

**2SSB 5532** - H COMM AMD

By Committee on Health Care & Wellness

**NOT 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.

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

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

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

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

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

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

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

33           (6) The authority shall provide administrative support to the  
34   board and any advisory group of the board and shall adopt rules  
35   governing their operation that shall include how and when the board  
36   will use and discuss confidential information that is exempt from  
37   public disclosure.

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 four  
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.

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

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

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

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

34 (d) Orphan drug status;

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

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

38 (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 confidential and not subject to public disclosure under  
20 chapter 42.56 RCW.

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

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

29 (2) The methodology must take into consideration:

30 (a) The cost of administering the drug;

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

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

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

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

1 prescription drug that extends life, the board's analysis of cost-  
2 effectiveness may not employ a measure or metric which assigns a  
3 reduced value to the life extension provided by a treatment based on  
4 a preexisting disability or chronic health condition of the  
5 individuals whom the treatment would benefit.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

30 **Sec. 12.** RCW 42.30.110 and 2019 c 162 s 2 are each amended to  
31 read as follows:

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

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

36 (ii) To consider, if in compliance with any required data  
37 security breach disclosure under RCW 19.255.010 and 42.56.590, and  
38 with legal counsel available, information regarding the

1 infrastructure and security of computer and telecommunications  
2 networks, security and service recovery plans, security risk  
3 assessments and security test results to the extent that they  
4 identify specific system vulnerabilities, and other information that  
5 if made public may increase the risk to the confidentiality,  
6 integrity, or availability of agency security or to information  
7 technology infrastructure or assets;

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

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

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

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

22 (f) To receive and evaluate complaints or charges brought against  
23 a public officer or employee. However, upon the request of such  
24 officer or employee, a public hearing or a meeting open to the public  
25 shall be conducted upon such complaint or charge;

26 (g) To evaluate the qualifications of an applicant for public  
27 employment or to review the performance of a public employee.  
28 However, subject to RCW 42.30.140(4), discussion by a governing body  
29 of salaries, wages, and other conditions of employment to be  
30 generally applied within the agency shall occur in a meeting open to  
31 the public, and when a governing body elects to take final action  
32 hiring, setting the salary of an individual employee or class of  
33 employees, or discharging or disciplining an employee, that action  
34 shall be taken in a meeting open to the public;

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

39 (i) To discuss with legal counsel representing the agency matters  
40 relating to agency enforcement actions, or to discuss with legal

1 counsel representing the agency litigation or potential litigation to  
2 which the agency, the governing body, or a member acting in an  
3 official capacity is, or is likely to become, a party, when public  
4 knowledge regarding the discussion is likely to result in an adverse  
5 legal or financial consequence to the agency.

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

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

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

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

21 (j) To consider, in the case of the state library commission or  
22 its advisory bodies, western library network prices, products,  
23 equipment, and services, when such discussion would be likely to  
24 adversely affect the network's ability to conduct business in a  
25 competitive economic climate. However, final action on these matters  
26 shall be taken in a meeting open to the public;

27 (k) To consider, in the case of the state investment board,  
28 financial and commercial information when the information relates to  
29 the investment of public trust or retirement funds and when public  
30 knowledge regarding the discussion would result in loss to such funds  
31 or in private loss to the providers of this information;

32 (l) To consider proprietary or confidential nonpublished  
33 information related to the development, acquisition, or  
34 implementation of state purchased health care services as provided in  
35 RCW 41.05.026;

36 (m) To consider in the case of the life sciences discovery fund  
37 authority, the substance of grant applications and grant awards when  
38 public knowledge regarding the discussion would reasonably be  
39 expected to result in private loss to the providers of this  
40 information;

1 (n) To consider in the case of a health sciences and services  
2 authority, the substance of grant applications and grant awards when  
3 public knowledge regarding the discussion would reasonably be  
4 expected to result in private loss to the providers of this  
5 information;

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

8 (p) To consider proprietary or confidential data collected or  
9 analyzed pursuant to chapter 70.--- RCW (the new chapter created in  
10 section 11 of this act).

11 (2) Before convening in executive session, the presiding officer  
12 of a governing body shall publicly announce the purpose for excluding  
13 the public from the meeting place, and the time when the executive  
14 session will be concluded. The executive session may be extended to a  
15 stated later time by announcement of the presiding officer."

16 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 drugs must have been on the market for only four years  
rather than ten, must include specialty and mail order prescription  
drugs, specifies that the prescriptions drugs must 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 HCA to adopt rules establishing the process for  
assessing fines.

Requires the HCA to establish rules 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.

--- END ---