

Massachusetts Pharmaceutical and Medical Device Manufacturers Code of Conduct: Recently Amended Requirements Related to Meals

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July 2012

On July 8, 2012, Massachusetts Governor Deval Patrick signed into law the fiscal year 2013 state budget¹ (“State Budget”), which included amendments to the Massachusetts pharmaceutical and medical device code of conduct law, Mass. Gen. Law. ch. 111N and 105 Mass. Code Regs. 970.000. The amendments will allow pharmaceutical and medical device manufacturers to, among other things, provide restaurant meals to health care professionals during certain educational programs. The original statute required that all meals provided to health care professionals by pharmaceutical and medical device manufacturers be limited to the hospital or office setting.² For an overview of the Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct and the Massachusetts Department of Public Health (“DPH”) implementing regulations, see the Epstein Becker Green Client Alerts available at <http://www.ebglaw.com/showclientalert.aspx?Show=8935> and <http://www.ebglaw.com/showclientalert.aspx?Show=9522>.

This Alert provides an overview of the amendments from the State Budget and discusses some key considerations for pharmaceutical and medical device manufacturers as they seek to implement these new provisions.

Overview of the Amendments to the Pharmaceutical and Medical Device Manufacturer Code of Conduct

Section 111 of the State Budget makes the following changes to the Pharmaceutical and

¹ Conference Committee, Fiscal Year 2013 Budget Recommendations, H. 4200, § 111-114 (Mass. 2012), available at <http://www.malegislature.gov/Budget/FY2013/Senate/ChamberActions>. The bill was approved by the Massachusetts House of Representatives and Senate on June 28, 2012, and then sent to the Governor for signature.

² Mass. Gen. Laws ch. 111N (2008); see also 105 Mass. Code Regs. 970.000 (2008).

Medical Device Manufacturer Code of Conduct:

- Permits payments for reasonable expenses necessary for technical training on the use of a medical device; and
- Allows for the provision of, or payment for, modest meals and refreshments in connection with non-continuing medical education (“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.

Section 112 of the State Budget states that the DPH must define “modest meals and refreshments” through regulation. Additionally, pharmaceutical and medical device manufacturers that provide modest meals at non-CME events must file quarterly reports with the DPH that include the following information:

- Location of the non-CME presentation;
- Description of any pharmaceutical products, medical devices, or other products discussed at such presentation; and
- Total amount expended on such presentation and an estimate of the amount expended per participant, including any meals, refreshments, or other items of economic value.

The DPH also may require pharmaceutical and medical device manufacturers to pay a fee to the DPH for the costs of administering these new reporting requirements.

Further, Section 113 of the State Budget provides that the DPH may not require pharmaceutical and medical device manufacturers to disclose information that has been disclosed pursuant to federal law³ and which may be obtained by the DPH from the federal agency. Additionally, Section 114 of the State Budget requires that the DPH make all data disclosed by pharmaceutical and medical device manufacturers in annual reports publicly available and easily searchable on its website not later than 90 days after receipt.

Key Considerations

The amendments to the Massachusetts pharmaceutical and medical device code of conduct law provide new compliance considerations and opportunities for pharmaceutical and medical device manufacturers that operate in the Commonwealth of Massachusetts. Manufacturers that seek to implement these amendments should use any opportunities through the DPH’s rulemaking process to provide comments regarding key definitions, such as “modest meals and refreshments,” “other items of

³ See, e.g., Patient Protection Affordable Care Act of 2010, Pub. L. No. 111-148, § 6002, 124 Stat. 395.

economic value,” and “non-CME educational presentations.” Manufacturers also should review and consider updates to current policies, procedures, systems, and training related to reporting requirements in order to capture and file quarterly reports regarding non-CME events.

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*This Client Alert was authored by **Sarah K. diFrancesca** and **Natasha F. Thoren**. For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

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