

SENATE No. 2128

The Commonwealth of Massachusetts

In the Year Two Thousand Fourteen

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. The General Laws are hereby amended by adding the following as Chapter
2 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, including aesthetic pharmaceutical products as
32 defined in section 9 of chapter 94C; provided, however, that products shall not include
33 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; provided further,
39 that nothing in this chapter shall be construed to authorize the sale or dispensing of medical and
40 pharmaceutical devices and products that is otherwise prohibited by Federal or State laws and
41 regulations; and provided further that nothing in this chapter shall be construed to replace or
42 exempt a health care practitioner from the requirements established pursuant to chapter 111N:

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

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

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

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

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

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

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

69 Section 4. Exemptions.

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

75 Section 5. Enforcement.

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

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

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

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

85 SECTION 2. Section 9(b) of chapter 94C, as so appearing, is hereby amended by
86 inserting after the paragraph that begins "For the purposes of this section, 'therapeutic contact
87 lenses'" the following paragraphs:

88 A physician may, when acting in accordance with applicable federal law and any
89 provision of this chapter which is consistent with federal law and in good faith and in the
90 practice of medicine, dispense and sell aesthetic pharmaceuticals directly to patients in amounts

91 greater than necessary for immediate and proper treatment. Physicians dispensing aesthetic
92 pharmaceuticals must comply with all applicable state and federal labeling and recordkeeping
93 requirement, and must, prior to each dispensing of said products, comply with the requirements
94 of chapter 111O. Records maintained under this section must be accessible as provided under
95 state and federal law. The department shall promulgate rules and regulation governing the
96 dispensing and sale of aesthetic pharmaceuticals pursuant to this section.

97 For purposes of this section “aesthetic pharmaceutical” shall mean, (i) bimatoprost,
98 hydroquinone, metronidazole, and tretinoin, or (ii) a prescription medication that (A) is classified
99 by the department as a schedule VI controlled substance; (B) has been approved by the federal
100 Food and Drug Administration; and (C) is prescribed for the treatment of a diagnosed skin
101 condition, or to alleviate symptoms of said condition that may affect the patient’s appearance.