
33 the upper payment limit for the drug established by the board.

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

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

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

10 (2) The data in the report must be aggregated and must not reveal
11 information specific to individual health carriers, pharmacy benefit
12 managers, pharmacy services administrative organizations, individual
13 prescription drugs, individual classes of prescription drugs,
14 individual manufacturers, or discount amounts paid in connection with
15 individual prescription drugs.

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

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

21 (5) For purposes of public policy, upon request of a legislator,
22 the authority must provide all data provided pursuant to RCW
23 43.71C.020 through 43.71C.080 and any analysis prepared by the
24 authority. Any information provided pursuant to this subsection must
25 be kept confidential within the legislature and may not be publicly
26 released.

27 (6) For the purpose of reviewing drug prices and conducting
28 affordability reviews, the prescription drug affordability board, as
29 established in chapter 70.--- RCW (the new chapter created in section
30 12 of this act), and the health care cost transparency board,
31 established in chapter 70.390 RCW, may access all data collected
32 pursuant to RCW 43.71C.020 through 43.71C.080 and any analysis
33 prepared by the authority.

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

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

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

5 NEW SECTION. **Sec. 12.** Sections 1 through 9 of this act
6 constitute a new chapter in Title 70 RCW.

7 **Sec. 13.** RCW 42.30.110 and 2019 c 162 s 2 are each amended to
8 read as follows:

9 (1) Nothing contained in this chapter may be construed to prevent
10 a governing body from holding an executive session during a regular
11 or special meeting:

12 (a) (i) To consider matters affecting national security;

13 (ii) To consider, if in compliance with any required data
14 security breach disclosure under RCW 19.255.010 and 42.56.590, and
15 with legal counsel available, information regarding the
16 infrastructure and security of computer and telecommunications
17 networks, security and service recovery plans, security risk
18 assessments and security test results to the extent that they
19 identify specific system vulnerabilities, and other information that
20 if made public may increase the risk to the confidentiality,
21 integrity, or availability of agency security or to information
22 technology infrastructure or assets;

23 (b) To consider the selection of a site or the acquisition of
24 real estate by lease or purchase when public knowledge regarding such
25 consideration would cause a likelihood of increased price;

26 (c) To consider the minimum price at which real estate will be
27 offered for sale or lease when public knowledge regarding such
28 consideration would cause a likelihood of decreased price. However,
29 final action selling or leasing public property shall be taken in a
30 meeting open to the public;

31 (d) To review negotiations on the performance of publicly bid
32 contracts when public knowledge regarding such consideration would
33 cause a likelihood of increased costs;

34 (e) To consider, in the case of an export trading company,
35 financial and commercial information supplied by private persons to
36 the export trading company;

37 (f) To receive and evaluate complaints or charges brought against
38 a public officer or employee. However, upon the request of such

1 officer or employee, a public hearing or a meeting open to the public
2 shall be conducted upon such complaint or charge;

3 (g) To evaluate the qualifications of an applicant for public
4 employment or to review the performance of a public employee.
5 However, subject to RCW 42.30.140(4), discussion by a governing body
6 of salaries, wages, and other conditions of employment to be
7 generally applied within the agency shall occur in a meeting open to
8 the public, and when a governing body elects to take final action
9 hiring, setting the salary of an individual employee or class of
10 employees, or discharging or disciplining an employee, that action
11 shall be taken in a meeting open to the public;

12 (h) To evaluate the qualifications of a candidate for appointment
13 to elective office. However, any interview of such candidate and
14 final action appointing a candidate to elective office shall be in a
15 meeting open to the public;

16 (i) To discuss with legal counsel representing the agency matters
17 relating to agency enforcement actions, or to discuss with legal
18 counsel representing the agency litigation or potential litigation to
19 which the agency, the governing body, or a member acting in an
20 official capacity is, or is likely to become, a party, when public
21 knowledge regarding the discussion is likely to result in an adverse
22 legal or financial consequence to the agency.

23 This subsection (1)(i) does not permit a governing body to hold
24 an executive session solely because an attorney representing the
25 agency is present. For purposes of this subsection (1)(i), "potential
26 litigation" means matters protected by RPC 1.6 or RCW 5.60.060(2)(a)
27 concerning:

28 (i) Litigation that has been specifically threatened to which the
29 agency, the governing body, or a member acting in an official
30 capacity is, or is likely to become, a party;

31 (ii) Litigation that the agency reasonably believes may be
32 commenced by or against the agency, the governing body, or a member
33 acting in an official capacity; or

34 (iii) Litigation or legal risks of a proposed action or current
35 practice that the agency has identified when public discussion of the
36 litigation or legal risks is likely to result in an adverse legal or
37 financial consequence to the agency;

38 (j) To consider, in the case of the state library commission or
39 its advisory bodies, western library network prices, products,
40 equipment, and services, when such discussion would be likely to

1 adversely affect the network's ability to conduct business in a
2 competitive economic climate. However, final action on these matters
3 shall be taken in a meeting open to the public;

4 (k) To consider, in the case of the state investment board,
5 financial and commercial information when the information relates to
6 the investment of public trust or retirement funds and when public
7 knowledge regarding the discussion would result in loss to such funds
8 or in private loss to the providers of this information;

9 (l) To consider proprietary or confidential nonpublished
10 information related to the development, acquisition, or
11 implementation of state purchased health care services as provided in
12 RCW 41.05.026;

13 (m) To consider in the case of the life sciences discovery fund
14 authority, the substance of grant applications and grant awards when
15 public knowledge regarding the discussion would reasonably be
16 expected to result in private loss to the providers of this
17 information;

18 (n) To consider in the case of a health sciences and services
19 authority, the substance of grant applications and grant awards when
20 public knowledge regarding the discussion would reasonably be
21 expected to result in private loss to the providers of this
22 information;

23 (o) To consider information regarding staff privileges or quality
24 improvement committees under RCW 70.41.205;

25 (p) To consider proprietary or confidential data collected or
26 analyzed pursuant to chapter 70.--- RCW (the new chapter created in
27 section 12 of this act).

28 (2) Before convening in executive session, the presiding officer
29 of a governing body shall publicly announce the purpose for excluding
30 the public from the meeting place, and the time when the executive
31 session will be concluded. The executive session may be extended to a
32 stated later time by announcement of the presiding officer.

33 NEW SECTION. **Sec. 14.** If specific funding for the purposes of
34 this act, referencing this act by bill or chapter number, is not
35 provided by June 30, 2022, in the omnibus appropriations act, this
36 act is null and void."

37 Correct the title.

EFFECT: Requires rather than authorizes the Health Care Authority (HCA) to adopt rules governing the operation of the Prescription Drug Affordability Board (Board) and mandates that the rules include how and when the Board will use and discuss confidential information.

Modifies the prescription drugs that the Board must identify so that the prescription drugs must have been on the market for only seven years rather than ten, must include drugs dispensed from specialty and mail order pharmacies, in addition to retail pharmacies, and the prescription drugs may not be designated by the U.S. Food and Drug Administration as a drug solely for the treatment of a rare disease or condition.

Requires the Board to submit a comprehensive report to the Legislature by December 15, 2022, and annually thereafter, detailing all actions the Board has taken in the past year.

Requires that any rules adopted by the HCA and any upper payment limits adopted by the Board may not go into effect until at least 90 days after the next regular legislative session.

Requires the HCA to adopt rules establishing the process for assessing fines and setting forth the methodology for setting upper payment limits that is established by the Board.

Requires a carrier to provide sufficient information, rather than carrier's compensation agreement, to indicate that reimbursement for a claim for that prescription drug will not exceed the upper payment limit.

Specifies that all information collected by the Board is confidential.

Specifies that all coordination with other boards, work groups, and commissioners, must comply with the Open Public Meetings Act (Act) and that nothing in the Act prohibits the holding of an executive session for the consideration of proprietary or confidential information by the Board.

Defines "prescription drug."

Corrects a reference to the three-year ban for manufacturers that withdraw a drug from the market.

Adds a null and void clause, making the bill null and void unless funded in the budget.

--- END ---