

New Flexibility for Pharmaceutical and Medical Device Companies in Massachusetts, but at a Price

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In July 2012 Massachusetts amended its Gift Ban Law and its Anti-Kickback Statute, both of which are among the most restrictive state laws of their kind. The amendments allow pharmaceutical and medical device manufacturers to resume certain educational and promotional activities that previously had been prohibited, and eliminate Massachusetts-specific payment disclosure obligations that are duplicative of disclosures required under federal law. Along with these welcome opportunities, however, the amendments established a new quarterly reporting obligation for certain educational expenditures.

On July 8, 2012, Massachusetts enacted a set of noteworthy amendments to two Massachusetts health care statutes, the so-called Gift Ban Law (Mass. General Laws (M.G.L.) Ch. 111N) and the Massachusetts Anti-Kickback Statute (M.G.L. Ch. 175H § 3). These changes, enacted as part of the fiscal 2013 budget, became effective as of July 1, 2012.

Gift Ban Law Modifications

In 2008 Massachusetts enacted a law, often referred to as the Gift Ban Law, that prohibited pharmaceutical and medical device companies from, among other things, providing or paying for meals that were offered, consumed or provided outside of the office or hospital setting (M.G.L. Ch. 111N § 2). The recent budget amendments modified the Gift Ban Law to allow pharmaceutical and medical device manufacturers to provide “modest meals and refreshments” to health care practitioners (HCPs) in connection with non-continuing medical education (CME) presentations outside of an HCP’s office or hospital setting “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 such presentations occur in a venue and manner conducive to informational communication.” The definition of “modest meals and refreshments” will be promulgated in regulations by the Massachusetts Department of Public Health (DPH). This change makes the Massachusetts law more consistent with industry standards, such as the PhRMA Code and AdvaMed Code.

Pharmaceutical and medical device manufacturers that provide modest meals and refreshments will be required to report associated expenses to the DPH on a quarterly basis. These quarterly reports must include: the location of the non-CME presentation, a description of any pharmaceutical

products, medical devices or other products discussed at the presentation, and the total amount expended on such presentation as well as an estimate of the amount expended per participant, factoring in meals, refreshments and/or other items of economic value.

This quarterly reporting requirement for modest meals and refreshments adds to the disclosure obligations previously established under the Gift Ban Law—i.e., disclosure of the value, nature, purpose and name of the recipient of any fee, payment, subsidy or other economic benefit greater than \$50 that a pharmaceutical or medical device company provides, directly or indirectly, to any HCP, hospital, nursing home, pharmacist, health benefit plan administrator or any other person authorized to prescribe, dispense or purchase pharmaceuticals or medical devices (M.G.L. Ch. 111N § 6). However, the amendments specify that pharmaceutical or medical device companies will no longer need to disclose any payments or transfers of value to the DPH if such information is disclosed to the federal government as required by federal law, i.e., pursuant to the federal Sunshine Act, expected to be implemented in 2013.

For payments or transfers of value within the scope of the federal Sunshine Act, the DPH will be required to make information from the annual reports of the U.S. Department of Health and Human Services (HHS) available and easily searchable on its website within 90 days of receiving these reports from HHS.

The new rules seek to align the Gift Ban Law with the preemption provisions of the federal Sunshine Act and consequently do provide some relief from duplicative reporting at the federal and state level. However, it is important to note that pharmaceutical and medical device companies will still be required to report to the DPH any payments or other transfers of value that are required by Massachusetts' Gift Ban Law, but are not required by the federal Sunshine Provisions (e.g., payments to nonphysician recipients such as nursing homes, pharmacists and health benefit plan administrators). In addition, given that federal Sunshine Act reporting is annual and the Massachusetts requirement for disclosure of non-CME educational expenses is quarterly, there remains some uncertainty as to how pharmaceutical and device manufacturers will determine, in real time through the course of a calendar year, whether Massachusetts reporting is preempted.

The new quarterly reporting requirement for non-CME educational expenses underscores the need for companies to continue investing in the necessary procedures and infrastructure to collect and submit information regarding financial relationships with HCPs and other stakeholders. Such investments are necessary not only for compliance with Massachusetts law, but also to ensure readiness for the Sunshine Act, which will take effect upon the issuance of final federal regulations, perhaps by the end of this year.

The Gift Ban Law also has been modified to permit medical device manufacturers to pay for reasonable expenses for technical training on the use of a medical device, regardless of whether the device is the subject of a contract. Previously, such reasonable, training-related expenses could be paid only if the expenses were part of a purchase contract for the device (M.G.L. Ch. 111N § 2).

Exception to the Anti-Kickback Statute for Certain Coupons

The budget amendments also amended the Massachusetts Anti-Kickback Statute to permit pharmaceutical manufacturers to offer coupons, discounts, rebates, product vouchers or other reductions in consumers' out-of-pocket expenses for biological products and some prescription drugs. Prior to this amendment, Massachusetts' Anti-Kickback Statute broadly prohibited any person from providing "any remuneration, including any bribe or rebate, directly or indirectly, overtly

or covertly, in cash or in kind to induce any person to purchase ... any good ... for which payment may be made in whole or in part by a health care insurer.”

The limited exception to the Anti-Kickback Statute allows the following types of coupons:

- Discount or free product vouchers provided by a retail pharmacy in connection with a pharmacy service, item or prescription transfer offer
- A discount, rebate, product voucher or other reduction in an individual's out-of-pocket expenses, including co-payments and deductibles

The exception specifies that such a discount, rebate, product voucher or other reduction must be provided directly or electronically to the consumer through a point-of-sale or mail-in rebate, or through “similar means.” Moreover, a pharmaceutical manufacturer may not limit the pharmacies where the coupon offer may be redeemed and may not offer a coupon for a product for which an AB-generic equivalent exists, as determined by the U.S. Food and Drug Administration.

This exception to the Anti-Kickback Statute is scheduled to sunset on July 1, 2015.

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Massachusetts' Gift Ban Law and Anti-Kickback Statute are among the most restrictive state laws of their kind. These modifications, therefore, afford welcome opportunities for pharmaceutical and medical device companies to resume certain HCP and consumer interactions that previously had been prohibited. The flexibility provided by these budget amendments is limited, however, and certain key parameters, such as the definition of “modest meals and refreshments,” still need to be determined. Thus pharmaceutical and medical device companies would be prudent to implement their Massachusetts gift and coupon programs with appropriate caution and to participate in any available rule-making opportunities that would give further definition and scope to these amendments.

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