SENATE DOCKET, NO. 432 FILED ON: 1/15/2015

SENATE . . . . . No. 1160

The Commonwealth of Massachusetts

PRESENTED BY:

John F. Keenan

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 relative to the in-office sales of medical devices and products.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
John F. Keenan	*Norfolk and Plymouth*

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SENATE . . . . . No. 1160

By Mr. Keenan, a petition (accompanied by bill, Senate, No. 1160) of John F. Keenan for legislation relative to the in-office sales of medical devices and products. Public Health.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE SENATE, NO. *1032* OF 2013-2014.]

The Commonwealth of Massachusetts

In the One Hundred and Eighty-Ninth General Court
(2015-2016)

An Act relative to the in-office sales of medical devices and products.

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. The General Laws are hereby amended by adding the following as Chapter 111O:

CHAPTER 111O.

Section 1. Short title; purpose.

It is the purpose of this chapter to protect patients from certain aspects of the practice of in-office sales of medical devices or products. The practice of health care practitioners selling products for profit in their offices to patients creates the potential for a conflict of interest, creates undue pressure on the patient, and may lead to adverse decision making by health care practitioners and patients. The conditions of this chapter are therefore established in the interest of transparency in the execution of these sales.

Section 2. Definitions.

As used in this chapter the following words shall, unless the context clearly requires otherwise, have the following meanings:—

"Board," the board of professional licensure that provides the license under which the health care practitioner conducts their practice, or that registers the health care practitioner to conduct their practice, or that otherwise regulates and establishes the standards for professional conduct relevant to that practitioner.

"Health care practitioner," any person licensed to provide health care under chapter 112 of the General Laws, 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 the employment, agency or contract related to or in support of the provision of health care to patients.

"In-office sale," the transfer, exchange, barter, lease, contract for use, or other financial transaction for the possession or use of a medical device or product, that occurs within the business office of a health care practitioner.

"Medical device" shall have the meaning given to the same in chapter 111N; provided further that for the purposes of this chapter only, medical device shall not include an item that must be dispensed only by prescription and that is commonly covered by a health insurance carrier.

"Product," or "products," health and non-health related drugs, devices, appliances, goods, supplements, vitamins, ointments, or procedures; provided, however, that products shall not

include items or items that must be dispensed only by prescription and that are commonly covered by a health insurance carrier.

Section 3. Conditions for in-office sales; and prohibitions.

(a) Any health care practitioner engaging in the in-office sale of medical devices or products shall comply with the following conditions. Except as described in section 4, in-office sales not in compliance with all of the conditions listed in this section shall be prohibited, and subject to the penalties established in section 5:

(1) The health care practitioner must disclose to the patient any profit gained or financial interest held by the health care practitioner, or any immediate family member, in the sale of the medical device or product, or any professional or other relationship between the health care practitioner and the manufacturer or marketer of the medical device or product; the terms "financial interest" and "professional or other relationship," for the purposes of this chapter only, shall be defined in regulation by the board;

(2) The health care practitioner must advise the patient as to the availability of the medical device or product, or any reasonable equivalents, for purchase at a retail pharmacy or other commercial retail source, and as to the market price of said devices or products or equivalents if purchased at another source;

(3) The medical device or product sold must provide a reasonable potential for therapeutic and medical gain specific to the patient's medical condition or complaint;

(4) The health care practitioner must have available, and upon request must provide to the patient or the patient's guardian or representative, easily understandable literature or an

explanation of the device's or product's medical or therapeutic benefits, and any risks associated with the device or product, and the scientific evidence upon which any claims of said benefits or risks are based;

(5) The office in which in-office sales occur must have notice prominently posted, or must otherwise reasonably communicate to the patient, that the patient is under no obligation to purchase the medical device or product in the office; provided further that such notice or communication shall also include an explanation to the patient of how to contact the board if the patient feels the in-office sale or discussion promoting said sale creates undue pressure on the patient to purchase a medical device or product, or otherwise violates the standards for professional conduct applicable to the health care practitioner.

(6) Any other conditions deemed appropriate and as may be established in regulation by the board under which the health care practitioner primarily involved in the execution of the in-office sale is registered or licensed.

Section 4. Exemptions.

The in-office sale of a medical device or product to a particular patient shall be exempt from the conditions stated in section 3, if forcing or allowing the patient to travel away from the health care practitioner's office without having obtained said device or product would bring harm, or cause undue pain or distress, to that patient, or put that patient's health and safety in immediate danger.

Section 5. Enforcement.

(a) This chapter shall be enforced by the board; provided that in the event that punishment for a violation includes assessment of a financial penalty, the board will refer the case to the Department of Public Health to assess that penalty. A health care practitioner that violates this chapter shall be penalized by any or all of the following:

(1) a fine of not more than $5,000 for each transaction, occurrence or event that violates any provision of this chapter;

(2) restitution payments to the patient for the costs incurred by the patient for the purchase of a medical device or product sold in violation of this chapter.

(3) suspension or revocation of the health care practitioner's licensure by the corresponding licensure board, if said board determines the violations to be willful and negligent.