EPSTEIN BECKER GREEN | HEALTH CARE & LIFE SCIENCES CLIENT ALERT

Thought Leaders in Health Law®

Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct: Final Amendments to Be Issued

by Wendy C. Goldstein and Natasha F. Thoren

December 2012

On November 21, 2012, the Massachusetts Public Health Council approved final amendments to 105 Mass. Code Regs. 970.000, the Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Law ("Massachusetts Marketing Code of Conduct"). These final amendments will implement changes to the Massachusetts Marketing Code of Conduct, Mass. Gen. Law ch. 111N,[1] which were included in the fiscal year ("FY") 2013 Commonwealth budget, effective July 8, 2012.[2] The Massachusetts Department of Public Health ("DPH") will file the amendments with the Secretary of the Commonwealth for final promulgation, which is scheduled to occur on December 7, 2012, at which time they will take effect. The final regulations can be found at http://www.mass.gov/dph/pharmamed.

Significantly, the final regulations adopt most of the September 19, 2012, emergency amendments, but with some substantive changes.[3] Specifically, the key areas that have changed from the emergency regulations include federal preemption for annual reporting and the content of quarterly reports. Those areas that generally have remained the same from the emergency rules include modest meals, expenses related to training, and the requirement for annual fees. This Client Alert provides an overview of the final regulations. It also briefly discusses some key considerations for pharmaceutical and medical device manufacturers as they seek to implement the final regulations.

---

[1] By way of background, the Massachusetts Marketing Code of Conduct was created as part of Chapter 305 of the Acts of 2008, "An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care." Per the statute, the Massachusetts Department of Public Health originally promulgated regulations in April of 2009. For more background information, see the Epstein Becker Green Client Alert *available at* http://www.ebglaw.com/showclientalert.aspx?Show=9522.

[2] For an overview of the amendments to Mass. Gen. Law ch. 111N, see the Epstein Becker Green Client Alert *available at* http://www.ebglaw.com/showclientalert.aspx?Show=16297.

[3] On September 19, 2012, members of the Massachusetts Public Health Council approved emergency amendments that were presented by staff. These emergency amendments were filed with the Secretary of the Commonwealth on the same day and were in effect for three months. During the three-month period, a public hearing was held and written comments were accepted.

Overview of Final Regulations Regarding Provision of Meals and Implementation of Recent Statutory Changes

"Modest Meals and Refreshments"

The final regulations define the term "modest meals and refreshments" as "food and/or drinks provided by or paid for by a pharmaceutical or medical device manufacturing company or agent to a health care practitioner that, as judged by local standards, are similar to what a health care practitioner might purchase when dining at his or her own expense."[4] The DPH did not impose a specific dollar limit on meals, staying consistent with the definitions in the most recent version of the Code on Interactions with Healthcare Professionals developed by the Pharmaceutical Research and Manufacturers of America and the Code on Interactions with Healthcare Professionals developed by the Advanced Medical Technology Association. The final regulations and statute are both silent regarding the provision of alcoholic beverages. The DPH explained that "the legislature chose the term 'modest meals and refreshments' rather than simply 'modest meals.'"[5]

Significantly, the final regulations maintain the quarterly reporting requirement from the amended statute.[6] Therefore, no pharmaceutical or medical device manufacturing company may provide payment for modest meals and refreshments unless the company files quarterly reports detailing all non-continuing medical education ("non-CME") educational presentations at which such meals or refreshments are provided.[7] This requirement will continue to exist even though the information will be included in the reports submitted under the Affordable Care Act (the relevant provisions known as the Physician Payments Sunshine Act)[8] and also likely preempted if challenged.[9]

The requirement for quarterly reports also includes a new catch-all provision, allowing the DPH to request reporting of additional information, as deemed necessary.

---

[4] 105 Mass. Code Regs. 970.000 (2012).

[5] Madeleine Biondolillo, Public Health Council Memorandum: Request to Promulgate Final Amendments to 105 CMR 970.000 (Pharmaceutical and Medical Device Manufacturer Conduct) (November 21, 2012), http://www.mass.gov/eohhs/gov/laws-regs/dph/proposed-regulations/pharmaceutical-and-medical-device-manufacturer-code.html.

[6] *See* Conference Committee, Fiscal year 2013 Budget Recommendations, H. 4200, § 111-114 (Mass. 2012).

[7] The final regulations state that all reports should include: the location of the non-CME presentation; a description of any pharmaceutical products, medical devices, or other products discussed at such presentations; 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; and such other information as determined necessary by the Commissioner of the DPH.

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

[9] Madeleine Biondolillo, Public Health Council Memorandum: Request to Promulgate Final Amendments to 105 CMR 970.000 (Pharmaceutical and Medical Device Manufacturer Conduct) (November 21, 2012), http://www.mass.gov/eohhs/gov/laws-regs/dph/proposed-regulations/pharmaceutical-and-medical-device-manufacturer-code.html.

"Venue and Manner Conducive to Informational Communication"

The final regulations do not include additional guidance as to the meaning of a "venue and manner conducive to informational communication."

"Expenses Related to Training"

The final regulations include the specific language from the FY 2013 budget stating that "nothing in 105 CMR 970.000 shall prohibit the following … payment or reimbursement for the reasonable expenses, including travel and lodging related expenses necessary for technical training of health care practitioners on the use of a medical device…."[10] Therefore, the payment of reasonable expenses necessary for technical training on the use of a medical device without a requirement for a pre-existing vendor purchase contract is permitted.

"Annual Fee and Federal Preemption"

The DPH codified the annual $2,000 registration fee by including this fee in a new section of the final regulations.[11]

Significantly, the final regulations provide that no pharmaceutical and medical device manufacturing company is required to disclose information to the DPH that has been disclosed to the federal agency pursuant to the Affordable Care Act. However, as stated above, the quarterly reports associated with modest meals provided at non-CME events will continue to be required, as well as reports of information not covered under the Affordable Care Act.

Key Considerations

The final regulations provide new compliance considerations for pharmaceutical and medical device manufacturers that operate in the Commonwealth of Massachusetts. However, the entire effect will remain unclear until the federal rules to the Affordable Care Act are promulgated, which is expected shortly. In the interim, companies should review current infrastructure and assess gaps that may exist that prevent compliance with the final regulations.

* * *

This Client Alert was authored by **Wendy C. Goldstein** *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.*

[10] *See* Conference Committee, Fiscal Year 2013 Budget Recommendations, H. 4200, § 111-114 (Mass. 2012); *see also* Mass. Code Regs. 970.000 (2012).
[11] *See* 105 Mass. Code Regs. 970.009(2) (2012).

About Epstein Becker Green

Epstein Becker & Green, P.C., founded in 1973, is a national law firm with approximately 300 lawyers practicing in 11 offices, in Atlanta, Boston, Chicago, Houston, Indianapolis, Los Angeles, New York, Newark, San Francisco, Stamford, and Washington, D.C. The firm is uncompromising in its pursuit of legal excellence and client service in its areas of practice: Health Care and Life Sciences, Labor and Employment, Litigation, Corporate Services, and Employee Benefits. Epstein Becker Green was founded to serve the health care industry and has been at the forefront of health care legal developments since 1973. The firm is also proud to be a trusted advisor to clients in the financial services and hospitality industries, among others, representing entities from startups to Fortune 100 companies. Our commitment to these practices and industries reflects the founders' belief in focused proficiency paired with seasoned experience. For more information, visit www.ebglaw.com.

The Epstein Becker Green Client Alert is published by EBG's Health Care and Life Sciences practice to inform health care organizations of all types about significant new legal developments.

Lynn Shapiro Snyder, Esq.
EDITOR

If you would like to be added to our mailing list or need to update your contact information, please contact Kristi Swanson at kswanson@ebglaw.com or 202-861-4186.