

Senate Bill 409

Sponsored by Senator LINTHICUM, Representative NOSSE, Senator STEINER HAYWARD; Senators GELSER, 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 **as introduced**.

Directs State Board of Pharmacy to develop program to allow wholesale importation of prescription drugs into Oregon. Requires report to interim committee of Legislative Assembly related to health care.

Takes effect on 91st day following adjournment sine die.

A BILL FOR AN ACT

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

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

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

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

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

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

17 Whereas the Food and Drug Administration has just signed reciprocity agreements with
18 European Union regulators to accept the results of European Union inspections of pharmaceutical
19 manufacturing plants, and the Food and Drug Administration has had a Memorandum of Under-
20 standing for regulatory cooperation around pharmaceuticals with the Canadian regulatory authori-
21 ties since 1973; and

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

24 Whereas Title II of the federal Drug Quality and Security Act (P.L. 113-54), Drug Supply Chain
25 Security, has resulted in improvements in drug security and safety through a system of pharmaceu-
26 tical track and trace that can be leveraged for safe importation; and

27 Whereas the United States Secretary of Health and Human Services may certify a prescription
28 drug reimportation program that is safe and saves consumers money; and
29

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.

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

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

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

6 **SECTION 1. Definition.** As used in sections 1 to 7 of this 2019 Act, “importation
7 program” means a state-administered wholesale importation program where the state is the
8 licensed wholesaler, importing drugs from a licensed, regulated Canadian supplier, solely for
9 distribution to voluntarily participating, state-licensed, in-state pharmacies and administer-
10 ing providers for the exclusive purpose of dispensing to state residents with valid pre-
11 scriptions.

12 **SECTION 2. Directive to develop a wholesale importation program design that complies**
13 **with the following administrative specifications.** The State Board of Pharmacy is directed to
14 design a wholesale prescription drug importation program in consultation with relevant state
15 stakeholders and federal offices and agencies that will meet relevant requirements of 21
16 U.S.C. 384, including safety and cost savings. In developing a prescription drug importation
17 program for federal certification, the board shall comply with the following specifications:

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

21 (2) That the program use Canadian suppliers regulated under the appropriate Canadian
22 and provincial laws;

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

25 (4) That the program import only those prescription pharmaceuticals expected to gener-
26 ate substantial savings for Oregon consumers;

27 (5) That the program ensure that imported products will not be distributed, dispensed
28 or sold outside Oregon’s borders;

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

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

35 (8) That the program ensure that participating health plans keep their formularies and
36 claims payment systems up to date with the prescription drugs provided through the whole-
37 sale importation program;

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

40 (10) That the program require participating health plans to demonstrate to the board how
41 savings on imported drugs are reflected in premiums;

42 (11) That the profit margin of any participating wholesaler or distributor of imported
43 pharmaceutical products be limited to a specified amount established by the board;

44 (12) That the program not import generic products that would violate United States
45 patent laws on U.S.-branded products;

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

6 (14) That the program be adequately financed through a fee on each prescription or an-
7 other appropriate approach, but that the size of the fee not jeopardize significant consumer
8 savings; and

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

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

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

15 (c) Imported drugs under the state program are not shipped, sold or dispensed outside
16 the state once in the possession of the state;

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

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

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

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

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

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

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

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

32 **SECTION 3. Monitoring for anticompetitive behavior.** The State Board of Pharmacy shall
33 enlist the assistance of the Attorney General to identify the potential for anticompetitive
34 behavior in industries that would be affected by an importation program.

35 **SECTION 4. Report back to authorizing committee.** The State Board of Pharmacy shall
36 submit a report to a interim committee of the Legislative Assembly related to health care
37 not later than June 30, 2020, on the final state wholesale importation program design that
38 takes into consideration at least the items in section 2 of this 2019 Act.

39 **SECTION 5. Submission of request for federal certification and approval.** The State Board
40 of Pharmacy shall submit a formal request to the United States Secretary of Health and
41 Human Services for certification of Oregon's wholesale drug importation program. The board
42 shall submit the request within two weeks of the date on which the board submits the report
43 required under section 4 of this 2019 Act.

44 **SECTION 6. Implementation and additional administrative requirements.** Upon certifica-
45 tion and approval by the United States Secretary of Health and Human Services, the State

1 Board of Pharmacy shall begin implementation of the wholesale importation program and
 2 have the program operational within six months of the date of the secretary's certification.
 3 As part of the implementation process the board shall, in accordance with state procurement
 4 and contracting laws and rules as appropriate:

- 5 (1) Become licensed as a wholesaler;
- 6 (2) Contract with a state-licensed distributor or distributors;
- 7 (3) Contract with a licensed, regulated Canadian supplier or suppliers;
- 8 (4) Engage health plans, employers, pharmacies, providers and consumers;
- 9 (5) Develop a registration process for health plans, pharmacies and administering pro-
 10 viders willing to participate;
- 11 (6) Create a publicly available source for listing prices of imported products that will be
 12 available to all participating entities and consumers;
- 13 (7) Create an outreach and marketing plan to generate program awareness;
- 14 (8) Create and staff a hotline to answer questions from any affected sector starting in
 15 the weeks before the program becomes operational that can address the needs and questions
 16 of consumers, employers, plans, pharmacies, providers and others;
- 17 (9) Establish the audit function and a two-year audit work plan cycle; and
- 18 (10) Conduct any other activities determined to be important to successful implementa-
 19 tion as determined by the board.

20 **SECTION 7. Ongoing oversight of program administration.** On June 30 and December 31
 21 of each year, the State Board of Pharmacy shall report to an interim committee of the
 22 Legislative Assembly related to health care. The report must include:

- 23 (1) The drugs covered in the wholesale importation program;
- 24 (2) The number of participating pharmacies, providers and health plans;
- 25 (3) The number of prescriptions dispensed under the program in the period;
- 26 (4) The estimated savings to consumers, health plans and employers that resulted from
 27 the program in the reporting period and to date;
- 28 (5) In the first three reporting periods, information on the implementation of the audit
 29 plan and, on an ongoing basis, audit findings for the reporting period; and
- 30 (6) Any other information of importance as determined by the board.

31 **SECTION 8.** (1) Sections 1 to 7 of this 2019 Act become operative on January 1, 2020.

32 (2) The State Board of Pharmacy may take any action before the operative date specified
 33 in subsection (1) of this section that is necessary to enable the board to exercise, on and
 34 after the operative date specified in subsection (1) of this section, all of the duties, functions
 35 and powers conferred on the board by sections 1 to 7 of this 2019 Act.

36 **SECTION 9.** The section captions used in this 2019 Act are provided only for the con-
 37 venience of the reader and do not become part of the statutory law of this state or express
 38 any legislative intent in the enactment of this 2019 Act.

39 **SECTION 10.** This 2019 Act takes effect on the 91st day after the date on which the 2019
 40 regular session of the Eightieth Legislative Assembly adjourns sine die.