



Health Law Alert

Legal and political developments affecting the health care industry

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Gift bans

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According to the Center for Disease Control, in 1982 the United States spent a cumulative \$15 billion on retail prescription drugs. By 2002, the aggregate spending grew to \$162 billion. Although a significant portion of this increase is due to the development and availability of new drugs, many attribute the massive increase to the sales and marketing techniques of the pharmaceutical industry. There is a growing concern that drug and medical device marketing geared towards physicians significantly increases prescribing patterns. Consequently, individual states are taking action to regulate the influence pharmaceutical and medical device manufacturers exert over prescribers. Massachusetts implemented one of the broadest statutes among the states, outright banning physician gift giving by pharmaceutical and medical device manufacturers. There is pending legislation in New York which focuses on the reporting of any gifts received.

Massachusetts legislation

Effective January 1, 2009, Massachusetts adopted a Pharmaceutical and Medical Device Manufacturer Code of Conduct, M.G.L. c. 111N, with the stated goal of ensuring that the relationship between health care practitioners and pharmaceutical or medical device manufacturers not interfere with the independent judgment of health care practitioners. One aspect of the new law important for health care practitioners licensed in Massachusetts is the prohibition against manufacturer's payments and provision of certain meals to health care practitioners.

By July 1, 2009, each pharmaceutical or medical device manufacturing company that employs or contracts with a pharmaceutical or medical device manufacturer agent and meets other specified criteria shall have adopted a marketing code of conduct in compliance with new Massachusetts regulations, 105 Code of Massachusetts Regulation 970.000. Such companies must also establish compliance and training programs pursuant to the Massachusetts code of conduct and, beginning July 1, 2010, disclose to state government marketing payments made to health care practitioners. Pharmaceutical and medical device manufacturing companies subject to the new law can no longer distribute to non-employee health care practitioners any entertainment and recreational items of any value, including theater or sporting event tickets, concert tickets, sporting equipment and leisure or vacation trips. Also prohibited are cash or cash equivalents, tangible items including complimentary items such as pens, coffee mugs, and gift cards. Further,

companies are prohibited from offering grants, scholarships, subsidies, supports, consulting contracts, and other educational or practice items in exchange for prescribing, disbursing or using or making a commitment to use a prescription drug or medical device.

The new law prohibits the manufacturer's provision of meals for health care practitioners that are part of an entertainment or recreational event; are offered without an informational presentation made by a pharmaceutical or medical device marketing agent or without an agent being present; are offered, consumed, or provided outside of the health care practitioner's office or hospital setting; or are provided to the practitioner's spouse or other guest. All permitted meals must be modest and occasional in nature and provided within the practitioner's office or hospital setting. The statute also specifies that any transaction violating the federal Anti-Kickback Statute and its Massachusetts counterpart also violates the new statute. Any knowing and willful violator may be fined up to \$5,000 per transaction, occurrence, or event.

The Massachusetts Code of Conduct applies to activities that either take place in Massachusetts or involve a Massachusetts-licensed health care practitioner.

Pending New York legislation

In 2008 and 2009, Governor Paterson proposed legislation similar to that of Massachusetts to prohibit pharmaceutical companies and drug device manufacturers from distributing gifts to prescribers exceeding fifty dollars in the aggregate per year. In both years, the gift ban legislation failed to pass. Currently, two bills are pending before the New York State Senate that would modify current New York general business and public health law. These bills provide significantly less stringent regulation in comparison to the gift bans proposed by Governor Paterson. The bills stipulate disclosure standards for gifts given by pharmaceutical and medical device manufacturers. The bills require regulated companies to report any gifts having a value of \$75 or more. Failure to disclose in a timely manner results in a fine of up to \$50 per day, with a maximum penalty of \$3,000 per violation. Unlike the Massachusetts gift ban, which outright prohibits most traditional physician gifts, the New York proposed legislation is designed exclusively to create transparency by providing consumers with information regarding potential conflicts of interest between medical providers and pharmaceutical and medical device manufacturers.

PhRMA code on interactions with health care professionals

While individual states are making efforts to curb physician gift giving, the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals already significantly restricted the practice as of January 2009. The PhRMA Code of Ethics is designed to ensure prescribers have the most up-to-date and accurate information regarding available medication to maximize patient benefit. The guidelines prohibit the distribution of non-educational and practice-related items including gifts displaying a company's logo. The code also limits pharmaceutical companies and medical device manufacturers to offering occasional, modest meals only to be provided in conjunction with a presentation of scientific or educational value. Additionally, these meals are restricted to in-office or in-hospital settings. Other PhRMA Code regulations prohibit pharmaceutical companies from providing entertainment and recreational benefits, regulate the provision of Continuing Medical Education programs, and limit compensatory arrangements between pharmaceutical companies and consultants. While PhRMA membership is not mandatory, major players in the pharmaceutical industry voluntarily subject themselves to membership certification. Therefore, those states implementing gift bans may not impact the health care industry as drastically as anticipated.

Impact

The general purposes of recent gift regulation laws are to increase consumer trust in prescribers by requiring transparency and to decrease the undue influence that a pharmaceutical or medical device manufacturing company may have on a medical provider's prescribing patterns. Alternatively, some argue that the gift ban will harm the local health care industry because pharmaceutical companies and medical device manufacturers may simply be deterred from engaging in business transactions within the legislating state or with health care practitioners licensed in the legislating state. Other critics are concerned that the new restrictions will have a trickle-down negative effect on other industries. Specifically, several Massachusetts hotels and convention centers expressed a concern that the visitor industry could be adversely affected because medical and scientific conferences may be less likely to be held in a state with a gift ban in place or with a prohibition against manufacturers paying for meals outside of a hospital setting. Under the Massachusetts law, continuing medical education and third party professional and scientific meetings may still be held in convention centers, hotels, or other special event venues. Third party organizers are permitted to use general funds from such manufacturers to provide meals.

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