

A-Engrossed
House Bill 2689

Ordered by the House April 12
Including House Amendments dated April 12

Sponsored by Representative NOSSE, Senators LINTHICUM, STEINER HAYWARD, Representatives MITCHELL, PRUSAK; Representatives ALONSO LEON, BARKER, DOHERTY, FAHEY, GOMBERG, GORSEK, HOLVEY, KENY-GUYER, NERON, POWER, SMITH WARNER, WALLAN, WILLIAMS, Senators GELSER, MANNING JR (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.

Requires Oregon Health Authority to design [*and, with federal approval, implement*] program to import wholesale prescription drugs from Canada. Specifies conditions and requirements. **If authority estimates program to produce cost savings for Oregon consumers, requires authority to seek federal approval and, with federal approval, to implement program.**

Authorizes administrator of Oregon Prescription Drug Program to contract with pharmacy benefit manager and to establish state-managed wholesale or retail drug distribution or dispensing system.

Declares emergency, effective on passage.

A BILL FOR AN ACT

1
2 Relating to prescription drugs; creating new provisions; amending ORS 413.032 and 414.312; and de-
3 clarating an emergency.

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

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

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

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

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

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

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

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

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

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

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

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

13 **SECTION 1. The Oregon Health Authority, in consultation with the State Board of**
14 **Pharmacy, stakeholders and appropriate federal officials, shall design a wholesale pre-**
15 **scription drug importation program that meets the criteria of section 3 of this 2019 Act.**

16 **SECTION 2. As used in sections 2 to 4 of this 2019 Act:**

17 **(1) "Health plan" includes:**

18 **(a) An insurer with a certificate of authority to transact insurance that offers health**
19 **insurance, as defined in ORS 731.162, in this state.**

20 **(b) The Public Employees' Benefit Board.**

21 **(c) A pharmacy benefit manager, as defined in ORS 735.530.**

22 **(d) An employer offering a self-insured health benefit plan to its employees.**

23 **(e) A health care service contractor, as defined in ORS 750.005.**

24 **(f) A multiple employer welfare arrangement, as defined in ORS 750.301.**

25 **(2) "Pharmacy" has the meaning given that term in ORS 689.005.**

26 **(3) "Prescription drug" has the meaning given that term in section 2, chapter 7, Oregon**
27 **Laws 2018.**

28 **(4) "Provider" means an individual or an entity that is licensed or certified by a board**
29 **or state agency to provide health care in this state.**

30 **SECTION 3. The Oregon Health Authority shall implement a wholesale prescription drug**
31 **importation program that includes the following features:**

32 **(1) The authority acts as a licensed drug wholesaler or contracts with a licensed drug**
33 **wholesaler to import prescription drugs from Canada;**

34 **(2) Prescription drugs are imported only from high quality Canadian prescription drug**
35 **suppliers that are subject to regulation under and are in full compliance with the laws of**
36 **Canada or one or more Canadian provinces;**

37 **(3) Prescription drugs imported under the program:**

38 **(a) Meet the requirements for safety and effectiveness adopted by the United States De-**
39 **partment of Health and Human Services and any requirements imposed by the laws of this**
40 **state;**

41 **(b) Are only those that are determined, using a sound methodology, to generate sub-**
42 **stantial savings for consumers in this state; and**

43 **(c) Are distributed only to pharmacies and providers that are licensed in this state to**
44 **dispense or administer prescription drugs;**

45 **(4) The applicable requirements under 21 U.S.C. 360eee, 360eee-1 and 384 are met both**

1 before and after the importation of the prescription drugs;

2 (5) The distribution, dispensing or sale of imported prescription drugs outside of this
3 state is prohibited;

4 (6) A fee, in an amount that is sufficient to pay for the administration of the program
5 without significantly impacting savings for consumers, is imposed on the sale of each pre-
6 scription drug imported under the program;

7 (7) There are effective systems and mechanisms in place to:

8 (a) Prevent any drugs imported under the program from being shipped, sold or dispensed
9 outside of this state;

10 (b) Ensure that prescription drugs imported under the program are pure, unadulterated,
11 potent and safe;

12 (c) Prevent participating pharmacies and providers from charging a consumer or health
13 plan more than the actual acquisition cost for a prescription drug imported under the pro-
14 gram;

15 (d) Ensure that participating health plans maintain formularies and claims processing
16 systems that are up to date and compatible with the program;

17 (e) Ensure that any coinsurance or other cost sharing imposed by participating health
18 plans is based on the actual acquisition cost for prescription drugs imported under the pro-
19 gram;

20 (f) Ensure that the program is adequately financed to support all administrative func-
21 tions that generate significant cost savings for consumers; and

22 (g) Ensure that consumers are not put at higher risk than if the program did not exist;

23 (8) Subsection (7)(a) of this section does not prohibit an individual who purchases an
24 imported drug for personal use to take the drug out of state; and

25 (9) An employer's self-insured health benefit plan may be exempt from any requirement
26 described in subsection (7) of this section to the extent required by the Employee Retirement
27 Income Security Act of 1974.

28 **SECTION 4.** On or before January 15 of each year, the Oregon Health Authority shall
29 report, to the interim committees of the Legislative Assembly related to health, the following
30 information from the previous calendar year regarding the wholesale prescription drug
31 importation program described in section 3 of this 2019 Act:

32 (1) The drugs that were imported;

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

34 (3) The number of prescriptions for drugs imported under the program that were dis-
35 pensed or administered in this state;

36 (4) The estimated savings for consumers and health plans in this state;

37 (5) The systems and mechanisms described in section 3 (7) of this 2019 Act;

38 (6) The findings of the Attorney General with respect to any anticompetitive behaviors
39 demonstrated by industries affected by the program; and

40 (7) Any other information the authority deems pertinent and useful to the committees.

41 **SECTION 5.** (1) No later than 12 months after the effective date of this 2019 Act, the
42 Oregon Health Authority shall report to the interim committees of the Legislative Assembly
43 related to health, as provided in ORS 192.245:

44 (a) The design and plan for the implementation of the wholesale prescription drug
45 importation program described in section 3 of this 2019 Act;

1 (b) An estimate of the annual cost of the program; and

2 (c) An estimate of the annual cost savings to Oregon consumers as a result of the pro-
3 gram.

4 (2) If the report described in subsection (1) of this section estimates cost savings to
5 Oregon consumers from the program, no later than six months after submitting the report,
6 the authority shall submit a formal request to the United States Department of Health and
7 Human Services to certify that the wholesale prescription drug importation program de-
8 scribed in section 3 of this 2019 Act meets the requirements of 21 U.S.C. 384(b). The authority
9 shall also seek all federal approvals necessary to enable all covered entities enrolled in or
10 eligible for the federal 340B Drug Pricing Program to participate in the wholesale pre-
11 scription drug importation program without jeopardizing eligibility for the federal 340B Drug
12 Pricing Program.

13 (3) The wholesale prescription drug importation program must be in operation no later
14 than six months after the United States Department of Health and Human Services certifies
15 that the program meets the requirements of 21 U.S.C. 384(b).

16 **SECTION 6.** To implement the wholesale prescription drug importation program, the
17 Oregon Health Authority shall, in accordance with the requirements in section 3 of this 2019
18 Act:

19 (1) Obtain a wholesale license or contract with a licensed wholesaler operating in this
20 state;

21 (2) Contract with one or more licensed distributors of prescription drugs operating in this
22 state;

23 (3) Contract with one or more Canadian prescription drug suppliers;

24 (4) Conduct outreach to employers, health plans, providers and consumers in this state;

25 (5) Establish a process to register health plans, pharmacies and providers who wish to
26 participate in the wholesale prescription drug importation program;

27 (6) Develop an Internet website to make available to the public the prices of prescription
28 drugs imported under the program;

29 (7) Create a marketing plan to raise public awareness of the program;

30 (8) Establish a toll-free telephone hotline with staff trained to answer questions from
31 consumers, employers, health plans and providers about the program;

32 (9) Create the systems and mechanisms required by section 3 (7) of this 2019 Act; and

33 (10) Take any other actions that the authority deems necessary to begin operating the
34 wholesale prescription drug importation program on the date specified in section 5 (3) of this
35 2019 Act.

36 **SECTION 7.** (1) The Attorney General, in consultation with the Oregon Health Authority,
37 shall identify the potential for and shall monitor for anticompetitive behavior by industries
38 affected by the wholesale prescription drug importation program described in section 3 of
39 this 2019 Act.

40 (2) The Attorney General shall report to the Oregon Health Authority the Attorney
41 General's findings under subsection (1) of this section for the purpose of the report described
42 in section 4 (6) of this 2019 Act.

43 **SECTION 8.** Section 4 of this 2019 Act becomes operative on January 1 in the second year
44 after the implementation of the wholesale prescription drug importation program in accord-
45 ance with section 5 (3) of this 2019 Act.

1 **SECTION 9.** ORS 413.032 is amended to read:

2 413.032. (1) The Oregon Health Authority is established. The authority shall:

3 (a) Carry out policies adopted by the Oregon Health Policy Board;

4 (b) Administer the Oregon Integrated and Coordinated Health Care Delivery System established
5 in ORS 414.620;

6 (c) Administer the Oregon Prescription Drug Program **and the wholesale prescription drug**
7 **importation program described in section 3 of this 2019 Act;**

8 (d) Develop the policies for and the provision of publicly funded medical care and medical as-
9 sistance in this state;

10 (e) Develop the policies for and the provision of mental health treatment and treatment of ad-
11 dictions;

12 (f) Assess, promote and protect the health of the public as specified by state and federal law;

13 (g) Provide regular reports to the board with respect to the performance of health services
14 contractors serving recipients of medical assistance, including reports of trends in health services
15 and enrollee satisfaction;

16 (h) Guide and support, with the authorization of the board, community-centered health initiatives
17 designed to address critical risk factors, especially those that contribute to chronic disease;

18 (i) Be the state Medicaid agency for the administration of funds from Titles XIX and XXI of the
19 Social Security Act and administer medical assistance under ORS chapter 414;

20 (j) In consultation with the Director of the Department of Consumer and Business Services, pe-
21 riodically review and recommend standards and methodologies to the Legislative Assembly for:

22 (A) Review of administrative expenses of health insurers;

23 (B) Approval of rates; and

24 (C) Enforcement of rating rules adopted by the Department of Consumer and Business Services;

25 (k) Structure reimbursement rates for providers that serve recipients of medical assistance to
26 reward comprehensive management of diseases, quality outcomes and the efficient use of resources
27 and to promote cost-effective procedures, services and programs including, without limitation, pre-
28 ventive health, dental and primary care services, web-based office visits, telephone consultations and
29 telemedicine consultations;

30 (L) Guide and support community three-share agreements in which an employer, state or local
31 government and an individual all contribute a portion of a premium for a community-centered health
32 initiative or for insurance coverage;

33 (m) Develop, in consultation with the Department of Consumer and Business Services, one or
34 more products designed to provide more affordable options for the small group market;

35 (n) Implement policies and programs to expand the skilled, diverse workforce as described in
36 ORS 414.018 (4); and

37 (o) Implement a process for collecting the health outcome and quality measure data identified
38 by the Health Plan Quality Metrics Committee and report the data to the Oregon Health Policy
39 Board.

40 (2) The Oregon Health Authority is authorized to:

41 (a) Create an all-claims, all-payer database to collect health care data and monitor and evaluate
42 health care reform in Oregon and to provide comparative cost and quality information to consumers,
43 providers and purchasers of health care about Oregon's health care systems and health plan net-
44 works in order to provide comparative information to consumers.

45 (b) Develop uniform contracting standards for the purchase of health care, including the fol-

1 lowing:

2 (A) Uniform quality standards and performance measures;

3 (B) Evidence-based guidelines for major chronic disease management and health care services
4 with unexplained variations in frequency or cost;

5 (C) Evidence-based effectiveness guidelines for select new technologies and medical equipment;
6 and

7 (D) A statewide drug formulary that may be used by publicly funded health benefit plans.

8 (3) The enumeration of duties, functions and powers in this section is not intended to be exclu-
9 sive nor to limit the duties, functions and powers imposed on or vested in the Oregon Health Au-
10 thority by ORS 413.006 to 413.042 and 741.340 or by other statutes.

11 **SECTION 10.** ORS 414.312 is amended to read:

12 414.312. (1) As used in ORS 414.312 to 414.318:

13 (a) "Pharmacy benefit manager" means an entity that negotiates and executes contracts with
14 pharmacies, manages preferred drug lists, negotiates rebates with prescription drug manufacturers
15 and serves as an intermediary between the Oregon Prescription Drug Program, prescription drug
16 manufacturers and pharmacies.

17 (b) "Prescription drug claims processor" means an entity that processes and pays prescription
18 drug claims, adjudicates pharmacy claims, transmits prescription drug prices and claims data be-
19 tween pharmacies and the Oregon Prescription Drug Program and processes related payments to
20 pharmacies.

21 (c) "Program price" means the reimbursement rates and prescription drug prices established by
22 the administrator of the Oregon Prescription Drug Program.

23 (2) The Oregon Prescription Drug Program is established in the Oregon Health Authority. The
24 purpose of the program is to:

25 (a) Purchase prescription drugs, replenish prescription drugs dispensed or reimburse pharmacies
26 for prescription drugs in order to receive discounted prices and rebates;

27 (b) Make prescription drugs available at the lowest possible cost to participants in the program
28 as a means to promote health;

29 (c) Maintain a list of prescription drugs recommended as the most effective prescription drugs
30 available at the best possible prices; and

31 (d) Promote health through the purchase and provision of discount prescription drugs and co-
32 ordination of comprehensive prescription benefit services for eligible entities and members.

33 (3) The Director of the Oregon Health Authority shall appoint an administrator of the Oregon
34 Prescription Drug Program. The administrator may:

35 (a) Negotiate price discounts and rebates on prescription drugs with prescription drug man-
36 ufacturers or group purchasing organizations;

37 (b) Purchase prescription drugs on behalf of individuals and entities that participate in the
38 program;

39 (c) Contract with a prescription drug claims processor to adjudicate pharmacy claims and
40 transmit program prices to pharmacies;

41 (d) Determine program prices and reimburse or replenish pharmacies for prescription drugs
42 dispensed or transferred;

43 (e) Adopt and implement a preferred drug list for the program;

44 (f) Develop a system for allocating and distributing the operational costs of the program and any
45 rebates obtained to participants of the program; and

1 (g) Cooperate with other states or regional consortia in the bulk purchase of prescription drugs.

2 (4) The following individuals or entities may participate in the program:

3 (a) Public Employees' Benefit Board, Oregon Educators Benefit Board and Public Employees
4 Retirement System;

5 (b) Local governments as defined in ORS 174.116 and special government bodies as defined in
6 ORS 174.117 that directly or indirectly purchase prescription drugs;

7 (c) Oregon Health and Science University established under ORS 353.020;

8 (d) State agencies that directly or indirectly purchase prescription drugs, including agencies that
9 dispense prescription drugs directly to persons in state-operated facilities;

10 (e) Residents of this state who lack or are underinsured for prescription drug coverage;

11 (f) Private entities; and

12 (g) Labor organizations.

13 (5) The administrator may establish different program prices for pharmacies in rural areas to
14 maintain statewide access to the program.

15 (6) The administrator may establish the terms and conditions for a pharmacy to enroll in the
16 program. A licensed pharmacy that is willing to accept the terms and conditions established by the
17 administrator may apply to enroll in the program.

18 (7) *[Except as provided in subsection (8) of this section,]* The administrator may not[:]

19 *[(a) Contract with a pharmacy benefit manager;]*

20 *[(b) Establish a state-managed wholesale or retail drug distribution or dispensing system; or]*

21 *[(c)]* require pharmacies to maintain or allocate separate inventories for prescription drugs dis-
22 pensed through the program, **except as necessary to enter into or carry out an agreement for**
23 **the bulk purchasing of prescription drugs.**

24 (8) The administrator shall contract with one or more entities to perform any of the functions
25 of the program, including but not limited to:

26 (a) Contracting with a pharmacy benefit manager and directly or indirectly with such pharmacy
27 networks as the administrator considers necessary to maintain statewide access to the program.

28 (b) Negotiating with prescription drug manufacturers on behalf of the administrator.

29 (9) Notwithstanding subsection (4)(e) of this section, individuals who are eligible for Medicare
30 Part D prescription drug coverage may participate in the program.

31 (10) The program may contract with vendors as necessary to utilize discount purchasing pro-
32 grams, including but not limited to group purchasing organizations established to meet the criteria
33 of the Nonprofit Institutions Act, 15 U.S.C. 13c, or that are exempt under the Robinson-Patman Act,
34 15 U.S.C. 13.

35 **SECTION 11. This 2019 Act being necessary for the immediate preservation of the public**
36 **peace, health and safety, an emergency is declared to exist, and this 2019 Act takes effect**
37 **on its passage.**

38