Dangerous Liaisons: Effective Management of the Associations Between Clinicians, Institutions, and Industry

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Why So Many rules?

* Extensive regulation of healthcare industry
* Medical device (and pharma) products are reimbursed by federal health care programs
* Anti-Kickback laws
* AdvaMed Code (Pharma Code)
Assistant Inspector General for Legal Affairs Testimony at Senate Hearing 2008

“Examining the Relationship Between the Medical Device Industry and Physicians”

“Researchers reporting in medical journals, such as the Journal of American Medical Association and the New England Journal of Medicine, have found that such financial industry-physician relationships are pervasive and that the impulse to reciprocate for even small gifts has a powerful influence on behavior.”

“Although most physicians believe that free lunches, subsidized trips, or gifts have no effect on their medical judgment, the research has shown that these types of perquisites can affect, often unconsciously, how humans act.”

Anti-Kickback Law in a Nutshell . . .

Prohibits offering, paying, soliciting or receiving something of value to induce referrals, or use of, items covered by Federal health care programs

- “Kickback” is anything of value paid or given as an inducement to recommend, purchase, use products

- $$, product, food, travel, other “things/experiences” for which there is no permitted legal purpose

Criminal and Civil Penalties (prison; $$)
Examples of Potential Kickbacks

Settlements

2006 - Medtronic - $40 Million fine for abuses of consulting agreements, training and education agreements, fellowships, charitable grants
2007 – Stryker Ortho - close government monitoring for 18 months, must post consulting agreements with doctors on their website
2009 - Pfizer $2.3B to settle compliance violations for unapproved uses and sham consulting, trips and perks for doctors using their drugs
2011 – Dine – $2.3 Million to settle claims of paying kickbacks in the form of survey compensation, travel expenses, lavish dinners, entertainment and promotional speaker fees to induce physicians to use spinal devices
2012 – Orthofix International NV – $42 Million to resolve lawsuit and 6 year criminal probe of kickback allegations in the form of sham consulting agreements, referral fees

DOCS pay too! 2x 2010 - Florida physicians paid $650,000 for allegedly receiving kickbacks in the form of consulting payments from two medical device manufactures in exchange for using their orthopedic hip and knee products
AdvaMed

* Advanced Medical Technology Association
* Represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies
* Code facilitates ethical interactions between Companies and healthcare professionals (“HCPs”)
  * Individuals, entities involved in provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ medical technologies in the US
* Companies adopt the Code and file certifications

Scope of AdvaMed Code

1. Company-Conducted Product Training and Education
2. Supporting Third-Party Educational Conferences
3. Sales, Promotional, and Other Business Meetings
4. Consulting Arrangements with HCPs
5. Prohibition on Entertainment and Recreation
6. Modest Meals Associated with HCP Business Interactions
7. Educational Items; Prohibition on Gifts
8. Provision of Coverage, Reimbursement and Health Economics Information
9. Research and Educational Grants and Charitable Donations
10. Evaluation and Demonstration Products
Company-Conducted Product Training and Education

* **Training**: safe & effective use of products

* **Education**: providing information related to our products, disease states and benefits to certain patient populations

* **Must Have’s**
  - *Bona fide* need for the education & training
  - Setting conducive to learning
    - Clinical, educational, conference, or other settings (hotels)
  - Agendas MUST be focused on training or education
  - Where there are objective reasons to support need for out-of-town travel, OK to pay for reasonable travel and modest lodging
  - Cannot pay for guests of HCPs

Sales, Promotional, and Other Business Meetings

* Sales, promotional, other business meetings with HCPs to discuss, for example, sales terms or contracts
* Close to HCP's place of business
* Appropriate to pay for reasonable travel costs when necessary (plant tour or demonstration of non-portable equipment)
* Modest meals OK – meal limits
* Not OK to pay for others who don’t have *bona fide* interest in the information being shared
Consulting Agreements with HCPs

* Research, product development, development and/or transfer of intellectual property, marketing, advisory boards, presentations
* FMV
* Legitimate business need
* In writing and signed by all parties
* Select HCP based on qualifications
* Documented, reasonable and actual expenses
* Appropriate venue for subject matter
* Modest meals OK
* Sales personnel should not control

Entertainment, Recreation, Gifts

* NO - theater, sporting events, golf, skiing, hunting, sporting equipment, leisure or vacation trips
* NO - items capable of use by HCP, family, staff for non-educational or non-patient related purposes (e.g. DVD player, MP3, iPad, iPod)
* NO – branded pens, notepads, mugs
* NO – cookies, wine, flowers, chocolates, gift baskets, holiday gifts, cash, cash equivalents
* YES – medical textbooks, anatomical models <$100
Research and Educational Grants

* Research
  * Independent medical research with scientific merit
  * Well-defined objectives & milestones
  * Not linked to purchase of products
* Educational
  * Conference sponsors, training institutions
  * Offset costs of producing event
  * Not to individual HCPs
  * Sales personnel should not influence

Evaluation and Demonstration Products

* Evaluation
  * Assess appropriate use and functionality of product to determine whether and when to use, order or recommend in the future
  * Used in patient care
  * Single use – only number necessary for adequate evaluation
  * Multiple use/capital equipment – limited time – return
  * Written agreement
* Demonstration
  * Promote awareness, education, training
  * Not used in patient care
Sunshine is Coming . . . .

Physician Payment Sunshine Act

- Federal Law
- Transparency regarding payments to physicians & teaching hospitals
- Section 6002 of Affordable Care Act
  - 10/1/11 – Draft Rule Due; 12/19/11 – Draft Rule Released
- Data collection – 90 days after final rule publication
- Data to be posted on public website (CMS)
- Media, consumers, HCPs and competitors will data mine
- $1,000 - $10,000 for each payment not reported
Physician Payment Sunshine Act

- $10
- Name, address of recipient
- Amount, dates, form (cash, in-kind, etc.), nature of payment
  - Consulting fees
  - Compensation (other than consulting)
  - Honoraria
  - Gift
  - Entertainment, Food
  - Travel, Education
  - Research, Charitable contribution
  - Royalty or license
  - Current or prospective ownership/investment interest
  - Direct compensation for serving as faculty member for medical education program
  - Grant
  - Other

DOES NOT INCLUDE:

* Transfers of value less than $10, unless aggregate amount exceeds $100/calendar year
* Product samples that are not intended to be sold and are intended for patient use
* Educational materials that directly benefit patients or are intended for patient use
* Evaluation equipment - not to exceed 90 days, to permit evaluation of the covered device
* Items or services provided under a contractual warranty
* Discounts, including rebates
* In-kind items used for the provision of charity care
Physician Payment Sunshine Act

- What are companies doing to prepare?
  - Nothing
  - Manual processes
    - Electronic e-forms
  - T&E systems
  - Vermont, Massachusetts, California
  - France
  - Other important steps
    - Educate, educate, educate
  - Continued relationships are important and critical to the development and safe and effective use of innovative medical technologies

Physician Payment Sunshine Act

U.S. to Force Drug Firms to Report Money Paid to Doctors
New York Times
17 January 2012

Who Paid for Your Doctor’s Bagel?
Wall Street Journal
23 January 2012
Physician Owned Distributors (PODs)

POD Issues

* PODs exist, so are they illegal?
* Who carries the risk and requirement to investigate?
  * Manufacturer?
  * Physician/POD?
  * Hospital?
POD Issues - Government

* Nothing inherently illegal about PODs
* But, what is the business purpose of the POD that is unrelated to referrals?
  * Senate Finance Committee, CMS, OIG concerned that PODs exist to permit physicians to profit directly from referrals of devices
  * Structure and operation of the POD itself, along with its relationships with the manufacturer and the hospital, must be considered under the Anti-Kickback Law
* Each party must evaluate its portion of the arrangement for compliance

POD Issues - Manufacturer

* Direct sales v. distributors
  * Larger manufacturers often use only direct sales force to sell products, no distributors, no PODs
  * Smaller manufacturers may use PODs for market penetration
* Purchase agreement with POD should be consistent with discounts and other arrangements (payment terms, etc.) with other distributors and hospital/ASC purchasers
  * No favorable discounts to the POD not otherwise available to other purchasers of same volume/terms
POD Issues - Distributor

* Distributor should be adequately capitalized with investment funds from physician, not manufacturer
* Distributor operations
  * Distributor should operate in the same manner as any other device distributor
  * Obtain applicable licenses (usually wholesale device distributor)
  * Maintain inventory and parts as necessary for the device
  * Expand distribution operations to include other devices that physician-owner does not personally order/refer
  * Maintain own sales force and other administrative personnel (marketing, contracting, servicing, etc.)

POD Issues - Hospital

* Determine if Hospital is currently buying from PODs
  * Did arrangement arise through normal vendor/purchasing process?
  * Who is aware of the arrangement?
  * How does arrangement fit within the Hospital’s purchasing policies and/or formularies for devices?
POD Issues - Hospital

* If Hospital determines to purchase from PODs
  * All purchase agreements should have the same or better terms than Hospital has obtained from the manufacturer
    * Pricing
    * Payment terms
    * Warranties
    * Returns
    * Non-exclusivity
  * All PODs should follow same purchasing policies as other vendors
  * Consider source of device: FDA-approved, reputable manufacturer, consistent with other devices

POD Issues - Hospital

* What should hospital know about the Distributor?
  * Maintains all applicable state licenses
  * Agreements between POD/Hospital are separate from agreements between POD/Manufacturer
    * POD, not Hospital, pays manufacturer
    * POD ships device to Hospital where possible
  * Distributor responsible for returns, training, etc.
  * Distributor is adequately capitalized and can meet the terms of the purchase agreement with the Hospital
  * Physician owner’s orders/use of device from POD is medically necessary
  * No coercion or pressure by POD on Hospital to buy from POD
POD Issues - Hospital

* Hospital may not have enough information about the POD to ensure overall compliance
  * Purchasing standards and policies should not be waived for PODs
  * Consider whether purchasing from a POD for a certain device could alienate other medical staff physicians
    * False Claims Act risk
  * What purpose does purchasing from a POD serve for the Hospital?
    * Is the device necessary?
    * Does Hospital maintain purchasing agreements with manufacturers and/or distributors to meet the needs of the medical staff without entering into a purchase agreement with the POD?

POD Issues

* PODs are on the government’s radar and the comments are not supportive
  * But, no government action to date despite an increasing number of PODs in the market
* Though PODs are not per se illegal, compliance standards for the structure and on all sides of the operations are tricky
* Hospitals likely bear the greatest risk because the hospital submits the claims to Medicare and Medicaid and the hospital likely has the least amount of information upon which to base an informed decision about overall compliance
Questions?