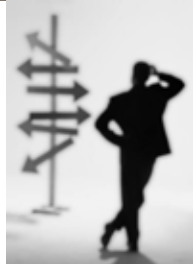
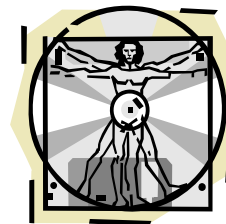


Conflict of Interest



John Falcetano, CHC-F, CCEP, CHRC, CIA
Chief Audit/Compliance Officer
University Health System of Eastern Carolina
Jfalcetano@suddenlink.net

CONFLICTS-OF-INTEREST



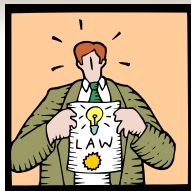
Conflict of Interest

- A conflict of interest is a situation in which someone in a position of trust, such as a **lawyer, insurance adjuster, a politician, executive or director of a corporation or a medical research scientist or physician**, has competing professional or personal interests.

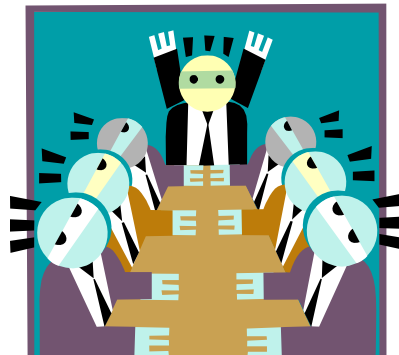
Common Forms of Conflicts of Interest

- Self-dealing
- Outside employment
- Family interests
- Gifts from friends
- Stock
- Bribes
- Self policing
- Position specific

Conflict of Interest Environment



Board of Directors




Employees

- A conflict of interest arises when anyone has two duties which conflict.
- Job specific
 - Purchasing staff
 - Department manager


Annual Conflicts of Interest Questionnaire

Certification

- 
1. During the past twelve (12) months, did you or any member of your immediate family (defined as your spouse, child, and/or other household members) hold any position or financial interest in a business enterprise that does business with or competes with your employer? If yes, please list company name, address and financial interest or position.


Answer: _____

(If “yes,” please explain.)

- 
2. With the exception of salary or other compensation regularly received by you as an officer or employee, did you or any member of your immediate family (defined as your spouse, child, and/or other household members) profit financially in any way during the past twelve months as the result of any decisions made or action taken by you in the capacity of officer or employee?


Answer: _____

(If “yes,” please explain.)

- 
3. During the past twelve (12) months, did you or any member of your immediate family (defined as your spouse, child, and/or other household members) provide any directive, managerial, consultative, or any other services to a business enterprise that does business with or competes with your employer?


Answer:

(If “yes,” please explain.)

- 
4. During the past twelve (12) months, did you or any member of your immediate family (defined as your spouse, children, and/or other household members) receive any gift or favor from any contractor, subcontractor, supplier or any representative thereof, who has a contract with your employer or any of the entities listed in #1 above, has performed such contract within the past twelve (12) months, or who anticipates bidding on such a contract in the future?

Answer:

(If “yes,” please explain.)

- 
5. Do you consider that during the past twelve (12) months there was any conflict in any way between your duties as an officer or employee and your personal interests?

Answer:

(If “yes,” please explain.)

- 
6. During the past 12 months, did you have dual employment:

Answer: _____

(If “yes,” please explain.)

Association of American Medical Colleges

Guidance – Academic/University Individual
& Institutions

AAMC Report: Industry Funding of Medical Education

- Calls for the eliminating the industry practice of providing gifts and gratuities to physicians, faculty, and students at academic medical centers but stops short of an outright ban on industry support.



AAMC Recommendations

- Eliminating drug samples
- Restricting access by pharmaceutical representatives
- Industry support for CME activities
- Discouraging participation in industry-sponsored speakers' bureaus
- Prohibiting presentations of any kind to be ghostwritten by industry representatives



American Medical Association



Ethical guidelines on gifts to
physicians from industry

2000 AMA Study

- Doctors who spend more time with sales representatives were less likely to prescribe generic medicines

- 1996 \$3 Billion
- 2001 \$5.5 Billion
- \$10,000 to \$14,000 per physician per year

AMA's House of Delegates


- Physician Gifts -1980s
 - Lavish
 - Frequent flier miles
 - Cash
 - Trips to luxury resorts
- AMA
 - Adopted CEJA's ethical guidelines to prevent inappropriate gift-giving practices
 - Code of Medical Ethics (CEJA Ethical Opinion 8.061).

Opinion 8.061, “Gifts to physicians from industry”

- Any gifts accepted by physicians:
 - benefit to patients
 - Should not be of substantial value.
 - Textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function.
 - Cash payments should not be accepted
 - Drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples


Opinion 8.061, “Gifts to physicians from industry”

- Individual gifts of minimal value are permissible as long as the gifts are related to the physician’s work
 - Pens
 - Notepads



Opinion 8.061, “Gifts to physicians from industry”

- Subsidies to underwrite the costs of continuing medical education conferences or professional meetings
- Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.

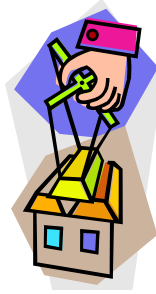


Opinion 8.061, “Gifts to physicians from industry”

- Scholarships or other special funds
 - Medical students
 - Residents
 - Fellows

Opinion 8.061, “Gifts to physicians from industry”

- Strings Attached



OIG Compliance Guidance for Pharmaceutical Companies

- Risk Areas
 - Kickbacks
 - Discounts
 - Educational grants
 - Research funding
 - Product support services

OIG Pharmaceutical Guidance

- Does the arrangement or practice have potential to interfere with or skew clinical decision-making? Is all provided information fully accurate?
- Does the arrangement or practice have the potential to increase costs to the federal healthcare program? Does the arrangement have the potential to be a disguised discount to circumvent the Medicaid Rebate Program Best Price calculation?

OIG Pharmaceutical Guidance

- Does the arrangement or practice have the potential to increase the risk of overutilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?
- The Guidance specifically addresses Anti-Kickback risks in manufacturer relationships with purchasers, physicians and sales agents.

Relationships with Purchasers

- Manufacturer discounts to induce the purchase of particular drugs
- Manufacturer grants to purchasers for research and education.
- Manufacturer relationships with health insurers and pharmacy benefit manufacturer companies

Relationships with Providers

- Potential Anti-Kickback
- payments to physicians engaged by manufacturers
 - consulting and advisory services
- Drug detailing practices
- Switching arrangements
- Questionable research
- Anti-Kickback Statute safe harbors
- Pharmaceutical Research and Manufacturers of America (PhRMA)

Pharmaceutical Industry Influence

- Survey of Medical Students
 - 85% - improper for politicians to accept gifts
 - 46% - improper for themselves to accept a gift of similar value from a pharmaceutical company

PhRMA Code

- Pharmaceutical Research and Manufacturers of America
 - Research-based pharmaceutical companies
 - Biotechnical companies
- Adopted voluntary Code
- Ethical relationships with health care professionals

Basic Interaction

- Promotional materials
 - Accurate
 - Properly substantiated
 - Risks and benefits
 - Consistent with FDA

Informational Presentations

- Health care professional's workday
- Occasional meals
 - Staff members
 - Value
 - Modest meals
 - Entertainment/recreational
 - Conducive informational communication
 - In-office/in-hospital
 - Spouse
 - Take out meals

Entertainment & Recreation

- Items
 - Tickets
 - Theater
 - Sporting Events/Equipment
 - Leisure or vacation trips
- Company Employees
- Value/Speaker/educational purpose

Continuing Medical Education

- CME grant making functions
- Selection criteria
- Financial support
- Non-faculty health care professionals
- Advice or guidance
- Meals

Third Party Educational or Professional Meetings

- Educational conferences/professional meetings
 - Appropriate location
 - Time & effort
 - Main incentive
- Financial support
- Content selection
- Non-faculty health care professionals
- Time compensation

Consultants

- Defined criteria
- Reasonable compensation
- FMV
- Token consultant or advisory arrangements
- Bona fide consultant arrangements
 - Written contract
 - Legitimate need
 - Criteria for selecting the consultant
 - Number of healthcare professionals
 - Maintain records
 - Appropriate venue
 - Modest meals
 - honoraria or travel or lodging expenses

Speaker Programs and Speaker Training Meetings

- Defined criteria
- No inducements
- Compensation
 - Extensive training
 - Valuable service
 - General criteria
 - FMV
- Venue
- Policies
- Modest meals
- CME Distinction

Committee Members that Set Formularies or Develop Clinical Practice Guidelines

- Committee/speaker disclosure
- Disclosure time
- Member recusing

Scholarships & Educational Funds

- Financial assistance
 - Medical students
 - Residents
 - Fellows
 - Other healthcare professionals in training
- Selection

Prohibition of Non-Educational and Practice-Related Items

- Minimal value items
 - Pens
 - Notepads
 - Mugs
 - Similar items with product logo
- Personal items
 - Floral arrangements
 - Artwork
 - Music CDs
 - Tickets to sporting events
- Cash or cash equivalent
- Product samples

Educational Items

- Value \$100 or ↓
 - Anatomical model
 - DVD/CD player
 - Frequency

Prescriber Data

- Non-patient identified data
 - Safety & risk
 - Conduct research
 - Comply with FDA
 - Track adverse events
 - Focus marketing activities
- Controls
 - Respect confidentiality
 - Develop policies
 - Educate employees
 - Internal contact person
 - Disciplinary action
- Restrict data use

Independence & Decision Making

- No grants, scholarships, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products

Training and Conduct of Company Representatives

- Employed or acting on behalf
- Training
 - Applicable laws
 - Regulations
 - Industry code
 - General science & product specific
 - Updates and additional training
- Assess compliance

Adherence to the Code

- All companies adopt & adhere
- Annual certification
 - Policies & procedures
 - Signed by CEO and CCO
- PhRMA notification to CCO
- External validation

PhRMA Code Q&A

- Under the Code, may items such as stethoscopes be offered to healthcare professionals?

PhRMA Code Q&A

- Under the Code, could a company provide healthcare professionals with pens or clipboards designed to be used by healthcare professionals or patients in the healthcare professional's office along with brochures that provide educational information about the company's product?

PhRMA Code Q&A

- Under the Code, what are examples of permissible items that may be provided to educate healthcare professionals?

PhRMA Code Q&A

- Under the Code, what types of patient education items may companies provide to healthcare professionals to help them in educating their patients?

PhRMA Code Q&A

- Under the Code, may golf balls and sports bags be provided if they bear a company or product name?

PhRMA Code Q&A

- Under the Code, may healthcare professionals be provided with gasoline for their cars if they are provided with product information at the same time?

PhRMA Code Q&A

- The Code states that company representatives or their immediate managers working in company field sales organizations may conduct informational presentations and discussions accompanied by occasional, modest meals in the healthcare professional's office or hospital setting. What types of presentations and meals would this include?

PhRMA Code Q&A

- Can a field sales representative of Company B conduct an informational presentation accompanied by a meal for a healthcare professional in a restaurant down the street from a hospital?

PhRMA Code Q&A

- A field sales representative of Company X provides pizza for the staff of a medical office during lunch time. Is this consistent with the Code?

PhRMA Code Q&A

- A field sales representative of Company X invites physicians to meet to hear a scientific and educational presentation about a new drug at the café at a nearby bookstore. Lunch is provided by the representative and, following the presentation (which is in small groups), each physician is given a gift certificate for books in the amount of \$30. Does this conform to the Code?

PhRMA Code Q&A

- A district sales manager at Company C invites 30 physicians to a corporate suite at a professional baseball game for a 45-minute scientific and educational presentation followed by a buffet and the three-hour game. Does this conform to the Code?

PhRMA Code Q&A

- Under the Code, could a senior business executive employed by a company provide a healthcare professional with an occasional meal outside of the healthcare professional's office or hospital?

PhRMA Code Q&A

- Company Y would like to engage an expert physician to discuss recent advances in therapy for a group of local healthcare professionals, and would like to meet and provide a meal to attendees in the private room of a local restaurant. Under what circumstances can this comply with the Code? Could a local field representative in the company's sales organization attend the event for purposes of assisting the outside speaker and helping to assure that the content of the presentation complies with FDA requirements?

PhRMA Code Q&A

- Under what circumstances would the Code permit a company to provide entertainment or recreational activities to healthcare practitioners?

PhRMA Code Q&A

- Company A retains a small group of 15 nationally known physicians regarding a therapeutic area relevant to company A's products to advise on general medical and business issues and provide guidance on product development and research programs for those products. These physicians are paid fees that are typical of the fees paid to thought leaders in this therapeutic area. They normally meet once or twice a year at resort locations to discuss the latest product data, research programs and Company plans. Does this comply with the Code? If it does, is it appropriate to pay for the spouse of the healthcare professional to attend, as well?

PhRMA Code Q&A

- Company A considers whether to invite 300 physicians/consultants to a two-day and one-night speaker-training program at a regional golf resort. All attendees would be compensated for their participation, and their expenses would be reimbursed. Prospective speakers would be selected based on recommendations of the Company's district managers and as assessment of their qualifications by the Company's medical or scientific personnel. Each of the attendees would be required to sign an agreement in advance covering the services they will provide. They would be educated by a faculty on the full range of data surrounding the disease state and the Company's drug product, on presentation skills, and on FDA regulatory requirements. The Company needs to train 300 speakers in order to ensure that enough speakers will actually be available when needed. Training sessions take both days, and the Company provides for a few hours of golf and expensive meals, such as lobster and filet mignon. Does this program conform to the Code? If so, it is appropriate to pay for a spouse of the Healthcare professional as well?

PhRMA Code Q&A

- A sales representative invites a physician out for a round of golf and lunch following the golf. The physician is very busy and is difficult to see in her office. The cost of the golf and lunch combined are \$65. Does this comply with the Code?

PhRMA Code Q&A

- Under the Code, may a healthcare professional's spouse or other guest be included in a meal with a pharmaceutical company representative that is provided in connection with an informational presentation by or on behalf of the company, if the healthcare professional pays for the spouse or guest?

PhRMA Code Q&A

- A company is asked to fund a CME program as a "platinum" level supporter. This level of support includes the opportunity for the company to directly sponsor a lunch at the event. May the company become a "platinum" level supporter?

PhRMA Code Q&A

- A national specialty society is holding its three-day annual conference, which includes business meetings, entertainment, and a half day of educational programs for which physicians may receive CME credit. May a company sponsor a reception or lunch at the conference?

PhRMA Code Q&A

- May a company publicize its interest in a general topic for a CME program for which a grant would be provided?

PhRMA Code Q&A

- Under the Code, may a company make a charitable contribution such as purchasing a table at a fundraising dinner or a foursome slot at a fundraising golf tournament?

PhRMA Code Q&A

- Under the Code, may a company compensate a consultant for bona fide services by providing an item with a legitimate patient benefit in lieu of paying an honorarium or fee?

PhRMA Code Q&A

- Does the Code apply to interactions with physician office managers, receptionists, and similar personnel who may not be healthcare professionals?

PhRMA Code Q&A

- Does the Code address the issue of disclosure of company interactions with healthcare professionals who are members of committees that develop formularies or clinical practice guidelines?

Eli Lilly Will Begin Disclosing Payments Exceeding \$500 Made to Individual Physicians



International Communication Research Prescription Drug Project

- **One-half of surveyed adults think the pharmaceutical industry has a very large influence on doctor's choice of Rx medicine**

Questions

