Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

2SSB 5532

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.).

Brief Summary of Second Substitute Bill

- Establishes the Prescription Drug Affordability Board (Board).
- Authorizes the Board to set upper payment limits for certain prescription drugs and biologics that the Board determines have led or will lead to excess costs.

Hearing Date: 2/17/22

Staff: Kim Weidenaar (786-7120).

Background:

Prescription Drug Purchasing Consortium.
In 2005 the Legislature directed the Health Care Authority (HCA) to establish a prescription drug purchasing consortium. In addition to state agencies, the consortium may include, on a voluntary basis, local government, private entities, labor organizations, and individuals without insurance, or who are underinsured for prescription drug coverage. In 2006 Washington and Oregon formed the Northwest Prescription Drug Consortium (Northwest Consortium) to expand their purchasing power. The Northwest Consortium offers access to retail pharmacy discounts, pharmacy benefit management services, rebate management services, and a prescription discount card for uninsured residents.

Prescription Drug Cost Transparency.

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.

In 2019 legislation was enacted to require the reporting of certain information to the HCA about the cost of prescription drugs. The legislation requires health carriers, pharmacy benefit managers, manufacturers, and pharmacy services administrative organizations to annually submit utilization, pricing, rebate, and discount data to the HCA. Drug manufacturers must provide the HCA with 60 days advance notice of price increases above a certain threshold. The HCA must compile and analyze the data into an annual report demonstrating the impact of drug costs on health care premiums. The data in the report must be aggregated, not reveal information to specific entities, and other than the report and the provision of information to legislators upon request, the HCA must keep all data confidential.

Health Care Cost Transparency Board.
The Health Care Cost Transparency Board (Transparency Board) was established in 2020 to calculate and analyze information and trends related to health care costs in Washington. The Transparency Board's activities relate to annually calculating total health care expenditures. The Transparency Board must also annually calculate health care cost growth and establish the health care cost growth benchmark for increases in total health expenditures.

U.S. Food and Drug Administration Designations.
The U.S. Food and Drug Administration (FDA) may designate drugs or biological products that prevent, diagnose, or treat a rare disease or condition as orphan-drugs. This designation qualifies drug sponsors for a number of incentives including tax credits for qualified clinical trials, exemptions for user fees, and a potential seven years of market exclusivity after approval. In addition to the Orphan Drug Designation Program, the FDA Office of Orphan Products Development includes a number of other programs intended to enable the development of drugs and biologic products for rare diseases including the Rare Pediatric Disease Priority Review Voucher Program and the Orphan Products Grant Program.

Summary of Bill:

Prescription Drug Affordability Board.
The Prescription Drug Affordability Board (Board) is established with five members appointed by the Governor who have expertise in health care economics or clinical medicine. The Board members must serve five-year terms. The Health Care Authority (HCA) must provide administrative support to the Board and any advisory groups and may adopt rules governing their operation. The Board may not hold its first meeting until at least one year after the HCA publishes its first prescription drug price transparency report.

By June 30, 2023, and yearly thereafter, the Board must identify drugs that have been on the market for at least 10 years, are dispensed at a retail pharmacy, are not designated by the U.S. Food and Drug Administration (FDA) as a drug for a rare disease or condition, and meet the following benchmarks:

- brand name prescription drugs and biologic products:
    - introduced at a wholesale acquisition cost 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 as 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;
- 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 prescription drug industry.

Affordability reviews must determine if the drug has led or will lead to excess costs, defined as costs exceeding the therapeutic benefit relative to other treatments or that are not sustainable to the health care system over a 10-year period. The Board must publicize the drugs that are subject to an affordability review before it begins. 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 cost sharing for the drug;
- the effect of the price on consumers' access to the drug;
- orphan drug status;
- the amount 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 (PBM) 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. The HCA may assess a fine up to $100,000 against a manufacturer for each failure to comply with an information request.

Upper Payment Limit.
The Board must establish a methodology in rule for setting an upper payment limit for drugs the Board determines have led or will lead to excess costs and 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 FDA; and
- other relevant administrative costs related to the production and delivery of the drug.

The Board may not establish an upper payment limit before January 1, 2027. Before setting an upper payment limit for a drug, the Board must post notice of the proposed upper payment limit including an explanation of the factors considered when setting the limit on the HCA's website and provide 30 days for public comment. The Board must notify the manufacturer of the drug subject to an upper payment limit 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 establish an effective date for each upper payment limit which must be at least six months after the adoption of the limit and the limit only applies to purchases, contracts, and plans that are issued on or renewed after the effective date.

Upper payment limits established by the Board apply to all purchases of the drug by any entity and reimbursements for a claim for the drug by a health carrier or health plan offered to public employees when the drug is dispensed or administered to an individual in the state in person, by mail, or other means. Employer-sponsored self-funded plans may elect to be subject to the upper payment limits. 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.

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. The Board may reassess the upper payment limit for any drug annually based on current economic factors.

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.

Savings.
Any savings generated for a health plan offered by a carrier or a health plan offered to public employees that are attributable to 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 the savings. By March 1 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.
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, must provide notice of withdrawal indicating that the drug will be withdrawn because of the limit at least 180 days before the withdrawal to the Office of the Insurance Commissioner, the HCA, and any entity in the state with the manufacturer has a contract for the sale or distribution of the drug. If a manufacturer chooses to withdraw the prescription drug from the state, it is prohibited from selling that drug in Washington for three years. A manufacturer that has withdrawn from the market may petition the authority to reenter the market before the expiration of the five-year ban if it agrees to make the drug available for sale in compliance with the upper payment limit.

Miscellaneous.
Board members and advisory group members may not be an employee, board member, or consultant of a prescription drug manufacturer, PBM, health carrier, prescription drug wholesale distributor, or related trade association, except for the representative on an advisory group from the prescription drug industry. Board members, advisory group members, staff members, and contractors of the Board must recuse themselves from a Board activity in which they have a conflict of interest. Board members must be compensated for the work of the Board in accordance with a personal services contract. The Board must coordinate and collaborate with the HCA, other boards, work groups, and commissions related to prescription drug costs and emerging therapies and may collaborate with prescription drug affordability boards established in other states.

All meetings of the Board must be open and public, except for executive sessions. The HCA is authorized to adopt rules necessary to implement these requirements.

For health plans issued or renewed on or after January 1, 2024, if the Board has established an upper payment limit for a prescription drug, a carrier's compensation agreement must provide sufficient information, as determined by the Insurance Commissioner, to indicate that reimbursement for a claim that a prescription drug will not exceed the upper payment limit.

Prescription Drug Price Transparency.
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 the HCA. Any information provided by the 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 the 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.

Appropriation: None.

Fiscal Note: Available.

Effective Date: The bill takes effect 90 days after adjournment of the session in which the bill is passed.