SENATE DOCKET, NO. 768 FILED ON: 1/13/2009

SENATE . . . . . No. 547

The Commonwealth of Massachusetts

In the Year Two Thousand Nine

An Act Making Technical Corrections to Health Care Practitioner and Pharmaceutical and Medical Device Manufacturer Conduct..

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

Section 1. Chapter 111N of the General Laws is hereby amended by striking the text in its entirety and replacing it with the following:-

Section 2. As used in this chapter, the following words shall have the following meanings:-

"Gift", a payment, entertainment, meals, travel, honorarium, subscription, advance, services or anything of value, unless consideration of equal or greater value is received and there is an explicit contract with specific deliverables which are not related to marketing and are restricted to medical or scientific issues. “Gift" shall not include anything of value received by inheritance, a gift received from a member of the health care practitioner’s immediate family or from a relative within the third degree of consanguinity of the health care practitioner or of the health care practitioner’s spouse or from the spouse of any such relative, or prescription drugs provided to a health care practitioner solely and exclusively for use by the health care practitioner’s patients.

“Health care practitioner” or “practitioner,” a person who prescribes prescription drugs for any person and is licensed 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.

"Immediate family", a spouse and any dependent children residing in the reporting person's household.

“Medical device”, 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 to them; (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. "Person", a business, individual, corporation, union, association, firm, partnership, committee, or other organization or group of persons.

“Pharmaceutical or medical device marketer”, a person who, while employed by or under contract to represent a pharmaceutical or, medical device manufacturing company that participates in a state health care program, engages in detailing, promotional activities or other marketing of prescription drugs, or medical devices in this state to any physician, hospital,

nursing home, pharmacist, health benefit plan administrator, any other health care practitioner or any other person authorized to prescribe, dispense, or purchase prescription drugs. The term does not include a wholesale drug distributor licensed under section 36A of chapter 112, a representative of such a distributor who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug, or a retail pharmacist registered under section 37 of chapter 112 if such person is not engaging in such practices under contract with a manufacturing company.

"Pharmaceutical or medical device manufacturing company", any entity that participates in a state health care program and which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs 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 any entity engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs. The term does not include a wholesale drug distributor licensed under section 36A of chapter 112 or a retail pharmacist registered under section 37 of chapter 112.

"Pharmaceutical or medical device manufacturer agent", a pharmaceutical or medical device marketer or any other person who for compensation or reward does any act to promote, oppose or influence the prescribing of a particular prescription drug, medical device, or category of prescription drugs or medical devices. The term shall not include a licensed pharmacist, licensed physician or any other licensed health care practitioner with authority to prescribe prescription drugs who is acting within the ordinary scope of the practice for which he is licensed.

"Physician", a person licensed to practice medicine by the board of medicine under section 2 of chapter 112 who prescribes prescription drugs for any person, or the physician's employees or agents.

"Prescription drugs", any and all 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."

Section 3. No pharmaceutical or medical device manufacturer agent shall knowingly and willfully offer or give to a health care practitioner, a member of a health care practitioner's immediate family, a health care practitioner's employee or agent, a health care facility or employee or agent of a health care facility, a gift of any value and no health care practitioner, a member of a health care practitioner's immediate family, a health care practitioner's employee or agent, a health care facility or employee or agent of a health care facility shall knowingly and willfully solicit or accept from any pharmaceutical or medical device manufacturer agent, a gift of any value. No pharmaceutical or medical device manufacturer agent shall knowingly and willfully offer or give to a health care practitioner, a member of a health care practitioner's immediate family, a health care practitioner's employee or agent, a health care facility or employee or agent of a health care facility indirectly by providing such benefit through a third party corporation, association or charitable organization.

Section 4. (a)(1) By July first of each year, every pharmaceutical or medical device manufacturing company shall disclose to the department of public health the value, nature, purpose, and recipient of any fee, payment, subsidy, or other economic benefit not prohibited in Section 2, including fees, payments subsidies or other economic benefits related to, 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 this state authorized to prescribe, dispense, or purchase prescription drugs 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. All non-marketing related economic benefits, including, but not limited to, research, education and consulting arrangements are expressly covered by this act.

(2) Each company subject to the provisions of this section also shall disclose to the department of public health 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 department of public health, to pay the costs of administering these provisions.

(b)(1) Information submitted to the department of public health pursuant to this section shall be a public record except to the extent that it includes information that is protected by state or federal law as a trade secret.

(2) 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 chapter shall not constitute confidential information or trade secrets protected under this section.

(3) The department of public health shall make all disclosed data publicly available and

easily searchable on its website.

(c) The department of public health shall report to the attorney general any payment, entertainment, meals, travel, honorarium, subscription, advance, services or anything of value provided in violation of this chapter, including anything of value provided when consideration of equal or greater value was not received or anything of value provided that was not subject to an explicit contract with specific deliverables which were restricted to medical or scientific issues.

Section 5. The department of public health, in consultation with the board of registration of pharmacy, and board of registration of medicine, shall promulgate regulations requiring the licensing of all pharmaceutical and medical device manufacturer agents. As a prerequisite to such licensing, pharmaceutical and medical device manufacturer agents shall complete such training as may be deemed appropriate by the department. As a prerequisite to the renewal of such license, pharmaceutical and medical device manufacturer agents shall complete continuing education as may be deemed appropriate by the department. The fee for such license shall be $3,000 per year. Revenue generated from this fee shall be divided in equal shares, 50 percent to the department of public health for enforcement and investigation pursuant to this act, 25 percent to the office of attorney general, line item 0810-0000, for investigation and prosecution pursuant to this chapter and 25 per cent to the board of registration in pharmacy, line item 4510-0722, to assist the board in implementing patient safety and medical error reduction programs.

Section 6. This chapter shall be enforced by the attorney general, or by any district attorney of the commonwealth with jurisdiction. A person who violates this chapter shall be punished by a fine of not less than $10,000 for each transaction, occurrence or event that violates this chapter, or by imprisonment for not more than 2 years, or both.

Section 7. Chapter 112 of the general laws, as appearing in the 2006 Official Edition, is hereby amended by inserting at the end the following new section:-

"Section 227. The department of public health, in consultation with the board of registration of pharmacy, shall promulgate regulations requiring the licensing of all pharmaceutical and medical device manufacturer agents. As a prerequisite to such licensing, pharmaceutical representatives shall complete such training as may be deemed appropriate by the department. As a prerequisite to the renewal of such license, pharmaceutical and medical device manufacturer agents shall complete continuing education as may be deemed appropriate by the department. The fee for such license shall be $2,000 per year. Revenue generated from this fee shall be divided in equal shares, 50 per cent to the department of public health for administration of this act, 25 percent to the office of attorney general, line item 0810-0000, for the investigation and prosecution of Medicaid fraud and other fraudulent drug pricing schemes disadvantaging the commonwealth or its citizens and 25 per cent to the board of registration in pharmacy, line item 4510-0722, to assist the board in implementing patient safety and medical error reduction programs.