S-5136.1

SENATE BILL 6110

State of Washington 66th Legislature 2020 Regular Session

By Senator Keiser

Prefiled 12/24/19.

AN ACT Relating to the importation of prescription drugs from Canada; and adding a new chapter to Title 69 RCW.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec. 1.** DEFINITIONS. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Authority" means the health care authority.

(2) "Drug wholesaler" means a facility licensed by the pharmacy quality assurance commission under chapter 18.64 RCW that buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

(3) "Health plan" has the same meaning as in RCW 48.43.005.

(4) "Pharmacy" means a facility licensed by the pharmacy quality assurance commission under chapter 18.64 RCW in which the practice of pharmacy is conducted.

(5) "Prescription drugs" has the same meaning as "legend drugs" as defined in RCW 69.41.010.

(6) "Program" means a wholesale prescription drug importation program where the authority is a licensed wholesaler or contracts with a licensed wholesaler, which imports drugs from licensed, regulated Canadian suppliers, solely for distribution to voluntarily

participating, state-licensed, in-state, pharmacies and administering providers for the exclusive purpose of dispensing to state residents with a valid prescription.

NEW SECTION. **Sec. 2.** DRUG IMPORTATION PROGRAM DESIGN. (1) The authority shall, in consultation with the pharmacy quality assurance commission and relevant federal agencies, design a wholesale prescription drug importation program that complies with the applicable requirements of 21 U.S.C. Sec. 384, including the requirements regarding safety and cost savings.

(2) The program shall:

(a) Designate that the authority become a licensed drug wholesaler or contract with a licensed drug wholesaler in order to seek federal certification and approval to import safe prescription drugs from Canada;

(b) Contract only with Canadian prescription drug suppliers that are licensed and regulated under the laws of Canada;

(c) Ensure that all imported prescription drugs meet the United States food and drug administration's safety, effectiveness standards, and any other standards and requirements designated in federal rule;

(d) Only import prescription drugs expected to generate substantial savings for Washington consumers;

(e) Prohibit the distribution, dispensing, or sale of imported prescription drugs outside of Washington;

(f) Ensure compliance with the tracking and tracing requirements of Title 21 U.S.C. Sec. 581-582 as enacted in Title II of the federal drug security and quality act to the extent feasible and practical before imported drugs come into the possession of the state wholesaler and ensure compliance fully after imported drugs are in the possession of the state wholesaler;

(g) Ensure the product component of the reimbursement provided by a participating health plan to a pharmacy does not exceed the actual acquisition cost of the drug;

(h) Ensure participating health plans keep their formularies and claims payment systems up-to-date with the prescription drugs provided through the program;

(i) Ensure participating health plans base enrollee cost-sharing on the actual acquisition cost of the drug;

(j) Require participating health plans to demonstrate how prescription drug savings achieved through the program are reflected in premiums;

(k) Ensure that no generic drugs are imported that would violate United States patent laws on United States branded products; and

(l) Include an auditing and oversight process to ensure the program yields savings for consumers.

NEW SECTION. **Sec. 3.** FEDERAL PROGRAM APPROVAL. By July 1, 2021, the authority shall, in consultation with the pharmacy quality assurance commission, submit a formal request to the secretary of the United States department of health and human services for certification of the state's wholesale prescription drug importation program.

NEW SECTION. **Sec. 4.** PROGRAM FUNDING. (1) The authority shall determine the cost for the administration and oversight of the program and set a per prescription fee at a level sufficient to recover the costs.

(2) The fee may be adjusted annually and shall not exceed actual administration and oversight costs. Adjustments for inflation may not exceed the percentage change in the consumer price index for all urban consumers in the United States as calculated by the United States department of labor as averaged by city for the twelve-month period ending with June of the previous year.

(3) All fees collected under this section must be deposited in the drug importation program account established in section 5 of this act.

NEW SECTION. **Sec. 5.** DRUG IMPORTATION PROGRAM ACCOUNT. The drug importation program account is created in the state treasury. All receipts received by the authority under this chapter must be deposited in the account. Moneys in the account may be spent only after appropriation. Expenditures from the account may be used by the authority only for administering this chapter.

NEW SECTION. **Sec. 6.** PROGRAM IMPLEMENTATION. (1) Upon certification and approval by the secretary of the United States department of health and human services, the authority shall implement the program and begin operation within six months.

(2) As part of the implementation process, the authority shall:

(a) Become a licensed drug wholesaler or contract with one or more licensed Washington drug wholesalers;

(b) Contract with one or more licensed Canadian drug suppliers;

(c) Develop a registration process for health plans and pharmacies willing to participate in the program;

(d) Create a publicly available source for listing the prices of imported prescription drugs;

(e) Create an outreach and marketing plan to generate program awareness;

(f) Create and staff a toll-free telephone number to answer questions from consumers, health plans, and pharmacies; and

(g) Conduct any other activities the authority deems necessary for successful implementation.

NEW SECTION. **Sec. 7.** ANNUAL PROGRAM REPORT TO THE LEGISLATURE. (1) By December 1st after the first full year following program certification by the secretary of the United States department of health and human services, and annually thereafter, the authority must submit a report to the legislature on the operation of the program during the previous calendar year.

(2) The report must include:

(a) A list of the prescription drugs that were imported as part of the program;

(b) The number of pharmacies, health care providers, and health plans participating in the program;

(c) The number of prescriptions dispensed through the program;

(d) The estimated savings to consumers, health plans, employers, and the state during the previous calendar year and to date; and

(e) Any other information the authority deems relevant.

NEW SECTION. **Sec. 8.** RULE MAKING. The authority shall adopt any rules necessary to implement this chapter.

NEW SECTION. **Sec. 9.** Sections 1 through 8 of this act constitute a new chapter in Title 69 RCW.

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