

Requested by Representative MOORE-GREEN

**PROPOSED AMENDMENTS TO
HOUSE BILL 2044**

1 On page 3 of the printed bill, delete lines 31 through 45 and delete pages
2 4 and 5.

3 On page 6, delete lines 1 through 41 and insert:

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

5 “646A.689. (1) As used in this section:

6 “(a) ‘Drug’ has the meaning given that term in ORS 689.005.

7 “(b) ‘Health care facility’ has the meaning given that term in ORS 442.015.

8 “(c) ‘Health care service contractor’ has the meaning given that term in
9 ORS 750.005.

10 “(d)(A) ‘Manufacture’ means:

11 “(i) The production, preparation, propagation, compounding, conversion
12 or processing of a drug, either directly or indirectly by extraction from sub-
13 stances of natural origin or independently by means of chemical synthesis,
14 or by a combination of extraction and chemical synthesis; and

15 “(ii) The packaging or repackaging of a drug or labeling or relabeling of
16 a drug container.

17 “(B) ‘Manufacture’ does not include the preparation or compounding of
18 a drug by an individual for the individual’s own use or the preparation,
19 compounding, packaging or labeling of a drug:

20 “(i) By a health care practitioner incidental to administering or dispens-
21 ing a drug in the course of professional practice;

1 “(ii) By a health care practitioner or at the practitioner’s authorization
2 and supervision for the purpose of or incidental to research, teaching or
3 chemical analysis activities and not for sale;

4 “(iii) By a health care service contractor for dispensing to a subscriber
5 or delivery to a health care facility or outpatient clinic owned or operated
6 by the health care service contractor or an affiliate of the health care service
7 contractor;

8 “(iv) By a centralized repackaging operation for distribution to subscrib-
9 ers of health care service contractors or to pharmacies, health care facilities
10 or outpatient clinics operated by or affiliated with a health care service
11 contractor; or

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

13 “(e) ‘Manufacturer’ means a person that manufactures a prescription drug
14 that is sold in this state.

15 “(f) ‘New prescription drug’ has the meaning prescribed by the Depart-
16 ment of Consumer and Business Services by rule.

17 “(g) ‘Patient assistance program’ means a program that a manufacturer
18 offers to the general public in which a consumer may reduce the consumer’s
19 out-of-pocket costs for prescription drugs by using coupons or discount cards,
20 receiving copayment assistance or by other means.

21 “(h) ‘Prescription drug’ means a drug that must:

22 “(A) Under federal law, be labeled ‘Caution: Federal law prohibits dis-
23 pensing without prescription’ prior to being dispensed or delivered; or

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

26 “(i) ‘Price’ means the wholesale acquisition cost as defined in 42 U.S.C.
27 1395w-3a(c)(6)(B).

28 “(2) No later than March 15 of each year, a manufacturer shall report the
29 information described in subsection (3) of this section to the department re-
30 garding each prescription drug for which:

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

3 “(b) There was a net increase of 10 percent or more in the price of the
4 prescription drug described in paragraph (a) of this subsection over the
5 course of the previous calendar year.

6 “(3) For each prescription drug described in subsection (2) of this section,
7 a manufacturer shall report to the department, in the form and manner pre-
8 scribed by the department:

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

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

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

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

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

18 “(f) The direct costs incurred by the manufacturer:

19 “(A) To manufacture the prescription drug;

20 “(B) To market the prescription drug;

21 “(C) To distribute the prescription drug; and

22 “(D) For ongoing safety and effectiveness research associated with the
23 prescription drug;

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

26 “(h) The manufacturer’s profit attributable to the prescription drug dur-
27 ing the previous calendar year;

28 “(i) The introductory price of the prescription drug when it was approved
29 for marketing by the United States Food and Drug Administration and the
30 net yearly increase, by calendar year, in the price of the prescription drug

1 during the previous five years;

2 “(j) The 10 highest prices paid for the prescription drug during the pre-
3 vious calendar year in any country other than the United States;

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

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

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

11 “(5) A manufacturer shall accompany the report provided under sub-
12 section (2) of this section with the following information about each patient
13 assistance program offered by the manufacturer to consumers residing in this
14 state for the prescription drugs described in subsection (2) 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
17 other reduction in costs provided to consumers in this state who participated
18 in the program;

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

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

23 “(e) The eligibility criteria for the program and how eligibility is verified
24 for accuracy.

25 “(6) No later than 30 days after a manufacturer introduces a new pre-
26 scription drug for sale in the United States at a price that exceeds the
27 threshold established by the Centers for Medicare and Medicaid Services for
28 specialty drugs in the Medicare Part D program, the manufacturer shall no-
29 tify the department, in the form and manner prescribed by the department,
30 of all the following information:

1 “(a) A description of the marketing used in the introduction of the new
2 prescription drug;

3 “(b) The methodology used to establish the price of the new prescription
4 drug;

5 “(c) Whether the United States Food and Drug Administration granted
6 the new prescription drug a breakthrough therapy designation or a priority
7 review;

8 “(d) If the new prescription drug was not developed by the manufacturer,
9 the date of and the price paid for acquisition of the new prescription drug
10 by the manufacturer;

11 “(e) The manufacturer’s estimate of the average number of patients who
12 will be prescribed the new prescription drug each month; and

13 “(f) The research and development costs associated with the new pre-
14 scription drug that were paid using public funds.

15 “(7)(a) After receiving the report or information described in subsections
16 (2), (3), (5) or (6) of this section, the department may make a written request
17 to the manufacturer for supporting documentation or additional information
18 concerning the report. The department shall prescribe by rule the periods:

19 “(A) Following the receipt of the report or information during which the
20 department may request additional information; and

21 “(B) Following a request by the department for additional information
22 during which a manufacturer may respond to the request.

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

25 “(8) A manufacturer may be subject to a civil penalty, as provided in ORS
26 646A.692, for:

27 “(a) Failing to submit timely reports or notices as required by this sec-
28 tion;

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

30 “(c) Failing to respond in a timely manner to a written request by the

1 department for additional information under subsection (7) of this section;
2 or

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

4 “(9) [*Except as provided in subsection (10) of this section,*] The department
5 shall post to its website all of the following information:

6 “(a) A list of the prescription drugs reported under subsection (2) of this
7 section and the manufacturers of those prescription drugs;

8 “(b) Information reported to the department under subsections (3) and (5)
9 to (7) of this section; and

10 “(c) Written requests by the department for additional information under
11 subsection (7) of this section.

12 “[*(10)(a) The department may not post to its website any information de-*
13 *scribed in subsection (9) of this section if:*]

14 “[*(A) The information is conditionally exempt from disclosure under ORS*
15 *192.345 as a trade secret; and*]

16 “[*(B) The public interest does not require disclosure of the information.*]

17 “[*(b) If the department withholds any information from public disclosure*
18 *pursuant to this subsection, the department shall post to its website a report*
19 *describing the nature of the information and the department’s basis for with-*
20 *holding the information from disclosure.*]

21 “[*(c) A person may petition the Attorney General, as provided in ORS*
22 *192.411, to review a decision by the department to withhold information pur-*
23 *suant to paragraph (a) of this subsection.*]

24 “**(10) A manufacturer may limit the information reported pursuant**
25 **to subsections (3), (5) and (6) of this section to that which is in the**
26 **public domain or publicly available.**

27 “(11) The department shall make available to consumers, online and by
28 telephone, a process for consumers to notify the department about an in-
29 crease in the price of a prescription drug. **Personally identifiable infor-**
30 **mation about a consumer who notifies the department of an increase**

1 **in the price of a prescription drug under this section, including the**
2 **consumer's name, address, telephone number or electronic mail ad-**
3 **dress, is confidential and not subject to further disclosure under ORS**
4 **192.311 to 192.478.**

5 “(12) The department may adopt rules as necessary for carrying out the
6 provisions of this section, including but not limited to rules establishing fees
7 to be paid by manufacturers to be used solely to pay the costs of the de-
8 partment in carrying out the provisions of this section.

9 “(13) No later than December 15 of each year, the department shall com-
10 pile and report the information collected by the department under this sec-
11 tion to the interim committees of the Legislative Assembly related to health.
12 The report shall include recommendations for legislative changes, if any, to
13 contain the cost of prescription drugs and reduce the impact of price in-
14 creases on consumers, the Department of Corrections, the Public Employees’
15 Benefit Board, the Oregon Health Authority, the Department of Human
16 Services, the Oregon Educators Benefit Board and health insurance premi-
17 ums in the commercial market.”.

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