Massachusetts DPH Proposes Revised Gift Ban Regulations

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Softens Rules on Meals at Industry-Sponsored Educational Programs, Rules on Expense Reporting, and Rules on Payment of Med Device Training Expenses

In July 2012 the Massachusetts legislature enacted several statutory amendments to the so-called physician gift ban law, Mass. Gen. L. c. 111N ("Chapter 111N"). Chapter 111N restricts transfers of value between pharmaceutical and medical device manufacturers and Massachusetts-licensed prescribers.

Prior to these statutory amendments, the law banned any manufacturer-sponsored meals for health care practitioners that were provided outside of the hospital setting. One of the recent statutory amendments now permits manufacturers to pay for "*modest meals and refreshments* in connection with non-CME educational presentations for the purpose of educating and informing healthcare 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 matter conducive to information communication" (emphasis supplied). In order to provide clarity on this new statutory provision, the amendments expressly required the Department of Public Health (DPH) to define "modest meals and refreshments" by regulation.

At a hearing of the Public Health Council on September 19, 2012, DPH presented emergency amendments to the Pharmaceutical and Medical Device Manufacturer Conduct regulations (105 CMR 970) in order to implement the recent amendments to Chapter 111N. Among other proposed changes, these emergency regulatory amendments define "modest" meals and refreshments as "food and or drinks provided by or paid for by a pharmaceutical or medical device manufacturing company or agent to a health care practitioner that, as judged by local standards, *are similar to what a health care practitioner might purchase when dining at his or her own expense*" (emphasis supplied). At the hearing, the DPH stated that this definition was based in part on guidance for health care practitioners published by the American Medical Association.

The emergency regulatory amendments propose two other changes of note. First, they would relieve companies from any disclosure of expense reports (and the payment of accompanying reporting fees to the DPH) for all calendar years after 2012, with one exception: companies reporting marketing expenses under the federal Sunshine Act (42 U.S.C. § 1320a-7h) to the U.S. Department of Health and Human Services (HHS) need only provide quarterly reports to DPH of the estimated amount expended on meals per participant at education programs held outside of the hospital setting. This regulatory amendment is likely intended to align the existing reporting requirements with the federal Sunshine Act, which pre-empts any state law requiring manufacturers to report to a state any marketing expense information that also must be reported to HHS.

Second, the emergency regulatory amendments confirm, as required by the recent statutory amendments to Chapter 111N, that medical device companies can reimburse health care practitioners for reasonable expenses necessary for technical training on the use of a medical device, regardless of whether such payments are permitted under a purchase contract for the device.

While the Public Health Council approved the emergency regulatory amendments to be effective immediately, the next step is for DPH to hold a public hearing on the emergency regulatory amendments. This public hearing is scheduled for October 19, 2012 at 10:00 AM. Written comments on the proposed emergency regulatory amendments must be submitted by October 26, 2012.

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