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To: Pharmaceutical and Medical Device Manufacturers

From: Madeleine Biondolillo, MD, Director

Date: December 28, 2011

RE: Continuing Pharmaceutical and Medical Device Manufacturer Disclosure Requirements for Calendar Year 2012

Background

Since the enactment of Massachusetts General Law c.111N, Pharmaceutical and Medical Device Manufacturer Conduct, and promulgation of Department of Public Health (Department) regulation 105 CMR 970.000 in 2009, manufacturers of pharmaceuticals and medical devices have been required to comply with the Massachusetts Code of Conduct ("gift ban") and to disclose marketing payments to "covered recipients" as defined in the law.

Physician Payments Sunshine Act and Future Federal Preemption of Certain Massachusetts Requirements

Promulgation of federal regulations pursuant to the provisions in the Affordable Care Act known as the Physician Payments Sunshine Act (the Sunshine Act) require manufacturers of drugs, biologics, devices, and medical supplies covered under Medicare, Medicaid, and the Children's Health Insurance Program to report payments and other transfers of value made to physicians and teaching hospitals to the Centers for Medicare and Medicaid Services (CMS) for subsequent public disclosure. The Sunshine Act also preempts any pertinent state law that requires the collection and reporting of the same data elements. Collection of information under the Sunshine Act was to begin January 1, 2012, but CMS announced in a proposed rule issued on December 14, 2011 that the agency would not require manufacturers to begin collection of information until after a final rule was promulgated, expected to be later in 2012. The proposed federal rule may be found in the December 19, 2011 *Federal Register* http://www.gpo.gov/fdsys/pkg/FR-2011-12-19/pdf/2011-32244.pdf.

Continuing Requirements

Until CMS publishes a final rule and certain Massachusetts requirements are preempted, ***pharmaceutical and medical device manufacturing companies must continue to collect and submit disclosures on all covered recipients as currently defined under the law,*** including physicians, nurse practitioners, physician assistants, pharmacists, dentists, clinics, clinical laboratories, all hospitals, nursing homes, and all other purchasers, prescribers, or dispensers of drugs, biologics, or medical devices.

Please note that all other requirements of the Department's regulation remain in effect. Continuing regulatory elements beyond the implementation of a final federal rule include the annual registration requirement and associated fee submitted to the Department, as well as the annual self-audit. Furthermore, the "gift ban" that prohibits specific types of payments and interactions between pharmaceutical and medical device companies and Massachusetts health care practitioners remains in effect and will not be altered by federal preemption. Consistent with the regulation, the Department expects companies to continue to report all instances of non-compliance.

If you have any questions regarding this message, please email pertinent Bureau of Health Care Safety and Quality policy staff, at pharmamedreg@massmail.state.ma.us.

CC: John Auerbach, Commissioner
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