

Senate Bill 844

Sponsored by Senator PATTERSON, Representatives WALLAN, PRUSAK

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**.

Establishes Prescription Drug Affordability Board in Department of Consumer and Business Services to review prices for prescription drug products meeting specified cost criteria. Requires board to establish upper payment limit for drugs that are or are expected to create affordability challenges for health systems and patients in Oregon or health inequities for communities of color. Requires board to establish and assess fees against manufacturers of prescription drug products sold in Oregon for costs of carrying out duties of board.

Establishes Prescription Drug Affordability Stakeholder Council to assist board in carrying out its duties.

A BILL FOR AN ACT

1
2 Relating to the price of prescription drugs.

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

4 **SECTION 1. As used in sections 1 to 7 of this 2021 Act:**

5 (1) **"Biological product" means a biological product that is produced or distributed in ac-**
6 **cordance with a license application approved under 42 U.S.C. 262.**

7 (2) **"Biosimilar" has the meaning given that term in 42 U.S.C. 262.**

8 (3)(a) **"Brand name drug" means a drug that is produced or distributed in accordance**
9 **with an original new drug application approved under 21 U.S.C. 355(c).**

10 (b) **"Brand name drug" does not include an authorized generic as defined by 42 C.F.R.**
11 **447.502.**

12 (4) **"Generic drug" means:**

13 (a) **A retail drug that is marketed or distributed in accordance with an abbreviated new**
14 **drug application approved under 21 U.S.C. 355(j);**

15 (b) **An authorized generic as defined by 42 C.F.R. 447.502; or**

16 (c) **A drug that entered the market before 1962 that was not originally marketed under**
17 **a new drug application.**

18 (5) **"Manufacturer" means an entity that:**

19 (a)(A) **Engages in the manufacture of a prescription drug product; or**

20 (B) **Enters into a lease with another manufacturer to market and distribute a pre-**
21 **scription drug product under the entity's own name; and**

22 (b) **Sets or changes the wholesale acquisition cost of the prescription drug product it**
23 **manufactures or markets.**

24 (6) **"Patient assistance program" has the meaning given that term in ORS 646A.689.**

25 (7) **"Prescription drug product" includes a:**

26 (a) **Brand name drug;**

27 (b) **Generic drug;**

28 (c) **Biological product; or**

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 (d) Biosimilar.

2 (8) "Wholesale acquisition cost" has the meaning given that term in 42 U.S.C.
3 1395w-3a(c)(6)(B).

4 **SECTION 2.** (1) The Prescription Drug Affordability Board is established in the Depart-
5 ment of Consumer and Business Services to protect residents of this state, state and local
6 governments, commercial health plans, health care providers, pharmacies licensed in this
7 state and other stakeholders within the health care system in this state from the high costs
8 of prescription drug products.

9 (2) The board consists of five members and three alternates appointed by the Governor.

10 (3) The term of office of each member of the board is four years, but a member serves
11 at the pleasure of the Governor. Before the expiration of the term of a member, the Gover-
12 nor shall appoint a successor whose term begins on January 1 next following. A member is
13 eligible for reappointment. If there is a vacancy for any cause, the Governor shall make an
14 appointment to become immediately effective for the unexpired term.

15 (4) The appointment of each member of the board is subject to confirmation by the Sen-
16 ate in the manner prescribed in ORS 171.562 and 171.565.

17 (5) A member of the board is entitled to compensation and expenses as provided in ORS
18 292.495.

19 (6) The members of the board must be residents of this state with expertise in health
20 care economics and clinical medicine.

21 (7) A member of the board may not be an employee of, a board member of or a consultant
22 to a manufacturer or a trade association of manufacturers.

23 (8) The board shall select one of its members as chairperson and another as vice chair-
24 person, for terms and with duties and powers necessary for the performance of the functions
25 of the offices as the board determines.

26 (9) A majority of the members of the board constitutes a quorum for the transaction of
27 business.

28 (10) The department shall appoint an executive director for the board, may employ con-
29 sultants, investigators or other staff and shall provide staff support necessary for the board
30 to carry out its duties.

31 (11) The board shall meet at least once every six weeks at a time and place determined
32 by the chairperson. The chairperson may cancel or postpone a regular meeting if there is
33 no prescription drug product to review. The board may also meet at other times and places
34 specified by the call of the chairperson or of a majority of the members of the board.

35 (12)(a) The following actions by the board shall be open to the public in accordance with
36 ORS 192.610 to 192.690:

37 (A) Any deliberation on whether to conduct an affordability review of a prescription drug
38 product under section 5 of this 2021 Act;

39 (B) Any decision on whether to impose an upper payment limit on a prescription drug
40 product sold in this state under section 5 of this 2021 Act; and

41 (C) Any decision or deliberation toward a decision on any matter before the board except
42 as provided in paragraph (b) of this subsection.

43 (b) The board may meet in executive session to discuss trade secret information.

44 (13) The board shall:

45 (a) Provide public notice of each board meeting at least two weeks in advance of the

1 meeting;

2 (b) Make materials for each board meeting available to the public at least one week in
3 advance of the meeting;

4 (c) Provide an opportunity for public comment at each open meeting of the board; and

5 (d) Provide the public with the opportunity to submit written comments on any pending
6 decision of the board.

7 (14) The board may allow expert testimony at board meetings, including when the board
8 meets in executive session.

9 (15)(a) Members of the board shall recuse themselves from decisions related to a pre-
10 scription drug product if the member, or an immediate family member of the member, has
11 received or could receive any of the following:

12 (A) A direct financial benefit of any amount deriving from the result or finding of a
13 study, review or determination by or for the board; or

14 (B) A financial benefit from any person that owns, manufactures, or provides pre-
15 scription drug products, services or items to be reviewed by the board that in the aggregate
16 exceeds \$5,000 per year.

17 (b) For the purposes of paragraph (a) of this subsection, a financial benefit includes
18 honoraria, fees, stock, the value of the member's or immediate family member's stock
19 holdings and any direct financial benefit deriving from the result or finding of a study, review
20 or determination by or for the board.

21 (c) A conflict of interest shall be disclosed:

22 (A) By the board when hiring board staff;

23 (B) By the Governor when appointing members and alternate members to the board and
24 members to the Prescription Drug Affordability Stakeholder Council; and

25 (C) By the board, when a member of the board is recused in any final decision resulting
26 from a review of a prescription drug product.

27 (d) A conflict of interest shall be disclosed at the earlier of:

28 (A) Prior to the first board meeting after the conflict is identified; or

29 (B) Within five days after the conflict is identified.

30 (e) A conflict of interest disclosed under this section shall be posted on the website of
31 the board unless the chairperson of the board recuses the member from any final decision
32 resulting from a review of a prescription drug product.

33 (f) A posting under paragraph (e) of this subsection shall include the type, nature and
34 magnitude of the conflict of interest of the member involved.

35 (16) Members and alternate members of the board, staff and third parties that contract
36 with the board may not accept any gift or donation of services or property that creates a
37 potential conflict of interest or has the appearance of biasing the work of the board.

38 (17)(a) The board may enter into a contract with a qualified, independent third party for
39 any service necessary to carry out the powers and duties of the board.

40 (b) Unless permission is granted by the board, a third party hired by the board may not
41 release, publish or otherwise use any information to which the third party has access under
42 its contract.

43 (18) In accordance with applicable provisions of ORS chapter 183, the board may adopt
44 rules necessary for the administration of sections 1 to 7 of this 2021 Act.

45 **SECTION 3.** The Prescription Drug Affordability Board, the executive director and au-

1 **thorized representatives of the board may administer oaths, take depositions and issue**
 2 **subpoenas to a manufacturer to compel the attendance of witnesses and the production of**
 3 **documents or other written information necessary to carry out the provisions of sections 1**
 4 **to 7 of this 2021 Act. If any person fails to comply with a subpoena issued under this section**
 5 **or refuses to testify on matters on which the person lawfully may be interrogated, the pro-**
 6 **cedure set out in ORS 183.440 shall be followed to compel obedience.**

7 **SECTION 4. (1) The Prescription Drug Affordability Stakeholder Council is established.**
 8 **The purpose of the stakeholder council is to provide stakeholder input to assist the Pre-**
 9 **scription Drug Affordability Board in carrying out its duties under sections 1 to 7 of this 2021**
 10 **Act. The stakeholder council consists of up to 23 members appointed as follows:**

11 **(a) The Speaker of the House of Representatives shall appoint:**

- 12 **(A) One representative of a statewide health care advocacy coalition;**
- 13 **(B) One representative of a statewide advocacy organization for seniors;**
- 14 **(C) One representative of a statewide organization for diverse communities;**
- 15 **(D) One representative of a labor union;**
- 16 **(E) Two health services researchers specializing in prescription drug product costs; and**
- 17 **(F) At the discretion of the Speaker, one public member.**

18 **(b) The President of the Senate shall appoint:**

- 19 **(A) One representative of doctors;**
- 20 **(B) One representative of nurses;**
- 21 **(C) One representative of hospitals;**
- 22 **(D) One representative of health insurers;**
- 23 **(E) One representative of the Oregon Department of Administrative Services;**
- 24 **(F) One clinical researcher; and**
- 25 **(G) At the discretion of the President, one public member.**

26 **(c) The Governor shall appoint:**

- 27 **(A) One representative of brand name drug manufacturers;**
- 28 **(B) One representative of generic drug manufacturers;**
- 29 **(C) One representative of employers;**
- 30 **(D) One representative of pharmacy benefit managers;**
- 31 **(E) One representative of pharmacists;**
- 32 **(F) One pharmacologist;**
- 33 **(G) One representative of coordinated care organizations;**
- 34 **(H) One representative of federally qualified health centers; and**
- 35 **(I) At the discretion of the Governor, one public member.**

36 **(2) The members of the stakeholder council shall have knowledge in one or more of the**
 37 **following:**

- 38 **(a) The pharmaceutical business;**
- 39 **(b) Supply chain business models;**
- 40 **(c) The practice of medicine or clinical training;**
- 41 **(d) Consumer or patient perspectives;**
- 42 **(e) Health care cost trends and drivers;**
- 43 **(f) Clinical and health services research; or**
- 44 **(g) The health insurance exchange.**
- 45 **(3) The chairperson of the Prescription Drug Affordability Board shall appoint two**

1 members from among the membership of the council to be cochairpersons of the council.

2 (4) The term of a member of the council is three years.

3 (5) Members of the council shall not receive compensation for their services but may
 4 receive actual and necessary travel or other expenses incurred in the performance of their
 5 official duties as members of the council, as provided in ORS 292.210 to 292.288.

6 **SECTION 5.** (1) The Prescription Drug Affordability Board shall identify prescription drug
 7 products that are:

8 (a) Brand name drugs or biological products that, as adjusted annually by the increase
 9 or decrease in the cost of living for the previous calendar year, based on changes in the
 10 Consumer Price Index for All Urban Consumers, West Region (All Items), as published by
 11 the Bureau of Labor Statistics of the United States Department of Labor, have:

12 (A) An introductory wholesale acquisition cost of \$30,000 or more per year or for a course
 13 of treatment; or

14 (B) A wholesale acquisition cost increase of \$3,000 or more in any 12-month period or for
 15 the period of a course of treatment if the course of treatment is less than 12 months;

16 (b) Biosimilar drugs that have introductory wholesale acquisition costs that are greater
 17 than 85 percent of the wholesale acquisition cost of referenced brand biological products at
 18 the time the biosimilars are introduced into the market;

19 (c) Generic drugs that, as adjusted annually by the increase or decrease in the cost of
 20 living for the previous calendar year, based on changes in the Consumer Price Index for All
 21 Urban Consumers, West Region (All Items), as published by the Bureau of Labor Statistics
 22 of the United States Department of Labor, have a wholesale acquisition cost:

23 (A) Of \$100 or more for:

24 (i) A 30-day supply or, if a course of treatment is less than 30 days based on the recom-
 25 mended dosage approved for labeling by the United States Food and Drug Administration, for
 26 the course of the treatment; or

27 (ii) One unit of the drug if the labeling approved by the United States Food and Drug
 28 Administration does not recommend a finite dosage; and

29 (B) That increased by 200 percent or more during the immediately preceding 12-month
 30 period, as determined by the difference between the wholesale acquisition cost as a result
 31 of the increase and the average of the wholesale acquisition cost reported over the imme-
 32 diately preceding 12 months; and

33 (d) Other prescription drug products, identified in consultation with the Prescription
 34 Drug Affordability Stakeholder Council, that may create affordability challenges for health
 35 care systems and patients or result in health inequities for communities of color across this
 36 state.

37 (2) To the extent practicable, the board shall access pricing information for prescription
 38 drug products by:

39 (a) Entering into an interagency agreement with the Department of Consumer and
 40 Business Services to share information collected by the department under ORS 646A.689;

41 (b) Entering into a memorandum of understanding with another state to which man-
 42 ufacturers already report pricing information; and

43 (c) Accessing other publicly available pricing information.

44 (3) After identifying prescription drug products as required by subsection (1) of this sec-
 45 tion, the board shall determine whether to conduct an affordability review for each identified

1 **prescription drug product by:**

2 **(a) Seeking input from the council about the prescription drug product; and**

3 **(b) Considering the estimated average patient cost share for the prescription drug prod-**
4 **uct.**

5 **(4) The information used to conduct an affordability review may include any document**
6 **and research related to a manufacturer's selection of the introductory price or price increase**
7 **of a prescription drug product, including life cycle management, net average price in this**
8 **state, market competition and context, projected revenue and the estimated value or cost-**
9 **effectiveness of the prescription drug product.**

10 **(5) Failure of a manufacturer to provide the board with the information for an**
11 **affordability review does not restrict the authority of the board to conduct such a review.**

12 **(6)(a) In reviewing the cost and affordability of a prescription drug product, the board**
13 **shall determine whether the use of the prescription drug product consistent with the labeling**
14 **approved by the United States Food and Drug Administration or standard medical practice**
15 **has led or will lead to affordability challenges for health care systems in this state or high**
16 **out-of-pocket costs for patients in this state.**

17 **(b) To the extent practicable, in determining whether a prescription drug product has led**
18 **or will lead to an affordability challenge or to health inequities in communities of color, the**
19 **board shall consider the following factors based on information described in subsection (2)**
20 **of this section:**

21 **(A) The wholesale acquisition cost for the prescription drug product sold in this state;**

22 **(B) The estimated average monetary price concession, discount or rebate the manufac-**
23 **turer provides to health insurance plans in this state or is expected to provide to health in-**
24 **surance plans in this state, expressed as a percent of the wholesale acquisition cost for the**
25 **prescription drug product under review;**

26 **(C) The estimated total amount of the price concession, discount or rebate the man-**
27 **ufacturer provides to each pharmacy benefit manager registered in this state for the pre-**
28 **scription drug product under review, expressed as a percent of the wholesale acquisition**
29 **costs;**

30 **(D) The estimated price for therapeutic alternatives to the drug that are sold in this**
31 **state;**

32 **(E) The estimated average monetary concession, discount or rebate the manufacturer**
33 **provides or is expected to provide to health insurance plans and pharmacy benefit managers**
34 **in this state for therapeutic alternatives;**

35 **(F) The estimated costs to health insurance plans based on patient use of the drug con-**
36 **sistent with the labeling approved by the United States Food and Drug Administration and**
37 **recognized standard medical practice;**

38 **(G) The impact on patient access to the drug considering standard prescription drug**
39 **benefit designs in health insurance plans offered in this state;**

40 **(H) The relative financial impacts to health, medical or social services costs as can be**
41 **quantified and compared to the costs of existing therapeutic alternatives;**

42 **(I) The estimated average patient copayment or other cost-sharing for the prescription**
43 **drug product in this state;**

44 **(J) Any information a manufacturer chooses to provide; and**

45 **(K) Any other factors as determined by the board in rules adopted by the board.**

1 (7) If the board finds that the cost of a prescription drug product reviewed under this
2 section has led or will lead to an affordability challenge for health systems or patients or to
3 health inequities for communities of color, the board may establish an upper payment limit
4 for the drug considering:

- 5 (a) The cost of administering the drug;
- 6 (b) The cost of delivering the drug to patients; and
- 7 (c) Other relevant administrative costs related to the drug.

8 (8) Except as provided in subsection (9) of this section, an upper payment limit estab-
9 lished by the board under subsection (7) of this section applies to all sales of and re-
10 imbursements claimed in this state for the prescription drug product distributed in person,
11 by mail or by other means.

12 (9)(a) An insurer, pharmacy benefit manager or other person that pays for or reimburses
13 the cost of prescription drugs in this state may elect to opt out of the upper payment limit
14 for specific drugs to allow the payer to negotiate with a manufacturer for the cost of the
15 drug. The board shall prescribe a simple process for a payer to opt out under this paragraph.

16 (b) A Medicare Advantage Plan or a payer that is exempt from the Insurance Code based
17 on the Employee Retirement Income Security Act of 1974 is not subject to the upper payment
18 limit established by the board and may choose to pay or reimburse the cost of drugs at a
19 higher price than the payer is billed.

20 (10) A health care provider licensed or certified in this state may not bill an amount for
21 a prescription drug product that exceeds the upper payment limit established for the drug
22 regardless of whether the drug is dispensed or administered to an individual enrolled in a
23 plan described in subsection (9) of this section.

24 (11) This section does not prevent a manufacturer from marketing a prescription drug
25 product approved by the United States Food and Drug Administration while the product is
26 under review by the board.

27 **SECTION 6.** (1) Any person aggrieved by a decision of the Prescription Drug Affordability
28 Board may request a contested case hearing, in accordance with ORS chapter 183, no later
29 than 30 days after the decision is issued.

30 (2) The board shall issue a final order no later than 60 days after the date of the request
31 for a contested case hearing.

32 **SECTION 7.** (1) The Prescription Drug Affordability Board shall annually assess fees to
33 be paid by manufacturers that sell prescription drug products in this state. The fees shall
34 be established in amounts necessary to meet the costs of the board in administering sections
35 1 to 7 of this 2021 Act. The fees shall be imposed based on a manufacturer's share of gross
36 revenue from sales of prescription drug products in this state.

37 (2) Fees collected under this section shall be deposited in the Prescription Drug
38 Affordability Account established in section 8 of this 2021 Act.

39 **SECTION 8.** The Prescription Drug Affordability Account is established as a subaccount
40 in the Consumer and Business Services Fund created in ORS 705.145, consisting of moneys
41 collected under section 7 of this 2021 Act and moneys that may be appropriated to the Pre-
42 scription Drug Affordability Account by the Legislative Assembly. Interest earned on the
43 account shall be credited to the account. Moneys in the account are continuously appropri-
44 ated to the Prescription Drug Affordability Board to carry out sections 1 to 7 of this 2021
45 Act.

1 **SECTION 9.** In addition to any other remedy available, if the Attorney General believes
2 that a person has engaged in, is engaging in or is about to engage in any act, practice or
3 transaction that violates section 5 of this 2021 Act or rules adopted by the Prescription Drug
4 Affordability Board, the Attorney General may apply to the court in the county in which the
5 act, practice or transaction occurs or will occur:

6 (1) For an injunction to restrain the person from engaging in the act, practice or trans-
7 action;

8 (2) For such orders or judgments as may be necessary to restore to any person any
9 moneys of which the person was deprived by any act, practice or transaction in violation of
10 section 5 of this 2021 Act; or

11 (3) Such orders or judgments as may be necessary to ensure cessation of the act, prac-
12 tice or transaction in violation of section 5 of this 2021 Act.

13 **SECTION 10.** No later than December 31 of each year, the Prescription Drug Affordability
14 Board shall report to the interim committees of the Legislative Assembly related to health,
15 in the manner provided in ORS 192.245, the following information:

16 (1) Price trends for prescription drug products, as defined in section 1 of this 2021 Act;

17 (2) The number of prescription drug products that were reviewed under section 5 of this
18 2021 Act, the results of the reviews and the number and disposition of administrative appeals
19 and judicial reviews of board decisions; and

20 (3) Recommendations, if any, for legislative changes necessary to make prescription drug
21 products more affordable in this state.

22 **SECTION 11.** (1) The Prescription Drug Affordability Board shall annually conduct a
23 study of the operation of the United States market for generic drugs, as defined in section
24 1 of this 2021 Act, both drugs dispensed by pharmacists and drugs administered by physi-
25 cians, including:

26 (a) The prices of generic drugs on a year to year basis;

27 (b) The degree to which generic drug prices affect insurance premiums;

28 (c) Annual changes in health insurance cost-sharing for generic drugs;

29 (d) The potential for and history of generic drug shortages;

30 (e) The degree to which generic drug prices affect annual spending in the state medical
31 assistance program; and

32 (f) Any other topic the board considers relevant to the cost of generic drugs.

33 (2) No later than June 1 of each calendar year, the board shall report to the Legislative
34 Assembly the findings of the board's study in the manner provided in ORS 192.245.

35 **SECTION 12.** Notwithstanding the term of office specified by section 2 of this 2021 Act,
36 of the members first appointed to the Prescription Drug Affordability Board:

37 (1) One member and one alternate shall serve for a term ending December 31, 2024.

38 (2) Two members and one alternate shall serve for a term ending December 31, 2025.

39 (3) Two members, including the chairperson, and one alternate shall serve for a term
40 ending December 31, 2026.

41 **SECTION 13.** Notwithstanding the term of office specified by section 4 of this 2021 Act,
42 of the members first appointed to the Prescription Drug Affordability Stakeholder Council:

43 (1) Seven members and any public members appointed under section 4 (1)(a)(F), (1)(b)(G)
44 and (1)(c)(I) of this 2021 Act shall serve for a term ending December 31, 2023.

45 (2) Seven members shall serve for a term ending December 31, 2024.

1 **(3) Seven members shall serve for a term ending December 31, 2025.**

2 **SECTION 14. (1) There is appropriated to the Prescription Drug Affordability Board, for**
3 **the biennium beginning July 1, 2021, out of the General Fund, the amount of \$_____ for the**
4 **purpose of carrying out the provisions of sections 1 to 8, 10 and 11 of this 2021 Act.**

5 **(2) When the board determines that moneys in sufficient amount are available in the**
6 **Prescription Drug Affordability Fund established in section 8 of this 2021 Act, but not later**
7 **than June 30, 2023, the board shall reimburse the General Fund without interest, in an**
8 **amount equal to the amount from the General Fund appropriated and expended as provided**
9 **in subsection (1) of this section. The moneys used to reimburse the General Fund under this**
10 **subsection shall not be considered as a budget item on which a limitation is otherwise fixed**
11 **by law, but shall be in addition to any specific biennial appropriations or amounts authorized**
12 **to be expended from continuously appropriated moneys for any biennial period.**

13
