

HEALTH CARE
&
HUMAN
SERVICES

David P. Glasel, Chair
518.429.4250
dglasel@hblaw.com

Marie A. Butchello
Linda J. Clark
Charles Z. Feldman
Sheila A. Gaddis
James S. Grossman
Holly J. Hoehner
Tara N. Kamble
Eugene M. Laks
Henry J. Nahal
Gabriel M. Nugent
Margaret Surowka Rossi
Robert G. Tengeler
Melissa M. Zambri

Strict New Marketing Rules for Drug and Medical Device Companies Now Final

On March 11, 2009, the Massachusetts Department of Public Health (DPH) issued final regulations interpreting the law passed last summer that imposes strict new limits on marketing activities conducted by pharmaceutical and medical device manufacturers in the commonwealth.

Signed into law on August 10, 2008, the "Act To Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care" requires pharmaceutical and medical device companies that market their products in the commonwealth or to Massachusetts-licensed healthcare practitioners to (1) adopt and comply with a state-authored marketing code of conduct, and to establish training programs and compliance procedures related thereto, and (2) disclose annually payments and other economic benefits with a value of at least \$50 made to healthcare practitioners in connection with the company's sales and marketing activities. This law marks the first comprehensive compliance program and marketing expenditure disclosure law in the country, and is the first to apply the disclosure requirement to medical device companies. The effective date of the new regulations is July 1, 2009.

Compliance Program Requirements

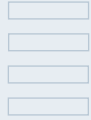
Under the new regulations, all pharmaceutical and medical device manufacturers that engage in marketing activities within the commonwealth, or that market their products to Massachusetts-licensed healthcare practitioners, must:

- Adopt a marketing code of conduct, similar to the guidelines issued by industry trade associations such as PhRMA and AdvaMed;
- Adopt and submit to the DPH a description of training under the code of conduct;
- Adopt and submit to the DPH policies and procedures for investigating and responding to instances of non-compliance, and reporting such instances to appropriate state authorities;
- Identify the compliance officer responsible for implementing and administering the code of conduct.

The code of conduct sets strict standards, including:

- Meals for healthcare practitioners are prohibited if they are (a) part of an entertainment or recreational event, (b) offered without an information presentation or without a company marketing agent present, (c) offered, consumed or provided outside of the healthcare practitioner's office or hospital setting, or (d) provided to a healthcare practitioner's spouse or other guest.
- Companies cannot pay for entertainment or recreational items of value, including tickets to theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare practitioner.

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- No sponsoring of continuing medical education (CME) that is not properly accredited or that provides payment directly to a healthcare practitioner.
- Companies cannot compensate healthcare practitioners for time spent at CME events, educational conferences, or professional meetings, nor can they provide meals to healthcare practitioners at such events.

Companies must certify that they have met the above requirements, and submit the required documents, to the DPH by July 1, 2009. On that date and annually thereafter, companies must certify that to the best of the companies' knowledge they are in compliance with their codes of conduct. Companies must also certify, beginning July 1, 2010, that they have conducted annual audits to monitor compliance with the regulations.

Disclosure Requirements

Pharmaceutical and medical device manufacturers are also required under the new regulations to disclose annually to the DPH the value, nature, purpose and recipient of any payments, fee or other economic benefit with a value of at least \$50 provided directly or indirectly to a healthcare practitioner in connection with the company's sales and marketing activities. Companies must begin tracking these expenditures on July 1, 2009, and the first disclosure report is due on July 1, 2010 for the period from July 1, 2009 to December 31, 2009. Thereafter, reports will be due on July 1 of each year for the entire previous calendar year.

For the purpose of computing the \$50 threshold, any payments relating to separate events or transactions must be calculated on an individual basis and may not be aggregated. Companies are prohibited from structuring payments to circumvent the reporting requirements.

Reports may be submitted electronically. Each annual report must be accompanied by a fee of \$2,000. Willful violation of the Act may result in a fine of up to \$5,000 for each event or transaction that should have been reported.

Next Steps

As the deadline for the first annual report approaches, all pharmaceutical and medical device manufacturers that market within the commonwealth should evaluate their marketing practices and ensure that their marketing codes of conduct comply with the Massachusetts requirements. It should also be noted that certain other states already impose or are considering compliance and disclosure requirements, and the federal government has proposed a disclosure law, known as the Physician Payments Sunshine Act, which would apply to both drug and device companies.

At Hiscock & Barclay, LLP, we can help you draft or revise your code of conduct, implement appropriate training, auditing, monitoring and enforcement policies and procedures, and develop a plan for tracking and reporting marketing expenditures. For more information, please contact Holly Hoehner or any member of the Health Care and Human Services Practice Area.



Holly J. Hoehner
 Partner, Syracuse
 hhoehner@hblaw.com
 (315) 425-2833



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