SENATE . . . . . No. 2274

Senate, July 15, 2014 --Text of the Senate amendment (Senator Keenan) for the Senate Bill relative to the in-office sales of medical devices and products (Senate, No. 2272)

The Commonwealth of Massachusetts

In the Year Two Thousand Fourteen

Transparency and Patient Protections.

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 is prescribed or commonly covered by a health insurance carrier.

"Patient," an individual who receives health services from a health care practitioner, as defined in this chapter at a hospital, health care facility, or long term care facility.

"Product," or "products," health and non-health related drugs, devices, appliances, goods, supplements, vitamins, ointments, or procedures, including aesthetic pharmaceutical products as defined in section 9 of chapter 94C; provided, however, that products shall not include prescription items or items commonly covered by health insurance carriers.

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 must observe the following conditions. Unless otherwise specified in section 4 of this chapter, 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 of this chapter; provided further, that nothing in this chapter shall be construed to authorize the sale or dispensing of medical and pharmaceutical devices and products that is otherwise prohibited by Federal or State laws and regulations; and provided further that nothing in this chapter shall be construed to replace or exempt a health care practitioner from the requirements established pursuant to chapter 111N:

(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; where 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 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, 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 punished 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.

SECTION 2. Section 9 of chapter 94C of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting after subsection (b) the following subsection:-

(b½) For the purposes of this section, "aesthetic pharmaceutical" shall mean a prescription medication that: (i) includes either hydroquinone or tretinoin, or both; (ii) is

classified by the department as a schedule VI controlled substance; (iii) has been approved by the federal Food and Drug Administration; and (iv) is prescribed for the treatment of a diagnosed skin condition or to alleviate symptoms of a diagnosed skin condition that affects the patient's appearance.

A physician may, in good faith and in the practice of medicine, dispense and sell aesthetic pharmaceuticals directly to patients in amounts greater than necessary for immediate and proper treatment. Physicians dispensing aesthetic pharmaceuticals shall: comply with all applicable state and federal storage, labeling and recordkeeping requirements; and comply with the requirements of this chapter prior to each dispensing of an aesthetic pharmaceutical. Records maintained under this section shall be accessible as required by state and federal law.

SECTION 3. The department shall promulgate regulations governing the dispensing and sale of aesthetic pharmaceuticals, including provisions to ensure patient safety, pursuant to this section.

SECTION 4. This act shall take effect 180 days after the passage of this act."