

7-2012 Legislative Changes to the Massachusetts Pharmaceutical and Device Manufactures Code of Conduct

SECTION 108. Section 1 of chapter 111N of the General Laws, as appearing in the 2010 Official Edition, is hereby amended by inserting before the definition of “Department” the following definition:

Annual reports”, the annual reports submitted by the Secretary of Health and Human Services to the commonwealth pursuant to Sec. 1128G(d)(2) of Part A of title XI of the federal Social Security Act.

SECTION 109. Said section 1 of said chapter 111N, as so appearing, is hereby further amended by adding the following definition:

“Secretary”, the Secretary of the United States Department of Health and Human Services.

SECTION 110. Section 2 of said chapter 111N, as so appearing, is hereby amended by inserting after the word “setting”, in line 26, the following words: , unless otherwise permitted under this section.

SECTION 111. The third paragraph of said section 2 of said chapter 111N, as so appearing, is hereby amended by striking out clause (5) and inserting in place thereof the following 2 clauses:

(5) payment for reasonable expenses necessary for technical training on the use of a medical device ; and

(6) the provision of or payment for modest meals and refreshments in connection with non-CME educational presentations for the purpose of educating and informing health care practitioners about the benefits, risks and appropriate uses of prescription drugs or medical devices, disease states or other scientific information, provided that such presentations occur in a venue and manner conducive to informational communication; and provided further, that any such provision of or payment for modest meals and refreshments complies with the requirements set forth in section 2A; provided that the department shall define modest meals and refreshments through regulation.

SECTION 112. Said chapter 111N is hereby further amended by inserting after section 2 the following section:

Section 2A. No pharmaceutical or medical device manufacturing company shall provide modest meals and refreshments, or provide payment for such meals and refreshments, in connection with non-CME educational presentations as permitted in section 2 unless such pharmaceutical or medical device manufacturing company files quarterly reports detailing all non-CME educational presentations at which such meals or refreshments are provided. Reports shall include: (1) the location of the non-CME presentation; (2) a description of any pharmaceutical products, medical devices or other products discussed at such presentation; and (3) the total amount expended on such presentation and an estimate of the amount expended per participant, factoring any meals, refreshments or other items of economic value provided at such presentation.

The department may require payment of a fee, to be determined by the department, to pay the costs of administering this section.

SECTION 113. Subsection (1) of section 6 of said chapter 111N, as so appearing, is hereby amended by adding the following sentence:- Notwithstanding the provisions of this section, the department shall not require a pharmaceutical or medical device manufacturing company to disclose information which has been disclosed to a federal agency pursuant to federal law and which may be obtained by the department from such federal agency.

SECTION 114. Said chapter 111N is hereby further amended by adding the following section:

Section 8. The department shall make all disclosed data in annual reports publicly available and easily searchable on its website not later than 90 days following the receipt thereof from the secretary.

SECTION 115. Section 5 of chapter 112 of the General Laws, as appearing in the 2010 Official Edition, is hereby amended by striking out the sixth, seventh and eighth paragraphs and inserting 1299 in place thereof the following 4 paragraph