A-Engrossed
Senate Bill 409

Ordered by the Senate April 16
Including Senate Amendments dated April 16

Sponsored by Senator LINTHICUM, Representative NOSSE, Senator STEINER HAYWARD; Senators FAGAN, GELSER, GOLDEN, MANNING JR, Representatives BARKER, DOHERTY, FAHEY, GORSEK, HOLVEY, NERON, NOBLE, POWER, WITT (Presession filed.)

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure.

Directs State Board of Pharmacy to **study feasibility of implementing, and to** develop **plan to implement,** program to allow wholesale importation of prescription drugs into Oregon. Requires **board to submit plan and** report to interim committee of Legislative Assembly related to health care **no later than June 30, 2020**.

Takes effect on 91st day following adjournment sine die.

A BILL FOR AN ACT

Relating to importation of prescription drugs; and prescribing an effective date.

Whereas United States citizens pay some of the highest prices for prescription drugs in the world, and the Canadian government estimated that U.S. consumers pay twice as much as Canadians for patented prescription drugs and 20 percent more for generics; and

Whereas under the discretion of the United States Food and Drug Administration not to enforce the law, individual patients may import a 90-day supply of prescription drugs from Canada that are less expensive than drugs approved by the Food and Drug Administration; and

Whereas individual importation via the Internet increases consumer health and safety risks because many Internet pharmacies are not licensed in Canada and it is difficult to verify the validity, reputation, actual identity and pharmacy practices of foreign online pharmacies; and

Whereas the United States allows patients to go to other countries for surgeries and other high-risk medical treatments without regulating that consumer purchasing activity and insurers sometimes facilitate and pay for foreign treatments; and

Whereas the Food and Drug Administration estimates that currently 40 percent of finished prescription drug products are produced outside the U.S. and 80 percent of raw product for U.S. pharmaceutical manufacturing comes from outside the U.S.; and

Whereas the Food and Drug Administration has just signed reciprocity agreements with European Union regulators to accept the results of European Union inspections of pharmaceutical manufacturing plants, and the Food and Drug Administration has had a Memorandum of Understanding for regulatory cooperation around pharmaceuticals with the Canadian regulatory authorities since 1973; and

Whereas Canada has a rigorous regulatory system to license prescription drugs that is considered to be on par with the U.S. approval system; and

Whereas Title II of the federal Drug Quality and Security Act (P.L. 113-54), Drug Supply Chain

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

Security, has resulted in improvements in drug security and safety through a system of pharmaceutical track and trace that can be leveraged for safe importation; and

Whereas the United States Secretary of Health and Human Services may certify a prescription drug reimportation program that is safe and saves consumers money; and

Whereas Oregon can ensure that wholesale importation of prescription drugs from Canada into Oregon will be safe and cost-saving for Oregon consumers; and

Whereas directing the State Board of Pharmacy to develop a plan to implement a wholesale drug importation program for the exclusive benefit of residents of Oregon benefits all Oregonians; now, therefore,

Be It Enacted by the People of the State of Oregon:

SECTION 1. The State Board of Pharmacy shall study the feasibility of implementing, and develop a plan to implement, a wholesale prescription drug importation program in which the state is a licensed wholesaler that imports prescription drugs from an authorized Canadian supplier for distribution to voluntarily participating pharmacies and providers for the purpose of dispensing to Oregon residents pursuant to validly issued prescriptions.

SECTION 2. The State Board of Pharmacy may consult with relevant stakeholders and federal offices and agencies in carrying out section 1 of this 2019 Act, and with the Attorney General to identify the potential for anticompetitive behavior in the industries that would be affected by an importation program. The plan required under section 1 of this 2019 Act must provide that:

(1) A state agency become a licensed wholesaler for the purpose of seeking federal certification and approval to import safe prescription drugs that will provide savings to Oregon consumers;

(2) The program use Canadian suppliers regulated under the appropriate Canadian and provincial laws;

(3) The program have a process to sample the purity, chemical composition and potency of imported products;

(4) The program import only those prescription drugs expected to generate substantial savings for Oregon consumers;

(5) The program ensure that imported products will not be distributed, dispensed or sold outside the borders of this state;

(6) The program ensure that voluntarily participating state-licensed pharmacies and administering providers charge individual consumers and health plans the actual acquisition cost of the dispensed imported product;

(7) The program ensure that health plan payment of the product component of pharmacy and provider billing reimburses no more than the actual acquisition cost of the dispensed imported product;

(8) The program ensure that participating health plans keep their formularies and claims payment systems up to date with the prescription drugs provided through the importation program;

(9) The program ensure that participating health plans base patient cost sharing on no more than the actual acquisition cost of the dispensed imported product;

(10) The program require participating health plans to demonstrate to the board how savings on imported products are reflected in premiums;

(11) The profit margin of any participating wholesaler or distributor of imported products

be limited to a specified amount established by the board;

(12) The program not import generic products that would violate United States patent laws on United States branded products;

(13) The program comply with the requirements of 21 U.S.C. 360eee and 360eee-1, pertaining to the track and trace requirements as enacted in Title II of the Drug Quality and Security Act (P.L. 113-54), to the extent practical and feasible before imported products come into possession of the state wholesaler, and comply fully after imported products are in the possession of the state wholesaler;

(14) The program be adequately financed through a fee on each prescription or another appropriate approach, but that the size of the fee not jeopardize significant consumer savings;

(15) The program will meet relevant requirements of 21 U.S.C. 384, including safety and cost savings; and

(16) That the program include an audit function to ensure that:

(a) The board has a sound methodology by which to determine the most cost-effective products to include in the importation program on an ongoing basis;

(b) The board has processes in place to select Canadian suppliers of high quality and high performance that are in full compliance with Canadian and provincial laws and regulations and with Oregon pharmacy or wholesaler laws;

(c) Imported products under the state program are not distributed, dispensed or sold outside this state once in the possession of the state wholesaler;

(d) Imported products are pure, unadulterated, potent and safe;

(e) Participating pharmacies and administering providers are not charging more than the actual acquisition cost to any consumer or any participating health plan;

(f) Participating health plan formularies and claims processing systems remain up to date with all relevant aspects of the importation program;

(g) Participating health plans base patient coinsurance and other cost sharing on the actual acquisition cost of covered imported products;

(h) Participating health plans reimburse participating pharmacies and administering providers for the actual acquisition cost of the dispensed imported product;

(i) The program is adequately financed to support all administrative functions while generating significant consumer savings;

(j) The program does not put consumers at higher risk than if the program did not exist; and

(k) The program continues to provide Oregon consumers with substantial savings on prescription drugs.

SECTION 3. The State Board of Pharmacy shall submit the plan described in section 2 of this 2019 Act, and a report with findings and recommendations for legislation, in the manner provided in ORS 192.245, to an interim committee of the Legislative Assembly related to health care not later than June 30, 2020. The board shall include in the report submitted under this section an analysis of the cost-benefit ratio of an importation program at five years and 10 years after the date of implementation.

SECTION 4. This 2019 Act takes effect on the 91st day after the date on which the 2019 regular session of the Eightieth Legislative Assembly adjourns sine die.
