

Proposed 105 CMR 970.000 -
*Pharmaceutical and Medical Device
Manufacturer Conduct*
Impact on the Massachusetts Medical
Device Industry



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DPH Rules – Three Regulated Areas

- **Code of Conduct**

- DPH applies AdvaMed as the Regulatory Floor
- Regulation beyond AdvaMed
 - Meals
 - “Gift Ban”
 - Free Demonstration and Evaluation Units
 - Product Training and Education
 - Sales, Promotional and other Business and Professional Meetings

- **Compliance**

- Generally consistent with AdvaMed Code’s requirements

- **Disclosure**

DPH Rules – Covered Medical Device Entities

- **Applies to both medical device manufacturers and distributors**
- **All medical device manufacturers that**
 - Employ a person to sell or market medical devices in the Commonwealth AND
 - Participate in a Commonwealth Health Care Program
- **All pharmaceutical or medical device distributors that**
 - Employ a person to sell or market medical devices in the Commonwealth
 - No required connection to a Commonwealth health care program?
 - Statute does not reference medical device distributors
 - AdvaMed has commented that the Rules should not apply to medical device distributors based on lack of statutory language

DPH Rules - Covered HCPs

- **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 the Commonwealth, including
 - A partnership or corporation comprised of a health care practitioner, or
 - An officer, employee, agent or contractor of such health care practitioner

- **Activities in other states involving Massachusetts HCPs ?**
 - Regulations follow the Massachusetts physician?
 - Compliance difficulties in other states
 - Industry comments

Meals: Purpose and Setting

Meals – AdvaMed

- **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 and having a bona fide interest in the presentation
 - 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 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**

- No meals offered, consumed or provided outside of the practitioner’s office or a “hospital setting”
 - Hospital or academic medical center or
 - Medical device specialized training facility specifically designed to:
 - approximate the conditions of a surgical suite or lab and
 - provide medical training that uses human tissue or cadavers, on large and/or technical medical devices, such as surgical equipment, implants, and imaging and clinical laboratory development
- Certification to DPH

“Gift Ban”

Gifts - AdvaMed

■ **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

■ **PROHIBITS**

- any type of non-educational branded promotional items, regardless of whether it may benefit the patient
 - No pens, notepads, mugs and other items that have a Company name, logo or the name or logo of the medical device
 - No cookies, wine, flowers chocolates, gift baskets, holiday gifts or cash
- payment for entertainment or recreational activity to non-employees
 - Regardless of value, or purpose (i.e. whether the event is secondary to educational purpose)

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

- **Unlike AdvaMed**

- Allows provision only of “peer reviewed academic, scientific, or clinical journals”
- No clear allowance for educational items such as textbooks and anatomical models
- Product brochures and pamphlets ?
- Educational materials for educating patients on products and surgery?

Free Demo and Evaluation Units

Demo and Evaluation Units - AdvaMed

- **Allows the provision of free medical device products for evaluation and demonstration purposes**
- **Evaluation products for Physician's Use**
 - Allows HCPs to assess the appropriate use and functionality of the product and determine whether or not to use, order, purchase or recommend the product in the future
 - Single use (consumable or disposable) products
 - Multiple use products (capital equipment) without transfer of title
- **Demonstration products for Physician and Patient's Use**
 - For physician and patient awareness, education and training
 - Implants
 - Not intended for use in actual patient care

Free Demo and Evaluation Units – DPH Rules

- **Like AdvaMed**

- Allows the provision of “medical device demonstration and evaluation units provided to a health care practitioner”

- **Unlike AdvaMed**

- Unit must be “exclusively for use by and education of the health care practitioner’s patients”
 - Appears to prohibit free evaluation units for the physician’s use in assessing the appropriate use and functionality of the product?

- **Comments:**

- Provision of demonstration units to physicians is important for informed purchase decisions
- Common practice in device industry to assist in effective device selection and use
- Do free evaluation units promote cost effective use of resources?

Device Training and Education

Device Training - AdvaMed

- **AdvaMed addresses training and education relative to device use by HCPs**
 - Covers Training, Education, Setting, Meals, and Travel and Lodging Reimbursement
- **“Training” – training on the effective use of the device**
- **“Education” – communicating information directly concerning or associated with the use of the device**
 - Hands on training sessions
 - Cadaver workshops
 - Lectures and presentations
 - Grand Rounds

Training Settings, Meals, Expenses - AdvaMed

- **Settings for training**
 - must be conducive to effective transmission and 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
- **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”
 - General rule for meals applies – “hospital” setting only
- 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 device purchase agreement between the health care practitioner and the vendor
 - DPH constrained by statutory language

Device Training Expenses – Industry Comments

■ Industry concerns

- Does not reflect how device companies provide technical training to practitioners?
 - Clinical education and training not always linked to a sales event, therefore not always addressed by a purchase agreement
 - Hospitals request trials of expensive devices at no charge
- Not all products are purchased under a written agreement
- Many products not purchased by practitioners, but by health care facilities
- There is uncertainty as to what type of training requirements may be needed in the future, even under purchase agreement
- Many trainings are for doctors or medical students that are unaffiliated with a hospital

Expense Reimbursement for Sales and Business Meetings

Sales and Other Business Meetings - AdvaMed

- **AdvaMed has separate category for “sales, promotional and other business meetings”**
- **Acknowledges importance of meetings to discuss medical device features, sales terms or contracts**
 - 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

- **No specific provisions related to medical device sales meetings**
 - References “professional meetings” without definition
- **Does not allow payment for reasonable expenses for device training, including travel and lodging, unless such expenses are spelled out in the purchase contract**
 - No pre-sales contract reimbursement of any expenses appear to be allowed for any education, training or promotional meeting?
- **Meals would still be allowed in connection with an “informational presentation”, so long as the company agent is present, and the meal is served in the hospital setting**

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 a “covered recipient”
 - In connection with “*sales and marketing activities*”

Sales and Marketing – DPH Rules

- **Who is a covered recipient?**
 - Broader than just HCPs
 - Includes persons in the Commonwealth authorized to prescribe, dispense, or purchase prescription drugs or medical devices in the Commonwealth, including a physician, hospital, nursing home, pharmacist, health plan administrator, or licensed wholesaler
- **What are sales and marketing activities ?**
 - product education and training
 - the provision of any fee, payment, subsidy or other benefit for any purpose
 - Only exclusion is reasonable compensation for the substantial professional or consulting services of a health care practitioner in connection with a genuine research project or clinical trial

Industry Comments

■ Industry concerns

- Includes rebates and other price concessions for sale of medical devices ?
 - Will public disclosure of rebates inhibit free negotiation of pricing ?
 - Will loss of access to discounts harm customers?
- Includes the value of free demonstration units?
 - Often distributed as part of an evaluation period
 - What about disclosure to competitors about a potential customer's interest in a product?
- “Clinical trial” definition appears to include only human research subjects?
 - Pre clinical stage research for devices may involve animals
 - Excluded from clinical trial disclosure exemption?



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