SENATE BILL REPORT
SB 6110

As of January 20, 2020

Title: An act relating to the importation of prescription drugs from Canada.

Brief Description: Importing prescription drugs from Canada.

Sponsors: Senators Keiser, Becker, Conway, Das, Frockt, Hasegawa, Hunt, Pedersen, Randall, Rolfes, Stanford, Van De Wege and Wilson, C.

Brief History:
Committee Activity: Health & Long Term Care: 1/17/20.

Brief Summary of Bill

- Directs the Health Care Authority to design a wholesale prescription drug importation program.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Staff: Greg Attanasio (786-7410)

Background: The Federal Food, Drug, and Cosmetic Act (FDCA) was amended in 2003 to include Section 804, authorizing the Department of Health and Human Services (DHHS) to issue regulations permitting pharmacists and wholesalers to import certain prescription drugs from Canada if the importer ensured each prescription drug met all federal safety and labeling requirements. In 2019, DHHS announced its intention to undertake rulemaking to implement Section 804 and allow time-limited importation demonstration projects, which would be authorized by the Food and Drug Administration (FDA) in two-year increments.

Under the proposed rule, states must contract with a United States licensed pharmacist or wholesaler to act as the importer and a drug supplier licensed by Health Canada and registered as a foreign seller with the FDA. Drugs approved by Health Canada's Health Products and Food Branch and that meet the conditions for an FDA-approved new drug application could be imported. The state and importer must ensure the drugs meet authenticity, degradation, and other testing requirements and comply with all FDCA labeling requirements.

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.

After importation, an importing state would be required to provide the FDA with data on cost savings to consumers and notifications of any adverse events or medication errors. The state would also be responsible for any necessary drug recalls.

Summary of Bill: The Health Care Authority (HCA), in consultation with the Pharmacy Quality Assurance Commission and relevant federal agencies, must design a wholesale prescription drug importation program that complies with all federal requirements. The program must:

- require HCA to contract with a licensed drug wholesaler and a licensed Canadian drug supplier;
- ensure all imported drugs meet federal safety, labeling, and tracking standards;
- ensure imported drugs generate savings for Washington consumers and are not distributed outside of Washington;
- ensure participating health plans keep formularies and payment systems up-to-date and demonstrate how drug savings are reflected in premiums;
- ensure no generic drugs are imported that would violate United States patent laws; and
- include an auditing and oversight process.

By July 1, 2021, HCA must submit a request to the secretary of DHHS for certification of the state's importation program. HCA must also determine the cost for administration and oversight of the program and set a per prescription fee at a level sufficient to recover costs. All fees collected must be deposited into the newly-created drug importation account.

HCA must implement the program within six months of receiving certification from DHHS. As part of the implementation process, HCA must:

- contract with a United States wholesaler and Canadian supplier;
- develop a registration process for health plans and pharmacies willing to participate in the program;
- create a publicly available source for listing the prices of imported drugs; and
- create an outreach and marketing program, including a toll-free number to answer questions from consumers, health plans, and pharmacies.

Following the first full year of the program, HCA must begin submitting annual reports to the Legislature including a list of the imported drugs, the number of participating pharmacies, providers, and health plans, the number of prescriptions dispensed, and the estimated savings generated by the program.

HCA is granted rulemaking authority to implement this act.

Appropriation: None.

Fiscal Note: Requested on January 9, 2020.

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: PRO: The bill is worth consideration and a good step to get a handle on prescription drug prices. Consumers have had enough of high drug prices and will look for any way to obtain more affordable prescription drugs.

CON: Attempts in other states to import drugs have failed and there have been medical error issues. The ability to track and trace drugs in Washington will be hurt. Canada is not in a position to help with drug supply in the U.S. A country of 38 million people does have the surplus supply for a country of 329 million people. Canada already has drug shortage problems. The program will not result in significant savings for consumers.

OTHER: The idea is interesting, but there are concerns about oversight, costs, and limited supply.

Persons Testifying: PRO: Senator Karen Keiser, Prime Sponsor; Dr. Sherry Weinberg, Physicians for a National Health Plan; Marcia Stedman, Health Care for All Washington; Cathy MacCaul, AARP.

CON: Shabbir Imber Safdar, The Partnership for Safe Medicines; John Adams, Best Medicines Coalition; Lee Newgent, PILMA.

OTHER: Jeff Rochon, Washington State Pharmacy Association.

Persons Signed In To Testify But Not Testifying: No one.