HOUSE BILL REPORT
ESSB 5203

As Reported by House Committee On:
Health Care & Wellness

Title: An act relating to the production, distribution, and purchase of generic prescription drugs.

Brief Description: Producing, distributing, and purchasing generic prescription drugs and distribution or purchase of insulin.

Sponsors: Senate Committee on Health & Long Term Care (originally sponsored by Senators Van De Wege, Carlyle, Frockt, Hasegawa, Keiser, Liias, Nguyen, Randall, Robinson, Salomon, Stanford and Wilson, C.).

Brief History:
Committee Activity:
Health Care & Wellness: 3/18/21, 3/24/21 [DPA].

Brief Summary of Engrossed Substitute Bill
(As Amended By Committee)

- Authorizes the Health Care Authority to enter into partnership agreements with other states, state agencies, or nonprofit entities to produce, distribute, or purchase generic prescription drugs and purchase and distribute insulin.
- Requires state purchased health care programs to purchase generic drugs and insulin through any available partnerships and allows other entities to purchase through a partnership voluntarily.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: Do pass as amended. Signed by 12 members: Representatives Cody, Chair; Bateman, Vice Chair; Bronoske, Davis, Macri, Maycumber, Riccelli, Rude, Simmons, Stonier, Tharinger and Ybarra.

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.

Minority Report: Do not pass. Signed by 2 members: Representatives Schmick, Ranking Minority Member; Harris.

Minority Report: Without recommendation. Signed by 1 member: Representative Caldier, Assistant Ranking Minority Member.

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. State purchased health care services purchased through health carriers and health maintenance organizations are exempt 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.

Total Cost of Insulin Work Group.
In 2020 Engrossed Second Substitute House Bill 2662 passed the Legislature and established the Total Cost of Insulin Work Group (work group). The work group was tasked with reviewing and designing strategies to reduce the cost of total expenditures on insulin and considering whether a state agency should become a licensed drug wholesaler, registered pharmacy benefit manager, or purchase prescription drugs from other states or in coordination with other states.

The HCA and the prescription drug purchasing consortium are authorized to implement any of the work group's strategies without further legislative direction, including becoming or designating a state agency to become a licensed drug wholesaler or registered pharmacy benefit manager, or purchase prescription drugs directly from other states or in coordination with other states.

Generic Drugs and Biologics.
A generic drug is a medication created to be the same as an existing approved brand-name drug in form, safety, strength, quality, and performance characteristics. New brand-name drugs are usually protected by patents that prohibit others from selling generic versions of the same drug, but once these patents and marketing exclusivities expire a generic drug can receive approval from the United States Food and Drug Administration (FDA) and be sold. To be approved, the FDA requires drug companies to demonstrate that the generic drug can be effectively substituted and provide the same clinical benefit as the brand-name medicine

through an abbreviated new drug application.

Biological products are also regulated by the FDA and include products such as therapeutic proteins, monoclonal antibodies, and vaccines. A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved biological product. An interchangeable product is a biosimilar product that meets additional requirements. Similar to generic drugs, biosimilars are approved through an abbreviated pathway.

Summary of Amended Bill:

The Health Care Authority (HCA) may enter into partnership agreements with another state, a group of states, a state agency, a nonprofit organization, or any other entity to produce, distribute, or purchase generic prescription drugs and purchase and distribute insulin. The HCA may only enter into partnerships to produce, distribute, or purchase a generic prescription drug or insulin at a price that results in savings to public and private purchasers and consumers. The HCA must comply with state procurement laws related to competitive procurement when purchasing or entering into purchasing agreements with nongovernmental entities. The generic prescription drugs and insulin must be produced or distributed by a drug company or generic drug manufacturer that is registered with the United States Food and Drug Administration (FDA).

State purchased health care programs must purchase the generic prescription drugs and insulin through any available partnership, unless the state purchased health care program can obtain the generic prescription drug or insulin at a cost savings through another purchasing mechanism. Local governments, private entities, health carriers, and others may choose to voluntarily purchase the generic prescription drugs and insulin from the HCA as available quantities allow.

A "generic drug" means a drug that is approved by the FDA pursuant to an application referencing an eligible prescription drug that is submitted under Section 505(j) of the federal Food, Drug, and Cosmetic Act or as a biosimilar or interchangeable under Section 351(k) of the federal Public Health Service Act. "Purchase" is defined as the acquisition of generic drugs and insulin, which is to be interpreted broadly and includes entering into contracts with manufacturers on behalf of those dispensing drugs and other innovative purchasing strategies to help increase access to the best price available for insulin and generic prescription drugs.

"State purchased health care" means medical and health care, pharmaceuticals, and medical equipment purchased with state and federal funds by the Department of Social and Health Services, Department of Health, the HCA, Department of Labor and Industries, Department of Corrections, and Department of Veterans Affairs, and does not include prescription drugs purchased for Medicaid programs.

Amended Bill Compared to Engrossed Substitute Bill:

The striking amendment:

- defines "purchase" as the acquisition of generic drugs and insulin, which is to be interpreted broadly and includes entering into contracts with manufacturers on behalf of those dispensing drugs and other innovative purchasing strategies to help increase access for Washington citizens to the best price available for insulin and generic prescription drugs;
- specifies that partnership agreements with other governmental entities are exempt from competitive solicitation agreements under current law; and
- replaces the requirement that the Health Care Authority (HCA) may only enter into partnerships with nongovernmental entities after a competitive bidding process with a requirement that the HCA must comply with state procurement laws when purchasing or entering into purchasing agreements with nongovernmental entities.

Appropriation: None.

Fiscal Note: Available. New fiscal note requested on March 24, 2021.

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:

(In support) There must be equitable access to medications. No one should have to go without medications that they need to live, and many individuals depend on daily prescription drugs to survive. People are still suffering and things need to be done to reduce the cost of prescription drugs, particularly those like insulin that are lifesaving.

Pharmaceutical companies do not have the patient's interests in mind and have tried to manipulate the language of this and other bills to make it difficult for patients. Pharmaceutical companies should not be allowed to block what could be a transformative piece of legislation. While this bill is not the only solution, it is one that can make a difference.

(Opposed) None.

(Other) This bill was amended on the Senate floor to include insulin products. There are some concerns about this and it should be clarified that the insulin is a generic product. This bill should be amended to allow the state to pursue innovative strategies like what the state has done to address Hepatitis C. There is appreciation for the opportunity that this bill presents for the state to make sure that is it getting the best value for generic drugs. However, any real drug price reform must happen on the federal level, though it is

important to pursue all options to lower drug costs.

Persons Testifying: (In support) Madison Johnson and Marcee Stone-Vekich, Washington Insulin 4 All; and Ronnie Shure, Health Care for All–Washington.

(Other) Jeff Gombosky, Pharmaceutical Research and Manufacturers of America; and Judy Zerzan-Thul, Health Care Authority.

Persons Signed In To Testify But Not Testifying: None.