2SSB 5532 - H COMM AMD
By Committee on Health Care & Wellness

Strike everything after the enacting clause and insert the following:

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

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

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

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

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

(5) "Excess costs" means:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) The authority may assess a fine of up to $100,000 against a manufacturer for each failure to comply with an information request from the board. The process for the assessment of a fine under this subsection shall be established by the authority in rule and is subject to review under the administrative procedure act, chapter 34.05 RCW.

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

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

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

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

(d) Orphan drug status;

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

(f) The price and availability of therapeutic alternatives;

(g) Input from:

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

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

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

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

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

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

(a) Life-cycle management;

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

(c) Market competition and context;

(d) Projected revenue;

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

(f) Any additional factors identified by the board.

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

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

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

(2) The methodology must take into consideration:

(a) The cost of administering the drug;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

NEW SECTION. **Sec. 7.** MANUFACTURER WITHDRAWAL FROM THE MARKET. (1) Any manufacturer that intends to withdraw a prescription drug from sale or distribution within the state because the board has established an upper payment limit for that drug shall provide a notice of withdrawal in writing indicating the drug will be withdrawn because of the establishment of the upper payment limit at least 180 days before the withdrawal to the office of the insurance commissioner, the authority, and any entity in the state with which the manufacturer has a contract for the sale or distribution of the drug.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

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