FINAL BILL REPORT
2SSB 5532

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Synopsis as Enacted

Brief Description: Establishing a prescription drug affordability board.

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

Senate Committee on Health & Long Term Care
Senate Committee on Ways & Means
House Committee on Health Care & Wellness
House Committee on Appropriations

Background: In 2005, the Legislature directed the Health Care Authority (HCA) to establish a prescription drug purchasing consortium. The Northwest Prescription Drug Consortium allows state agencies, local governments, businesses, labor organizations, and uninsured consumers to pool their purchasing power to purchase prescription drugs at lower prices. The consortium offers access to retail pharmacy discounts, pharmacy benefit management services, rebate management services, and a prescription discount card for uninsured residents.

Statutory authority allows for drug purchasing cost controls including negotiating discounts with manufacturers, central purchasing, volume contracting, and setting maximum prices to be paid.

In 2019, the Legislature passed prescription drug cost transparency legislation. The legislation requires:

- health carriers, pharmacy benefit managers, manufacturers, and pharmacy services administrative organizations to annually submit utilization, pricing, rebate, and discount data to HCA;
- HCA to compile the data and into an annual report demonstrating the effect of drug costs on health care premiums; and
- manufacturers to provide HCA with 60 days advance notice of price increases above a certain threshold.

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not part of the legislation nor does it constitute a statement of legislative intent.

Summary: Prescription Drug Affordability Board Duties. The Prescription Drug Affordability Board (Board) is established within HCA with five members appointed by the Governor, who have expertise in health care economics or clinical medicine. The Board may not convene until at least one year after HCA publishes its first prescription drug price transparency report. All meetings of the Board must be open and public, except for executive sessions. All coordination and collaboration with HCA, other work groups, boards, and other entities must comply with the Open Public Meetings Act. HCA is authorized to adopt rules necessary to implement these requirements, however, the rules may not go into effect until at least 90 days after the next regular legislative session following the adoption of the rules. By June 30, 2023, and yearly thereafter, the Board must identify drugs that have been on the market for at least seven years; are dispensed at a retail, specialty, or mail order pharmacy; are not designated by the United States Food and Drug Administration as a drug solely for the treatment of a rare disease or condition; and meet the following benchmarks:

- brand name prescription drugs introduced at a price of $60,000 or more per year, or course of treatment, or have a price increase of 15 percent or more in any 12-month period or 50 percent over a three year period;
- biosimilar products with an initial price less than 15 percent below the reference brand price; and
- generic drugs costing $100 or more for a 30-day supply or less that have increased in price by 200 percent or more in the last 12 months.

The Board may choose to conduct up to 24 affordability reviews each year of drugs it identifies meeting the above thresholds. When deciding whether to conduct a review, the Board must consider:

- the class of the prescription drug and whether any therapeutically equivalent prescription drugs are available for sale;
- input from relevant advisory groups; and
- the average patient's out-of-pocket cost for the drug.

For any drug chosen for a review, the Board must establish an advisory group consisting of relevant stakeholders, including patients and patient advocates for the condition treated by the drug and a representative from the pharmaceutical industry.

Affordability reviews must determine if the drug has led or will lead to excess costs, defined as costs exceeding therapeutic benefit relative to other treatments, or are not sustainable to the health care system over a ten-year period. When conducting a review, the board must consider:

- the relevant factors contributing to the price paid for the prescription drug, including the wholesale acquisition cost, discounts, rebates, or other price concessions;
- the average patient copay or other cost sharing for the drug;
- the effect of the price on consumers' access to the drug in the state;
- orphan drug status;
- the dollar value and accessibility of patient assistance programs offered by the

manufacturer for the drug;
- the price and availability of therapeutic alternatives;
- input from patients affected by the condition or disease treated by the drug and individuals with medical or scientific expertise related to the condition or disease treated by the drug;
- the impact of pharmacy benefit manager policies on the price consumers pay for the drug;
- any other information the drug manufacturer or other relevant entity chooses to provide; and
- any other relevant factors as determined by the Board.

The Board may request confidential and proprietary information about the drug from the manufacturer to complete its review, and the manufacturer must submit all requested information within 30 days. HCA may assess a fine up to $100,000 against a manufacturer for each failure to comply with an information request. All information collected by the Board is confidential and not subject to public disclosure.

HCA must adopt rules, which may not go into effect until 90 days after the next regular legislative session, setting forth a methodology established by the Board for setting an upper payment limit for drugs the Board determines have led or will lead to excess costs. The methodology must consider:
- the cost of administering the drug;
- the cost of delivering the drug to patients;
- the status of the drug on the drug shortage list published by the United States Food and Drug Administration; and
- other relevant administrative costs related to the production and delivery of the drug.

Each year, beginning January 1, 2027, the Board may set an upper payment limit for up to 12 prescription drugs. An upper payment limit for a prescription drug applies to all purchases of the drug by any entity and reimbursements for a claim for the drug by a health carrier when the drug is dispensed or administered to an individual in the state. Employer-sponsored self-funded plans may elect to be subject to the upper payment limits.

The Board must establish an effective date for each upper payment limit which may not go into effect until at least 90 days after the next regular legislative session following the adoption of the rules, and at least six months after the adoption of the limit. The Board may reassess the upper payment limit for any drug annually, based on current economic factors.

The Board must monitor the supply of drugs subject to an upper payment limit and may suspend that limit if there is a shortage of a drug in the state.

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 a denial through the carrier's grievance and appeal process, or through an independent

review organization following the grievance and appeal process. 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.

Use of Savings. Any savings generated for a health plan that are attributable to the establishment of an upper payment limit must be used to reduce costs to consumers, prioritizing the reduction of out-of-pocket costs for prescription drugs. By January 1, 2024, the Board must establish a formula for calculating savings for complying with this section.

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 and how the savings were used to reduce costs to consumers.

Manufacturer Withdrawal. If a manufacturer chooses to withdraw a drug from the market due to an upper payment limit for that drug, it must provide written notice to the state at least 180 days in advance. If a manufacturer withdraws a drug, it will be prohibited from selling the drug in the state for three years, unless it petitions HCA to reenter the market on the condition that it will make the drug available in compliance with the upper payment limit.

Annual Report. By December 15, 2022, and annually thereafter, the Board must submit a comprehensive report to the Legislature detailing all actions taken by the Board in the past year, including any rules adopted by HCA, the list of prescription drugs identified by the Board, the drugs the Board completed an affordability review of and any determinations of whether the drug had led or will lead to excess costs, and the establishment of any upper payment limits.

Data Access. The Board and the Health Care Cost Transparency Board (Transparency Board) are authorized to access all data collected under the prescription drug price transparency statutes and any analysis prepared by HCA. Any information provided by HCA to legislators, the Board, or Transparency Board must be kept confidential and may not be publicly released. Recipients of data within the Board and Transparency Board must follow all rules adopted by HCA regarding appropriate data use and protection and 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.

Votes on Final Passage:

Senate	29	20	
House	57	39	(House amended)
Senate	28	20	(Senate concurred)

Effective: June 9, 2022