

House Bill 4147

Sponsored by Representatives WALLAN, PRUSAK, Senator LINTHICUM, Representative NOSSE, Senators BEYER, GOLDEN; Representatives ALONSO LEON, CLEM, DOHERTY, GOMBERG, GORSEK, GREENLICK, HELT, HERNANDEZ, HOLVEY, KENY-GUYER, LIVELY, MEEK, MITCHELL, NERON, NOBLE, PILUSO, REARDON, SALINAS, SANCHEZ, SCHOUTEN, SOLLMAN, WILDE, WILLIAMS, WITT, ZIKA, Senators BOQUIST, DEMBROW, FREDERICK, GELSER, ROBLAN, WAGNER (at the request of Oregon Coalition for Affordable Prescriptions (OCAP)) (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**.

Requires Oregon Health Authority to design program to import wholesale prescription drugs from Canada. Specifies conditions and requirements. If authority estimates program would produce substantial 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.

Modifies duties of Task Force on the Fair Pricing of Prescription Drugs and extends sunset on task force.

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
3 sections 11 and 12, chapter 7, Oregon Laws 2018; and declaring 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 signed reciprocity agreements with European
20 Union regulators to accept the results of European Union inspections of pharmaceutical manufac-
21 turing plants, and the Food and Drug Administration has had a Memorandum of Understanding for
22 regulatory cooperation around pharmaceuticals with the Canadian regulatory authorities since 1973;
23 and

24 Whereas Canada has a rigorous regulatory system to license prescription drugs that is consid-

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 ered to be on par with the U.S. approval system; and

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

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

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

9 Whereas directing the Oregon Health Authority to implement a wholesale drug importation
10 program for the exclusive benefit of residents of Oregon benefits all Oregonians; now, therefore,

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

12
13 **WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM**

14
15 **SECTION 1. The Oregon Health Authority, in consultation with the State Board of**
16 **Pharmacy, stakeholders and appropriate federal officials, shall design a wholesale pre-**
17 **scription drug importation program that meets the criteria of section 3 of this 2020 Act.**

18 **SECTION 2. As used in sections 2 to 4 of this 2020 Act:**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

45 **(c) Are distributed only to pharmacies and providers that are licensed in this state to**

1 dispense or administer prescription drugs;

2 (4) The applicable requirements under 21 U.S.C. 360eee, 360eee-1 and 384 are met both
3 before and after the importation of the prescription drugs;

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

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

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

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

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

14 (c) Prevent participating pharmacies and providers from charging a consumer or health
15 plan more than the actual acquisition cost plus a dispensing fee for a prescription drug im-
16 ported under the program;

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

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

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

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

25 (8) Subsection (7)(a) of this section does not prohibit an individual who purchases an
26 imported prescription drug for personal use from transporting the prescription drug outside
27 this state; and

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

31 **SECTION 4.** On or before January 15 of each year, the Oregon Health Authority shall
32 report to the interim committees of the Legislative Assembly related to health the following
33 information from the previous calendar year regarding the wholesale prescription drug
34 importation program described in section 3 of this 2020 Act:

35 (1) The prescription drugs that were imported;

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

37 (3) The number of prescriptions for drugs dispensed or administered in this state that
38 were imported under the program;

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

40 (5) The systems and mechanisms described in section 3 (7) of this 2020 Act;

41 (6) The findings of the Attorney General with respect to any anticompetitive behaviors
42 demonstrated by industries affected by the program, as required by section 7 of this 2020
43 Act; and

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

45 **SECTION 5.** (1) No later than 12 months after the effective date of this 2020 Act, the

1 Oregon Health Authority shall report to the interim committees of the Legislative Assembly
 2 related to health, as provided in ORS 192.245:

3 (a) The design and plan for the implementation of the wholesale prescription drug
 4 importation program described in section 3 of this 2020 Act;

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

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

8 (2) If the report described in subsection (1) of this section estimates substantial cost
 9 savings to Oregon consumers from the program, no later than six months after submitting
 10 the report, the authority shall submit a formal request to the United States Department of
 11 Health and Human Services to certify that the wholesale prescription drug importation pro-
 12 gram described in section 3 of this 2020 Act meets the requirements of 21 U.S.C. 384(b). The
 13 authority shall also seek all federal approvals necessary to enable all covered entities en-
 14 rolled in or eligible for the federal 340B Drug Pricing Program to participate in the wholesale
 15 prescription drug importation program without jeopardizing eligibility for the federal 340B
 16 Drug Pricing Program.

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

20 SECTION 6. To implement the wholesale prescription drug importation program, the
 21 Oregon Health Authority shall, in accordance with the requirements in section 3 of this 2020
 22 Act:

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

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

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

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

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

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

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

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

36 (9) Create the systems and mechanisms required by section 3 (7) of this 2020 Act; and

37 (10) Take any other actions that the authority deems necessary to begin operating the
 38 wholesale prescription drug importation program on the date specified in section 5 (3) of this
 39 2020 Act.

40 SECTION 7. (1) The Attorney General, in consultation with the Oregon Health Authority,
 41 shall identify the potential for and shall monitor for anticompetitive behavior by industries
 42 affected by the wholesale prescription drug importation program described in section 3 of
 43 this 2020 Act.

44 (2) The Attorney General shall report to the Oregon Health Authority the Attorney
 45 General's findings under subsection (1) of this section for the purpose of the report described

1 **in section 4 (6) of this 2020 Act.**

2 **SECTION 8. Section 4 of this 2020 Act becomes operative on January 1 in the second**
 3 **calendar year after the implementation of the wholesale prescription drug importation pro-**
 4 **gram in accordance with section 5 (3) of this 2020 Act.**

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

6 413.032. (1) The Oregon Health Authority is established. The authority shall:

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

8 (b) Administer the Oregon Integrated and Coordinated Health Care Delivery System established
 9 in ORS 414.570 **and the wholesale prescription drug importation program described in section**
 10 **3 of this 2020 Act;**

11 (c) Administer the Oregon Prescription Drug Program;

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

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

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

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

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

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

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

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

27 (B) Approval of rates; and

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

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

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

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

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

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

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

45 (a) Create an all-claims, all-payer database to collect health care data and monitor and evaluate

1 health care reform in Oregon and to provide comparative cost and quality information to consumers,
 2 providers and purchasers of health care about Oregon’s health care systems and health plan net-
 3 works in order to provide comparative information to consumers.

4 (b) Develop uniform contracting standards for the purchase of health care, including the fol-
 5 lowing:

6 (A) Uniform quality standards and performance measures;

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

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

10 (D) A statewide drug formulary that may be used by publicly funded health benefit plans; and

11 (E) Standards that accept and consider tribal-based practices for mental health and substance
 12 abuse prevention, counseling and treatment for persons who are Native American or Alaska Native
 13 as equivalent to evidence-based practices.

14 (3) The enumeration of duties, functions and powers in this section is not intended to be exclu-
 15 sive nor to limit the duties, functions and powers imposed on or vested in the Oregon Health Au-
 16 thority by ORS 413.006 to 413.042, 415.012 to 415.430 and 741.340 or by other statutes.

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

18 414.312. (1) As used in ORS 414.312 to 414.318:

19 (a) “Pharmacy benefit manager” means an entity that negotiates and executes contracts with
 20 pharmacies, manages preferred drug lists, negotiates rebates with prescription drug manufacturers
 21 and serves as an intermediary between the Oregon Prescription Drug Program, prescription drug
 22 manufacturers and pharmacies.

23 (b) “Prescription drug claims processor” means an entity that processes and pays prescription
 24 drug claims, adjudicates pharmacy claims, transmits prescription drug prices and claims data be-
 25 tween pharmacies and the Oregon Prescription Drug Program and processes related payments to
 26 pharmacies.

27 (c) “Program price” means the reimbursement rates and prescription drug prices established by
 28 the administrator of the Oregon Prescription Drug Program.

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

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

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

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

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

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

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

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

45 (c) Contract with a prescription drug claims processor to adjudicate pharmacy claims and

1 transmit program prices to pharmacies;

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

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

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

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

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

9 (a) Public Employees' Benefit Board, Oregon Educators Benefit Board and Public Employees
10 Retirement System;

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

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

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

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

17 (f) Private entities; and

18 (g) Labor organizations.

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

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

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

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

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

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

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

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

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

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

37 (10) The program may contract with vendors as necessary to utilize discount purchasing pro-
38 grams, including but not limited to group purchasing organizations established to meet the criteria
39 of the Nonprofit Institutions Act, 15 U.S.C. 13c, or that are exempt under the Robinson-Patman Act,
40 15 U.S.C. 13.

41
42 **TASK FORCE ON FAIR PRICING OF PRESCRIPTION DRUGS**

43
44 **SECTION 11.** Section 11, chapter 7, Oregon Laws 2018, is amended to read:

45 **Sec. 11.** (1) The Task Force on the Fair Pricing of Prescription Drugs is established.

- 1 (2) The task force consists of 18 members appointed as follows:
- 2 (a) The President of the Senate shall appoint:
- 3 (A) One member from the Senate who is a member of the majority party.
- 4 (B) One member from the Senate who is a member of the minority party.
- 5 (b) The Speaker of the House of Representatives shall appoint:
- 6 (A) One member from the House of Representatives who is a member of the majority party.
- 7 (B) One member from the House of Representatives who is a member of the minority party.
- 8 (c) The Governor shall appoint the following members:
- 9 (A) One representative from the Department of Consumer and Business Services;
- 10 (B) One representative from the Oregon Health Authority;
- 11 (C) One representative from the Oregon Health Policy Board; and
- 12 (D) Individuals representing:
- 13 (i) Pharmaceutical manufacturers;
- 14 (ii) Insurance companies offering health insurance in this state;
- 15 (iii) Pharmacy benefit managers;
- 16 (iv) Prescription drug wholesalers;
- 17 (v) Consumers;
- 18 (vi) Independent pharmacies;
- 19 (vii) Large retail pharmacy chains;
- 20 (viii) Hospitals;
- 21 (ix) Biopharmaceutical companies based in Oregon;
- 22 (x) Coordinated care organizations; and
- 23 (xi) Medical providers.
- 24 (3) The task force shall *[develop a strategy to create transparency for drug prices across the entire*
- 25 *supply chain of pharmaceutical products, including but not limited to manufacturers, insurers, phar-*
- 26 *macy benefit managers, distributors, wholesalers and retail pharmacies.]*:
- 27 **(a) Evaluate legislation enacted during the 2019 regular session of the Eightieth Legisla-**
- 28 **tive Assembly that was intended to address transparency in the cost of prescription drugs**
- 29 **and any similar legislation that has been enacted in other states; and**
- 30 **(b) Evaluate additional strategies that may be used to reduce the cost of prescription**
- 31 **drugs for Oregon consumers.**
- 32 (4) A majority of the voting members of the task force constitutes a quorum for the transaction
- 33 of business.
- 34 (5) Official action by the task force requires the approval of a majority of the voting members
- 35 of the task force.
- 36 (6) The task force shall elect one of its members to serve as chairperson.
- 37 (7) If there is a vacancy for any cause, the appointing authority shall make an appointment to
- 38 become immediately effective.
- 39 (8) The task force shall meet at times and places specified by the call of the chairperson or of
- 40 a majority of the voting members of the task force.
- 41 (9) The task force may adopt rules necessary for the operation of the task force.
- 42 (10) The task force shall submit a report **of its findings under subsection (3) of this section**
- 43 **in the manner provided by ORS 192.245, and may include recommendations for legislation, to the**
- 44 **interim committees of the Legislative Assembly related to health no later than [November 1, 2018]**
- 45 **September 15, 2020.** The report must contain a cost-effective and enforceable solution that exposes

1 the cost factors that negatively impact prices paid by Oregonians for pharmaceutical products.

2 (11) The Legislative Policy and Research Director shall provide staff support to the task force.

3 (12) Members of the Legislative Assembly appointed to the task force are nonvoting members
4 of the task force and may act in an advisory capacity only.

5 (13) Members of the task force who are not members of the Legislative Assembly are not enti-
6 tled to compensation or reimbursement for expenses and serve as volunteers on the task force.

7 (14) All agencies of state government, as defined in ORS 174.111, are directed to assist the task
8 force in the performance of the task force's duties and, to the extent permitted by laws relating to
9 confidentiality, to furnish information and advice the members of the task force consider necessary
10 to perform their duties.

11 **SECTION 12.** Section 12, chapter 7, Oregon Laws 2018, is amended to read:

12 **Sec. 12.** Section 11, [*of this 2018 Act*] **chapter 7, Oregon Laws 2018**, is repealed on December
13 31, [2020] **2021**.

14
15 **CAPTIONS**

16
17 **SECTION 13.** **The unit captions used in this 2020 Act are provided only for the conven-**
18 **ience of the reader and do not become part of the statutory law of this state of express any**
19 **legislative intent in the enactment of this 2020 Act.**

20
21 **EMERGENCY CLAUSE**

22
23 **SECTION 14.** **This 2020 Act being necessary for the immediate preservation of the public**
24 **peace, health and safety, an emergency is declared to exist, and this 2020 Act takes effect**
25 **on its passage.**