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
- Research Grants and Consulting Agreements
- 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 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
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
Bibliography

- AMA Guidelines on Gifts to Physicians from Industry CEJA Ethical Opinion E-8.061

- PhRMA Code on Interactions with Health Care Professionals

- DHHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers
  - http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/pdf/03-10949.pdf

- AdvaMed Code of Ethics on Interactions with Health Care Professionals

- California Pharmaceutical Marketing Practices
Questions?