

CLIENT ALERT

Massachusetts Finalizes Regulations and Code of Conduct for Medical Device and Pharmaceutical Relationships with Health Care Practitioners

Mar.13.2009

This week, Massachusetts approved regulations creating a new state-authored marketing code of conduct for interactions between health care practitioners and pharmaceutical and medical device manufacturers. The regulations are effective on July 1, 2009.

The regulations require manufacturers to designate a compliance officer and establish compliance and training programs. The regulations also require manufacturers to adopt a code of conduct, which incorporates voluntary industry codes adopted by the Pharmaceutical Research and Manufacturers of America and the Advanced Medical Technology Association. Notably, the state-mandated code of conduct incorporates requirements in addition to these two voluntary industry codes and explicitly restricts a broad variety of conduct, including a ban on providing items such as pens and mugs.

The subject of much debate among stakeholders, the new regulations also establish reporting requirements for certain payments made to "covered recipients," including mandating that manufacturers report certain payments exceeding a \$50 threshold made to healthcare practitioners, hospitals, nursing homes, pharmacists and health benefit plan administrators. The \$50 limit is not cumulative but calculated on an individual transactional basis. The law does provide for several disclosure exemptions, such as certain payments made in conjunction with research and clinical trials, demonstration or evaluation units, and rebates and discounts; however, several categories of indirect payments are not exempt, including charitable donations to universities or hospitals, sponsorship of continuing medical education, and third-party professional or scientific meetings or conferences. The first disclosure reports are due on July 1, 2010.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.