

B-Engrossed
House Bill 2376

Ordered by the House June 25
Including House Amendments dated April 7 and June 25

Sponsored by Representatives GREENLICK, TOMEI; Representatives BARTON, DEMBROW, C EDWARDS (Pre-session 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 certain manufacturers of pharmaceuticals and other medical products to report annually to Department of Justice any payment or other transfer of value that manufacturer provides to certain recipients of those pharmaceuticals and products.

Directs department to make reported information available on website.

Directs department to report to Legislative Assembly.

Makes violation of reporting requirement unlawful business practice.

Declares emergency, effective on passage.

A BILL FOR AN ACT

1
2 Relating to reporting of economic benefits provided by pharmaceutical manufacturers; creating new
3 provisions; amending ORS 646.608; and declaring an emergency.

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

5 **SECTION 1. (1) As used in this section:**

6 (a) **“Applicable group purchasing organization” means a group purchasing organization,**
7 **as defined by the Department of Justice by rule, that purchases or arranges for or negotiates**
8 **the purchase of a covered drug, device, biological product or medical supply.**

9 (b) **“Applicable manufacturer” means a manufacturer of a covered drug, device, biological**
10 **product or medical supply.**

11 (c) **“Clinical investigation” means any experiment involving one or more human subjects**
12 **in which a drug or device is administered, dispensed or used.**

13 (d) **“Covered device” means any device that is covered by Medicare or the medical as-**
14 **sistance program.**

15 (e) **“Covered drug, device, biological product or medical supply” means any drug, device,**
16 **biological product or medical supply that is covered by Medicare or the medical assistance**
17 **program.**

18 (f)(A) **“Covered recipient” means:**

19 (i) **A physician.**

20 (ii) **A physician medical practice.**

21 (iii) **A physician group practice.**

22 (iv) **A pharmacist licensed under ORS chapter 689.**

23 (v) **A health practitioner, as defined by the department by rule, who is licensed, certified,**
24 **registered or otherwise authorized by law to prescribe and administer drugs in this state.**

25 (vi) **A provider of continuing medical education.**

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 (B) "Covered recipient" does not include an employee of an applicable manufacturer that
2 is required to submit information under subsections (2) to (5) of this section.

3 (g) "Employee" has the meaning given that term in 42 U.S.C. 1395nn(h)(2).

4 (h) "Manufacturer of a covered drug, device, biological product or medical supply" means
5 any entity that is engaged in the production, preparation, propagation, compounding, con-
6 version, processing, marketing or distribution of a covered drug, device, biological product
7 or medical supply or any subsidiary of or entity affiliated with such entity.

8 (i) "Payment or other transfer of value":

9 (A) Means a transfer of anything of value.

10 (B) Includes, subject to subparagraph (C) of this paragraph, without limitation, any
11 compensation, gift, honorarium, speaking fee, consulting fee, travel, services, dividend, profit
12 distribution, stock or stock option grant, or ownership or investment interest.

13 (C) Does not mean:

14 (i) Any payment or other transfer of value provided by an applicable manufacturer to a
15 covered recipient if the aggregate amount transferred to, requested by or designated on be-
16 half of the covered recipient does not exceed \$500 during the calendar year, excluding items
17 described in sub-subparagraphs (ii) to (ix) of this subparagraph.

18 (ii) Product samples that are not intended to be sold and are intended for patient use.

19 (iii) Educational materials that directly benefit patients or are intended for patient use.

20 (iv) The loan of a covered device for a short-term trial period, not to exceed 90 days, to
21 permit evaluation of the covered device by the covered recipient.

22 (v) Items or services provided under a contractual warranty, including the replacement
23 of a covered device, for which the terms of the warranty are set forth in the purchase or
24 lease agreement for the covered device.

25 (vi) A transfer of anything of value to a covered recipient if the covered recipient is a
26 patient and is not acting in the professional capacity of a covered recipient.

27 (vii) Discounts, including rebates.

28 (viii) In-kind items used in the provision of charity care.

29 (ix) A dividend or other profit distribution from, or ownership or investment interest in,
30 a publicly traded security or mutual fund.

31 (j) "Physician" means:

32 (A) A doctor of medicine or osteopathy who is legally authorized to practice medicine and
33 surgery in the state where the person practices medicine and surgery.

34 (B) A doctor of dental surgery or dental medicine who is legally authorized to practice
35 dentistry in the state where the person practices dentistry.

36 (C) A doctor of podiatric medicine who is legally authorized to practice podiatric medicine
37 in the state where the person practices podiatric medicine.

38 (D) A doctor of naturopathic medicine who is legally authorized to practice naturopathic
39 medicine in the state where the person practices naturopathic medicine.

40 (2) Except as provided in subsection (10) of this section, on or before the 90th day of each
41 calendar year, any applicable manufacturer that provides a payment or other transfer of
42 value to a covered recipient, or to an entity or individual at the request of or designated on
43 behalf of a covered recipient, shall submit to the department, in such electronic form as the
44 department requires, the following information with respect to the preceding calendar year:

45 (a) The name of the covered recipient.

1 **(b) The business address of the covered recipient and, in the case of a covered recipient**
2 **who is a physician, the specialty and Medicare billing number of the covered recipient.**

3 **(c) The value of the payment or other transfer of value.**

4 **(d) The dates on which the payment or other transfer of value was provided to the cov-**
5 **ered recipient.**

6 **(e) A description of the form of the payment or other transfer of value, indicated as:**

7 **(A) Cash or a cash equivalent;**

8 **(B) In-kind items or services;**

9 **(C) Stock, a stock option or any other ownership interest, dividend, profit or other return**
10 **on investment; or**

11 **(D) Any other form of payment or other transfer of value as defined by the department**
12 **by rule.**

13 **(f) A description of the nature of the payment or other transfer of value, indicated, as**
14 **appropriate for all that apply, as:**

15 **(A) Consulting fees;**

16 **(B) Compensation for services other than consulting;**

17 **(C) Honoraria;**

18 **(D) Gifts;**

19 **(E) Entertainment;**

20 **(F) Food;**

21 **(G) Travel;**

22 **(H) Education;**

23 **(I) Research;**

24 **(J) Charitable contributions;**

25 **(K) Royalties or licenses;**

26 **(L) Current or prospective ownership or investment interest;**

27 **(M) Compensation for serving as faculty or as a speaker for a continuing medical edu-**
28 **cation program;**

29 **(N) Grants; or**

30 **(O) Any other payment or other transfer of value as defined by the department by rule.**

31 **(g) If the payment or other transfer of value is related to marketing, education or re-**
32 **search specific to a covered drug, device, biological product or medical supply, the name of**
33 **that covered drug, device, biological product or medical supply.**

34 **(h) Any other categories of information regarding the payment or other transfer of value**
35 **that the department determines appropriate.**

36 **(3) Information submitted by an applicable manufacturer under subsection (2) of this**
37 **section must include the aggregate amount of all payments or other transfers of value pro-**
38 **vided during the preceding calendar year by the applicable manufacturer to covered recipi-**
39 **ents and to entities or individuals at the request of or designated on behalf of a covered**
40 **recipient.**

41 **(4) If an applicable manufacturer provides a payment or other transfer of value to an**
42 **entity or individual at the request of or designated on behalf of a covered recipient, the ap-**
43 **licable manufacturer shall disclose that payment or other transfer of value under the name**
44 **of the covered recipient.**

45 **(5) In addition to the requirements of subsection (2) of this section, on or before the 90th**

1 day of each calendar year, any applicable manufacturer or applicable group purchasing or-
2 ganization shall submit to the department, in such electronic form as the department re-
3 quires, the following information regarding any ownership or investment interest in the
4 applicable manufacturer or applicable group purchasing organization during the preceding
5 calendar year, other than an ownership or investment interest in a publicly traded security
6 or mutual fund held by a physician or an immediate family member of the physician:

7 (a) The dollar amount invested by each covered recipient holding such an ownership or
8 investment interest.

9 (b) The value and terms of each such ownership or investment interest.

10 (c) Any payment or other transfer of value provided to a covered recipient, including the
11 information described in subsection (2)(a) to (g) of this section.

12 (d) Any other information regarding the ownership or investment interest the depart-
13 ment determines appropriate.

14 (6) The department shall establish procedures:

15 (a) For applicable manufacturers and applicable group purchasing organizations to sub-
16 mit information to the department under subsections (2) to (5) of this section; and

17 (b) For the department to make the information submitted available to the public.

18 (7) The department shall make available the information submitted under subsections (2)
19 to (5) of this section with respect to the preceding calendar year through a website that:

20 (a) Is searchable and is in a format that is clear and understandable;

21 (b) Contains the name of the applicable manufacturer or applicable group purchasing
22 organization, the name of the covered recipient, the business address of the covered recipi-
23 ent, the specialty of the covered recipient, the value of the payment or other transfer of
24 value, the date on which the payment or other transfer of value was provided to the covered
25 recipient, the form of the payment or other transfer of value indicated under subsection
26 (2)(e) of this section, the nature of the payment or other transfer of value indicated under
27 subsection (2)(f) of this section and the name of the covered drug, device, biological product
28 or medical supply;

29 (c) Contains information that is able to be easily aggregated and downloaded;

30 (d) Contains a description of any enforcement actions taken to carry out this section
31 during the preceding calendar year;

32 (e) Contains background information on the relationships of the pharmaceutical industry
33 and covered recipients;

34 (f) Separates the information submitted with respect to a payment or other transfer of
35 value described in subsection (10) of this section, from the information submitted under
36 subsections (2) to (5) of this section and designates the separately listed information as
37 funding for clinical research;

38 (g) Contains any other information that the department deems to be helpful to the av-
39 erage consumer; and

40 (h) Provides the covered recipient an opportunity to submit corrections to the informa-
41 tion to be made available to the public with respect to the covered recipient.

42 (8) In establishing the procedures under subsections (6) and (7) of this section, the de-
43 partment shall consult with the affected industry, consumers, consumer advocates and other
44 interested parties in order to ensure that the information made available to the public under
45 subsections (6) and (7) of this section is presented in the appropriate overall context.

1 **(9) No later than April 1 of each year, the department shall submit to the Legislative**
2 **Assembly or to the interim legislative committees related to health a report that includes**
3 **the following:**

4 **(a) The information submitted under subsections (2) to (5) of this section during the**
5 **preceding calendar year, aggregated for each applicable manufacturer and applicable group**
6 **purchasing organization that submitted the information.**

7 **(b) A description of any enforcement actions taken to carry out this section during the**
8 **preceding calendar year.**

9 **(10) In the case of a payment or other transfer of value made to a covered recipient by**
10 **an applicable manufacturer pursuant to a product development agreement for services fur-**
11 **nished in connection with the development of a new drug, device, biological product or med-**
12 **ical supply, or by an applicable manufacturer in connection with a clinical investigation, the**
13 **applicable manufacturer may report the value of such payment or other transfer of value in**
14 **the first reporting period under subsections (2) to (5) of this section after the earlier of the**
15 **following:**

16 **(a) The date of the approval or clearance of the covered drug, device, biological product**
17 **or medical supply by the United States Food and Drug Administration.**

18 **(b) Two calendar years after the date the payment or other transfer of value was made.**

19 **(11) The department may adopt rules to carry out this section, including rules defining**
20 **terms not otherwise defined in subsection (1) of this section.**

21 **SECTION 2.** ORS 646.608, as amended by section 8, chapter 19, Oregon Laws 2008, and section
22 5, chapter 31, Oregon Laws 2008, is amended to read:

23 646.608. (1) A person engages in an unlawful practice when in the course of the person's busi-
24 ness, vocation or occupation the person does any of the following:

25 (a) Passes off real estate, goods or services as those of another.

26 (b) Causes likelihood of confusion or of misunderstanding as to the source, sponsorship, ap-
27 proval, or certification of real estate, goods or services.

28 (c) Causes likelihood of confusion or of misunderstanding as to affiliation, connection, or asso-
29 ciation with, or certification by, another.

30 (d) Uses deceptive representations or designations of geographic origin in connection with real
31 estate, goods or services.

32 (e) Represents that real estate, goods or services have sponsorship, approval, characteristics,
33 ingredients, uses, benefits, quantities or qualities that they do not have or that a person has a
34 sponsorship, approval, status, qualification, affiliation, or connection that the person does not have.

35 (f) Represents that real estate or goods are original or new if they are deteriorated, altered,
36 reconditioned, reclaimed, used or secondhand.

37 (g) Represents that real estate, goods or services are of a particular standard, quality, or grade,
38 or that real estate or goods are of a particular style or model, if they are of another.

39 (h) Disparages the real estate, goods, services, property or business of a customer or another
40 by false or misleading representations of fact.

41 (i) Advertises real estate, goods or services with intent not to provide them as advertised, or
42 with intent not to supply reasonably expectable public demand, unless the advertisement discloses
43 a limitation of quantity.

44 (j) Makes false or misleading representations of fact concerning the reasons for, existence of,
45 or amounts of price reductions.

1 (k) Makes false or misleading representations concerning credit availability or the nature of the
2 transaction or obligation incurred.

3 (L) Makes false or misleading representations relating to commissions or other compensation to
4 be paid in exchange for permitting real estate, goods or services to be used for model or demon-
5 stration purposes or in exchange for submitting names of potential customers.

6 (m) Performs service on or dismantles any goods or real estate when not authorized by the
7 owner or apparent owner thereof.

8 (n) Solicits potential customers by telephone or door to door as a seller unless the person pro-
9 vides the information required under ORS 646.611.

10 (o) In a sale, rental or other disposition of real estate, goods or services, gives or offers to give
11 a rebate or discount or otherwise pays or offers to pay value to the customer in consideration of
12 the customer giving to the person the names of prospective purchasers, lessees, or borrowers, or
13 otherwise aiding the person in making a sale, lease, or loan to another person, if earning the rebate,
14 discount or other value is contingent upon occurrence of an event subsequent to the time the cus-
15 tomer enters into the transaction.

16 (p) Makes any false or misleading statement about a prize, contest or promotion used to publi-
17 cize a product, business or service.

18 (q) Promises to deliver real estate, goods or services within a certain period of time with intent
19 not to deliver them as promised.

20 (r) Organizes or induces or attempts to induce membership in a pyramid club.

21 (s) Makes false or misleading representations of fact concerning the offering price of, or the
22 person's cost for real estate, goods or services.

23 (t) Concurrent with tender or delivery of any real estate, goods or services fails to disclose any
24 known material defect or material nonconformity.

25 (u) Engages in any other unfair or deceptive conduct in trade or commerce.

26 (v) Violates any of the provisions relating to auction sales, auctioneers or auction marts under
27 ORS 698.640, whether in a commercial or noncommercial situation.

28 (w) Manufactures mercury fever thermometers.

29 (x) Sells or supplies mercury fever thermometers unless the thermometer is required by federal
30 law, or is:

31 (A) Prescribed by a person licensed under ORS chapter 677; and

32 (B) Supplied with instructions on the careful handling of the thermometer to avoid breakage and
33 on the proper cleanup of mercury should breakage occur.

34 (y) Sells a thermostat that contains mercury unless the thermostat is labeled in a manner to
35 inform the purchaser that mercury is present in the thermostat and that the thermostat may not be
36 disposed of until the mercury is removed, reused, recycled or otherwise managed to ensure that the
37 mercury does not become part of the solid waste stream or wastewater. For purposes of this para-
38 graph, "thermostat" means a device commonly used to sense and, through electrical communication
39 with heating, cooling or ventilation equipment, control room temperature.

40 (z) Sells or offers for sale a motor vehicle manufactured after January 1, 2006, that contains
41 mercury light switches.

42 (aa) Violates the provisions of ORS 803.375, 803.385 or 815.410 to 815.430.

43 (bb) Violates ORS 646A.070 (1).

44 (cc) Violates any requirement of ORS 646A.030 to 646A.040.

45 (dd) Violates the provisions of ORS 128.801 to 128.898.

- 1 (ee) Violates ORS 646.883 or 646.885.
- 2 (ff) Violates any provision of ORS 646A.020.
- 3 (gg) Violates ORS 646.569.
- 4 (hh) Violates the provisions of ORS 646A.142.
- 5 (ii) Violates ORS 646A.360.
- 6 (jj) Violates ORS 646.553 or 646.557 or any rule adopted pursuant thereto.
- 7 (kk) Violates ORS 646.563.
- 8 (LL) Violates ORS 759.690 or any rule adopted pursuant thereto.
- 9 (mm) Violates the provisions of ORS 759.705, 759.710 and 759.720 or any rule adopted pursuant
- 10 thereto.
- 11 (nn) Violates ORS 646A.210 or 646A.214.
- 12 (oo) Violates any provision of ORS 646A.124 to 646A.134.
- 13 (pp) Violates ORS 646A.254.
- 14 (qq) Violates ORS 646A.095.
- 15 (rr) Violates ORS 822.046.
- 16 (ss) Violates ORS 128.001.
- 17 (tt) Violates ORS 646.649 (2) to (4).
- 18 (uu) Violates ORS 646A.090 (2) to (4).
- 19 (vv) Violates ORS 87.686.
- 20 (ww) Violates ORS 646.651.
- 21 (xx) Violates ORS 646A.362.
- 22 (yy) Violates ORS 646A.052 or any rule adopted under ORS 646A.052 or 646A.054.
- 23 (zz) Violates ORS 180.440 (1).
- 24 (aaa) Commits the offense of acting as a vehicle dealer without a certificate under ORS 822.005.
- 25 (bbb) Violates ORS 87.007 (2) or (3).
- 26 (ccc) Violates ORS 92.405 (1), (2) or (3).
- 27 (ddd) Engages in an unlawful practice under ORS 646.648.
- 28 (eee) Violates ORS 646A.365.
- 29 (fff) Violates ORS 98.854 or 98.858 or a rule adopted under ORS 98.864.
- 30 (ggg) Sells a gift card in violation of ORS 646A.276.
- 31 (hhh) Violates ORS 646A.102, 646A.106 or 646A.108.
- 32 (iii) Violates ORS 646A.430 to 646A.450.
- 33 (jjj) Violates a provision of sections 2 to 6, chapter 19, Oregon Laws 2008.
- 34 (kkk) Violates section 2, chapter 31, Oregon Laws 2008, 30 or more days after a recall notice,
- 35 warning or declaration described in section 2, chapter 31, Oregon Laws 2008, is issued for the chil-
- 36 dren's product, as defined in section 1, chapter 31, Oregon Laws 2008, that is the subject of the vi-
- 37 olation.
- 38 **(LLL) Violates section 1 of this 2009 Act.**
- 39 (2) A representation under subsection (1) of this section or ORS 646.607 may be any manifesta-
- 40 tion of any assertion by words or conduct, including, but not limited to, a failure to disclose a fact.
- 41 (3) In order to prevail in an action or suit under ORS 646.605 to 646.652, a prosecuting attorney
- 42 need not prove competition between the parties or actual confusion or misunderstanding.
- 43 (4) An action or suit may not be brought under subsection (1)(u) of this section unless the At-
- 44 torney General has first established a rule in accordance with the provisions of ORS chapter 183
- 45 declaring the conduct to be unfair or deceptive in trade or commerce.

1 (5) Notwithstanding any other provision of ORS 646.605 to 646.652, if an action or suit is brought
2 under subsection (1)(zz) of this section by a person other than a prosecuting attorney, relief is lim-
3 ited to an injunction and the prevailing party may be awarded reasonable attorney fees.

4 (6) **If a court finds that section 1 of this 2009 Act is preempted by a federal law, a vio-**
5 **lation of that federal law shall be an unlawful practice under this section.**

6 **SECTION 3. Section 1 of this 2009 Act becomes operative on November 1, 2009.**

7 **SECTION 4. The Department of Justice may take any action before the operative date**
8 **of section 1 of this 2009 Act that is necessary for the department to carry out, on or after**
9 **the operative date of section 1 of this 2009 Act, the duties and functions of the department**
10 **under section 1 of this 2009 Act.**

11 **SECTION 5. This 2009 Act being necessary for the immediate preservation of the public**
12 **peace, health and safety, an emergency is declared to exist, and this 2009 Act takes effect**
13 **on its passage.**

14