

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

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

o 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

o 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

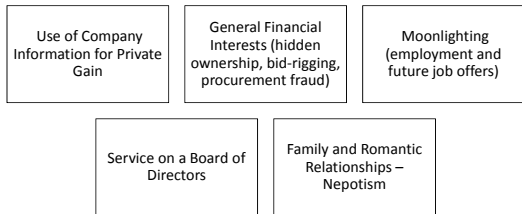
Conflict of Commitment

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

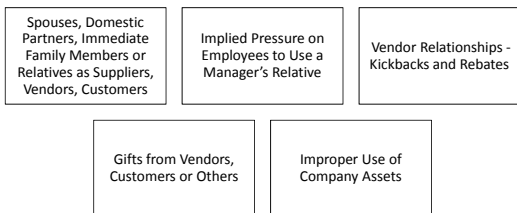
Types of Conflicts

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

Common Conflicts Of Interest



Common Conflicts Of Interest



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

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

AdvaMed Code of Ethics

- Company training and education
- Third party training and education
- Sales and promotional meetings
- Consulting arrangements
- Gifts
- Reimbursement information
- Education Grants

OIG Special Advisory Bulletin

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

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.

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

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

Gifts and Entertainment

Common area for conflicts of interest

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

20 20

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

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

Prevention.....Training

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

Auditing and Monitoring

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

Closing Thoughts

- o Conflicts are not bad, they just need to be managed.
- o We need to effectively manage conflicts by:
 - o Understanding that appearances matter. Often conflicts are perceived vs. actual conflicts.
 - o Recognizing that conflicts of interest are inevitable and do imply guilt – most are manageable
 - o 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.

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.

28

Questions?

Thank you

29 29
