SENATE DOCKET, NO. 1767 FILED ON: 1/18/2013

SENATE . . . . . No. 1032

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 passage of the accompanying:

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

PETITION OF:

NAME:	DISTRICT/ADDRESS:
John F. Keenan	*Norfolk and Plymouth*
Martin J. Walsh	*13th Suffolk*
Mark C. Montigny	*Second Bristol and Plymouth*
James M. Murphy	*4th Norfolk*
Karen E. Spilka	*Second Middlesex and Norfolk*

SENATE DOCKET, NO. 1767 FILED ON: 1/18/2013

SENATE . . . . . No. 1032

By Mr. Keenan, a petition (accompanied by bill, Senate, No. 1032) of John F. Keenan, Martin J. Walsh, Mark C. Montigny, James M. Murphy and other members of the General Court for legislation relative to the in-office sales of medical devices and products. Public Health.

The Commonwealth of Massachusetts

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:

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

2 SECTION 1.

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

4 CHAPTER 111O.

5 Section 1. Short title; purpose.

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

12 Section 2. Definitions.

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

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

19 “Health care practitioner,” any person licensed to provide health care under chapter 112
20 of the General Laws, or a partnership or corporation comprised of such persons, or an officer,
21 employee, agent or contractor of such person acting in the course and scope of the employment,
22 agency or contract related to or in support of the provision of health care to patients.

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

26 “Medical device” shall have the meaning given to the same in chapter 111N; provided
27 further that for the purposes of this chapter only, medical device shall not include an item that is
28 prescribed or commonly covered by a health insurance carrier.

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

31 “Product,” or “products,” health and non-health related drugs, devices, appliances, goods,
32 supplements, vitamins, ointments, or procedures; provided, however, that products shall not
33 include prescription items or items commonly covered by health insurance carriers.

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

35 (a) Any health care practitioner engaging in the in-office sale of medical devices or
36 products must observe the following conditions. Unless otherwise specified in section 4 of this
37 chapter, in-office sales not in compliance with all of the conditions listed in this section shall be
38 prohibited, and subject to the penalties established in section 5 of this chapter:

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

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

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

51 (4) The health care practitioner must have available, and upon request must provide to the
52 patient, easily understandable literature or an explanation of the device’s or product’s medical or

53 therapeutic benefits, and any risks associated with the device or product, and the scientific
54 evidence upon which any claims of said benefits or risks are based;

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

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

65 Section 4. Exemptions.

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

71 Section 5. Enforcement.

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

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

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

80 (3) suspension or revocation of the health care practitioner's licensure.