



Dr. Disclosure: What the Massachusetts Pharmaceutical and Medical Device Marketing Laws Mean for You



The Massachusetts Pharmaceutical and Medical Device Marketing Rules and their Impact on the Medical Device Industry

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DPH Rules – Two Regulated Areas

■ Code of Conduct

- By underlying law, DPH applies AdvaMed as the Regulatory Floor
 - AdvaMed recently revised code as of July 1, 2009
- How does the MA DPH Code compare to AdvaMed ?
 - Meals
 - “Gift Ban”
 - Product Training
 - Professional/Sales Meetings

■ Disclosure

- Massachusetts is the first state in the nation to require disclosure of marketing expenses by medical device companies
- Vermont’s recent marketing law amendments

DPH Rules – Covered Medical Device Entities

Do the regulations apply to you ?

Rules apply to:

- All medical device manufacturers AND
- All medical device non-wholesale distributors that
 - Employ a person to sell or market medical devices in the Commonwealth
 - *DPH Guidance*: company must have at least one commercially available product cleared, approved or exempted by the FDA
 - Clarification was intended to relieve smaller, research level companies from compliance with the regulations

DPH Rules - Covered HCPs

Which doctors are covered ?

- **DPH Code of Conduct applies to interactions between covered medical device companies and “health care practitioners” (HCPs)**
 - Persons who prescribe drugs, and
 - are licensed to provide health care in Massachusetts, including
 - A partnership or corporation comprised of a health care practitioner (physician practices, dentist offices), or
 - An officer, employee, agent or contractor acting in support of such health care practitioner

- **Activities in other states involving Massachusetts HCPs?**
 - Regulations follow the Massachusetts physician regardless of where the marketing activity takes place

I. Meals

Meals – AdvaMed: Purpose and Setting

- **Purpose: Meals should be incidental to a bona fide presentation of scientific, educational or business information**
 - Should not be part of an entertainment or recreational event
 - Only provided to health care practitioners attending the meeting
Representative of company must be present (no “dine and dash”)
 - No meals for spouses or guests

- **Setting: Conducive to bona fide scientific or educational business discussions**
 - May include practitioner’s place of business and patient care setting
 - AND other settings where patient care may be inappropriate
 - Where transportation of device to setting is difficult or impossible or
 - Confidentiality is required or
 - No private space onsite

Meals – DPH Rules

- **Like AdvaMed**
 - Should not be part of an entertainment or recreational event
 - Representative of company must be present
 - No meals for spouses or guests
- **Unlike AdvaMed – *Less Flexibility with “Hospital Setting” Restriction***
 - No meals offered, consumed or provided outside of the practitioner’s office or a “hospital setting”
 - Hospital or academic medical center or
 - Medical device training facility specifically designed to approximate the conditions of:
 - a surgical suite or lab;
 - a working clinical laboratory or
 - to provide training on large or technical medical devices

II. “GIFT BAN”

Gifts - AdvaMed

■ PROHIBITS

- any type of non-educational branded promotional items, regardless of whether it may benefit the patient
 - No pens, notepads, mugs and other items with logos
 - No cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash
- payment for entertainment or recreational activity for non-employee HCPs
 - Regardless of value, or purpose (i.e. whether the event is secondary to educational purpose)

■ ALLOWS

- provision of items that benefit patients or serve a “genuine educational function” with a value of less than \$100 per item
- medical textbooks or anatomical models regardless of value

Gifts – DPH Rules

- **Like AdvaMed**

- PROHIBITS any gifts, including complimentary items such as pens, coffee mugs and gift cards
- PROHIBITS entertainment or recreational items of any value to non-employees
- DPH has noted in guidance that “the provision of educational items consistent with the PhRMA and AdvaMed Codes is permitted”
 - Includes medical textbooks and anatomical models?

III. Device Training and Education

Device Training Expenses - AdvaMed

- **AdvaMed recognizes the value of both training and education relative to device use by HCPs**
 - Hands on training sessions
 - Cadaver workshops
 - Lectures and presentations
 - Grand rounds
- **Settings for training – some flexibility**
 - must be conducive to effective transmission of information (including clinical, educational, conference or other settings such as hotels or meeting facilities)
 - “hands on” training must be at “appropriate facilities” including training facilities, medical institutions or labs
- **Modest meals for attendees are allowed**
- **Expenses for out of town travel and lodging for attending physicians are allowed where there are “objective reasons”**

Device Training Expenses - DPH Rules

■ Unlike Advamed

- No specific reference to “training” settings or meals at “trainings”
- Allows payment for travel and lodging related expenses necessary for technical training on the use of a medical device, but only so long as the provision of such expenses is addressed in the “written agreement between the HCP and the device vendor for the purchase of the device”
 - General rule for meals applies even in device training sessions – “hospital setting” only

Device Training Expenses – Industry Comments

■ Industry concerns

- Does not reflect how device companies provide technical training to practitioners on devices?
 - Not all products purchased under a written agreement
 - Hospitals often request trials of expensive devices at no charge, and outside of written agreements
 - There is uncertainty as to what type of training requirements may be needed in the future for devices that are already purchased

IV. Sales/ Business Meetings

Sales and Other Business Meetings - AdvaMed

- **AdvaMed has separate category governing “sales, promotional and other business meetings” held by manufacturers**
- **Acknowledges importance of meetings to discuss medical device features and sales terms**
 - Plant tours and non-portable equipment demonstrations
- **Allows payment for reasonable travel costs when necessary**
- **Allows payment for modest meals and refreshments**
 - Recipient must have a bona fide professional interest in the information shared at the meeting
 - no guests

Sales and Other Business Meetings – DPH Rules

- **Does not allow payment for travel and lodging expenses for attendance at sales meetings unless spelled out in a purchase contract**
- **Meals would still be allowed in connection with an “informational presentation,” but only so long as the company agent is present, and the meal is served in the hospital setting**

V. Disclosure Requirement

Disclosure Requirement – DPH Rules

- **Requires companies employing marketers to disclose annually the:**
 - Value
 - Nature
 - Purpose
 - Recipient
 - of any fee, payment, subsidy, or other economic benefit with a value of at least \$50 which the company provides, directly or through its agents
 - to any physician, hospital, nursing home, pharmacist, health plan administrator, health care practitioner or other person authorized to prescribe, dispense or purchase prescription drugs or medical devices in the Massachusetts
 - In connection with “*sales and marketing activities*”

Sales and Marketing – DPH Rules

- **What are sales and marketing activities ?**

- the provision of any fee, payment, subsidy or other benefit for any purpose

- product education and training

- Exclusions:

- Reasonable compensation for the substantial professional or consulting services of a health care practitioner in connection with a genuine research project or clinical trial
- Demonstration or evaluation units
- In-kind items used for the provision of charity care
- Confidential price concessions

Recent Developments in Vermont

Former Vermont Pharma Disclosure Law

- **Former law in place since 2002 – Disclosure only**
 - Exempted medical device manufacturing companies
 - Required pharmaceutical manufacturing companies to disclose the
 - value, nature, purpose, recipient of
 - any gift, fee, payment, subsidy or other economic benefit in connection with marketing activities
 - Exempted from disclosure:
 - Free drug samples
 - Compensation and expense reimbursements related to clinical trials
 - Any payment less than \$25
 - Scholarships and grants for medical students, residents and fellows
 - Rebates and discounts
 - Trade secret information preserved as confidential

New Vermont Marketing Law – Effective July 1, 2009

- **New features of the VT law signals a radical increase in regulation:**
 - Adds new code of conduct with comprehensive gift ban
 - Includes medical device manufacturers
 - Expands annual disclosure requirement to include clinical trial related expenses
 - Removes trade secret protections for annual disclosures

New VT Law: Comprehensive Gift/ Meal Ban

- **All gifts banned unless expressly allowed**
 - No monetary donations to HCPs or clinics
 - No fellowship grants for residency programs even if company does not select recipient
 - No meals without reimbursement by HCP, regardless of setting or if an informational presentation is made

New VT Law: Expanded Disclosure Requirement

- **Expands existing reporting requirement**

- Now includes, beginning October 1, 2010, mandatory reporting by medical device companies of all clinical trial expenditures since January 1, 2010
 - Two year delay for reporting of clinical trial expenses for products not yet approved by the FDA
- Manufacturers can no longer designate any of the disclosed information as a “trade secret”
 - Reported information designated as trade secrets under previous statute will be kept confidential



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