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Massachusetts Adopts Revisions to Health Care Practitioner "Gift Ban" Law

Amendments permit pharmaceutical and medical device companies to pay reasonable expenses for medical device training, and for modest meals and refreshments for educational interactions.

On July 8, Massachusetts Governor Deval Patrick signed the commonwealth's FY 2013 budget, which included legislation that amended the Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct. In essence, the amendments to the Code of Conduct struck down part of the so-called "Gift Ban" Law (Gift Ban), codified at Mass. Gen. Laws Ch. 111N (2008). Before it was amended, the Gift Ban imposed certain restrictions on the provision of meals, gifts, and other transfers of value by pharmaceutical and medical device manufacturers to health care practitioners. The law also required drug and device manufacturers to annually report allowable gifts and other transfers of value provided to health care practitioners. The implementation regulation issued by the Massachusetts Department of Public Health (Department) is codified at 105 C.M.R. 970.000 (2009).

Changes to the Gift Ban

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 amendment will allow medical device manufacturers to provide essential training on new and innovative medical devices without a written sales agreement in place between the device manufacturer and the health care practitioner.

- Permits pharmaceutical and medical device companies to pay for "modest meals and refreshments" for health care practitioners, in connection with non-CME educational presentations made 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 the following requirements are met:
  - Such meals and refreshments "occur in a venue and manner conducive to informational communication."
  - Pharmaceutical or medical device manufacturers comply with the new quarterly reporting requirement described below.

  This significantly eases the Gift Ban's previous meal and refreshment provision restriction (i.e., only allowing meals within a health care practitioner's office or in a hospital setting), and now permits meals and refreshments in other venues, such as restaurants.

- Requires pharmaceutical and medical device manufacturers to submit quarterly reports related to non-CME educational presentations at which meals or refreshments are provided. Although the Department will be issuing regulations for implementation, the amendment does specify that such reporting will require companies to report, at a minimum, the following information:
  - The location of the non-CME presentation.

  - A description of any products discussed at the non-CME presentation.
  - The 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.

  The amendments include a provision to allow the Department to assess an administrative fee to pay for the costs related to these new reporting requirements.

- Provides the Department with the discretion to determine the definition of "modest" as it relates to "modest meals and refreshments."

- 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 that pharmaceutical and medical device manufacturers will not be required to disclose under the amended Massachusetts law information that is required to be disclosed to the federal government. The Department will obtain this data directly from the Centers for Medicare and Medicaid Services (CMS).

These significant amendments to the Gift Ban help to eliminate redundancies that would have existed after the implementation of federal transparency reporting requirements under Section 6002 of the Patient Protection and Affordable Care Act, known broadly as the U.S. Sunshine Act. However, until CMS issues its final rule implementing the U.S. Sunshine Act, companies will have to continue to report required data to the Department. CMS issued its proposed transparency reporting rule in December 2011 and has since indicated that tracking requirements will not be effective prior to January 2013.

These amendments to the Gift Ban do not impact the recent July 1 reporting deadline for pharmaceutical and medical device companies. Undoubtedly, affected companies will look forward to conforming amendments to regulation 105 C.M.R. 970.000 effectuating these changes. Given the nature of these amendments, the upcoming registration renewal process is likely to remain unchanged

As part of the upcoming registration renewal process, which must be completed annually by August 31, pharmaceutical and medical device manufacturers must complete a compliance filing, including the company's compliance officer contact information, a certification of compliance with 105 C.M.R. 970.000, and remittance of an annual fee of $2,000 payable to the Commonwealth of Massachusetts. Information related to the online or manual renewal process can be found at www.mass.gov.

Implications

While the amendments passed on July 8 did not specify an effective date, the Department is tasked with providing guidance on the new quarterly reporting on non-CME presentations and any modest meals and refreshments or other items of value provided to a health care practitioner at the educational presentations. This and other significant changes will likely necessitate the amendment of regulation 105 C.M.R. 970.000. Until such action has taken place, companies should continue to comply with the regulation currently in effect.

Morgan Lewis counsels the health industry on federal and state transparency requirements, including medical device and pharmaceutical companies, hospitals, physicians, and other healthcare entities. We invite you to visit our Transparency Compliance Resource Center for updates regarding health industry transparency compliance, regulations, and industry codes of ethics. If you have questions, please contact our Transparency Compliance team at TransparencyCompliance@MorganLewis.com.

Contacts

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