

Hospital & Physician Relationships with Medical Device Companies

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Agenda

- What is Changing and Why
- AdvaMed Code of Ethics
- Who is a Health Care Professional
- Why Providers Should Care
- High Risk Interactions
- Meals, Lodging, and Travel
- Manufacturer-Sponsored Product Training
- Educational Grants
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- Charitable Contributions
- Reimbursement and Other Economic Information
- Gifts
- Direct Impact on Providers

What is Changing and Why?

- AMA Code of Ethics on Gifts to Physicians from Industry
 - ◆ Adopted 1990
- PhRMA Code
 - ◆ Effective July, 2002
- HHS Office of Inspector General (OIG)
 - ◆ Issued the Compliance Program Guidance for Pharmaceutical Manufacturers April, 2003
- AdvaMed Code of Ethics
 - ◆ Published September, 2003, effective January 2004
- California SB 1765 Requiring Pharmaceutical Marketing Compliance Plan (includes medical device companies)
 - ◆ Enacted September, 2004, effective July, 2005

AdvaMed Code of Ethics

- AdvaMed is trade association for 1,100+ medical device manufacturers
- Addresses manufacturer relationships with “Health Care Professionals.”
- Why?
 - ◆ \$2+ Billion paid by paid by pharma industry in past 4 years.
 - ◆ Public statements by federal law enforcement that medical device is next
 - ⊗ Significant overlap
 - ✓ Reduces law enforcement’s learning curve
- 12 Months of Anecdotal Feedback
 - ◆ Prohibited interactions are continuing
 - ⊗ Not all medical device companies are vigorously implementing and enforcing
 - ◆ HCPs are confused by changing and different practices
 - ⊗ Changes in practices within a single manufacturer
 - ⊗ Differences among multiple manufacturers
 - ◆ AdvaMed is an excuse to avoid the costs of sponsorships and grants

Who is a Health Care Professional?

- Broad definition
 - ◆ Includes any person or entity that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe medical devices
 - ⊗ Includes:
 - ✓ Surgeons
 - ✓ Purchasing and materials management staff
 - ✓ GPOs
 - ✓ Operating room nurses
 - ✓ Physician staff
 - ◆ Research sites and investigators are probably always HCPs
- Applies to U.S.-based HCPs
 - ◆ Applies to HCPs who's primary place of business is in the U.S., even when they are having the interaction outside of the U.S.
 - ◆ Does not apply to non-U.S. based HCPs.
 - ⊗ Need to comply with the rules from the home country of non-U.S. HCPs
 - ✓ Last year Italy initiated prosecution of over 4,000 HCPs for anti-kickback-like activities by GlaxoSmithKline

Why HCPs Should Care?



- Law Enforcement
 - ◆ Although law enforcement primary focus is on manufacturers, it says it will continue to prosecute HCPs who receive illegal kickbacks
 - ⊗ 6 TAP physicians indicated and plead guilty or agreed to civil settlements
 - ⊗ State attorney general actions
 - ⊗ Insurance coverage for defense costs and settlements or penalties?
- Good Business Practice
 - ◆ What should be basis for making purchase decisions?
 - ⊗ Quality and Service vs. Holiday Food Basket?

High Risk Interactions

- Educational grants
- Fundraisers and other charitable contributions
- Paying for journals, textbooks, and other educational materials
- Sponsoring fellowships
- Paying for referral dinners and patient brochures
- Sponsoring professional association's annual congress
- Research grants
- Consulting services



Meals, Lodging, and Travel



- Modest meals and receptions
 - ◆ Conducive to underlying purpose of the meeting or gathering
- Reasonable lodging and travel
 - ◆ Necessary for intended purpose

Meals, Travel and Lodging Examples

■ Permitted

- ◆ Modest meals during:
 - ⊗ Meetings to discuss company products, negotiate contracts, and explain sales and service terms
 - ⊗ Consultant meetings
 - ⊗ Training programs on company products
- ◆ Modest lodging (Marriott vs. Ritz Carlton; Chicago vs. Aspen or Napa Valley)
- ◆ Coach airfare
- ◆ Taxi or comparably priced car services

■ Prohibited

- ◆ “Drop-off” meals
- ◆ Meals for spouses and other guests
- ◆ “Immodest” meals or lodging
 - ⊗ \$125 per person vs. \$500 per person
- ◆ “Unreasonable” travel
 - ⊗ Travel that is not necessary for intended purpose
 - ⊗ Always first class
- ◆ Referral dinner, unless legitimate co-marketing

Manufacturer-Sponsored Product Training

■ Permitted:

- ◆ Providing education and training to HCPs about the effective and appropriate use of products
- ◆ Providing modest meals and hospitality and reasonable travel and lodging that is subordinate in time and focus to the training.
- ◆ Providing training to an HCP's spouse who is him/herself an HCP appropriate for training, i.e., operating room nurse.

■ Prohibited:

- ◆ Paying an HCP to attend
- ◆ Using lavish locations and providing immodest meals and other hospitality
- ◆ Training HCPs and/or staff who do not need the training
- ◆ Offering training, particularly involving travel, to reward a HCP for past or future business
- ◆ Paying for HCP's spouse or other guests who are not themselves HCPs qualified to attend

Educational Grants

- Unrestricted educational grants are (or should be) a thing of the past
- Three permissible types of educational grants under AdvaMed Code:
 - ◆ Financially supporting Third Party Educational Conferences (Article III)
 - ⊗ Bona fide independent, educational, scientific, or policymaking conference that promotes scientific knowledge, medical advancement and the delivery of effective health care
 - ◆ Charitable donation to advance medical education (Article VIII)
 - ◆ Scholarships for health care professionals in training to attend Third Party Educational Conferences



Educational Grant Examples

■ Permitted

- ◆ Financial support to reduce overall costs resulting in lower registration fees
- ◆ Sponsoring \$75/person reception
- ◆ Reasonable and modest travel and lodging for a grand rounds speaker
- ◆ Scholarships to training institution or meeting organizer for HCPs in training
- ◆ Charitable organization public disease state education program
- ◆ Fellowships at academic medical institutions

■ Prohibited

- ◆ Paying honorarium or travel costs to third party conference faculty (as opposed to conference organizer)
- ◆ Paying registration and/or travel costs to third party conference attendee not in training
- ◆ Sponsoring private practice fellowship
- ◆ Sponsoring \$500/person reception
- ◆ Paying registration fees and travel costs directly to HCP in training

Research Grants and Consulting Agreements



- Unrestricted research grants are (or should be) a thing of the past
- Consulting agreements with little or no value to the medical device company are (or should be) a thing of the past
- Requirements:
 - ◆ Legitimate need and purpose for research and/or consulting services
 - ◆ Compensation for consulting services is consistent with fair market value
 - ⊗ May have different mechanisms for establishing FMV
 - ⊗ May be asked to provide income information

Charitable Contributions

- Typical types of charitable contribution requests:
 - ◆ Fundraisers
 - ◆ Products for charitable missions and indigent patients
 - ◆ Medical research
 - ◆ Educational activities, including fellowships
 - ◆ Purchasing educational materials
- Requirements
 - ◆ Cannot be for purposes of inducing business with customer
 - ◆ Requires a charitable organization, unless individual is engaged in genuine charitable mission.
 - ⊗ Typically, a charitable organization is involved in charitable missions.



Charitable Contribution Examples

■ Permitted

- ◆ Fundraiser for tax-exempt charitable organization
- ◆ Free products for charitable mission to provide free health care in other countries
- ◆ Travel and shipping costs related to charitable mission
- ◆ Fellowship at an academic institution
- ◆ Buying or subscribing for scientific journals, medical textbooks, and other educational materials for charitable hospital library

■ Prohibited

- ◆ Paying a private practice physician's marketing costs
 - ◉ Legitimate co-marketing arrangements permitted
- ◆ Paying a private practice's administrative or operational costs, i.e., free medical practice consulting services
- ◆ Sponsoring a fellow at a private practice
- ◆ Purchasing textbooks for a private practice or non-charitable hospital, unless qualifies as a gift.

Reimbursement and Other Economic Information

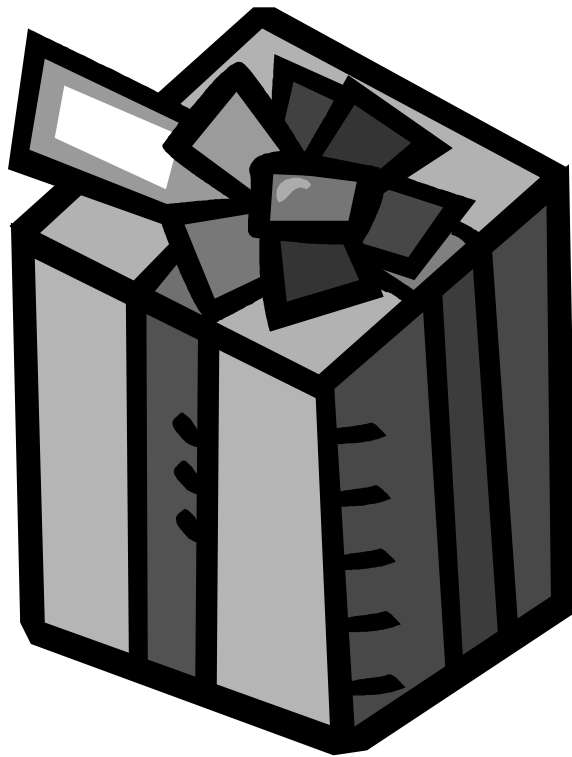
■ Permitted

- ◆ Accurate and responsible third party billing information about the Company's products:
 - ⊗ Coverage
 - ⊗ Coding
 - ⊗ Billing
- ◆ Technical or other support that aids in the appropriate and efficient use of the Company's products

■ Prohibited

- ◆ Providing broad base consulting services beyond third party billing information, i.e.,
 - ⊗ General revenue enhancement
 - ⊗ Practice management
- ◆ Use such information to induce an HCP to purchase the Company's products

Gifts



- The holiday gift basket and drop-off lunch for staff are (or should be) a thing of the past
- Requirements for gifts:
 - ◆ Occasional; and
 - ◆ No cash or cash equivalents; and
 - ◆ Benefits patients, or
 - ◆ Services a genuine educational function, and
 - ◆ Under \$100, except for text books or anatomical models, or
 - ◆ Branded promotional items related to the HCP's work or benefits patients.

Gift Examples

■ Permitted

- ◆ Medical textbooks and anatomical models
 - ⊗ Undefined maximum, may be established by individual companies
- ◆ Minimal value branded pens, post-its, pad folios, etc.
 - ⊗ Undefined “minimal value,” may be established by individual companies
- ◆ X-ray bags costing less than \$100
- ◆ Computer memory sticks with educational information costing less than \$100

■ Prohibited

- ◆ Anything valued at more than \$100, except for medical textbooks and anatomical models.
- ◆ Food for staff not provided as part of a legitimate meeting or training program.
- ◆ Food, wine, etc. gift baskets
- ◆ Golf balls and other golfing or sports related items
- ◆ Non-medical related clothing
- ◆ Sports tickets
- ◆ Computers, PDAs, etc.

Direct Impact on HCPs

■ Limitations on Sales Rep Authority

- ◆ Sales reps will have less authority to offer, authorize or agree to contributions, grants, consulting agreements, etc.
 - ⊗ By removing from Sales budget and authority, looks less like a sales inducement.
 - ✓ Law enforcement perception of contribution reviewed and authorized by non-sales staff vs. contribution offered by sales rep.
 - ⊗ Companies will vary on what sales reps can and cannot offer, authorize or agree to.



Direct Impact on HCPs (cont)

■ Limitations on meals

- ◆ What constitutes “modest” meals?
 - ⊗ \$\$ value differences
 - ⊗ Geographic differences
 - ⊗ Customers paying excess amounts
- ◆ Limited to customer staff appropriate to attend meeting or training
 - ⊗ Drop-off meals are prohibited gifts
- ◆ No spouses or other guests who are not appropriate to attend
 - ⊗ Spouse customers ok if appropriate for meeting or training
 - ✓ Office manager spouse
 - ✓ Operating room nurse spouse
 - ⊗ Invitations prohibiting spouses/guest or establishing \$\$ for spouse/guest

■ Lodging and Travel

- ◆ What constitutes “reasonable” lodging and travel?
 - ⊗ Airfare
 - ✓ Fare class differences
 - ✓ Customer arranged and paid upgrades
 - ⊗ Meeting locations
 - ✓ Resort vs. non-resort locations
 - ⊗ Hotel accommodations
 - ✓ Upgrades
 - ✓ Spouse accommodations
 - ✓ Limits on room charges

■ Gifts

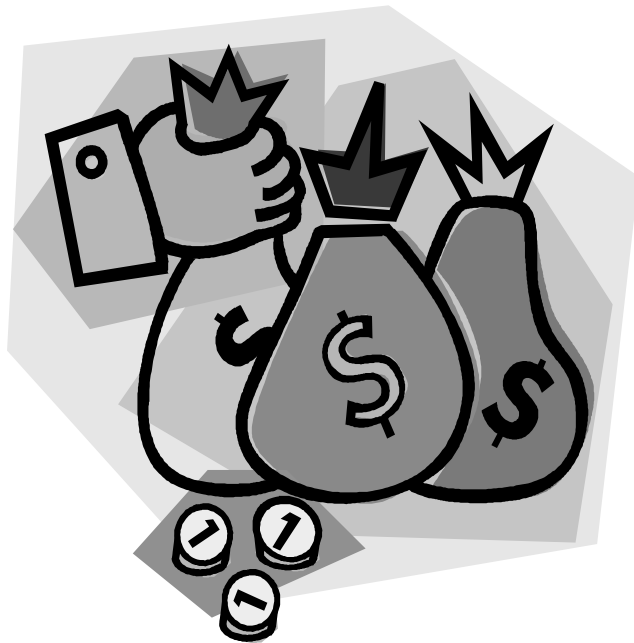
- ◆ Gift type restrictions
 - ⊗ No gifts that do not benefit patients or have educational purpose
- ◆ \$\$ value differences among companies
 - ⊗ Annual limits
 - ⊗ Limits on textbooks and anatomical models
 - ⊗ \$\$ value limit on branded promotional items

Direct Impact on HCPs (cont)



- Increased formality in relationships
 - ♦ Application or request form requirements
 - ⊗ Charitable contributions
 - ✓ Defined purpose
 - ✓ Establishing charitable organization status
 - ⊗ Third party conference sponsorship and scholarships
 - ✓ Agenda and budget
 - ⊗ Research funding
 - ✓ e.g., requiring research protocol and other information to substantiate research legitimacy
 - ♦ Establishing consultant qualifications
 - ♦ Agreements (vs. “hand shakes”)
 - ♦ Periodic reporting, e.g.,
 - ⊗ Detailed time and work reporting for consulting agreements
 - ⊗ Expense reporting
 - ⊗ Periodic fellowship reporting
 - ⊗ Research progress reporting

Direct Impact on HCPs (cont)



- Fair market value compensation
 - ◆ More objective and independent mechanisms for establishing consultant, researcher, and other compensation amounts
 - ⊗ Compensation surveys
 - ⊗ HCP income information – W-2s
 - ⊗ Fixed rate services
 - ◆ Restrictions on pre-service payments
 - ◆ Compensation not tied to past or future use or purchases

Direct Impact on Providers (cont)

■ Financial Support for Marketing Programs

◆ Referral Dinners and Patient Brochures

⊗ Qualify as “Co-Marketing Activity”

- ✓ Does not just market the physician’s practice, but also markets the manufacturer’s product
- ✓ Companies may establish criteria or requirements for co-marketing activities, e.g.,
 - ▶ Limiting payment to ½ of costs
 - ▶ Requiring representation in agenda/brochure roughly equal to customer’s
 - ▶ Meal/reception limits

◆ Practice Newsletter/Magazine Advertising

- ⊗ Legitimate advertising that markets the manufacturer’s products to potential purchasers or purchase decision-makers.
 - ✓ May make non-sales marketing personnel responsible for decision based on use of overall marketing budget



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Questions?