Implementing Policies on Physician / Vendor Relationships: How, When and Why?

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Road Map

- Pop Quiz (How did you do?)
- Key Laws impacting vendor-healthcare professional relationships
- Government/Industry-developed compliance and ethical guidelines
- The Journals Speak
- Recent initiatives at Academic Medical Centers
- Implementation Tactics
- Best practices for your organization
Examples of Vendor-Healthcare Professional Arrangements

- Free samples
- Pens or other items of low value
- Meals with or without educational component
- Continuing medical education (CME) grants or other financial support
- Compensation for participation in speakers bureaus
- Consulting or research agreements

Legitimate Function VERSUS Conflicts of Interest /AKS Violation

- Legitimate Functions
  - The federal Food and Drug Administration’s (FDA’s) Prescription Drug Marketing rules allow sample distribution to practitioners that are licensed to prescribe the drugs. See 21 CFR part 203.
  - The federal FDA requires vendor education for some products.
  - The HHS’ Office of Inspector General (OIG) has blessed vendor provision of reimbursement support programs and some charitable giving programs.
Legitimate Function VERSUS Conflicts of Interest

- Conflicts of Interest
  - Various physician groups have raised the conflict of interest concern, as have recent publications. The claim is that practitioners are making decisions NOT based on what is best for the patient, but based on influence from other sources, e.g., vendor influence.

Legitimate Function VERSUS AKS Violation

- ANTI-KICKBACK ISSUES
  - The OIG has found that certain arrangements implicate the federal Anti-Kickback Statute (AKS), stating:

  [O]ne does not have to be a “provider” or make an actual “referral” to be covered by the anti-kickback statute. The statute covers any persons who offer, pay, solicit, or receive any unlawful remuneration. The scope of prohibited conduct includes not only that which is intended to induce referrals, but also that which is intended to induce the purchasing, leasing, ordering or arranging for any good, facility, service or item paid for by Medicare or Medicaid.
Recent State Marketing Laws and Legislation

- State laws and legislation seek to prohibit or limit gifts, free samples and other promotional items given by vendors to healthcare professionals
- **Current Laws:** CA, DC, ME, MN, NV, VT and WV require gift reporting
  - CA – goes a step beyond disclosure, requiring pharma companies to adopt and publicly disclose compliance programs that are in compliance with the OIG Pharma Guidance and PhRMA Code
  - MN – prohibits gifts by pharma manufacturers and distributors to practitioners of over $50 with certain exceptions

Recent State Marketing Laws and Legislation

- **Proposed Legislation**
  - Examples: HI, IL, MA, NY, OH, PA
  - Most require public disclosure of any gifts from pharma manufacturers valued at $25 or more, while others go further and require public disclosure of pharma manufacturer marketing budgets
Recent State Marketing Laws and Legislation

- **RETAILATION** - "Groups Cite Massachusetts Gift Law In Moving Their Conferences From Boston" – BNA Reporter 01/26/08.

- **BOSTON**—Citing a new Massachusetts law governing gifts by pharmaceutical and medical device companies, at least three medical organizations are in the process of moving planned conferences away from Boston.
  - The American Academy of Allergy Asthma & Immunology, the American Society of Gene Therapy, and the Heart Rhythm Society said they may scrap plans to hold conferences in Boston.
  - Organizations object to provisions of the new law, and pending regulations for its implementation, that would place restrictions on sponsorship of continuing medical education (CME). Enacted last August, the new law also limits gifts to health care providers and requires disclosure of any gifts with a value of at least $50.

Government Guidance

- **Office of Inspector General (OIG)**
  - 1992 Report and Investigation
  - 1994 Special Fraud Alert

- **Prescription Drug Marketing Act (PDMA)**
  - One of the acts prohibited is knowingly selling, purchasing, trading or offering to sell, purchase, or trade a prescription drug sample. This offense is punishable by up to 10 years in prison.
Industry/Professional Guidance

- Pharmaceutical Research & Manufacturers of America (PhRMA)
- Code in Interactions with Healthcare Professionals
- Updated January, 2009
- http://www.phrma.org/code_on_interactions_with_healthcare_professionals/

Industry/Professional Guidance

- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- Code of Pharmaceutical Marketing Practices
Industry/Professional Guidance

- Advanced Medical Technology Association (AdvaMed)
- Code of Ethics
- Updated December, 2008
- http://www.advamed.org/MemberPortal/About/code/

Industry/Professional Guidance

- Medical Device Manufacturers Association (MDMA)
- Code of Conduct
- http://www.medicaldevices.org/public
Industry/Professional Guidance

- American Medical Association (AMA)
- Ethical Guidelines for Gifts to Physicians from Industry

Industry/Professional Guidance

- American Academy of Neurology
- Code of Professional Conduct
Industry/Professional Guidance

- American Association of Orthopaedic Surgeons (AAOS)
- Code of Ethics and Professionalism for Orthopaedic Surgeons
- [http://www.aaos.org/about/papers/ethics/code.asp](http://www.aaos.org/about/papers/ethics/code.asp)

The Journals Speak

Journal of the American Medical Association, January 19, 2000
Physicians and the Pharmaceutical Industry – Is a Gift Ever Just a Gift?
*JAMA.* 2000; 283:383-380
Health Industry Practices that Create Conflicts of Interest – A Policy Proposal for Academic Medical Centers
JAMA. 2006; 295:429-433

Academic Medicine, February 2006
Guidelines for Interaction Between Clinical Faculty and the Pharmaceutical Industry: One Medical School's Approach
Academic Medicine. 81(2):154-160
The Journals Speak

Academic Medicine, July 2006
Resident's Perceptions Over Time of Pharmaceutical Industry Interactions and Gifts and the Effect of an Educational Intervention
Academic Medicine. 81(7):595-602

The Journals Speak

New England Journal of Medicine, April 2007
A National Survey of Physician-Industry Relationships
The Journals Speak

Journal of the American Medical Association, October 17, 2007
Institutional Academic–Industry Relationships

The Journals Speak

Characteristics of Recipients of Free Prescription Drug Samples: A Nationally Representative Analysis
2008 0: AJPH.2007.114249.
The Journals Speak

Journal of the American Medical Association, February 13, 2008
Responses of Medical Schools to Institutional Conflicts of Interest.

The Journals Speak

Journal of the American Medical Association, September 3, 2008
New Developments in Managing Physician-Industry Relationships.
JAMA. 2008;300(9):1067-1069
Academia Responds

The Accreditation Counsel for Graduate Medical Education (ACGME)

The ACGME implemented new Institutional Requirements mandating that all member institutions implement a policy of vendor relationships effective July 1, 2007.

Vendor interactions: Provision of a statement or institutional policy (not necessarily GME-specific) that addresses interactions between vendor representatives/corporations and residents/GME programs.

Academia Responds

The Association of American Medical Colleges (AAMC)

The Scientific Basis of Influence and Reciprocity: A Symposium. AAMC/BCM, 2007
The AAMC published the findings of a symposium on the scientific basis of influence and reciprocity.

The symposium summarized the latest evidence from neuroscience and the behavioral sciences that addresses the challenges to objectivity presented by gifts, favors, and influence in academic medicine.

Jointly sponsored by the AAMC and the Baylor College of Medicine Department of Neuroscience and its Computational Psychiatry Unit, the symposium provided a forum for review and discussion of the latest scientific research documenting the important role played by unconscious influences that affect behavior and may lead to unwitting conflicts of interest.
AAMC


AAMC

Industry Funding of Medical Education. AAMC, 2008.
American Medical Student Association (AMSA)

With a membership of more than 68,000 medical students, premedical students, interns, residents and practicing physicians from across the country, AMSA is the oldest and largest independent association of physicians-in-training in the United States.

AMSA's PharmFree Movement

PharmFree Pledge:

"I am committed to the practice of medicine in the best interests of patients and to the pursuit of an education that is based on the best available evidence, rather than on advertising or promotion.

I therefore pledge to accept no money, gifts, or hospitality from the pharmaceutical industry; to seek unbiased sources of information and not rely on information disseminated by drug companies; and to avoid conflicts of interest in my medical education and practice."

http://www.amsa.org/prof/pharmfree.cfm
Academia Responds

No Free Lunch Movement

- No Free Lunch is a not-for-profit organization incorporated in the State of New York as the Corporation for Non-Promotion-Based Medicine.

- No Free Lunch believes that pharmaceutical promotion should not guide clinical practice.

- Their mission is to encourage health care providers to practice medicine on the basis of scientific evidence rather than on the basis of pharmaceutical promotion.

- They discourage the acceptance of all gifts from industry by health care providers, trainees, and students.
No Free Lunch Movement

- No Free Lunch believes that:

- There is ample evidence in the literature - contrary to the beliefs of most health care providers - that drug companies, by means of samples, gifts, and food, exert significant influence on provider behavior.

- There is ample evidence in the literature that promotional materials and presentations are often biased and non-informative.

- Health care professionals, precisely because they are professionals, should not allow themselves to be bought by the pharmaceutical industry: It is time to “Just say no” to drug reps and their pens, pads, calendars, coffee mugs, and of course, lunch.

- www.nofreelunch.org
Academia Responds

The Institute on Medicine as a Profession

- On September 10, 2008, the Institute on Medicine as a Profession on September 10 launched its database of policies on drug representative access, samples, and other conflict-of-interest issues at U.S. academic medical centers.

- Some entries in the database include a copy of the medical center's policy.

- http://www.imapny.org/coi_database
Pressured, Schools Review Ties to Drug Firms

Academia Responds

**Yale University**

- Yale University
- *Policy on Conflict of Interest and Conflict of Commitment*

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Academia Responds

**University of Pennsylvania**

In July 2006, the University of Pennsylvania Health System broadened its policies surrounding pharmaceutical marketing to include accepting honoraria for talks, free lunches and sales visits by pharmaceutical marketing. The rules prohibit students, faculty and medical staff from accepting "even small gifts."
Academia Responds

University of Pennsylvania

- Hospital & Clinical Practices of the University of Pennsylvania
- Pharmaceutical Company Representative Activity
- Guidelines for Interactions between Healthcare Professionals and Industry

Academia Responds

Stanford University

In October of 2006, Stanford University Medical Center prohibited its physicians from accepting even small gifts like pens and mugs from pharmaceutical sales representatives under a new policy intended to limit industry influence on patient care and doctor education.
Academia Responds

**Stanford University**

- Stanford University School of Medicine, the Stanford Hospital and Clinics, and Lucile Packard Children’s Hospital
- *Policy and Guidelines for Interactions with the Pharmaceutical, Biotech, Medical Device, and Hospital and Research Equipment and Supplies Industries*

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Academia Responds

**University of California**

The University of California, Davis, Health System decided in late November 2006 to forbid its Medical staff to accept any gifts from drug salesmen, including drug samples, pens, mugs and meals, however small they might be.
Academia Responds

- University of California Davis Health System

- Pharmaceutical Manufacturers’ Representative Visitation Policies


Focusing on The Process. . .

CONFLICT OF INTEREST COMMITTEE

10 Issue Questionnaire
Conflict of Interest Questionnaire

1. Presence of pharmaceutical or device industry representatives ("Pharma Reps") in areas where physicians carry out their official duties.

2. Meals for faculty, trainees and staff provided by pharmaceutical or device industry companies (Industry) on campus and off campus.

3. Gifts for faculty, trainees and staff provided by Industry.

4. Participation in consulting activities for Industry.

5. Participation in research funded by Industry.

6. Acceptance of grants from Industry to fund post doctoral positions.

7. Guest speakers sponsored by Industry.

8. Acceptance and dispensing of pharmaceutical or device samples.

9. Acceptance of educational materials from Industry

10. Monitoring and enforcement of this COI policy.
Step 1: Starting the Process

1. Presence of Pharma Reps in areas where physicians carry out their official duties:

- Complete ban (AAMC recommended).
- Allowed in areas where there are no students or trainees.
- Allowed if accompanied by a physician after prior registration and ID issued.
- Allowed only during a designated “Pharma Rep day” organized by GME office or compliance office or other designated office.
- Allowed only for pre-approved on-site courses for training, processed by CME office and outside of patient care areas. If training requires presence in patient care areas, the Pharma Rep must comply completely with policies for such activity.
- Other options.

Step 2: Focusing on Specifics

1. Presence of Pharma Reps in areas where physicians carry out their official duties:

- Pharma Reps are not allowed in areas where physicians carry out their official duties. The exceptions to this policy are:
- Pharma Reps are allowed on campus during a designated “Pharma Rep day” organized by GME office.
- Pharma Reps are allowed only for pre-approved on-site courses for training, processed by CME office and outside of patient care areas. If training requires presence in patient care areas, or the presence of the Pharma Rep is requested for his/her technical expertise, he/she must comply with hospital policy for such activity and his/her presence on campus is limited to a pre-specified time that is enough to accomplish the task.
- Pharma Reps are allowed in non-clinical areas designated by each Department if they have a prior appointment with the faculty member, with resident or with students.

- Approve                   Disapprove                   More Discussion
Step 1: Starting the Process

2. Meals for faculty, trainees and staff provided by Industry on campus and off campus:

- Complete ban (AAMC recommended).
- Allowed off campus but not on campus.
- Allowed only while attending National meetings.
- Allowed if no Pharma Reps are present but the meeting is attended by scientific liaisons or medical directors employed by Industry.
- Allowed off-campus if it is organized through a grant from Industry provided to a central education fund. Industry support is acknowledged but Pharma Reps are not allowed to attend the meeting.
- Allowed and Pharma Rep can attend the meeting as long as they do not bring Industry brochures or make any marketing presentations.
- Other options.

Step 2: Focusing on Specifics

2. Meals for faculty, trainees and staff provided by Industry on campus and off campus:

- In general off campus meals for faculty, trainees and staff provided by Industry are discouraged but not banned primarily because of difficulties in enforcing the ban. Meals provided in the course of CME-office approved activities are allowable. Meals “off campus” and “on campus” are also allowed if it is organized through a grant from Industry provided to a central education fund. Industry support is acknowledged but Pharma Reps are not allowed to attend or to make any marketing presentations. Meals purchased by Industry for “on campus” activities are not allowed.
Step 1: Starting the Process

3. Gifts for faculty, trainees and staff provided by Industry:

- Complete ban (AAMC recommended).
- Allowed for up to $50.00 (or more or less) value per year.
- Allowed if it is approved and channeled through the GME office.
- Other options.

Step 2: Focusing on Specifics

3. Gifts for faculty, trainees and staff provided by Industry:

- Gifts for faculty, trainees and staff provided by Industry are completely banned.

- Approve  Disapprove  More Discussion
Step 1: Starting the Process

4. Participation in consulting activities for Industry:
   - Allowed with no limit on compensation as long as it is approved by the supervisor and the activity does not interfere with regular responsibilities or use any employer assets.
   - Allowed as above with an upper limit of compensation.
   - Complete ban for those engaged in (human subject) research funded by Industry.
   - Other options.

Step 2: Focusing on Specifics

4. Participation in consulting activities for Industry:
   - Consulting activities for Industry are allowed as long as it is approved by the supervisor and the activity does not interfere with regular responsibilities or use any employer assets. Faculty engaged in human subject research sponsored by Industry should refrain from accepting any honoraria or consulting fees from the company sponsoring the research.
   - Approve  Disapprove  More Discussion
Step 1: Starting the Process

5. Participation in research funded by Industry:

- Physicians encouraged to participate in both investigator initiated and Industry initiated research activities so long as they are compliant with current policies governing research activities on campus.
- All requests for grants to support research should be initiated through the Research Office.
- Other options.

Step 2: Focusing on Specifics

5. Participation in research funded by Industry:

- Physicians are encouraged to participate in both investigator initiated and industry initiated research activities so long as they are compliant with current policies governing research activities on campus. All requests for grants to support research should be initiated through the Research Office.

- Approve  Disapprove  More Discussion
Step 1: Starting the Process

6. Acceptance of grants from Industry to fund post doctoral positions:

- Allowable if it is approved by the GME office and the funds are deposited in GME accounts.
- Physicians may negotiate the funding with Industry independently and the funds are deposited in a central account.
- Unrestricted program support funds provided by Industry to physicians is allowed (or not allowed).
- All requests for grants to support trainees should be initiated through the GME office.
- Other options.

Step 2: Focusing on Specifics

6. Acceptance of grants from Industry to fund post doctoral positions:

- All grants from Industry to fund post doctoral positions should be pre-approved by the GME office prior to submission of the application. There grants should be free of any restrictions imposed by the funding company. The funds received should be deposited in a GME account. Only the GME office will acknowledge the support of the sponsoring entity in an official communication.

- Approve Disapprove More Discussion
Step 1: Starting the Process

7. Guest speakers sponsored by Industry:

- Complete ban (AAMC recommended)
- Allowed if the costs of the guest speaker are covered through a grant to the CME/GME office. The candidate speaker should be chosen by the host without any input of the sponsoring company.
- Allowed if the activity is off campus and does not conflict with policy of industry sponsored meals (i.e. One can attend the talk but cannot have a free meal).
- Allowed if the presentation is reviewed by the host to ensure compliance with principles of fair presentation and lack of marketing slant.
- Other options.

Step 2: Focusing on Specifics

7. Guest speakers sponsored by Industry:

- Guest speakers sponsored by Industry are allowed if the costs of the guest speaker are covered through a grant to the CME office. The candidate speaker should be chosen by the host without any input of the sponsoring company. The presentation should be reviewed by the host (or the GME office) to ensure compliance with the principles of fair presentation and lack of marketing slant.

- Approve       Disapprove       More Discussion
Step 1: Starting the Process

8. Acceptance and dispensing of samples:

- Complete ban.
- Allowed when it is accepted at a centralized unit (e.g. pharmacy or materials management) that will monitor the distribution and dispensing.
- Allowed if it is shipped or delivered by a courier to individual “interested” provider who will be responsible for stocking and monitoring of its use.
- Allowed if it is shipped or delivered by a courier to the Chief of Service or his or her designee in the clinics who will be responsible for stocking and monitoring of its use. This should not be used as a mechanism for Pharma Reps to have access to clinic staff or trainees.
- Other options.

Step 2: Focusing on Specifics

8. Acceptance and dispensing of samples:

- Pharmaceutical or device sampling is allowed when it is accepted at a centralized unit (e.g. pharmacy or materials management) that will monitor the distribution and dispensing of the samples. Alternatively, the samples can be shipped or delivered by a courier to the Chief of Service or his/her designee in the clinics who will be responsible for stocking and monitoring of its use. This should not be used as a mechanism for Pharma Reps to have access to clinic staff or trainees.

- Approve
- Disapprove
- More Discussion
Step 1: Starting the Process

9. Acceptance of educational materials from Industry:

- Ban all educational materials prepared and provided by Industry.
- Ban only “branded” educational materials provided by industry.
- Ban only “branded” patient educational materials provided by industry.
- Teaching aids, books and support for scholarships or fellowships may be provided if a vendor wishes to support the educational mission of the institution. These may be provided only through unrestricted educational grants placed in a central fund, and monitored by the Dean or his/her designated compliance committee.
- Other options.

Step 2: Focusing on Specifics

9. Acceptance of educational materials from Industry:

- Teaching aids, books and support for scholarships or fellowships may be provided if Industry wishes to support the educational mission of the institution. These may be provided only through unrestricted educational grants placed in a central fund, and monitored by a designated compliance committee. “Branded” educational materials provided by Industry are not allowed.

- Approve        Disapprove        More Discussion
Step 1: Starting the Process

10. Monitoring and enforcement of this COI policy:

- Establish an office of compliance to monitor and oversee all faculty interactions with Industry.
- The current policy of approval of outside activities is adequate and can be used as the mechanism to enforce the COI policy.
- Require an annual or semiannual declaration by faculty members of all potential COI incidents.
- Transparency is sufficient to address all COI concerns as long as it is publicized to our trainees, patients and clinical trial volunteers.
- Other options.

Step 2: Focusing on Specifics

10. Monitoring and enforcement of this COI policy:

- Establish an office of compliance to monitor and oversee all faculty interactions with Industry. The current policy of approval of outside activities will remain in effect and can be used as the mechanism to enforce the COI policy. Physicians are required to declare all potential COI incidents annually and within 4 weeks of any new incident of COI. In accordance with Florida Public Records Law all faculty COI declarations will be available for the public.

- Approve
- Disapprove
- More Discussion
Best Practices: GAP Analysis

- Prohibit all gifts, including samples, or adopt a less extreme approach
- Gap Analysis
  - Where are Pharma Reps allowed in your organization?
  - Promotional activities?
  - Grants, sponsorships, conferences, scholarships?
  - Differentiate between device reps and pharmaceutical reps?
  - Does your organization maintain a formulary? If so, how are drugs chosen for the formulary?
  - How are medical devices (implantable) chosen at the organization?

Best Practices: GAP Analysis

- Develop Balanced Policies that Address Educational Issues Confronting Physicians and Patients.
- How do current and any future policies impact patient access to drugs?
- Consider limiting access:
  - Pharma Rep registration
  - Industry relationship tracking
  - Disclosure of Industry relationships to patients
  - Committees to evaluate drugs and devices
Best Practices: GAP Analysis

- Invite Industry to participate. Consider options for Industry to gain access to physicians.
  - Structured times for clinical presentations
  - Educational presentations
  - Same or similar events sponsored by pharma/device companies
- Medical staff-by-law considerations

Best Practices: GAP Analysis

- Train and Test
  - Incorporate Industry policies into compliance training.
  - Include "real world" examples in training.
  - Test understanding of training.
  - Invite Pharma Reps to education sessions; consider possible question and answer session for Industry.