SENATE BILL REPORT
SB 5532

As Reported by Senate Committee On:
Health & Long Term Care, January 28, 2022

Title: An act relating to establishing a prescription drug affordability board.

Brief Description: Establishing a prescription drug affordability board.

Sponsors: Senators Keiser, Robinson, Conway, Hasegawa, Nobles, Pedersen, Randall, Stanford and Wilson, C..

Brief History:
Committee Activity: Health & Long Term Care: 1/19/22, 1/28/22 [DPS-WM, DNP, w/oRec].

Brief Summary of First Substitute Bill

- Establishes the Prescription Drug Affordability Board (Board).
- Requires the Board to identify prescription drugs priced above a certain threshold.
- Authorizes the Board to conduct affordability reviews of identified drugs and set upper payment limits beginning in 2027.
- Allows the Board to impose a penalty on increased revenue for certain drugs.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Majority Report: That Substitute Senate Bill No. 5532 be substituted therefor, and the substitute bill do pass and be referred to Committee on Ways & Means.

Signed by Senators Cleveland, Chair; Frockt, Vice Chair; Conway, Keiser, Randall, Robinson and Van De Wege.

Minority Report: Do not pass.

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.

Signed by Senators Muzzall, Ranking Member; Padden, Rivers and Sefzik.

Minority Report: That it be referred without recommendation.
Signed by Senator Holy.

Staff: Greg Attanasio (786-7410)

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 must compile the data and into an annual report demonstrating the effect of drug costs on health care premiums; and
- manufacturers must provide HCA with 60 days advance notice of price increases above a certain threshold.

Summary of Bill (First Substitute): 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. 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 as a treatment for a rare disease or condition, and meet the following benchmarks:

- brand name prescription drugs introduced at a price of $25,000 or more per year, or course of treatment, or have a price increase of $3,000 or more in any 12-month period;
- biosimilar products with a 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 an affordability review of any drug 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.

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 10-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.

The Board must establish a methodology for setting upper payment limits for prescription drugs that the Board has determined have led or will lead to excess costs based on its affordability review. 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 effective date of an upper payment limit must be at least six months after the adoption of the limit by the Board. The Board may reassess the upper payment limit for any drug annually based on current economic factors.

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 five 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.

Price Increase Penalty. If the Board determines, after an affordability review, that a drug will result in excess costs for patients, but does not impose an upper payment limit on the drug, the board may impose a penalty on the increased revenue generated in the state resulting from the price increase. The penalty must be 80 percent of the difference between the revenue generated by sales within the state and the revenue that would have been generated if the manufacturer had maintained the wholesale acquisition cost from the previous calendar year.

Data Access. The prescription drug price transparency statutes are amended to allow the board to review all data collected pursuant to that program for conducting affordability review.

EFFECT OF CHANGES MADE BY HEALTH & LONG TERM CARE

COMMITTEE (First Substitute):

- Adds a definition of manufacturer, which exclude wholesalers and distributors.
- States that the Board may not meet until at least one year after HCA publishes its first drug price transparency report.
- Limits the drugs the Board may review to those that have been on the market for at least ten years, are dispensed at a retail pharmacy, are not designated to treat a rare disease, and meeting the price thresholds in the bill.
- Requires the Board to consider the impact of PBM policies on the price of the drug when conducting an affordability review.
- Prohibits the Board from setting an upper payment limit until 2027.
- Clarifies that manufacturers would be prohibited from the market only if they withdraw a drug for sale because the drug has an upper payment limit.
- Assigns the Board the authority to impose price increase penalties.

Appropriation: None.

Fiscal Note: Requested on January 10, 2022.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony on Original Bill:

The committee recommended a different version of the bill than what was heard. PRO: The prices for drugs continue to go up, which leads to higher insurance premiums. People need to be able to afford drugs for conditions they have no control over. Even with insurance covering high priced drugs it is impossible for many patients to afford the out-of-pocket expenses. Drugs are the fastest growing part of insurance premiums. High drug prices disproportionately affect seniors and those with chronic health conditions.

CON: This bill goes too far and could reduce access to drugs. The bill doesn't account for negotiations on price and might lead to carriers or pharmacies not carrying the drug. The US leads research and development of new drugs and this bill will frustrate that effort. Prohibiting drugs from the market will reduce competition. Without drug transparency information this bill can't work properly. HCA has struggled to implement the transparency legislation and is not capable of implementing this bill. Reforms should be made to what consumers pay out-of-pocket at the pharmacy.

OTHER: The board should have more authority to look at other ways to control drug prices. Confidentiality should be strengthened. Physicians are concerned about how this bill will affect access to drugs provided in-clinic.

Persons Testifying: PRO: Senator Karen Keiser, Prime Sponsor; Cindi Laws, Health Care for All Washington; elyette weinstein, retired; Ella Goodman, WashPIRG student; Sam Hatzenbeler, Economic Opportunity Institute; Veronica Chase; Carrie Tellefson, Pharmaceutical Care Management Association; Chris Bandoli, Association of WA Healthcare Plans; Jim Freeburg, Patient Coalition of Washington; Lacey Stanage, AARP.

CON: Dharia McGrew, PhRMA; Amy Anderson, Association of Washington Business; Brett Michelin, Association for Accessible Medicines; Brian Warren, BIO; Marc Cummings, Life Science Washington; Lee Newgent, PILMA; Michael Transue, Oregon Biosciences Association; Liisa Bozinovic, Oregon Biosciences Association.

OTHER: Jenny Arnold, Washington State Pharmacy Association; Drew Gattine, NASHP; Steve Horn, ICAN, International Cancer Advocacy Network; Katie Kolan, WA St Medical Oncology Society.

Persons Signed in to Testify But Not Testifying: No one.