

Massachusetts “Gift Ban” Law: Emergency Regulations Implement Partial Repeal

On September 19, 2012, the Massachusetts Department of Public Health (“DPH”) amended the Pharmaceutical and Medical Device Manufacturer Code of Conduct [regulations](#) (the “Code of Conduct”). The amended regulations modify the obligations of pharmaceutical and medical device manufacturers by: (1) implementing recent changes to the governing [statute](#); (2) eliminating certain disclosure requirements; and (3) clarifying manufacturer obligations with respect to registration and reporting non-compliance.

The revised Code of Conduct relaxes certain restrictions on interactions between manufacturers and health care practitioners.

- Meals in Connection with Educational Presentations. Manufacturers may now provide “modest meals and refreshments” to health care practitioners *outside* the office or hospital setting if: (1) the food or drink is provided in connection with educating or informing the health care practitioners about a drug or medical device product, disease states or other scientific information; *and* (2) any such communications occur in a venue and manner conducive to informational communication. In order to provide the food or drink, manufacturers must also agree to quarterly reports detailing the locations, products discussed, and the associated total and per-participant expenditures. Significant ambiguities remain:
 - “Modest meals and refreshments” are defined as food or drinks that “as judged by local standards, are similar to what a health care practitioner might purchase when dining at his or her own expense.” This definition creates a potentially variable standard. By contrast, many manufacturers have established and seek to apply uniform meal limits that reflect general standards regarding modest meals.
 - A “venue ...conducive to informational communication” remains undefined.
 - The full scope of educational and informational presentations that would support a meal *outside* an office or hospital setting is not clear. The new disclosure requirements suggest that the presentations must be educational presentations (other than continuing medical educational presentations) rather than simply informal communications (regardless of whether educational for the health care practitioner).

These ambiguities will hopefully be resolved by DPH through clarifying guidance.

- Product Training Expenses. Manufacturers may now pay the reasonable expenses incurred by health care practitioners when participating in technical training in medical device use *without the need to include the obligation to pay the expenses in a written purchase agreement.*

The revised Code of Conduct would also phase out manufacturer reporting obligations. After calendar year 2012, manufacturers would no longer have to collect and report payments of \$50 or more to health care practitioners and health care providers, as is currently required. A manufacturer would also be deemed to comply with the new quarterly reporting requirements on meals provided outside an office or hospital setting if the manufacturer made all the disclosures required under the Federal Sunshine Law to the U.S. Department of Health and Human Services (“HHS”) (which are then provided to DPH by HHS).

The revised Code of Conduct also expressly states that manufacturers must annually register and pay the annual registration fee. The revisions further require manufacturers to self-report non-compliance with the Code of Conduct.

Because DPH issued the amendments as emergency regulations, the new rules became legally effective immediately for a period of three months. During that time, DPH must hold a public hearing in order for the regulations to be permanently adopted. Following public comment, DPH may revise the amendments, permanently publish them as initially adopted, or allow the emergency regulations to expire.

We continue to monitor these evolving requirements. If you have questions with respect to these regulations, please contact your usual Ropes & Gray advisor or the attorneys listed below:

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