

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 adoption of the accompanying bill:

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

PETITION OF:

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

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

—————
In the Year Two Thousand Thirteen
—————

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 SECTION 1.

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

3 CHAPTER 111O.

4 Section 1. Short title; purpose.

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

11 Section 2. Definitions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

64 Section 4. Exemptions.

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

70 Section 5. Enforcement.

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

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

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

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