SENATE DOCKET, NO. 1585 FILED ON: 2/17/2021

SENATE . . . . . No. 1481

The Commonwealth of Massachusetts

PRESENTED BY:

Mark C. Montigny

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act to restore integrity in the marketing of pharmaceutical products and medical devices.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Mark C. Montigny	*Second Bristol and Plymouth*

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SENATE . . . . . No. 1481

By Mr. Montigny, a petition (accompanied by bill, Senate, No. 1481) of Mark C. Montigny for legislation to restore integrity in the marketing of pharmaceutical products and medical devices. Public Health.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE SENATE, NO. *1304* OF 2019-2020.]

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Second General Court
(2021-2022)

An Act to restore integrity in the marketing of pharmaceutical products and medical devices.

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 sections 1 through 7 in their entirety and inserting in place thereof the following:

Section 1. As used in this chapter, the following words shall have the following meanings:-

“Department”, the department of public health.

“Education program”, a medical school, teaching hospital, or teaching health center licensed to operate in the commonwealth.

"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 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 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.

“Pharmaceutical or medical device manufacturing company”, any entity that participates in a commonwealth 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 marketer”, a person who, while employed by or under contract to represent a pharmaceutical or, medical device manufacturing company that participates in a commonwealth health care program, engages in detailing, promotional activities

or other marketing of prescription drugs, or medical devices in the commonwealth 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 38 of chapter 112 if such person is not engaging in such practices under contract with a manufacturing company.

"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 2. 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, an employee or agent of a health care facility, an education program, or an employee or agent of an education program a gift of any value.

Nothing in the section shall prohibit the provision, distribution, dissemination, or receipt of peer reviewed academic, scientific or clinical information. Nothing in this section shall prohibit the purchase of advertising in peer reviewed academic, scientific or clinical journals.

Section 3. (a)(1) By July first of each year, every pharmaceutical or medical device manufacturing company shall disclose to the department the value, nature, purpose, and recipient of any fee, payment, subsidy, or other economic benefit not prohibited in section 2, which is provided by the company, directly or through its agents, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, education program, health care practitioner or any other person in this commonwealth authorized to prescribe, dispense, or purchase prescription drugs or medical devices. Required disclosures under this section shall include, but are not limited to, any payments made for board memberships, research, or consulting services. 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 department 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) Information disclosed pursuant to this section shall be accompanied by payment of a fee, to be set by the department, 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 shall make all disclosed data publicly available and easily searchable on its website.

(c) The department 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 4. The department, 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 determined by the department, in conjunction with the board of registration in pharmacy and the board of registration in medicine at a rate sufficient to provide the administration and enforcement of this chapter. Revenue generated from this fee shall be divided in equal shares, 75 per cent to the department of public health and 25% to the office of attorney general, line item 0810-0000, for the administration of this chapter.

Section 5. This chapter shall be enforced by the attorney general, the district attorney with jurisdiction over a violation, or the department. 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.