

House Bill 2044

Introduced and printed pursuant to House Rule 12.00. Pre-session filed (at the request of Governor Kate Brown for Department of Consumer and Business Services)

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**.

Allows Department of Consumer and Business Services to access data in All Payer All Claims database by certifying data will only be used to carry out department's duties.

Protects from disclosure personally identifiable information about consumers who report to department price increases for prescriptions drugs. Requires pharmaceutical manufacturers to report to department information about patient assistance programs offered to consumers for certain new prescription drugs introduced for sale in United States.

Requires all insurers offering health benefit plans to annually report to department data about prescription drugs covered by plans.

A BILL FOR AN ACT

1
2 Relating to information reported to the Department of Consumer and Business Services; amending
3 ORS 442.373, 646A.689 and 743.025.

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

5 **SECTION 1.** ORS 442.373 is amended to read:

6 442.373. (1) The Oregon Health Authority shall establish and maintain a program that requires
7 reporting entities to report health care data for the following purposes:

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

10 (b) Identifying the demands for health care.

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

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

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

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

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

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

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

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

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

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

27 (B) Specifying a uniform coding system that reflects all health care utilization and costs for

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 health care services provided to Oregon residents in other states; and

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

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

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

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

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

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

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

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

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

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

28 (A) Displayed in a consumer friendly format;

29 (B) Easily accessible by consumers; and

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

31 (d) The authority shall apply for and receive donations, gifts and grants from any public or
32 private source to pay the cost of posting health care price information to its website in accordance
33 with this subsection. Moneys received shall be deposited to the Oregon Health Authority Fund.

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

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

42 (7) The authority shall facilitate a collaboration between the Department of Human Services, the
43 authority, the Department of Consumer and Business Services and interested stakeholders to de-
44 velop a comprehensive health care information system using the data reported under this section
45 and collected by the authority under ORS 442.370 and 442.400 to 442.463. The authority, in consul-

1 tation with interested stakeholders, shall:

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

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

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

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

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

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

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

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

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

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

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

27 **(b) Personally identifiable information disclosed to the department under paragraph (a)**
28 **of this subsection, including a consumer's name, address, telephone number or electronic**
29 **mail address, is confidential and not subject to further disclosure under ORS 192.311 to**
30 **192.478.**

31 **SECTION 2.** ORS 646A.689 is amended to read:

32 646A.689. (1) As used in this section:

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

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

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

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

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

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

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

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

45 (ii) By a health care practitioner or at the practitioner's authorization and supervision for the

1 purpose of or incidental to research, teaching or chemical analysis activities and not for sale;

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

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

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

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

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

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

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

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

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

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

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

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

26 (b) There was a net increase of 10 percent or more in the price of the prescription drug de-
27 scribed in paragraph (a) of this subsection over the course of the previous calendar year.

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

30 (a) The name and price of the prescription drug and the net increase, expressed as a percentage,
31 in the price of the drug over the course of the previous calendar year;

32 (b) The length of time the prescription drug has been on the market;

33 (c) The factors that contributed to the price increase;

34 (d) The name of any generic version of the prescription drug available on the market;

35 (e) The research and development costs associated with the prescription drug that were paid
36 using public funds;

37 (f) The direct costs incurred by the manufacturer:

38 (A) To manufacture the prescription drug;

39 (B) To market the prescription drug;

40 (C) To distribute the prescription drug; and

41 (D) For ongoing safety and effectiveness research associated with the prescription drug;

42 (g) The total sales revenue for the prescription drug during the previous calendar year;

43 (h) The manufacturer's profit attributable to the prescription drug during the previous calendar
44 year;

45 (i) The introductory price of the prescription drug when it was approved for marketing by the

1 United States Food and Drug Administration and the net yearly increase, by calendar year, in the
 2 price of the prescription drug during the previous five years;

3 (j) The 10 highest prices paid for the prescription drug during the previous calendar year in any
 4 country other than the United States;

5 (k) Any other information that the manufacturer deems relevant to the price increase described
 6 in subsection (2)(b) of this section; and

7 (L) The documentation necessary to support the information reported under this subsection.

8 (4) The department may use any prescription drug price information the department deems ap-
 9 propriate to verify that manufacturers have properly reported price increases as required by sub-
 10 sections (2) and (3) of this section.

11 (5) A manufacturer shall accompany the report **or notification** provided under [subsection (2)]
 12 **subsections (2) and (6)** of this section with the following information about each patient assistance
 13 program offered by the manufacturer to consumers residing in this state for the prescription drugs
 14 described in [subsection (2)] **subsections (2) and (6)** of this section:

15 (a) The number of consumers who participated in the program;

16 (b) The total value of the coupons, discounts, copayment assistance or other reduction in costs
 17 provided to consumers in this state who participated in the program;

18 (c) For each drug, the number of refills that qualify for the program, if applicable;

19 (d) If the program expires after a specified period of time, the period of time that the program
 20 is available to each consumer; and

21 (e) The eligibility criteria for the program and how eligibility is verified for accuracy.

22 (6) No later than 30 days after a manufacturer introduces a new prescription drug for sale in
 23 the United States at a price that exceeds the threshold established by the Centers for Medicare and
 24 Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify
 25 the department, in the form and manner prescribed by the department, of all the following informa-
 26 tion:

27 (a) A description of the marketing used in the introduction of the new prescription drug;

28 (b) The methodology used to establish the price of the new prescription drug;

29 (c) Whether the United States Food and Drug Administration granted the new prescription drug
 30 a breakthrough therapy designation or a priority review;

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

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

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

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

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

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

45 (b) The department may extend the period prescribed under paragraph (a)(B) of this subsection,

1 as necessary, on a case-by-case basis.

2 (8) A manufacturer may be subject to a civil penalty, as provided in ORS 646A.692, for:

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

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

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

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

8 (9) Except as provided in subsection (10) of this section, the department shall post to its website
9 all of the following information:

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

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

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

16 (10)(a) The department may not post to its website any information described in subsection (9)
17 of this section if:

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

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

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

24 (c) A person may petition the Attorney General, as provided in ORS 192.411, to review a deci-
25 sion by the department to withhold information pursuant to paragraph (a) of this subsection.

26 (11) The department shall make available to consumers, online and by telephone, a process for
27 consumers to notify the department about an increase in the price of a prescription drug. **Per-
28 sonally identifiable information about a consumer who notifies the department of an increase
29 in the price of a prescription drug under this section, including the consumer's name, ad-
30 dress, telephone number or electronic mail address, is confidential and not subject to further
31 disclosure under ORS 192.311 to 192.478.**

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

35 (13) No later than December 15 of each year, the department shall compile and report the in-
36 formation collected by the department under this section to the interim committees of the Legisla-
37 tive Assembly related to health. The report shall include recommendations for legislative changes,
38 if any, to contain the cost of prescription drugs and reduce the impact of price increases on con-
39 sumers, the Department of Corrections, the Public Employees' Benefit Board, the Oregon Health
40 Authority, the Department of Human Services, the Oregon Educators Benefit Board and health in-
41 surance premiums in the commercial market.

42 **SECTION 3.** ORS 743.025 is amended to read:

43 743.025. (1) An insurer shall *[include with any filing under ORS 743.018]* **annually report to the**
44 **Department of Consumer and Business Services, in the manner and format prescribed by the**
45 **department,** the following information regarding drugs reimbursed by the insurer under *[policies*

1 *or certificates]* **health benefit plans, as defined in ORS 743B.005, issued by the insurer** in this
2 state:

3 (a) The 25 most frequently prescribed drugs;

4 (b) The 25 most costly drugs as a portion of total annual spending;

5 (c) The 25 drugs that have caused the greatest increase in total plan spending from one year to
6 the next; and

7 (d) The impact of the costs of prescription drugs on premium rates.

8 (2) The department [*of Consumer and Business Services*] shall conduct a public hearing annually
9 on prescription drug prices, information reported to the department under ORS 646A.689 and infor-
10 mation described in subsection (1) of this section.

11 (3) The department shall regularly update the interim committees of the Legislative Assembly
12 related to health on the information described in subsection (1) of this section.

13 (4) Subsection (1) of this section applies to an insurer that issues policies or certificates of
14 health insurance for sale in this state that include a prescription drug benefit.

15
