Massachusetts Amended Regulation

105 C.M.R. 970.000

The amended Gift Ban now does the following:

- Permits the payment of reasonable expenses necessary for technical training on the use of medical devices. This allows medical device manufacturers to provide essential training on new and innovative medical devices without a written sales agreement between the device manufacturer and the healthcare practitioner.

- Permits pharmaceutical and medical device companies to pay for modest meals and refreshments for healthcare practitioners, in connection with non-CME educational presentations made 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 the following occur:

- Such meals and refreshments occur in a venue and manner conducive to informational communication
- Such educational presentations are not used to promote off-label uses of prescription drugs or medical devices
- Pharmaceutical or medical device manufacturers comply with the new quarterly reporting requirement described below

This expands the current law significantly from only allowing meals within a healthcare practitioner's office or a hospital setting to include other venues such as a restaurant.

- Defines 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."

- Requires pharmaceutical and medical device manufacturers to submit quarterly reports related to non-CME educational presentations at which meals or refreshments are provided. These quarterly reports are to include the following:

- Location of the non-CME presentation
- Description of any products discussed at the non-CME presentation
- Total amount expended for the non-CME presentation, including the amount expended per participant—factoring in meals, refreshments, and other items of economic value provided

- Highlights that a company will be deemed to have met the quarterly non-CME meal reporting requirement if the company "makes all disclosures required under federal law" that are then provided by the Centers for Medicare and Medicaid Services (CMS) to the Department on an annual basis.

- Requires the Department to make publicly available and searchable on its website all data disclosed in annual reports from drug and device companies within 90 days of receipt.

- Provides a sunset date for required reporting to the Department. No reporting will be required subsequent to the reporting of payment activities for calendar year 2012, provided that the company makes all appropriate disclosures required under federal law.

- Outlines that after the payment of the annual $2,000 registration fee due July 1, 2012, the Department will no longer require such payment.

- Notably, establishes a **new requirement** that each pharmaceutical or medical device manufacturer "**must**report all incidents of noncompliance with 105 C.M.R. 970.000 to the Department and to the Office of the Attorney General in a format specified by the Department [emphasis added]." Companies that have not reported as required or knowingly have incomplete reports should assess the applicability of this provision, including whether it is has prospective or retroactive applicability from the effective date of the amendments.