



January 18, 2008

Model Legislation

The Prescription Project promotes appropriate prescribing, free of conflicts of interest caused by pharmaceutical marketing and based on the best available medical evidence.

It is promoting policy change by working with

- *State and Federal Policymakers*
- *Academic Medical Centers*
- *Professional Medical Societies*
- *Private Payers*

Created with The Pew Charitable Trusts, the Project is led by Community Catalyst in partnership with the Institute on Medicine as a Profession.

Prescription Drug and Medical Device Marketing Restrictions and Disclosure Act

Section 1. Purposes.

The purposes of the Legislature in enacting this Act are to improve the public health and the quality of prescribing and medical decision making; promote consumer access to information relating to medical care, marketing and gifts; reduce the inappropriate influence of gifts and payments on provider medical decisions; limit annual increases in the cost of health care; and assist the State in its role as a purchaser of health care services and an administrator of health care programs by enabling the State to determine the scope of advertising and marketing costs and their effect on the cost, utilization and delivery of health care services.¹

Section 2. Definitions.

As used in this chapter, unless the context otherwise indicates, the following terms shall have the following meanings:

(a) "Bona fide clinical trial" means any 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.

¹ It may be appropriate to make specific findings in the legislation, although many state legislatures do not do so as a matter of bill drafting policy. The failure to do so was cited by the District Court's decision, currently on appeal, in *IMS v. Ayotte* overturning the New Hampshire data mining restriction law. Findings should be based on information available to the legislature including information presented at public hearings, as well as related state policy and laws. Findings appropriate to this legislation might include reference to the cost of health care and prescription drugs in the state, the role of marketing in affecting that cost, other state laws addressing marketing and evidence-based prescribing, and studies related to public health implications of marketing practices.

(b) "Gift" means a payment, food, entertainment, travel, honorarium, subscription, advance, service, product sample² or anything of value, unless consideration of equal or greater value is received. A gift includes anything of value provided to a health care practitioner for less than market value.

(c) "Health care practitioner" or "practitioner" means a person who prescribes prescription drugs for any person and is licensed by this State to provide or is otherwise lawfully providing health care or a partnership or corporation made up of those persons or an officer, employee, agent or contractor of that person acting in the course and scope of employment, agency or contract related to or supportive of the provision of health care to individuals.

(d) "Labeler" means a person or entity that:

- (1) receives prescription drugs or biologics from a manufacturer or wholesaler;
- (2) repackages the drugs or biological products for later resale; and
- (3) has a labeler code from the federal Food and Drug Administration under section 207.20 of Title 21 of the Code of Federal Regulations.

(e) "Manufacturer" means anyone who is engaged in the manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, distributing, or labeling of prescription drugs, biologics, or medical devices.

(f) "Marketing" means any of the following activities undertaken or materials or products made available to prescribers or to their employees or agents, or to the general public, related to the transfer of prescription drugs, biologics or medical devices from the producer or seller to the consumer or buyer:

- (1) Advertising, publicizing, promoting or selling a prescription drug, biologic or medical device through any media or method including electronic and Internet means;

² The model bill is drafted to ban samples, as a number of hospitals and medical practices have already done. Nonetheless, because of either the perception or the reality that samples are used to provide access to pharmaceuticals for needy patients, there may be a reluctance to include samples in the gift ban. There is growing evidence of the problematic role of samples as a marketing tool that generally are not used for needy patients, see "Characteristics of Recipients of Free Prescription Drug Samples: A Nationally Representative Analysis," by Cutrona and Woolhandler, et al (American Journal of Public Health, February 2008). The better practice is to ban samples and to instead facilitate patient access to existing programs that provide low-cost or free medications to patients and do not depend on direct interaction between clinicians and pharmaceutical representatives. If samples are allowed, the legislation should require disclosure of this spending and the following protocol: (1) samples must be donated generally to the practice or facility, and accepted and dispensed centrally at practice sites, not by individual clinicians; (2) to protect patient safety, sample dispensing must meet standards for inventory control, drug interaction and dosage screening, labeling and documentation as established by the Joint Commission or comparable accrediting organization; and (3) the personal use of samples by clinicians, staff or their families who are not patients of the practice site should be forbidden.

(2) Activities undertaken for the purpose of influencing the market share of a prescription drug or biologic or medical device, or the prescribing patterns of a prescriber, a detailing visit or a personal appearance;

(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, biologic or medical device.

(g) "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, which is:

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement thereto;

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

(h) "Person" means a business, individual, corporation, union, association, firm, partnership, committee, or other organization or group of persons.

(i) "Significant educational, scientific or policy-making conference or seminar" means an educational, scientific or policy-making conference or seminar that:

(1) is accredited by the Accreditation Council for Continuing Medical Education or a comparable organization, and

(2) offers continuing medical education credit, features multiple presenters on scientific research, or is authorized by the sponsoring association to recommend or make policy.

(j) "State health care program" means a program for which the State purchases pharmaceuticals, biologics or medical devices, including but not limited to Medicaid, state employees, corrections, and retirement system.

Section 3. Gifts to practitioners prohibited.

(a)(1) It is unlawful for any manufacturer or wholesale drug, biologic, or medical device distributor who participates in a state health program,³ or any agent thereof,

³ This section and parallel language in Sections 4 and 5 links the gift ban and requirements for disclosure to manufacturers that participate in programs administered by the state that purchase

to offer or give any gift, fee, payment, subsidy, or other economic benefit to a health care practitioner.

(a)(2) Exclusions.⁴ The following gifts are excluded from the prohibition in this section but must be disclosed under Section 4 and Section 5 of this chapter:

A. Payment to the sponsor of a significant educational, scientific or policy-making conference or seminar medical conference, provided (i) the payment is not made directly to a health care practitioner; (ii) funding is used solely for bona fide educational purposes; and (iii) 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 bona fide significant educational, scientific or policy-making conference or seminar medical conference provided (i) there is an explicit contract with specific deliverables which are restricted to scientific issues, not marketing efforts, and (ii) the content of the presentation, including slides and written materials, are determined by the clinician.

C. Compensation for the substantial professional or consulting services of a practitioner in connection with a bona fide clinical trial provided there is an explicit contract with specific deliverables which are restricted to scientific issues, not marketing efforts.

Section 4. Disclosure of exempted gifts.

(a)(1) Annually on or before [date] of each year, every manufacturer of prescription drugs, biologics, or medical devices that participates in a state health care program shall disclose to the [agency]⁵ the value, nature, purpose, and recipient of any gift, fee, payment, subsidy, or other economic benefit not prohibited in Section 3 of this Act, which is provided by the company, directly or through its agents, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, health care practitioner or any other person in [state] authorized to prescribe,

drugs, devices and/or biologics, such as the Medicaid program. By linking to these state programs, in which the companies voluntarily participate, the legislation makes clear the state's interest and legal authority to impose the gift ban and require the information requested, and directly addresses both Commerce Clause and trade secret legal issues that may be raised by the regulated community. See also the definition of "state health care program" in Section 2(j).

⁴ If product samples are not banned, then language should be added to section 3(a)(2) excluding "samples of a drug, biologic or device provided to a prescriber for free distribution to patients" from the ban in Section 3(a)(1) and the protocols outlined in footnote 2 should be added in a new section.

⁵ Each state should identify the agency within which the administration of this program fits most easily and is most capable of producing and insuring public access to the reports required by this section. Other states have delegated authority to the state department of health (Maine), the attorney general (Vermont) or board of pharmacy (Minnesota).

dispense, or purchase prescription drugs, biologics, or medical devices in this State. For each expenditure, the company must also identify the recipient and the recipient's address, credentials, institutional affiliation, and state board or DEA numbers.

(2) Each company subject to the provisions of this section also shall disclose to the [agency] the name and address of the individual responsible for the company's compliance with the provisions of this section, or if this information has been previously reported, any changes to the name or address of the individual responsible for the company's compliance with the provisions of this section.

(3) The report shall be accompanied by payment of a fee, to be set by the [agency], to pay the costs of administering these provisions.

(c) The [agency] shall make all disclosed data publicly available and easily searchable on its website.

Section 5. Advertising and Marketing Expenditure Reporting.

(a) Annually on or before [date] of each year, every manufacturer of prescription drugs, biologics, or medical devices that participates in a state health care program shall submit to the [agency] a report on advertising and marketing expenditures.

(b) The report must be in the form and manner provided by the [agency] and accompanied by payment of a fee, as set by the [agency], to support the work of the [agency] under this section.

(c) The annual report required by this section must include the following information as it pertains to marketing activities conducted within this State in a form that provides the value, nature, purpose and recipients of the expense:

(1) Information on gifts reported under Section 4 of this Act;

(2) All other expenses, whether direct or indirect, associated with advertising, marketing and promotion of prescription drugs, biologics and medical devices including without limitation:

A. Expenses associated with 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;

B. Any other expenses relating to the indirect promotion of prescription drugs, biologics and medical devices including without limitation, support of independent or continuing medical education programs, including payments to medical education companies; design, printing and production costs of patient education materials and disease management materials distributed within the State; consulting fees and expenses, participation in speakers' bureaus and honoraria or other payments for time while speaking at or attending meetings, lectures or conferences; writing articles or publications; charitable grants, either directly or earmarked, even if unrestricted; product samples if allowed; market research surveys or other activities undertaken in support of developing advertising and/or marketing strategies; 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 (1) through (3) of this section 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.

(d) Each company subject to the provisions of this section also shall disclose to the [agency] the name and address of the individual responsible for the company's compliance with the provisions of this section, or if this information has been previously reported, any changes to the name or address of the individual responsible for the company's compliance with the provisions of this section.

Section 6. [Agency] reports.

The [agency] shall provide a report annually to the legislature and the governor on or before [date] containing an analysis of the data submitted to the [agency] under Sections 4 and Section 5. The report shall include the following:

- (1) Information on gifts required to be disclosed under section 4, which shall be presented in (i) aggregate form and (ii) by selected types of prescribers or individual prescribers, as prioritized each year by the [agency], and analyzed to determine whether prescribing patterns by these prescribers of prescription drugs, biologics or medical devices reimbursed by Medicaid or other state health care programs may reflect manufacturer influence; and
- (2) Information on all marketing activities, whether direct or indirect, including the scope of prescription drug, biologics and medical device 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, biologics and medical device manufacturers and labelers; and
- (3) Information on violations and enforcement actions brought pursuant to this Act.

Section 7. Public records.

The information required to be submitted pursuant to Sections 4 and 5, and the data and reports compiled by the [agency] pursuant to section 6, are public records. Notwithstanding any other provision of law, the identity of health care practitioners and other recipients of gifts, payments and materials required to be reported in this section do not constitute confidential information or "trade secrets."⁶

⁶ Some states have allowed manufacturers to exempt data from public disclosure by claiming trade secret protection or to provide gift and payment information in aggregated format only. Such an approach has proved to undermine the effectiveness of the law because companies make broad claims of secrecy. Although companies may claim that the gifts and marketing information required to be disclosed in this Act is a "trade secret," the mere claim that information is confidential does not in and of itself constitute a legally protected trade secret. States may require disclosure of business information, especially where, as here, disclosure is tied to a company's voluntary participation in state health care programs such as Medicaid and supports the state's purpose of protecting the public health.

Section 8. Enforcement.

The [agency] may bring an action for injunctive relief, costs, and attorneys fees, and to impose on a company that fails to comply with any provision of this chapter a civil penalty of no more than \$10,000.00 per violation.⁷

Section 9. Rulemaking.

The [agency] may adopt rules as necessary to implement this chapter.

Section 10. Severability.

If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.⁸

The model legislation was prepared for the Prescription Project by Sharon Treat, Esq., Executive Director, National Legislative Association on Prescription Drug Prices, with assistance from Sean Flynn, Esq., Associate Director, Program on Information Justice and Intellectual Property, American University, Washington College of Law; Prescription Policy Choices; and the Public Citizen Litigation Unit.

⁷ Other potential penalties include: 1) suspending interactions between physicians and pharmaceutical companies for periods of time, 2) appropriately limiting the use of products in Medicaid or state and county hospital formulary procedures where there is a satisfactory therapeutic alternative, and 3) including the violation within the state consumer fraud or unfair business practices law, which generally provide for a private right of action as well as enforcement by the attorney general, fines and injunctive relief. At least one state, Minnesota, has made disclosure a part of its state licensing requirements. Disputes are resolved through special administrative disciplinary process. Possible penalties include suspension of license or civil fines.

⁸ Some states have freestanding law that governs severability which is automatically applied to all legislation. In those states, bill drafts will not include a severability clause, but the same standard would nonetheless be applied in the event of a legal challenge.