

A-Engrossed
Senate Bill 1535

Ordered by the Senate February 17
Including Senate Amendments dated February 17

Sponsored by Senators STEINER HAYWARD, LINTHICUM, Representatives NOBLE, NOSSE; Senator RILEY
(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 Department of Consumer and Business Services to investigate methods for collecting information about rebates and markups used in pharmaceutical supply chain and to report to interim committees of Legislative Assembly recommendations for collecting information.

Authorizes department to access, use and disclose data from all payer, all claims database under specified conditions.

Modifies increase in price of prescription drug that triggers pharmaceutical manufacturer's obligation to report data under Prescription Drug Price Transparency Act.

Requires prescription drug manufacturers to respond promptly to requests by department in administering Prescription Drug Price Transparency Act.

Allows department to disclose information about consumers' notifications of increases in prices of prescription drugs but not personally identifiable information about consumers.

[Provides immunity to department from liability in civil action for certain disclosures of trade secrets.]

Modifies membership of, charge to and reporting requirements for Task Force on the Fair Pricing of Prescription Drugs. Extends sunset of task force to December 31, 2022.

Declares emergency, effective on passage.

A BILL FOR AN ACT

1
2 Relating to the cost of prescription drugs; creating new provisions; amending ORS 442.373, 646A.689
3 and 646A.692 and sections 11 and 12, chapter 7, Oregon Laws 2018; and declaring an emergency.

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

5 **SECTION 1. The Department of Consumer and Business Services shall investigate**
6 **methods for collecting information about the rebates and markups used in the pharmaceu-**
7 **tical supply chain. No later than October 1, 2020, the department shall report to the interim**
8 **committees of the Legislative Assembly related to health the department's recommendations**
9 **for collecting the information.**

10 **SECTION 2.** ORS 442.373 is amended to read:

11 442.373. (1) The Oregon Health Authority shall establish and maintain a program that requires
12 reporting entities to report health care data for the following purposes:

13 (a) Determining the maximum capacity and distribution of existing resources allocated to health
14 care.

15 (b) Identifying the demands for health care.

16 (c) Allowing health care policymakers to make informed choices.

17 (d) Evaluating the effectiveness of intervention programs in improving health outcomes.

18 (e) Comparing the costs and effectiveness of various treatment settings and approaches.

19 (f) Providing information to consumers and purchasers of health care.

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 (g) Improving the quality and affordability of health care and health care coverage.

2 (h) Assisting the authority in furthering the health policies expressed by the Legislative As-
3 sembly in ORS 442.310.

4 (i) Evaluating health disparities, including but not limited to disparities related to race and
5 ethnicity.

6 (2) The authority shall prescribe by rule standards that are consistent with standards adopted
7 by the Accredited Standards Committee X12 of the American National Standards Institute, the
8 Centers for Medicare and Medicaid Services and the National Council for Prescription Drug Pro-
9 grams that:

10 (a) Establish the time, place, form and manner of reporting data under this section, including
11 but not limited to:

12 (A) Requiring the use of unique patient and provider identifiers;

13 (B) Specifying a uniform coding system that reflects all health care utilization and costs for
14 health care services provided to Oregon residents in other states; and

15 (C) Establishing enrollment thresholds below which reporting will not be required.

16 (b) Establish the types of data to be reported under this section, including but not limited to:

17 (A) Health care claims and enrollment data used by reporting entities and paid health care
18 claims data;

19 (B) Reports, schedules, statistics or other data relating to health care costs, prices, quality,
20 utilization or resources determined by the authority to be necessary to carry out the purposes of
21 this section; and

22 (C) Data related to race, ethnicity and primary language collected in a manner consistent with
23 established national standards.

24 (3) Any third party administrator that is not required to obtain a license under ORS 744.702 and
25 that is legally responsible for payment of a claim for a health care item or service provided to an
26 Oregon resident may report to the authority the health care data described in subsection (2) of this
27 section.

28 (4) The authority shall adopt rules establishing requirements for reporting entities to train pro-
29 viders on protocols for collecting race, ethnicity and primary language data in a culturally compe-
30 tent manner.

31 (5)(a) The authority shall use data collected under this section to provide information to con-
32 sumers of health care to empower the consumers to make economically sound and medically appro-
33 priate decisions. The information must include, but not be limited to, the prices and quality of health
34 care services.

35 (b) The authority shall, using only data collected under this section from reporting entities de-
36 scribed in ORS 442.372 (1) to (3), post to its website health care price information including the
37 median prices paid by the reporting entities to hospitals and hospital outpatient clinics for, at a
38 minimum, the 50 most common inpatient procedures and the 100 most common outpatient proce-
39 dures.

40 (c) The health care price information posted to the website must be:

41 (A) Displayed in a consumer friendly format;

42 (B) Easily accessible by consumers; and

43 (C) Updated at least annually to reflect the most recent data available.

44 (d) The authority shall apply for and receive donations, gifts and grants from any public or
45 private source to pay the cost of posting health care price information to its website in accordance

1 with this subsection. Moneys received shall be deposited to the Oregon Health Authority Fund.

2 (e) The obligation of the authority to post health care price information to its website as re-
3 quired by this subsection is limited to the extent of any moneys specifically appropriated for that
4 purpose or available from donations, gifts and grants from private or public sources.

5 (6) The authority may contract with a third party to collect and process the health care data
6 reported under this section. The contract must prohibit the collection of Social Security numbers
7 and must prohibit the disclosure or use of the data for any purpose other than those specifically
8 authorized by the contract. The contract must require the third party to transmit all data collected
9 and processed under the contract to the authority.

10 (7) The authority shall facilitate a collaboration between the Department of Human Services, the
11 authority, the Department of Consumer and Business Services and interested stakeholders to de-
12 velop a comprehensive health care information system using the data reported under this section
13 and collected by the authority under ORS 442.370 and 442.400 to 442.463. The authority, in consul-
14 tation with interested stakeholders, shall:

15 (a) Formulate the data sets that will be included in the system;

16 (b) Establish the criteria and procedures for the development of limited use data sets;

17 (c) Establish the criteria and procedures to ensure that limited use data sets are accessible and
18 compliant with federal and state privacy laws; and

19 (d) Establish a time frame for the creation of the comprehensive health care information system.

20 (8) Information disclosed through the comprehensive health care information system described
21 in subsection (7) of this section:

22 (a) Shall be available, when disclosed in a form and manner that ensures the privacy and secu-
23 rity of personal health information as required by state and federal laws, as a resource to insurers,
24 employers, providers, purchasers of health care and state agencies to allow for continuous review
25 of health care utilization, expenditures and performance in this state;

26 (b) Shall be available to Oregon programs for quality in health care for use in improving health
27 care in Oregon, subject to rules prescribed by the authority conforming to state and federal privacy
28 laws or limiting access to limited use data sets;

29 (c) Shall be presented to allow for comparisons of geographic, demographic and economic factors
30 and institutional size; and

31 (d) May not disclose trade secrets of reporting entities.

32 (9) The collection, storage and release of health care data and other information under this
33 section is subject to the requirements of the federal Health Insurance Portability and Accountability
34 Act.

35 **(10)(a) Notwithstanding subsection (9) of this section, in addition to the comprehensive**
36 **health care information system described in subsection (7) of this section, the Department**
37 **of Consumer and Business Services shall be allowed to access, use and disclose data collected**
38 **under this section by certifying, in writing, that the department will use the data only to**
39 **carry out the department's duties.**

40 **(b) Personally identifiable information disclosed to the department under paragraph (a)**
41 **of this subsection is confidential and not subject to further disclosure under ORS 192.311 to**
42 **192.478.**

43 **SECTION 3.** ORS 646A.689 is amended to read:

44 646A.689. (1) As used in this section:

45 (a) "Drug" has the meaning given that term in ORS 689.005.

1 (b) "Health care facility" has the meaning given that term in ORS 442.015.

2 (c) "Health care service contractor" has the meaning given that term in ORS 750.005.

3 (d)(A) "Manufacture" means:

4 (i) The production, preparation, propagation, compounding, conversion or processing of a drug,
5 either directly or indirectly by extraction from substances of natural origin or independently by
6 means of chemical synthesis, or by a combination of extraction and chemical synthesis; and

7 (ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.

8 (B) "Manufacture" does not include the preparation or compounding of a drug by an individual
9 for the individual's own use or the preparation, compounding, packaging or labeling of a drug:

10 (i) By a health care practitioner incidental to administering or dispensing a drug in the course
11 of professional practice;

12 (ii) By a health care practitioner or at the practitioner's authorization and supervision for the
13 purpose of or incidental to research, teaching or chemical analysis activities and not for sale;

14 (iii) By a health care service contractor for dispensing to a subscriber or delivery to a health
15 care facility or outpatient clinic owned or operated by the health care service contractor or an af-
16 filiate of the health care service contractor;

17 (iv) By a centralized repackaging operation for distribution to subscribers of health care service
18 contractors or to pharmacies, health care facilities or outpatient clinics operated by or affiliated
19 with a health care service contractor; or

20 (v) By a health care facility for dispensing to a patient or other person.

21 (e) "Manufacturer" means a person that manufactures a prescription drug that is sold in this
22 state.

23 (f) "New prescription drug" has the meaning prescribed by the Department of Consumer and
24 Business Services by rule.

25 (g) "Patient assistance program" means a program that a manufacturer offers to the general
26 public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs
27 by using coupons or discount cards, receiving copayment assistance or by other means.

28 (h) "Prescription drug" means a drug that must:

29 (A) Under federal law, be labeled "Caution: Federal law prohibits dispensing without pre-
30 scription" prior to being dispensed or delivered; or

31 (B) Under any applicable federal or state law or regulation, be dispensed only by prescription
32 or restricted to use only by health care practitioners.

33 (i) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

34 (2) No later than March 15 of each year, a manufacturer shall report the information described
35 in subsection (3) of this section to the department regarding each prescription drug for which:

36 (a) The price was \$100 or more for a one-month supply or for a course of treatment lasting less
37 than one month; and

38 (b)(A) There was a [*net*] **cumulative** increase of 10 percent or more in the price of the pre-
39 scription drug [*described in paragraph (a) of this subsection*] over the course of the previous calendar
40 year[.]; **or**

41 **(B) During the previous calendar year, one or more increases in the price of the drug**
42 **resulted in the price being at least 10 percent higher than the price of the drug at any other**
43 **time during that calendar year.**

44 (3) For each prescription drug described in subsection (2) of this section, a manufacturer shall
45 report to the department, in the form and manner prescribed by the department:

- 1 (a) The name and price of the prescription drug and the [*net*] **cumulative** increase, expressed
2 as a percentage, in the price of the drug over the course of the previous calendar year;
- 3 (b) The length of time the prescription drug has been on the market;
- 4 (c) The factors that contributed to the price increase;
- 5 (d) The name of any generic version of the prescription drug available on the market;
- 6 (e) The research and development costs associated with the prescription drug that were paid
7 using public funds;
- 8 (f) The direct costs incurred by the manufacturer:
- 9 (A) To manufacture the prescription drug;
- 10 (B) To market the prescription drug;
- 11 (C) To distribute the prescription drug; and
- 12 (D) For ongoing safety and effectiveness research associated with the prescription drug;
- 13 (g) The total sales revenue for the prescription drug during the previous calendar year;
- 14 (h) The manufacturer's profit attributable to the prescription drug during the previous calendar
15 year;
- 16 (i) The introductory price of the prescription drug when it was approved for marketing by the
17 United States Food and Drug Administration and the [*net*] **cumulative** yearly increase, by calendar
18 year, in the price of the prescription drug during the previous five years;
- 19 (j) The 10 highest prices paid for the prescription drug during the previous calendar year in any
20 country other than the United States;
- 21 (k) Any other information that the manufacturer deems relevant to the price increase described
22 in subsection (2)(b) of this section; and
- 23 (L) The documentation necessary to support the information reported under this subsection.
- 24 (4) The department may use any prescription drug price information the department deems ap-
25 propriate to verify that manufacturers have properly reported price increases as required by sub-
26 sections (2) and (3) of this section.
- 27 (5) A manufacturer shall accompany the report provided under subsection (2) of this section with
28 the following information about each patient assistance program offered by the manufacturer to
29 consumers residing in this state for the prescription drugs described in subsection (2) of this section:
- 30 (a) The number of consumers who participated in the program;
- 31 (b) The total value of the coupons, discounts, copayment assistance or other reduction in costs
32 provided to consumers in this state who participated in the program;
- 33 (c) For each drug, the number of refills that qualify for the program, if applicable;
- 34 (d) If the program expires after a specified period of time, the period of time that the program
35 is available to each consumer; and
- 36 (e) The eligibility criteria for the program and how eligibility is verified for accuracy.
- 37 (6) No later than 30 days after a manufacturer introduces a new prescription drug for sale in
38 the United States at a price that exceeds the threshold established by the Centers for Medicare and
39 Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify
40 the department, in the form and manner prescribed by the department, of all the following informa-
41 tion:
- 42 (a) A description of the marketing used in the introduction of the new prescription drug;
- 43 (b) The methodology used to establish the price of the new prescription drug;
- 44 (c) Whether the United States Food and Drug Administration granted the new prescription drug
45 a breakthrough therapy designation or a priority review;

1 (d) If the new prescription drug was not developed by the manufacturer, the date of and the
2 price paid for acquisition of the new prescription drug by the manufacturer;

3 (e) The manufacturer's estimate of the average number of patients who will be prescribed the
4 new prescription drug each month; and

5 (f) The research and development costs associated with the new prescription drug that were paid
6 using public funds.

7 (7)(a) After receiving the report or information described in subsections (2), (3), (5) or (6) of this
8 section, the department may make a written request to the manufacturer for supporting documen-
9 tation or additional information concerning the report. The department shall prescribe by rule the
10 periods:

11 (A) Following the receipt of the report or information during which the department may request
12 additional information; and

13 (B) Following a request by the department for additional information during which a manufac-
14 turer may respond to the request.

15 (b) The department may extend the period prescribed under paragraph (a)(B) of this subsection,
16 as necessary, on a case-by-case basis.

17 **(8) The department may request information from any manufacturer regarding any**
18 **matter related to the administration of this section and ORS 646A.692. The manufacturer**
19 **must respond promptly and in the format requested by the department. The department may**
20 **require any response to be verified by an officer of the manufacturer.**

21 [(8)] **(9)** A manufacturer may be subject to a civil penalty, as provided in ORS 646A.692, for:

22 (a) Failing to submit timely reports or notices as required by this section;

23 (b) Failing to provide information required under this section;

24 (c) Failing to respond in a timely manner to a written request by the department for additional
25 information under subsection (7) of this section; or

26 (d) Providing inaccurate or incomplete information under this section.

27 [(9)] **(10)** Except as provided in subsection [(10)] **(11)** of this section, the department shall post
28 to its website all of the following information:

29 (a) A list of the prescription drugs reported under subsection (2) of this section and the man-
30 ufacturers of those prescription drugs;

31 (b) Information reported to the department under subsections (3) and (5) to (7) of this section;
32 and

33 (c) Written requests by the department for additional information under subsection (7) of this
34 section.

35 [(10)(a)] **(11)(a)** The department may not post to its website any information described in sub-
36 section [(9)] **(10)** of this section if:

37 (A) The information is conditionally exempt from disclosure under ORS 192.345 as a trade secret;
38 and

39 (B) The public interest does not require disclosure of the information.

40 (b) If the department withholds any information from public disclosure pursuant to this sub-
41 section, the department shall post to its website a report describing the nature of the information
42 and the department's basis for withholding the information from disclosure.

43 [(c)] **(12)** A person may petition the Attorney General, as provided in ORS 192.411, to review a
44 decision by the department to withhold information pursuant to [paragraph (a) of this subsection]
45 **subsection (11)(a) of this section.**

1 [(11)] (13)(a) The department shall make available to consumers, online and by telephone, a
2 process for consumers to notify the department about an increase in the price of a prescription drug.

3 (b) **The department may, upon request, disclose information about notifications received**
4 **from consumers about increases in prices of prescription drugs under this subsection, but**
5 **may not disclose personally identifiable information about the consumers, including**
6 **consumers' names, addresses, telephone numbers or electronic mail addresses.**

7 [(12)] (14) The department may adopt rules as necessary for carrying out the provisions of this
8 section, including but not limited to rules establishing fees to be paid by manufacturers to be used
9 solely to pay the costs of the department in carrying out the provisions of this section.

10 [(13)] (15) No later than December 15 of each year, the department shall compile and report the
11 information collected by the department under this section to the interim committees of the Legis-
12 lative Assembly related to health. The report shall include recommendations for legislative changes,
13 if any, to contain the cost of prescription drugs and reduce the impact of price increases on con-
14 sumers, the Department of Corrections, the Public Employees' Benefit Board, the Oregon Health
15 Authority, the Department of Human Services, the Oregon Educators Benefit Board and health in-
16 surance premiums in the commercial market.

17 **SECTION 4.** ORS 646A.692 is amended to read:

18 646A.692. (1) A manufacturer that fails to report or provide **timely** information as required by
19 ORS 646A.689 **or that files inaccurate or incomplete information under ORS 646A.689** may be
20 subject to a civil penalty as provided in this section.

21 (2) The Department of Consumer and Business Services shall adopt a schedule of penalties, not
22 to exceed \$10,000 per day of violation, based on the severity of each violation.

23 (3) The department shall impose civil penalties under this section as provided in ORS 183.745.

24 (4) The department may remit or mitigate civil penalties under this section upon terms and
25 conditions the department considers proper and consistent with the public health and safety.

26 (5) Civil penalties collected under this section shall be paid over to the State Treasurer and
27 deposited in the General Fund to be made available for general governmental expenses.

28 **SECTION 5.** Section 11, chapter 7, Oregon Laws 2018, is amended to read:

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

30 (2) The task force consists of [(18)] **23** members appointed as follows:

31 (a) The President of the Senate shall appoint:

32 (A) One member from the Senate who is a member of the majority party.

33 (B) One member from the Senate who is a member of the minority party.

34 (b) The Speaker of the House of Representatives shall appoint:

35 (A) One member from the House of Representatives who is a member of the majority party.

36 (B) One member from the House of Representatives who is a member of the minority party.

37 (c) The Governor shall appoint the following members:

38 (A) One representative from the Department of Consumer and Business Services;

39 (B) One representative from the Oregon Health Authority;

40 (C) One representative from the Oregon Health Policy Board; [and]

41 **(D) Two consumer advocates; and**

42 [(D)] **(E)** Individuals representing:

43 (i) Pharmaceutical manufacturers;

44 (ii) Insurance companies offering health insurance in this state;

45 (iii) Pharmacy benefit managers;

- 1 (iv) Prescription drug wholesalers;
- 2 (v) Consumers;
- 3 (vi) Independent pharmacies;
- 4 (vii) Large retail pharmacy chains;
- 5 (viii) Hospitals;
- 6 (ix) Biopharmaceutical companies based in Oregon;
- 7 **(x) Generic drug manufacturers;**
- 8 [(x)] **(xi)** Coordinated care organizations; [and]
- 9 [(xi)] **(xii)** Medical providers[.];
- 10 **(xiii) A large Oregon business that is self-insured; and**
- 11 **(xiv) A small Oregon business that offers health insurance coverage to the employees of**
- 12 **the business.**

13 (3) The task force shall [*develop a strategy to create transparency for drug prices across the entire*
14 *supply chain of pharmaceutical products, including but not limited to manufacturers, insurers, phar-*
15 *macy benefit managers, distributors, wholesalers and retail pharmacies] **explore transparency initi-**
16 **atives to expose the reasons for the financial burdens imposed on individuals, businesses and**
17 **state government by the costs of prescription drugs in order to identify fair methods by**
18 **which all of the entities in the pharmaceutical supply chain may reduce the burden.***

19 (4) A majority of the voting members of the task force constitutes a quorum for the transaction
20 of business.

21 (5) Official action by the task force requires the approval of a majority of the voting members
22 of the task force.

23 (6) The task force shall elect one of its members to serve as chairperson.

24 (7) If there is a vacancy for any cause, the appointing authority shall make an appointment to
25 become immediately effective.

26 (8) The task force shall meet at times and places specified by the call of the chairperson or of
27 a majority of the voting members of the task force.

28 (9) The task force may adopt rules necessary for the operation of the task force.

29 (10) The task force shall submit a report **of its findings under subsection (3) of this section**
30 **in the manner provided by ORS 192.245, and may include recommendations for legislation, to the**
31 **interim committees of the Legislative Assembly related to health no later than [November 1, 2018]**
32 **October 1, 2020.** The report must contain a cost-effective and enforceable solution that exposes the
33 cost factors that negatively impact prices paid by Oregonians for pharmaceutical products. **The task**
34 **force shall provide a final report to the committees no later than September 15, 2022.**

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

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

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

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

44 **SECTION 6.** Section 12, chapter 7, Oregon Laws 2018, is amended to read:

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

1 31, [2020] **2022**.

2 **SECTION 7. This 2020 Act being necessary for the immediate preservation of the public**
3 **peace, health and safety, an emergency is declared to exist, and this 2020 Act takes effect**
4 **on its passage.**

5
