

## Massachusetts DPH Finalizes Revised “Gift Ban” Regulations

Written by Pat A. Cerundolo, Colin J. Zick, Tad Heuer

November 26, 2012

Softens Rules on Meals, Expense Reporting, and Payment of Med Device Training Expenses

On November 21, 2012, the Public Health Council promulgated final revised regulations relating to the so-called physician gift ban law, Mass. Gen. Laws c. 111N (“Chapter 111N”). Most notably, the revised regulations now permit “modest” meals to be provided at manufacturer-sponsored educational presentations held outside of the hospital setting, streamline marketing expense reporting requirements for manufacturers, and authorize manufacturers to reimburse health care practitioners for medical device training expenses.

In July 2012, the Massachusetts legislature enacted several statutory amendments to Chapter 111N. Prior to these statutory amendments, Chapter 111N banned any manufacturer-sponsored meals for health care practitioners that were provided outside of the hospital setting, and required manufacturers to report to the Massachusetts Department of Public Health (DPH) a broad range of marketing expenses and other transfers made to drug prescribers and purchasers.

One of the new statutory amendments permits manufacturers to provide “modest meals and refreshments” to health care practitioners outside of the hospital setting in connection with “non-CME educational presentations for the purpose of educating and informing healthcare 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 matter conducive to information communication” (emphasis supplied). The statutory amendments expressly require DPH to define “modest meals and refreshments” by regulation.

At a hearing of the Public Health Council on September 19, 2012, DPH presented emergency amendments to the Pharmaceutical and Medical Device Manufacturer Conduct regulations (105 CMR 970). The Public Health Council heard public testimony on the emergency amendments at a public hearing on October 19, 2012. On November 21, 2012, the Public Health Council voted to promulgate final regulations (effective upon publication in the Massachusetts Register on December 7, 2012).

The final regulations make the following three significant changes to 105 CMR 970. First, with respect to meals, manufacturers may now provide “modest” meals and refreshments at manufacturer-sponsored educational presentations outside of the hospital setting. “Modest” meals and refreshments are defined 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” (emphasis supplied). DPH has stated that this definition is based in part on guidance for health care practitioners published by the American Medical Association.

Manufacturers sponsoring meals at educational programs must disclose on a quarterly basis (a) the location of the presentation, (b) a description of the products discussed, (c) the total amount expended on such presentation, (d) an estimate of the per-participant expenditure for meals, refreshments and other items of economic value, and (e) any other information determined necessary by DPH. The Public Health Council has suggested that in the category of “any other information,” DPH may consider such other expense categories as alcohol costs and speaker qualifications.

Second, with respect to the reporting of marketing expenses, under the revised regulations, manufacturers reporting marketing expenses under the federal Sunshine Act (42 U.S.C. § 1320a-7h) to the U.S. Department of Health and Human Services are relieved from reporting the same information to DPH. However, manufacturers must continue to comply with all other expense reporting requirements under 105 CMR 970.009. This regulatory amendment is likely intended to align the existing Massachusetts reporting requirements with the federal Sunshine Act, which pre-empts any state law requiring manufacturers to report to a state any marketing expense information that also must be reported to HHS.

Finally, the final regulations confirm, as required by the recent statutory amendments to Chapter 111N, that medical device companies can reimburse health care practitioners for reasonable expenses necessary for technical training on the use of a medical device, regardless of whether such payments are permitted under a purchase contract for the device.

#### RELATED INDUSTRIES

- [Life Sciences](#)
  - [Healthcare](#)
- 

This communication is intended for general information purposes and as a service to clients and friends of Foley Hoag LLP. This communication should not be construed as legal advice or a legal opinion on any specific facts or circumstances, and does not create an attorney-client relationship.

United States Treasury Regulations require us to disclose the following: Any tax advice included in this document was not intended or written to be used, and it cannot be used, for the purpose of avoiding penalties under the Internal Revenue Code.

Attorney advertising. Prior results do not guarantee a similar outcome. © 2017 Foley Hoag LLP. All rights reserved.