HOUSE BILL REPORT SSB 6088

As Passed House - Amended:

March 6, 2020

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

Brief Description: Establishing a prescription drug affordability board.

Sponsors: Senate Committee on Ways & Means (originally sponsored by Senators Keiser, Conway, Das, Frockt, Hasegawa, Hunt, Kuderer, Pedersen, Randall, Rolfes, Stanford and Wilson, C.).

Brief History:

Committee Activity:

Health Care & Wellness: 2/26/20, 2/27/20 [DP];

Appropriations: 3/2/20 [DPA].

Floor Activity:

Passed House - Amended: 3/6/20, 94-3.

Brief Summary of Substitute Bill (As Amended by House)

- Establishes the Prescription Drug Affordability Board (Board).
- Authorizes the Board to make recommendations to mitigate the cost of certain prescription drugs or biological products and to request that manufacturers enter into negotiations to reduce the cost of certain prescription drugs or biological products that meet certain pricing thresholds.
- Requires the Board to coordinate and complement the work of the Health Care Authority, other boards, and work groups related to prescription drug costs and emerging therapies.
- Allows the Office of the Governor, the Office of the Attorney General, the Board, and legislative committees to obtain submitted prescription drug price data through a nondisclosure agreement.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

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

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Majority Report: Do pass. Signed by 9 members: Representatives Cody, Chair; Macri, Vice Chair; Chopp, Davis, Riccelli, Robinson, Stonier, Thai and Tharinger.

Minority Report: Do not pass. Signed by 3 members: Representatives Schmick, Ranking Minority Member; Chambers and DeBolt.

Minority Report: Without recommendation. Signed by 2 members: Representatives Harris and Maycumber.

Staff: Kim Weidenaar (786-7120).

HOUSE COMMITTEE ON APPROPRIATIONS

Majority Report: Do pass as amended. Signed by 27 members: Representatives Ormsby, Chair; Robinson, 1st Vice Chair; Bergquist, 2nd Vice Chair; Rude, Assistant Ranking Minority Member; Caldier, Chandler, Chopp, Cody, Corry, Dolan, Dye, Fitzgibbon, Hansen, Hudgins, Kilduff, Macri, Pettigrew, Pollet, Ryu, Schmick, Senn, Springer, Steele, Sullivan, Tarleton, Tharinger and Ybarra.

Minority Report: Do not pass. Signed by 6 members: Representatives Stokesbary, Ranking Minority Member; MacEwen, Assistant Ranking Minority Member; Hoff, Kraft, Mosbrucker and Sutherland.

Staff: Meghan Morris (786-7119).

Background:

State Purchased Prescription Drugs.

In 2003 the Legislature created an evidence-based prescription drug program for state agencies purchasing prescription drugs directly or through reimbursement to pharmacies. The program is part of the Washington Prescription Drug Program and uses a preferred drug list (PDL), which is a list of prescription drug classes having gone through an evidence-based review process to determine their safety, efficacy, and effectiveness.

Washington contracts with the Oregon Health and Science University Center for Evidence-Based Policy to independently review drug classes. Their recommendations are reviewed by the Pharmacy and Therapeutics Committee, an independent group of pharmacists and physicians, which then makes recommendations regarding the drugs on the PDL.

Prescription Drug Purchasing Consortium.

In 2005 the Legislature directed the Health Care Authority 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. State purchased health care services purchased through health carriers and health maintenance organizations are exempted from participating in the consortium. 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 Price Transparency Legislation.

In 2019 enacted legislation required health carriers, prescription drug manufacturers, pharmacy benefit managers (PBMs), and pharmacy service administration organizations (PSAOs) to report certain drug pricing information to the Health Care Authority (HCA), which the HCA would then use to publish an annual report. By March 1 of each year, a PBM must provide the HCA with information from the previous calendar year regarding all drug discounts, negotiated prices, reimbursements, terms, and fees. Beginning October 1, 2019, and yearly thereafter, health carriers, prescription drug manufacturers, and PSAOs must provide the HCA with certain information regarding the costs, expenses, rebates, and increases of prescription drugs.

The HCA must compile the information collected from health carriers, PBMs, drug manufacturers, and PSAOs and prepare an annual report for the Legislature demonstrating the overall impact of drug costs on health care premiums. The data in the report must be aggregated and not reveal information specific to individual health carriers, PBMs, PSAOs, prescription drugs, classes of prescription drugs, or manufacturers. The data collected is not subject to public disclosure. Upon the request of a legislator, the HCA must provide all data submitted under the act and any analysis prepared by the HCA. Any information provided must be kept confidential within the Legislature and may not be publicly released.

Summary of Amended Bill:

Prescription Drug Affordability Board.

Subject to the availability of amounts appropriated, the Prescription Drug Affordability Board (Board) is established. The Board consists of five members appointed by the Governor who have expertise in health care economics or clinical medicine. Board members may not be an employee, board member, or consultant to a prescription drug manufacturer, pharmacy benefit manager, health carrier, prescription drug wholesale distributor, or related trade association.

The Board may establish advisory groups of relevant stakeholders. The advisory group members are immune from civil liability for any official act performed in good faith as a member of the group. The Health Care Authority (HCA) must provide administrative support to the Board and any advisory groups. The HCA may adopt rules governing the operation of the Board and any advisory groups. Board members must be compensated in accordance with a personal services contract.

The Board must coordinate with and complement the work of the HCA, other boards, and work groups related to prescription drug costs and emerging therapies. By May 1, 2021, the Board must provide the Health Care Cost Transparency Board with recommendations for the means and methodologies to establish a cost growth benchmark related to prescription drugs.

A simple majority of the Board constitutes a quorum for purposes of conducting business. All meetings must be open and public, except that the Board may hold executive sessions to the extent permitted by the Open Public Meetings Act.

Board Actions.

By June 30, 2021, and yearly thereafter, the Board must identify:

- brand name prescription drug and biologic products that:
 - are introduced to the market with a wholesale acquisition cost (WAC) of \$30,000 or more per year or course of treatment lasting less than a year; or
 - have a price increase of \$2,000 or more in any 12-month period;
- biosimilar products with a launch WAC that is not at least 15 percent lower the reference brand biologic product at the time the biosimilar is launched;
- generic drugs with a WAC 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;
- any prescription drug or biological products exceeding the relevant benchmark established by the Health Care Cost Transparency Board; and
- any other prescription drug product the Board determines may create excess cost for Washington and patients.

The Board may choose to conduct a cost review of any drug it identifies as meeting the above thresholds. The Board must determine whether the manufacturer's pricing of the prescription drug or biological product substantially exceeds the proposed value of the prescription drug or biological product. The Board may examine publicly available information and collect information from the drug manufacturer and other relevant sources.

During a review the Board may consider:

- relevant factors contributing to the price paid by Washington for the drug, such as WAC, discounts, and rebates;
- the average patient co-pay or cost sharing for the drug;
- the dollar value of the drug manufacturer's patient assistance programs;
- the price of therapeutic alternatives;
- the amount of public funding received or provided for the development of the drug;
- the manufacturer's research and development costs;
- the portion of direct-to-consumer marketing costs eligible for favorable federal tax treatment;
- the manufacturer's gross and net revenues; and
- any additional factors identified by the Board.

Any information collected by the Board for review purposes is not subject to public disclosure. Any proprietary information submitted by a prescription drug or biological product manufacturer must be kept confidential.

If, after the cost review, the Board determines that the manufacturer's pricing of the prescription drug or biological product does not substantially exceed the proposed value of the prescription drug or biological product, the Board must notify the manufacturer of its determination and must evaluate other ways to mitigate the cost in order to improve patient access. The Board may engage with the manufacturer and other stakeholders to explore options for mitigating the cost and may issue recommendations on ways to reduce the cost and improve patient access. Recommendations must be posted on the HCA's website.

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If, after the cost review, the Board determines that the manufacturer's pricing of the prescription drug or biological product substantially exceeds the proposed value of the prescription drug or biological product, the Board must request the manufacturer provide further information related to the pricing of the prescription drug or biological product. No later than 90 days within receiving the additional information from the manufacturer, the Board must confidentially issue a determination on whether the manufacturer's pricing still substantially exceeds the Board's proposed value of the prescription drug or biological product and request the manufacturer enter into negotiations to reduce the cost of the prescription drug or biological product. If the manufacturer refuses to enter into negotiations, the HCA must post the Board's proposed value on its website.

Prescription Drug Price Transparency.

The data in the HCA's prescription drug price transparency report must be aggregated and not reveal information specific to individual health carriers, pharmacy benefit managers, pharmacy services administrative organizations, or manufacturers, except in the case of single source drugs. Prescription drug price transparency data provided under chapter 43.71C RCW may be used only for enumerated and statutorily authorized purposes.

Upon the request of the Office of the Governor, the Office of the Attorney General, the Board, or a committee or subcommittee of the Legislature with jurisdiction over matters relating to drug transparency, the HCA must provide all submitted data and any analysis prepared by the HCA. Any information provided must be kept confidential and may not be publicly released. Recipients of this data must follow all rules adopted by the HCA regarding appropriate data use and protection and sign a nondisclosure agreement that includes acknowledgments that the recipient is solely responsible for any liability arising from misuse of the data, that the recipient does not have any conflicts under the Ethics in Public Service Act that would prevent them from accessing or using the data, and that any violations of the nondisclosure agreement may result in losing the right to access or use the data.

Appropriation: None.

Fiscal Note: Available.

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

Staff Summary of Public Testimony (Health Care & Wellness):

(In support) Washington is in a good position to make some progress on the affordability of drugs. The state already has a number of tools in place that can be utilized to lower prices. The first was the creation of the All Payer Claims Database, which provides real information on the true cost of health care. Second, there is last year's drug price transparency law, which is being implemented now. This bill is the third piece which will allow the state to actually utilize those tools. The state is a big purchaser of health care and drugs, between public employees, school employees, and local governments, which can give the state a lot of leverage as a payer, but there is currently no tool to utilize this leverage. It costs multiple sclerosis patients about \$70,000–90,000 per year for their drugs that have been around for 30 years, because of drug price increases. This cost curve must be addressed.

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This bill puts teeth to the drug price transparency bill. The majority of research on new drugs is funded by the National Institutes of Health, which is funded by taxpayers, not the pharmaceutical industry. The industry spends lots of money on advertising and lobbying. Maryland was the first to pass this type of bill in 2019. This bill creates a tool that Washington can use to counter the greed of the pharmaceutical industry. This bill is a start. It provides the main benefit to state purchasers, which is a considerable number of people, but it should include everyone. Many people do not have robust health insurance and this can make a big difference to help.

(Opposed) This Legislature has taken a number of steps to reduce drug prices. In the past it created the Prescription Drug Purchasing Consortium for state purchasers and Washington participates with Oregon in the Northwest Prescription Drug Consortium. It has also created the preferred drug list and last year passed the prescription drug price transparency law, which the Health Care Authority is currently drafting rules for. This bill is premature. The Legislature should wait until it receives the drug price transparency information to know what potential solutions may be. The upper payment limit in this bill could harm patients.

The majority of members of certain biologic groups are still completing research and do not have any current products on the market. Instead they are supported by outside investors. Price caps like these drive away investors, which means that while not all biotech innovation will stop, there will be fewer treatments for patients. Last year's drug price transparency law is a good, comprehensive review of the whole supply chain so that factors driving cost can be identified. Any policy that drives away innovation is not a good policy.

Discussions of drug affordability are very important. However, this bill is short sighted and targets drug spending in ways that will likely have long-term, harmful effects on innovation and development of new, lifesaving therapies without improving affordability for patients. It is the failure of plans to pass on rebate savings that is placing many drugs out of reach for patients. Accordingly, it is requested that the Prescription Drug Affordability Board's (Board) authority to establish upper payment limits is removed, that the implementation is delayed, and that the Board ensures that it uses patient-centered standards.

(Other) Price transparency can only lead to better marketplace conversations and policy decisions. However, there are significant concerns about creating upper payment limits because we are unsure about what the possible consequences of this type of policy may be.

Staff Summary of Public Testimony (Appropriations):

(In support) None.

(Opposed) Last year the Legislature passed House Bill 1224, which directed the HCA to comprehensively study all of the components of the drug pricing world to determine the major cost drivers. The Health Care Authority has just begun the rulemaking to implement that study. It makes more sense to wait for that information before adopting a policy that establishes a Prescription Drug Cost Board (Board). There are many activities happening in this space, including multiple emerging therapies task forces, a Health Cost Transparency Board in House Bill 2457, the rulemaking under House Bill 2710, and now this Board. This

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creates one more board while there are three other similar activities. There is also an issue of rebates and changing prices can implicate rebates to the state that can be used to fund Medicaid through federal Medicaid agreements.

The striking amendment is better and addresses many concerns, but there may still be issues around the release of proprietary information.

Persons Testifying (Health Care & Wellness): (In support) Senator Keiser, prime sponsor; Sherry Weinberg, Physicians for a National Health Program; Cindi Laws, Health Care for All Washington; and Cathy MacCaul, AARP.

(Opposed) Cliff Webster, Pharmaceutical Research and Manufacturers of America; Brian Warren, Biotechnology Innovation Organization; Amy Anderson, Association of Washington Business; and Lee Newgent, Pharmaceutical Industry Labor-Management Association.

(Other) Chris Bandoli, Association of Washington Healthcare Plans.

Persons Testifying (Appropriations): Cliff Webster, Pharmaceutical Research and Manufacturers of America; and Bill Clarke, Biotechnology Innovation Organization.

Persons Signed In To Testify But Not Testifying (Health Care & Wellness): None.

Persons Signed In To Testify But Not Testifying (Appropriations): None.

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