

# **Health Law Alert: Massachusetts Department of Public Health Issues Guidance Document IV To Clarify the Pharmaceutical and Medical Device Manufacturers Code of Conduct**

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The Massachusetts Pharmaceutical and Medical Device Manufacturers Code of Conduct (the “Code of Conduct”), enacted in 2008, continues to vex pharmaceutical and medical device manufacturing companies (PMDMCs) responsible for implementation of its requirements. To assist PMDMCs in their efforts, the Massachusetts Department of Public Health (DPH) recently issued “Guidance Number IV.”<sup>1</sup>

Among other things, the Code of Conduct obligates PMDMCs to disclose to DPH annually the “value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50” provided to “covered recipients” in connection with sales and marketing activities.<sup>2</sup> As the July 1, 2010 deadline for the first disclosure quickly approaches, several of the issues covered in Guidance Number IV may be of particular interest, and they are highlighted below.

## **Application of the Code of Conduct to Certain Entities**

Guidance Number IV states that the Code of Conduct does not apply to a clinical laboratory that is a business unit of a PMDMC, or a private MRI company service provider not affiliated with any hospital, *unless* it “for compensation or reward does any act to promote, oppose or influence the prescribing of a particular prescription drug, medical device, or category of prescription drugs or medical devices” or “engages in detailing, promotional activities or other marketing of prescription drugs or medical devices in the commonwealth” to any covered recipient. In addition, a reimbursement hotline that contracts with a PMDMC to handle the appeal of an insurance carrier’s refusal to authorize payment for a drug or medical device is not covered by the Code of Conduct.

The Code of Conduct does, however, apply to a PMDMC’s interactions with any physician who has an active Massachusetts license and is authorized to prescribe, even if the physician has never practiced in Massachusetts.

## **Ability of Health Care Practitioners To Review Data and Make Corrections**

There is currently no mechanism for health care practitioners to review data submitted by PMDMCs before it is posted on DPH’s website, and “such a system is not anticipated at this

time.” After the data is posted on DPH’s website, a health care practitioner’s only option is to contact the PMDMC directly to dispute any disclosed information.

## Reporting/Disclosure Requirements

Guidance Number IV clarifies both the reach of the reporting obligations and information that may be subject to disclosure.

- PMDMCs are responsible for reporting payments to covered recipients even if those payments are made by an agent. Guidance Number IV offers an example: if Company A is a PMDMC and sells the product to Company B, and Company B in turn labels the product as its own and markets the product to health care practitioners, Company A must report payments made to covered recipients on its behalf by Company B.
- Coffee or other snacks made available at a booth at a conference are not considered a prohibited meal.
- PMDMCs may cover the meals and other travel costs incurred in connection with *bona fide* recruitment activities, but such costs must be disclosed as *bona fide* services.
- Payments made by a marketing research company conducting a double-blind study of health care practitioners on behalf of a PMDMC need not be reported if the health care practitioner is not paid by the PMDMC or aware of its involvement.
- The provision of any “marketing or product-related” materials, even if scientific rather than sales or marketing-related, is subject to the Code of Conduct’s restrictions.

The discussion above does not cover all questions and answers covered in Guidance Document IV. Please see [Guidance Document IV](#) for additional detail and contact Mintz Levin with any specific questions.

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### Endnotes

<sup>1</sup> “Frequently Asked Questions: Pharmaceutical and Medical Device Manufacturer Conduct, Guidance Number IV” is available [here](#). Since the release of the Code of Conduct, DPH has issued a series of answers to “Frequently Asked Questions,” available [here](#).

<sup>2</sup> 105 C.M.R. 970.000. *et seq.* For additional background information about the Code of Conduct, Mintz Levin summarized the Code of Conduct in two previous Alerts: “[Massachusetts DPH Releases Final Rules for Pharmaceutical and Medical Device Manufacturers’ Conduct](#),” and “[Review of the Massachusetts Marketing Code of Conduct for Pharmaceutical and Medical Device Manufacturers](#).”

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