

Proposed Massachusetts Laws Would Ban Gifts By Drug and Device Marketers, Require Licensing of Pharmaceutical Representatives

The Massachusetts Senate recently approved legislation that, if enacted into law, would impose criminal and civil penalties on the practice of pharmaceutical and device marketing agents' giving of gifts to physicians and other health care providers. The legislation would also require the licensing of pharmaceutical sales representatives. If enacted into law, these proposals could have a wide-reaching impact – and some unintended consequences – on common interactions and business relationships between pharmaceutical and device companies and physicians and other health care providers in Massachusetts.

Ban on "Gifts" to Physicians and Other Providers

The two proposed laws approved by the Massachusetts Senate, which are similar to each other, would prohibit pharmaceutical and medical device marketing agents from offering or giving gifts of any value to physicians and members of their immediate families. Physicians and their family members would be prohibited from soliciting or accepting gifts from marketing agents. One proposed law would also ban gifts from marketers to hospitals and other health care facilities, their employees and agents, and public officials. Violations would be punishable by fines up to \$5,000 or imprisonment for not more than two years, or both.

Who Would Be Affected By The Gift Ban?

The scope of the proposed ban is much broader than it initially appears because of the way terms such as "pharmaceutical manufacturer agent" are defined. A pharmaceutical manufacturer agent means not only an individual pharmaceutical sales representative, but also any medical device company sales representative and any individual or company "who for compensation or reward does any act to promote, oppose or influence the prescribing of a particular prescription drug or medical device." Limited exceptions apply for licensed pharmacists, physicians and other health care professionals acting within the scope of their licensed practice.

The proposed statute that would apply the gift ban to health care facilities and their employees does not define health care facility. "Health care facility" is defined elsewhere in the Massachusetts General Laws to include hospitals, clinics, nursing homes, and community health agencies licensed by the Department of Public Health.

What Is A Prohibited Gift?

A gift is also defined very broadly as "anything of value . . . unless consideration of equal or greater value is received." Specific examples of prohibited gifts in the legislation include any payment, travel, honorarium, entertainment, advance, subscription or service.

The proposed ban exempts only a few categories of gifts, namely inheritances, gifts given in a familial context, and commercially reasonable loans made in the ordinary course of business. Drug samples provided to a physician (but not any other type of prescriber or health care facility) are also exempted if the drugs are to be used for the physician's patients.

Violations

Although the proposed gift ban would be a criminal statute, the only intent requirement is to "knowingly and willfully" offer, give, solicit or accept a gift. A party could be prosecuted and penalized regardless of whether the gift was intended to influence prescribing behavior. The prohibition contains no *de minimis* exception; one gift of any value could violate the statute.

Licensing Of Sales Representatives

Another proposed law approved by the Massachusetts Senate directs the Department of Public Health to promulgate regulations requiring all pharmaceutical representatives to be licensed. These regulations, to be developed in consultation with the Board of Registration of Pharmacy, may require training before the initial license is granted, as well as continuing education. The proposal sets the license fee at \$500 per year.

Possible Impact And Unanswered Questions

- In comparison to the 2004 California law that requires pharmaceutical companies operating in that state to maintain comprehensive compliance programs, the proposed Massachusetts legislation contemplates more direct regulation of drug and device marketing by the state government.
- These proposals are not limited to transactions that involve items or services reimbursed by Medicaid or other governmental programs. Rather, they would apply regardless of who ultimately reimburses the physician or health care facility for the drug or device involved.
- The broad definitions of “gift” and “pharmaceutical manufacturer agent” could have a chilling effect on standard business arrangements between physicians and health care facilities, on the one hand, and pharmaceutical and device companies, on the other hand. The proposed statutes give no guidance as to how to interpret “consideration of equal or greater value,” and the penalty for guessing wrong could include imprisonment.
- Compensation arrangements that are permissible under the federal anti-kickback statute and under the existing Massachusetts anti-kickback statute could still violate the proposed Massachusetts gift ban law. In addition, the proposed law contains no safe harbors and only a short list of exceptions to the broad prohibition.
- It is unknown what licensure requirements would be imposed on pharmaceutical representatives by the Department of Public Health, and under what circumstances the Department would have the authority to suspend or revoke representatives’ licenses.

These proposals were approved by the Massachusetts Senate on May 25, 2006 as amendments to the state budget for fiscal year 2007 (the current fiscal year ends on June 30, 2006). In early June, the Massachusetts House and the Massachusetts Senate each appointed members to a joint conference committee to reconcile the House and Senate versions of the state budget. If these proposals are in the version of the state budget approved by the joint committee, Massachusetts Governor Mitt Romney will have ten days to review, sign, veto, or recommend changes to this budget.

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