General Assembly

Raised Bill No. 270

February Session, 2010

LCO No. **1514**

*01514_____PH_*

Referred to Committee on Public Health

Introduced by:
(PH)

AN ACT CONCERNING THE ESTABLISHMENT OF A REGIONAL POLICY ON THE PROHIBITION OF CERTAIN GIFTS FROM PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURING COMPANIES TO HEALTH CARE PROVIDERS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective July 1, 2010*) As used in sections 1 to 8, inclusive, of this act:

(1) "Biologic" means a "biological product" as defined in 42 USC 262(i), as amended from time to time, that is regulated as a drug under the federal Food, Drug and Cosmetic Act, 21 USC 301 et seq.;

(2) "Bona fide services" means an arrangement for services including, but not limited to: (A) Research, (B) participation on advisory boards, (C) collaboration with nonprofit organizations, as described in Section 501(c)(3) of the Internal Revenue Code of 1986, or any subsequent corresponding internal revenue code of the United States, as from time to time amended, that are dedicated to the promotion of health and the prevention of disease, and (D) presentations at pharmaceutical or medical device manufacturing

company-sponsored medical education and training, including the federal Food and Drug Administration required education and training involved in producing safe and effective medical devices, provided such arrangement is formalized in a written agreement specifying the services to be provided, based on the fair market value of the services and characterized by the following factors: (i) A legitimate need for the services clearly identified in advance; (ii) a connection between the competence and expertise of the health care provider and the purpose of the arrangement; (iii) the number of health care providers retained is not greater than the number reasonably necessary to achieve the identified purpose; (iv) the retaining pharmaceutical or medical device manufacturing company maintains records concerning the arrangement and makes appropriate use of the services provided by the health care provider; (v) the venue and circumstances of any meeting with the health care provider is conducive to the services and activities related to the services are the primary focus of the meeting; and (vi) the decision to retain a health care provider is not unduly influenced by a pharmaceutical or medical device manufacturing company's sales personnel;

(3) "Charitable donation" means the provision of financial support to a nonprofit organization, as described in Section 501(c)(3) of the Internal Revenue Code of 1986, or any subsequent corresponding internal revenue code of the United States, as from time to time amended or the in-kind provision of prescription drugs, biologics or medical devices for charity care of patients;

(4) "Clinical trial" means a genuine research project involving a prescription drug, biologic or medical device that evaluates the safety or effectiveness of the particular prescription drug, biologic or medical device in the screening, prevention, diagnosis, evaluation or treatment of a disease or health condition or evaluates the safety or efficacy of the prescription drug, biologic or medical device in comparison with other therapies, that has been approved by the federal Food and Drug Administration and, if the trial involves volunteer human research

subjects, such trial has been approved by a duly constituted institutional review board after reviewing and evaluating the trial in accordance with the human subject protection standards set forth at 21 CFR Part 50, 45 CFR Part 46, or equivalent standards of another federal agency;

(5) "Covered recipient" means a person authorized to prescribe, dispense or purchase prescription drugs or medical devices in this state, including a hospital, nursing home, pharmacist, health benefit plan administrator or a health care provider. "Covered recipient" does not include a bona fide employee of a pharmaceutical or medical device manufacturing company or a consumer who purchases prescription drugs or medical devices;

(6) "Conference" or "meeting" means any convening where responsibility for and control over the selection of content, faculty, educational methods, materials and venue belong to the event's organizers in accordance with their guidelines, held in a venue that is appropriate and conducive to informational communication and training about medical information, where (A) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse and one or more educational presentations are the primary reason for the gathering, and (B) the main purpose for bringing attendees together is to further their knowledge on the topic or topics being presented;

(7) "Department" means the Department of Public Health;

(8) "Genuine research project" means a project intended to add to medical knowledge about the care and treatment of patients that constitutes a systematic investigation, designed to develop or contribute to generalized knowledge, when the results can be published by the researcher and reasonably can be considered to be of significant interest or value to scientists or health care providers working in the particular field of inquiry;

(9) "Health care provider" means a person who prescribes prescription drugs for any person and is licensed to provide health care in this state, or a partnership or corporation comprised of such persons, or an officer, employee, agent or contractor of such person acting in the course and scope of his employment, agency or contract related to or in support of the provision of health care to individuals. "Health care provider" does not include hospitals and full-time employees and members of the board of directors of pharmaceutical or medical device manufacturers;

(10) "Hospital setting" means (A) a hospital, (B) academic medical center, or (C) pharmaceutical or medical device specialized training facility, where the facility, as certified by the pharmaceutical or medical device manufacturing company to the Department of Public Health, is specifically designed to (i) approximate the conditions of a surgical suite or a working clinical laboratory; or (ii) provide medical training on large or technical medical devices, such as surgical equipment, implants and imaging and clinical laboratory equipment;

(11) "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: (A) Recognized in the official National Formulary or the United States Pharmacopeia or any supplement thereto; (B) intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease, in persons or animals; or (C) intended to affect the structure or function of the body of a person or animal, and that does not achieve its primary intended purposes through chemical action within or on such body and that is not dependent upon being metabolized for the achievement of its primary intended purposes;

(12) "Nonfaculty" means a health care provider who does not serve as a speaker or provide actual and substantive services as a faculty organizer or academic program consultant for a continuing medical

education event, third-party scientific or educational conference or professional meeting;

(13) "Person" means a business, individual, corporation, union, association, firm, partnership, committee or other organization;

(14) "Pharmaceutical or medical device manufacturer agent" means a person who, while employed by or under contract with a pharmaceutical or medical device manufacturing company, engages in detailing, promotional activities or other marketing of prescription drugs, biologics, or medical devices in this state to any physician, hospital, nursing home, pharmacist, health benefits plan administrator other health care provider or person authorized to prescribe, dispense or purchase prescription drugs, biologics or medical devices. "Pharmaceutical or medical device manufacturer agent" does not include: (A) A licensed pharmacist, (B) a licensed physician or any other licensed health care provider with authority to prescribe prescription drugs, biologics or medical devices who is acting within the ordinary scope of the practice for which he or she is licensed, (C) a wholesale drug distributor licensed in this state, (D) a representative of such distributor who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug, or (E) a retail pharmacy licensed in this state, provided such person is not engaging in such practices while employed by or under contract with a pharmaceutical or medical device manufacturing company;

(15) "Pharmaceutical or medical device manufacturing company" means any entity that: (A) Is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, biologics or medical devices, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or (B) is directly engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, biologics or medical devices. "Pharmaceutical or medical device

manufacturing company does not include a health care provider, physician practice, home health agency, hospital licensed in this state, wholesale drug distributor licensed in this state or a retail pharmacy licensed in this state; and

(16) "Prescription drugs" means drugs upon which the manufacturer or distributor has placed or is required by federal law and regulations to place the following or a comparable warning: "Caution federal law prohibits dispensing without prescription".

Sec. 2. (NEW) (*Effective July 1, 2010*) (a) Each pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent shall adopt a marketing code of conduct in compliance with the provisions of sections 1 to 8, inclusive, of this act and adopt and submit to the Department of Public Health a description of a training program to provide regular training to appropriate employees including, but not limited to, all sales and marketing staff, on the marketing code of conduct. The training program shall ensure that all representatives who are employed by or acting on behalf of a pharmaceutical or medical device manufacturing company and who visit health care providers have sufficient knowledge of the marketing code of conduct, general science and product-specific information in order to provide accurate, up-to-date information, consistent with state law and federal Food and Drug Administration requirements. The training program shall also provide for regular assessments of persons who are employed by or acting on behalf of the company to ensure that such persons comply with the provisions of sections 1 to 8, inclusive, of this act and other relevant company policies.

(b) Each pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent shall (1) certify to the department to the best of the company's knowledge, information and belief that it is in compliance with the provisions of sections 1 to 8, inclusive, of this act; (2) adopt

and submit to the department policies and procedures for investigating noncompliance with the provisions of sections 1 to 8, inclusive, of this act, taking corrective action in response to noncompliance and reporting instances of noncompliance to the appropriate state authorities; and (3) submit to the department the name, title, address, telephone number and electronic mail address of the compliance officer it has identified as responsible for certifying compliance with the provisions of sections 1 to 8, inclusive, of this act and implementing, monitoring and enforcing the company's marketing code of conduct.

(c) Each pharmaceutical manufacturing company that uses prescriber data unrelated to the identity of a patient to facilitate communications with health care providers shall (1) maintain the confidential nature of prescriber data; (2) develop policies regarding the use of the data; (3) educate company employees and pharmaceutical or medical device manufacturer agents concerning such policies and designate an internal contact person to handle inquiries regarding the use of the data; (4) identify appropriate disciplinary actions for misuse of the data; and (5) comply with the request of any health care provider who requests that prescriber data not be made available to company sales representatives. Prior to utilizing health care provider prescriber data for marketing purposes, a pharmaceutical manufacturing company shall give health care providers the opportunity to request that their prescriber data be withheld from company sales representatives and not be used for marketing purposes.

(d) Nothing in subsection (c) of this section shall prohibit pharmaceutical manufacturing companies from using prescriber data to impart important safety and risk information to prescribers of a particular drug or device, conduct research, comply with federal Food and Drug Administration mandated risk management plans that require manufacturers to identify and interact with health care providers who prescribe certain drugs or devices or track adverse

events of marketed prescription drugs, biologics or devices.

(e) In all speaker and commercial consultant contracts, pharmaceutical manufacturing companies shall require any health care provider who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for the company to disclose to the committee the nature and existence of the provider's relationship with the company. The disclosure requirement shall extend for not less than two years following the date of the termination of any speaker or consultant arrangement.

(f) Not later than July 1, 2011, and annually thereafter, each pharmaceutical and medical device manufacturing company shall certify to the department that the company has conducted annual audits to monitor compliance with the provisions of sections 1 to 8, inclusive, of this act.

Sec. 3. (NEW) (*Effective July 1, 2010*) (a) Except as provided in sections 4 and 5 of this act, no pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent may provide or pay for meals for health care providers that are (1) part of an entertainment or recreational event; (2) offered without an informational presentation made by a pharmaceutical or medical device marketing agent or without such an agent being present; (3) offered, consumed or provided outside of the health care provider's office or a hospital setting; or (4) provided to a healthcare provider's spouse or other guest.

(b) Meals provided to health care providers that are otherwise in compliance with the provisions of subsection (a) of this section shall be modest and occasional in nature.

Sec. 4. (NEW) (*Effective July 1, 2010*) (a) No pharmaceutical or medical device manufacturing company that employs or contracts

with a pharmaceutical or medical device manufacturer agent may provide: (1) Financial support for the costs of travel, lodging or other personal expenses of nonfaculty health care providers attending any continuing medical education event, third-party scientific or educational conference or professional meetings, either directly to the individuals participating in the event or indirectly to the event's sponsor; (2) funding to compensate for the time spent by health care providers participating in any continuing medical education event, third-party scientific or educational conferences or professional meetings; (3) payment for meals directly to a health care provider at any continuing medical education event, third-party scientific or educational conferences or professional meetings, except that a continuing medical education provider or conference or meeting organizer may, at its own discretion, apply any financial support provided by a pharmaceutical or medical device manufacturing company for the event to provide meals for all participants; (4) sponsorship or payment for continuing medical education or independent medical education, that (A) does not meet the Standards for Commercial Support as established by the Accreditation Council for Continuing Medical Education or equivalent commercial support standards of the relevant continuing education accrediting body, or (B) provides payment directly to a health care provider.

(b) A pharmaceutical manufacturing company shall separate its continuing medical education grant-making functions from its sales and marketing departments.

(c) A pharmaceutical manufacturing company shall not provide any advice or guidance to the continuing medical education provider regarding the content or faculty for a particular continuing medical education program funded by the company.

(d) Nothing in sections 1 to 8, inclusive, of this act shall prohibit: (1) Compensation or reimbursement made to a health care provider serving as a speaker or providing actual and substantive services as a

faculty organizer or academic program consultant for a continuing medical education event, third-party scientific or educational conference or professional meeting, provided the payment is reasonable, based on fair market value and complies with the standards for commercial support as established by the relevant accreditation entity; (2) sponsorship or payment for any portion of a third-party scientific or educational conference, charitable conference or meeting or professional meeting, where the payment is made directly to the conference or meeting organizers; (3) the use of hotel facilities, convention center facilities or other special event venues for continuing medical education or other third-party scientific, educational or professional meetings or conferences.

Sec. 5. (NEW) (*Effective July 1, 2010*) (a) No pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent may provide: (1) Entertainment or recreational items of any value, including, but not limited to, tickets to the theater, concerts or sporting events, sporting equipment or leisure or vacation trips, to any health care provider who is not a salaried employee of the pharmaceutical or medical device manufacturing company; (2) payments of any kind, including cash or cash equivalents, equity, in kind or tangible items, including any complimentary items such as pens, coffee mugs or gift cards to health care providers either directly or indirectly, except as compensation for bona fide services; (3) any grants, scholarships, subsidies, supports, consulting contracts or educational or practice related items in exchange for prescribing, disbursing or using prescription drugs, biologics or medical devices or for a commitment to continue prescribing, disbursing or using prescription drugs, biologics or medical devices; or (4) any other payment or remuneration, in cash or in kind, directly or indirectly, including any rebate or kickback that is prohibited under applicable federal or state fraud and abuse laws or regulations, including, but not limited to, 42 USC 1320a-7b.

(b) Nothing in this section shall prohibit: (1) Reasonable compensation for bona fide services or the reimbursement of other reasonable out-of-pocket costs incurred by the health care provider directly as a result of the performance of such services, where the compensation and reimbursement is specified in, and paid for under, a written agreement; (2) payment or reimbursement for the reasonable expenses, including travel and lodging-related expenses necessary for technical training of health care providers on the use of a medical device if the commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid are described in the written agreement between the health care provider and the device vendor for the purchase of the device; (3) the provision, distribution, dissemination or receipt of peer reviewed academic, scientific or clinical information; (4) the purchase of advertising in peer reviewed academic, scientific or clinical journals; (5) the provision of prescription drugs to a health care provider solely and exclusively for use by the health care provider's patients; (6) the provision of reasonable quantities of medical device demonstration and evaluation units provided to a health care provider to assess the appropriate use and functionality of the product and determine whether or not and when to use or recommend the product in the future; (7) the provision of price concessions, such as rebates or discounts, in the normal course of business; (8) the provision of reimbursement information regarding products, including (A) identifying appropriate coverage, coding or billing of products, (B) procedures for using such products and information, in support of accurate and responsible billing to Medicare and other payors, and (C) information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of products, except that such technical or other support shall not be offered or provided for the purpose of inducing health care providers to purchase, lease, recommend, use or arrange for the purchase, lease or prescription of such products; (9) the provision of payments or the provision of free outpatient prescription drugs to health care providers for the benefit of low income individuals,

through established patient assistance programs, provided the program meets the criterion for a permissible program in accordance with the relevant published guidance available from the Office of the Inspector General of the United States Department of Health and Human Services, or is otherwise permitted under applicable federal laws and regulations including, but not limited to, 42 USC 1320a-7b; or (10) the provision of charitable donations provided the donation (A) is not provided in exchange for prescribing, disbursing or using prescription drugs, biologics or medical devices or for a commitment to continue prescribing, disbursing or using prescription drugs, biologics or medical devices, and (B) does not otherwise violate the provisions of sections 1 to 8, inclusive, of this act.

Sec. 6. (NEW) (*Effective July 1, 2010*) (a) As used in this section, "sales and marketing activities", means: (A) The advertising, promotion or any other activity that is intended to be used or is used to: (i) Influence sales or the market share of a prescription drug, biologic or medical device; (ii) influence or evaluate the prescribing behavior of a covered recipient to promote a prescription drug, biologic or medical device; (iii) market a prescription drug, biologic or medical device; or (iv) evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force; (B) any product education, training or research project that is designed or sponsored by the marketing division of a pharmaceutical or medical device manufacturing company or has marketing, product promotion or advertising as its purpose; (C) the provision of any fee, payment, subsidy or other economic benefit with a value of fifty dollars or more to a covered recipient. "Sales and marketing activities" does not include: (I) Clinical trials and genuine research, particularly where the primary purpose is to generate data in support of an application filed with the federal Food and Drug Administration seeking approval for a new prescription drug, biologic or medical device or new use or similar marketing or labeling claim requiring federal Food and Drug Administration approval, (II) clinical trials that are posted on the federal Food and Drug Administration's Internet web site, and (III) the

provision of prescription drugs to a covered recipient solely and exclusively for use by patients, demonstration or evaluation units, in-kind items used for the provision of charity care or confidential price concessions established in contracts between pharmaceutical or medical device manufacturing companies and insurers, pharmacies, pharmacy benefit managers or health plan administrators and their affiliates that are offered in connection with the acquisition of prescription drugs, biologics or medical devices or the management of a health plan's formulary.

(b) On or before July 1, 2011, and annually thereafter, a pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent shall disclose to the department the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of fifty dollars or more, that the company provides, directly or through its agents, to any covered recipient in connection with the company's sales and marketing activities.

(c) Each annual disclosure report shall be accompanied by a fee of two thousand dollars.

(d) Disclosures shall be made for the previous calendar year on such form as the Commissioner of Public Health prescribes. Pharmaceutical or medical device manufacturing companies shall certify that to the best of the company's knowledge, information and belief, the disclosure report is true and accurate.

(e) For the purposes of computing the fifty-dollar threshold, fees, payments, subsidies and other economic benefits relating to separate events or transactions shall be calculated on an individual transactional basis and shall not be aggregated. Pharmaceutical or medical device manufacturing companies shall not structure fees, payments, subsidies or other economic benefits to health care providers in such a way as to circumvent the reporting requirements

of this section.

Sec. 7. (NEW) (*Effective July 1, 2010*) No pharmaceutical or medical device manufacturing company shall discharge, refuse to hire, refuse to serve or in any manner retaliate or take any adverse action against any employee, applicant, health care provider or covered recipient if such employee, applicant, health care provider or covered recipient takes or has taken any action in furtherance of the enforcement of the provisions of sections 1 to 8, inclusive, of this act.

Sec. 8. (NEW) (*Effective July 1, 2010*) (a) A person who knowingly and wilfully violates any provision of sections 1 to 8, inclusive, of this act shall be liable for a civil fine of not more than five thousand dollars for each transaction, occurrence or event that constitutes a violation of sections 1 to 8, inclusive, of this act.

(b) The Department of Public Health may assess a civil fine in accordance with the provisions of subsection (a) of this section. Upon request of the Commissioner of Public Health, the Attorney General may petition the superior court for collection of such fine and such equitable and injunctive relief as the court deems appropriate.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*July 1, 2010*	New section
Sec. 2	*July 1, 2010*	New section
Sec. 3	*July 1, 2010*	New section
Sec. 4	*July 1, 2010*	New section
Sec. 5	*July 1, 2010*	New section
Sec. 6	*July 1, 2010*	New section
Sec. 7	*July 1, 2010*	New section
Sec. 8	*July 1, 2010*	New section

Statement of Purpose:

To adopt in this state the recently enacted Massachusetts standards concerning restrictions on gifts and payments from pharmaceutical and medical device manufacturing companies to health care providers.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]