

Conflicts of Interest

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Introduction

- What are Conflicts of Interest?
 - What are Conflicts of Commitment?
 - Why should you be concerned?
 - Consequences if not handled properly
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Who Can Have a Conflict of Interest?

- Conflicts of Interest may involve organizations.
- Questions to ask:
 - To whom are the duties owed?
 - What interests are in possible conflict?
 - What are the company's compensation models?
(Incentives, Commissions, Bonuses)

Definition of a Conflict of Interest

- Financial or other considerations that may compromise (or have the appearance of compromising) one's objectivity or independent professional judgment in meeting an entities duties or responsibilities

- A conflict of interest occurs when an individual's private interest interferes in any way—or even appears to interfere—with the interests of the corporation as a whole.

Section 303A of the NYSE Corporate Governance Rules

Conflict of Interest in Clinical Care

Defined as “A set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.”

**AAMC Report of the Task Force on Financial Conflicts of Interest in Clinical Care,
June 2010**

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Conflict of Commitment

When pursuit of outside activities involves an inordinate investment of time that interferes with one's obligations to an entities responsibilities

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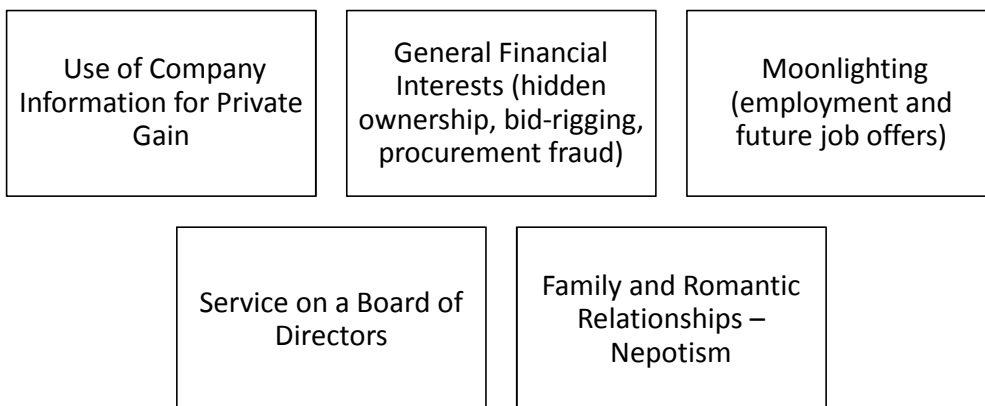
Types of Conflicts

- Physician/Patient
- Researcher/Research Subject
- Researcher/Institution
- Physician/Other Provider
- Executive/Organization
- Employee/Organization

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Common Conflicts Of Interest



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Common Conflicts Of Interest

Spouses, Domestic Partners, Immediate Family Members or Relatives as Suppliers, Vendors, Customers

Implied Pressure on Employees to Use a Manager's Relative

Vendor Relationships - Kickbacks and Rebates

Gifts from Vendors, Customers or Others

Improper Use of Company Assets

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Addressing Conflicts

Federal legislation

Research

PhRMA Code on Interactions with Healthcare Professionals

Guidance for Pharmaceutical Manufacturers

2002 & 2017 OIG Special Advisory Bulletin

AdvaMed Code of Ethics 1/1/2004

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PHRMA Code

Adopted voluntary Code

Ethical relationships with health care professionals

Basic Interactions

- Intended to benefit patients

Promotional material

- Be accurate and not misleading
- Make claims about a product only when properly substantiated
- Reflect the balance between risks and benefits; and
- Be consistent with all other FDA requirements

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AdvaMed Code of Ethics

Company training and education

Third party training and education

Sales and promotional meetings

Consulting arrangements

Gifts

Reimbursement information

Education Grants

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OIG Special Advisory Bulletin

Providers can offer beneficiaries/patients inexpensive gifts, \$15 per item but cannot exceed \$75 annually

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Internal Revenue Service 501(c)3

Not-for-Profit-Entities

The purpose of the conflict of interest policy is to protect this tax-exempt organization's interest when it is contemplating entering into a transaction or arrangement that might benefit the private interest of an officer or director of the organization or might result in a possible excess benefit transaction.

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Physician Payment Sunshine Act

Drug and device manufacturers must disclose to government on an annual basis anything of value provided to physicians or teaching hospitals

Conflict of Interest Policy

A conflict of interest arises when a person in a position of authority over an organization, such as a director, officer, or manager, may benefit personally from a decision he or she could make. A conflict of interest policy consists of a set of procedures to follow to avoid the possibility that those in positions of authority over an organization may receive an inappropriate benefit.

Define a process for what you do when you get a disclosure

Conflict of Interest Process

- Track completion of disclosures
- Assure action plan is appropriate for managing the conflict and/or resolving the conflict
- Review and approve action plan
- Communicate conflicts to appropriate management chain of command, governing body, where appropriate
- Monitor action plans and outcomes
- Trend conflicts and assist with training and tools for use by employees and management

Gifts and Entertainment

Common area for conflicts of interest

- Usually the policy in this area is separate from the conflict of interest policy.
- Do you have a gift and entertainment policy that:
 - Defines parameters* of acceptable gifts and entertainment
 - Dollar values, thresholds, annual limit

*Nominal, customary, inexpensive, reasonable and appropriate-tough words for an employee or organization to have to interpret

Gifts and Entertainment

Does your policy:

- Require proper management approvals for exceptions
- Describe how gifts and entertainment are disclosed and documentation maintained
- When non-compliance in gifts and entertainment is reported and/or escalated?

Conflict of Interest

- Conflicts are inevitable
- Conflict does not imply guilt
- Disclosure does not equal conflict
- Conflict is manageable
- Education, guidance and awareness are essential

Managing Conflicts of Interest

- Company responsibility to identify those who:
 - Have commitments or relationships with competing organizations
 - Have outside employment relationships with businesses that seek to do business with company or are competitors of company
 - Work in targeted areas/departments
 - Previously had a conflict identified

Managing Conflicts of Interest

- Solicit information on conflicts:
 - Routine reports of external financial interests
 - Questionnaires
- Updates annually and/or as circumstances change
 - Credentialing
- Monitor new contractual relationship
- Publication Oversight
- Limits on Meals/Entertainment
- Certifications

Prevention.....Training

- Ongoing company-wide compliance education and awareness
- New employees orientation, management training and executive seminars
- Interactive, scenario-based training
- Does your code of conduct and training have a conflict of interest scenarios?
- Disclose – Be Transparent
- If anything changes, disclose
- If you think there is a conflict of interest, disclose
- Appropriate disciplinary action for violators must be evident -must enforce policy

Auditing and Monitoring

- Be proactive: audit and/or monitor each process step
- Is policy effective for ongoing risks? Business changes?
- Is training effective?
- Were there any surprises related to conflicts of interest?
- Should we have an independent audit or monitoring plan?
- Does your process remediate conflicts timely?
- Are conflicts traced and trended?

Closing Thoughts

- Conflicts are not bad, they just need to be managed.

- We need to effectively manage conflicts by:
 - Understanding that appearances matter. Often conflicts are perceived vs. actual conflicts.
 - Recognizing that conflicts of interest are inevitable and do imply guilt – most are manageable
 - Education, guidance and awareness are essential

Anchor Health System

Doctor Poppy, a physician in the Tribal Health System, asks the hospital CEO to purchase widgets from a specific vendor. The widgets are produced by a manufacturer called Widgets R Us.

Doctor Poppy owns 35% of Widgets R Us and has disclosed the relationship on his annual conflict of interest questionnaire.

Anchor Health System

A staff member completes purchase orders and approves invoices for supplies. The Home Health Agency has a preferred suppliers, however the staff member has been ordering from a non-preferred supplier. The non-preferred supplier is owned by the staff member's sister.

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Anchor Health System

Ms. Smith is the nursing department head at the Skilled Nursing Facility and currently has a vacant position within the department. Ms. Smith's daughter just graduated from college and is looking for work. To avoid a conflict of interest, Ms. Smith directs the manager reporting to her to interview her daughter for the position.

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Questions?

Thank you