A-Engrossed
House Bill 2376

Ordered by the House April 7
Including House Amendments dated April 7

Sponsored by Representatives GREENLICK, TOMEI (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 pharmaceutical manufacturer to annually report to Department of Justice gifts, fees, payments, subsidies or other economic benefits manufacturer provides to purchasers, providers or dispensers of manufacturer's prescription drugs in this state.*]

[*Authorizes imposition of civil penalty, not to exceed $10,000 for each violation, for failure to report required information.*]

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 [*and Governor*].

[*Establishes Pharmaceutical Marketing Reporting Fund. Appropriates moneys in fund to department for administration of Act.*]

Makes violation of reporting requirement unlawful business practice.

Declares emergency, effective on passage.

A BILL FOR AN ACT

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

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

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

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

(b) "Applicable manufacturer" means a manufacturer of a covered drug, device, biological product or medical supply.

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

(d) "Covered device" means any device that is covered by Medicare or the medical assistance program.

(e) "Covered drug, device, biological product or medical supply" means any drug, device, biological product or medical supply that is covered by Medicare or the medical assistance program.

(f)(A) "Covered recipient" means:

(i) A physician.

(ii) A physician medical practice.

(iii) A physician group practice.

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.

(iv) A pharmacist licensed under ORS chapter 689.

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

(vi) A provider of continuing medical education.

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

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

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

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

(A) Means a transfer of anything of value.

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

(C) Does not mean:

(i) Any payment or other transfer of value provided by an applicable manufacturer to a covered recipient if the aggregate amount transferred to, requested by or designated on behalf of the covered recipient does not exceed $100 during the calendar year, excluding items described in sub-subparagraphs (ii) to (ix) of this subparagraph.

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

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

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

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

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

(vii) Discounts, including rebates.

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

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

(j) "Physician" means:

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

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

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

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

(2) Except as provided in subsection (10) of this section, on or before the 90th day of each calendar year, any applicable manufacturer that provides a payment or other transfer of

value to a covered recipient, or to an entity or individual at the request of or designated on behalf of a covered recipient, shall submit to the department, in such electronic form as the department requires, the following information with respect to the preceding calendar year:

(a) The name of the covered recipient.

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

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

(d) The dates on which the payment or other transfer of value was provided to the covered recipient.

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

(A) Cash or a cash equivalent;

(B) In-kind items or services;

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

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

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

(A) Consulting fees;

(B) Compensation for services other than consulting;

(C) Honoraria;

(D) Gifts;

(E) Entertainment;

(F) Food;

(G) Travel;

(H) Education;

(I) Research;

(J) Charitable contributions;

(K) Royalties or licenses;

(L) Current or prospective ownership or investment interest;

(M) Compensation for serving as faculty or as a speaker for a continuing medical education program;

(N) Grants; or

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

(g) If the payment or other transfer of value is related to marketing, education or research specific to a covered drug, device, biological product or medical supply, the name of that covered drug, device, biological product or medical supply.

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

(3) Information submitted by an applicable manufacturer under subsection (2) of this section must include the aggregate amount of all payments or other transfers of value provided during the preceding calendar year by the applicable manufacturer to covered recipients and to entities or individuals at the request of or designated on behalf of a covered recipient.

(4) If an applicable manufacturer provides a payment or other transfer of value to an

entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer shall disclose that payment or other transfer of value under the name of the covered recipient.

(5) In addition to the requirements of subsection (2) of this section, on or before the 90th day of each calendar year, any applicable manufacturer or applicable group purchasing organization shall submit to the department, in such electronic form as the department requires, the following information regarding any ownership or investment interest in the applicable manufacturer or applicable group purchasing organization during the preceding calendar year, other than an ownership or investment interest in a publicly traded security or mutual fund held by a physician or an immediate family member of the physician:

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

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

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

(d) Any other information regarding the ownership or investment interest the department determines appropriate.

(6) The department shall establish procedures:

(a) For applicable manufacturers and applicable group purchasing organizations to submit information to the department under subsections (2) to (5) of this section; and

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

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

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

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

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

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

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

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

(g) Contains any other information that the department deems to be helpful to the average consumer; and

(h) Provides the covered recipient an opportunity to submit corrections to the information to be made available to the public with respect to the covered recipient.

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

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

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

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

(10) In the case of a payment or other transfer of value made to a covered recipient by an applicable manufacturer pursuant to a product development agreement for services furnished in connection with the development of a new drug, device, biological product or medical supply, or by an applicable manufacturer in connection with a clinical investigation, the applicable manufacturer may report the value of such payment or other transfer of value in the first reporting period under subsections (2) to (5) of this section after the earlier of the following:

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

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

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

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

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

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

(b) Causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of real estate, goods or services.

(c) Causes likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another.

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

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

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

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

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

(i) Advertises real estate, goods or services with intent not to provide them as advertised, or

with intent not to supply reasonably expectable public demand, unless the advertisement discloses a limitation of quantity.

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

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

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

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

(n) Solicits potential customers by telephone or door to door as a seller unless the person provides the information required under ORS 646.611.

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

(p) Makes any false or misleading statement about a prize, contest or promotion used to publicize a product, business or service.

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

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

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

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

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

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

(w) Manufactures mercury fever thermometers.

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

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

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

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

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

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

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

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

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

(ee) Violates ORS 646.883 or 646.885.

(ff) Violates any provision of ORS 646A.020.

(gg) Violates ORS 646.569.

(hh) Violates the provisions of ORS 646A.142.

(ii) Violates ORS 646A.360.

(jj) Violates ORS 646.553 or 646.557 or any rule adopted pursuant thereto.

(kk) Violates ORS 646.563.

(LL) Violates ORS 759.690 or any rule adopted pursuant thereto.

(mm) Violates the provisions of ORS 759.705, 759.710 and 759.720 or any rule adopted pursuant thereto.

(nn) Violates ORS 646A.210 or 646A.214.

(oo) Violates any provision of ORS 646A.124 to 646A.134.

(pp) Violates ORS 646A.254.

(qq) Violates ORS 646A.095.

(rr) Violates ORS 822.046.

(ss) Violates ORS 128.001.

(tt) Violates ORS 646.649 (2) to (4).

(uu) Violates ORS 646A.090 (2) to (4).

(vv) Violates ORS 87.686.

(ww) Violates ORS 646.651.

(xx) Violates ORS 646A.362.

(yy) Violates ORS 646A.052 or any rule adopted under ORS 646A.052 or 646A.054.

(zz) Violates ORS 180.440 (1).

(aaa) Commits the offense of acting as a vehicle dealer without a certificate under ORS 822.005.

(bbb) Violates ORS 87.007 (2) or (3).

(ccc) Violates ORS 92.405 (1), (2) or (3).

(ddd) Engages in an unlawful practice under ORS 646.648.

(eee) Violates ORS 646A.365.

(fff) Violates ORS 98.854 or 98.858 or a rule adopted under ORS 98.864.

(ggg) Sells a gift card in violation of ORS 646A.276.

(hhh) Violates ORS 646A.102, 646A.106 or 646A.108.

(iii) Violates ORS 646A.430 to 646A.450.

(jjj) Violates a provision of sections 2 to 6, chapter 19, Oregon Laws 2008.

(kkk) Violates section 2, chapter 31, Oregon Laws 2008, 30 or more days after a recall notice, warning or declaration described in section 2, chapter 31, Oregon Laws 2008, is issued for the children's product, as defined in section 1, chapter 31, Oregon Laws 2008, that is the subject of the violation.

(LLL) Violates section 1 of this 2009 Act.

(2) A representation under subsection (1) of this section or ORS 646.607 may be any manifestation of any assertion by words or conduct, including, but not limited to, a failure to disclose a fact.

(3) In order to prevail in an action or suit under ORS 646.605 to 646.652, a prosecuting attorney

need not prove competition between the parties or actual confusion or misunderstanding.

(4) An action or suit may not be brought under subsection (1)(u) of this section unless the Attorney General has first established a rule in accordance with the provisions of ORS chapter 183 declaring the conduct to be unfair or deceptive in trade or commerce.

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

(6) If a court finds that section 1 of this 2009 Act is preempted by a federal law, a violation of that federal law shall be an unlawful practice under this section.

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

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

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