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H.P. 881 House of Representatives, March 31, 2009

An Act To Restrict Gifts to Health Care Practitioners from Pharmaceutical and Medical Device Manufacturers

Reference to the Committee on Health and Human Services suggested and ordered printed.

Millicent M. MacFarland

MILLICENT M. MacFARLAND
Clerk

Presented by Representative TREAT of Hallowell.
Cosponsored by Representatives: MARTIN of Eagle Lake, MILLER of Somerville, PERCY of Phippsburg, PERRY of Calais, STUCKEY of Portland, WEBSTER of Freeport, Senator: SIMPSON of Androscoggin.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §2697, sub-§1, as enacted by PL 1999, c. 786, Pt. A, §3, is amended to read:

1. Definitions. As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 207.20 (1999).

A-1. "Health care practitioner" means a person who is licensed in the State to provide health care and prescribe prescription drugs, including an organization consisting of persons licensed in the State to provide health care and prescribe prescription drugs and an employee, agent or contractor of a person licensed to provide health care in the State and to prescribe prescription drugs.

B. "Manufacturer" means a ~~manufacturer of~~ person who manufactures, prepares, propagates, compounds, processes, packages, repackages, distributes or labels prescription drugs and includes a subsidiary or affiliate of a manufacturer.

C. "Medical device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory that is recognized in the official United States Pharmacopeia and National Formulary or accessory issued by the United States Pharmacopeial Convention and is intended:

(1) For use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease in a human being or animal; or

(2) To affect the structure or any function of the body of a human being or animal and does not achieve its primary intended purpose by being metabolized or through chemical action within or on the body of the human being or animal.

D. "Prescription drugs" means pharmaceuticals, biologics or medical devices.

E. "State health care program" means a health care program for which the State purchases prescription drugs, including but not limited to Medicaid.

Sec. 2. 22 MRSA §2698-A, as amended by PL 2005, c. 286, §§1 and 2, is further amended to read:

§2698-A. Marketing costs

A manufacturer or labeler of prescription drugs dispensed in this State that employs, directs or utilizes marketing representatives in this State shall report marketing costs for prescription drugs in this State as provided in this section.

1. Purposes. Marketing costs for prescription drugs in this State must be reported to the department for the purposes of assisting this State in its role as a purchaser of

prescription drugs and an administrator of prescription drug programs, enabling this State to determine the scope of prescription drug marketing costs and their effect on the cost, utilization and delivery of health care services and furthering the role of this State as guardian of the public interest.

2. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

~~A. "Labeler" has the same meaning as provided in section 2697, subsection 1.~~

~~B. "Manufacturer" has the same meaning as provided in section 2697, subsection 1.~~

C. "Marketing" means ~~advertising and promotional activities, including, but not limited to, the activities described in subsection 4.~~ an activity undertaken or materials or products made available to a health care practitioner or to the general public related to the transfer of prescription drugs from the manufacturer or seller to the consumer or buyer, including:

(1) Advertising, publicizing, promoting or selling through any media or method including electronic and Internet means;

(2) A detailing visit or a personal appearance for the purpose of influencing the market share or the prescribing patterns of a health care practitioner;

(3) Activities undertaken to evaluate or improve the effectiveness of a sales force; or

(4) A brochure, media advertisement or announcement, poster or free sample of a prescription drug.

3. Manner of reporting. Beginning in 2007, by July 1st each year, a manufacturer or labeler of prescription drugs that directly or indirectly distributes prescription drugs for dispensation to residents of this State or participates in a state health care program shall file a report with the department in the form and manner provided by the department. The department shall require an Internet-based form that allows the information required by this subsection to be searched online by a consumer. The report must be accompanied by payment of a fee, as set by the department in rule, to support the work of the department under this section.

4. Content of annual report by manufacturer or labeler. The annual report filed under subsection 3 must include the following information for each calendar year, beginning with calendar year 2006, as it pertains to marketing ~~activities~~ conducted within this State in a form that provides the value, nature, purpose and recipient of the expense:

A. All expenses, whether direct or indirect, associated with ~~advertising, marketing and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail and telephone communications as they pertain to residents of this State, except for expenses associated with advertising purchased for a regional or national market that includes advertising within the State;~~:

(1) Advertising, marketing and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail and telephone communications as they pertain to residents of this State, including a reasonable

estimate of the value of expenses associated with advertising purchased for a regional or national market that includes advertising within the State;

(2) The indirect promotion of prescription drugs, including:

(a) Support of an independent or continuing medical education program including payment to a medical education company;

(b) Design, printing and production costs of patient education and disease management materials distributed within the State;

(c) Consulting fees and expenses, participation in a speakers' bureau and honoraria or other payment for time while speaking at or attending a meeting, lecture or conference;

(d) Writing an article or publication;

(e) A charitable grant, given either directly or through an earmark, even if unrestricted;

(f) A product sample; and

(g) A market research survey or other activity undertaken in support of developing advertising or market strategies; and

(3) Information reported under section 2698-C, subsection 4;

B. With regard to all persons and entities licensed to provide health care in this State, including health care professionals and persons employed by them in this State, carriers licensed under Title 24 or Title 24-A, health plans and benefits managers, pharmacies, hospitals, nursing facilities, clinics and other entities licensed to provide health care under this Title, the following information:

(1) All expenses associated with educational or informational programs, materials and seminars and remuneration for promoting or participating in educational or informational sessions, regardless of whether the manufacturer or labeler provides the educational or informational sessions or materials;

(2) All expenses associated with food, entertainment, gifts received in a calendar year that are valued in the aggregate at more than $25 and anything provided to a health care professional for less than market value;

(3) All expenses associated with trips and travel; and

(4) All expenses associated with product samples~~, except for samples that will be distributed free of charge to patients~~; and

C. The aggregate cost of all employees or contractors of the manufacturer or labeler who directly or indirectly engage in the advertising or promotional activities listed in paragraphs A and B, including all forms of payment to those employees. The cost reported under this paragraph must reflect only that portion of payment to employees or contractors that pertains to activities within this State or to recipients of the advertising or promotional activities who are residents of or are employed in this State.

A person subject to this subsection shall report to the department the name and address of the individual responsible for the person's compliance with this subsection or, if this information has already been reported to the department, a change to the name or address of the individual responsible for the person's compliance with this subsection. The individual named in this paragraph as responsible for the person's compliance with this subsection shall certify that the report required under this section is complete and accurate.

5. Exceptions. The following marketing expenses are not subject to the requirements of this section:

A. Expenses of $25 or less;

B. Reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy or treatment; and

C. Scholarships and reimbursement of expenses for attending a significant educational, scientific, medical or policy-making conference or seminar of a national, regional or specialty medical or other professional association if the recipient of the scholarship is chosen by the association sponsoring the conference or seminar.

6. Department reports. ~~Beginning in 2007, by~~ By November 30th each year, the department shall provide an annual report~~, providing information in aggregate form,~~ on prescription drug marketing expenses to the Legislature and the Attorney General. By January 1, 2008 and every 2 years after that date, the department shall provide a report to the Legislature and the Attorney General~~, providing information in aggregate form,~~ containing the raw data and an analysis of the data submitted to the department under subsection 4, including ~~the scope of prescription drug marketing activities and expenses and their effect on the cost, utilization and delivery of health care services and any recommendations with regard to marketing activities of prescription drug manufacturers and labelers.~~:

A. Information disclosed under section 2698-C, subsection 4, which must be:

(1) Presented on a per health care practitioner basis;

(2) Organized by selected types of health care practitioner as prioritized each year by the department; and

(3) Analyzed to determine whether prescribing patterns by the health care practitioners of prescription drugs reimbursed by a state health care program may reflect manufacturer influence;

B. The scope of prescription drug marketing and expenses and their effect on the cost, use and delivery of health care services and any recommendations with regard to marketing by manufacturers and labelers; and

C. Information on violations and enforcement action under this section.

The department must post a report required by this subsection on a publicly accessible portion of the department's website.

7. Confidentiality; public information. Notwithstanding any provision of law to the contrary, information submitted to the department pursuant to this section is not

confidential and is ~~not~~ a public record as defined in Title 1, section 402, subsection 3. ~~Disclosure may be made by the department to a contractor providing services to the department under this section; however, that disclosure does not change the confidential status of the information. Data compiled in aggregate form by the department for the purposes of reporting required by this section is a public record as defined in Title 1, section 402, subsection 3, as long as it does not reveal trade information that is protected by state or federal law.~~

8. Penalty. This section may be enforced in a civil action brought by the Attorney General. A manufacturer or labeler that fails to provide a report as required by this section commits a civil violation for which a fine of $1,000 plus costs and attorney's fees may be adjudged.

9. Rulemaking. The department ~~shall~~ may adopt rules to implement this section. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 3. 22 MRSA §2698-C is enacted to read:

§2698-C. Gifts to practitioners

1. Definitions. As used in this section, the following terms have the following meanings.

A. "Bona fide clinical trial" means a research project that prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and a health outcome.

B. "Gift" means anything of value provided to a health care practitioner for less than market value, including a payment, food, entertainment, travel, honorarium, subscription, advance or service, unless consideration of equal or greater value is received. "Gift" does not mean a product sample.

C. "Significant educational, scientific, medical or policy-making conference or seminar " means an educational, scientific or policy-making conference or seminar that offers continuing medical education credit, features multiple presenters on scientific research or is authorized by the sponsoring association to recommend or make policy and is accredited by the Accreditation Council for Continuing Medical Education or a successor organization.

2. Gifts prohibited. Except for a gift under subsection 3 or a product sample under subsection 5, a manufacturer or wholesale prescription drug distributor who participates in a state health care program may not offer or give a gift, fee, payment, subsidy or other economic benefit to a health care practitioner.

3. Exemptions. The following gifts are excluded from the prohibition under subsection 2:

A. Payment to a sponsor of a significant educational, scientific, medical or policy-making conference or seminar at which:

(1) The payment is not made directly to a health care practitioner;

(2) Funding is used solely for educational purposes; and

(3) All activities are objective, free from industry influence and do not promote specific products;

B. Reasonable honoraria and payment of the reasonable expenses of a health care practitioner who serves on the faculty at a significant educational, scientific, medical or policy-making conference or seminar at which:

(1) There is an explicit contract that is restricted to scientific issues and not marketing efforts; and

(2) The content of the presentation, including slides and written materials, is determined by the health care practitioner; and

C. Compensation for substantial professional or consulting services of a health care practitioner in connection with a bona fide clinical trial as long as there is an explicit contract that is restricted to scientific issues and not marketing efforts.

4. Disclosure. By July 1st of each year beginning in 2010, a manufacturer that participates in a state health care program shall disclose to the department the value, nature, purpose and recipient of a gift, fee, payment, subsidy, product sample or other economic benefit under subsection 3 or subsection 5 that is provided by the manufacturer, directly or indirectly through an agent, to a health care practitioner, hospital, nursing home, pharmacist, health benefit plan administrator or any other person in the State authorized to prescribe, dispense or purchase prescription drugs. For each gift, fee, payment, subsidy, product sample or other economic benefit disclosed under this subsection, the manufacturer shall identify the recipient's name, address, credentials, institutional affiliation and any governmental registration, license or identification number.

5. Product sample. A product sample may be dispensed by a manufacturer under the following conditions:

A. The product sample must be donated generally to a health care facility, not to an individual, and accepted and dispensed centrally;

B. Product sample dispensing must meet standards for inventory control, drug interaction and dosage screening, labeling and documentation as required by the department; and

C. A health care practitioner or a member of the practitioner's staff or family who is not a patient of the health care facility may not use a product sample.

Sec. 4. 22 MRSA §2700-A, sub-§1, ¶B-2 is enacted to read:

B-2. "Prescription drugs" means pharmaceuticals, biologics or medical devices.

Sec. 5. 22 MRSA §2700-A, sub-§4, as amended by PL 2007, c. 327, §2, is further amended to read:

4. Fees. Beginning April 1, 2006, each manufacturer of prescription drugs that are provided to Maine residents through the MaineCare program under section 3174-G or the elderly low-cost drug program under section 254-D shall pay a fee of $1,000 per calendar year to the State. Fees collected under this subsection must be used to cover the cost of overseeing implementation of this section, including but not limited to maintaining links to publicly accessible websites to which manufacturers are posting clinical trial information under subsection 3 and other relevant sites, assessing whether and the extent to which Maine residents have been harmed by the use of a particular drug and undertaking the public education initiative under subsection 5 and the prescription drug academic detailing program under section 2685. One half of the annual revenues from this subsection must be allocated to and used for the academic detailing program under section 2685. Revenues received under this subsection, with the exception of funding designated for the academic detailing program under section 2685, must be deposited into an Other Special Revenue Funds account to be used for the purposes of this subsection. The department may increase the fee under this subsection to cover the department's reasonable cost of administering this section.

SUMMARY

This bill:

1. Prohibits most gifts and payments to health care practitioners from pharmaceutical and medical device manufacturers;

2. Includes medical devices in the definition of "prescription drug" for the purposes of requirements involving a pharmaceutical manufacturer's giving of gifts to health care practitioners and reporting marketing expenses;

3. Establishes requirements for pharmaceutical manufacturers' giving sample products to health care practitioners;

4. Requires the Department of Health and Human Services to report a pharmaceutical manufacturer's gifts and payments per health care practitioner instead of in the aggregate;

5. Limits the confidentiality of pharmaceutical manufacturers' reporting information to trade information protected by state and federal law;

6. Requires the Department of Health and Human Services to post the department's annual report regarding a pharmaceutical manufacturer's marketing expenses on a publicly accessible portion of the department's website; and

7. Allows the Department of Health and Human Services to raise the fees of pharmaceutical manufacturers to cover reasonable costs of the department.