Conflicts of Interest... A Discussion and Case Study

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AGENDA

- Audience Poll
- Evolution of Thought on Conflicts of Interest
- Categories of COI
  - Research related: NIH/PHS Regulations
  - IRS related: Form 990, the Board and “Key Employees”
  - Internal Policy: Fiduciary Responsibility
- Physician Payment Sunshine Provisions of ACA
- Increased Scrutiny
- COI Management Challenges
- Case Study: Via Christi Health

Conflicts of Interest in Medicine
Evolution of the Concept
The Evolution of Thought on COI

- Relations between Physicians, Hospitals and the Medical Industry are Important!
  - Contributions to Medical Education
  - Funding Clinical Trials
  - Providing Product Samples
- To support the Teaching, Research and Clinical Missions of Academic Medicine

The Evolution of Thought on COI

1980s
- Any suggestion that such relationships were improper was met with indignation and dismissive denial
- Physician Self Referrals led to the Stark Laws, a recognition that financial considerations could affect care decisions

The Evolution of Thought on COI

1990s
- Concern on the part of the Public Health Service that research could be biased by “conflicting financial interest”
- 1995 saw first regulations requiring development of COI policies and disclosure of conflicts, but only to the institution and not the government
- 1999 Jesse Gelsinger case
The Evolution of Thought on COI

2000s
- JAMA Articles
  - "A Social Science Perspective on Gifts to Physicians from Industry", Dana J, Loewenstein G., July 2003

COI in The News

Top Psychiatrist Didn’t Report Drugmakers’ Pay
- Dr. Charles Nemeroff
  - Chair of Psychiatry, Emory University
  - Paid >$2.8 Million by Drug Companies
  - 2000 to 2007 while a full-time university professor
  - While testing their drugs (in some cases)
  - Repeatedly failed to disclose to university

COI in The News

Research Center Tied to Drug Company
- Dr. Joseph Beiderman, Prominent Child Psychiatrist, Harvard University
- Studies funded by and articles drafted by industry
- Promoted Johnson & Johnson drugs
- 40-fold increase in diagnosis of pediatric bipolar disorder
- Failed to disclose at least $1.4 million in payments
Study: Doctors often fail to disclose company payments

“A study of orthopedic specialists earning $1 million or more from medical device companies found that doctors often fail to disclose lucrative company ties in medical journal articles, researchers reported Monday”

USA TODAY, September 13, 2010

Grassley’s Greatest Hits

- Senator Queries FDA and Spinal Disk Maker
- Senator Moves to Block Medical Ghostwriting
- Senator Asks Pfizer About Harvard Payments
- Senators Question Financial Ties Between Doctors and Stent Manufacturers
- U.S. to Force Drug Firms to Report Money Paid to Doctors

Industry Interaction National Statistics

- Percent of physicians interacting with industry: 29%
- Average # of interactions per physician with at least one interaction: 2.7
- Average amount of total $ value per physician with at least one interaction: $6,400
- Average amount per interaction: $2,350
- Number of physicians receiving over $10,000: 14,390
- Number of physicians receiving over $100,000: 2,875

Era of Increased Scrutiny and Transparency

- Significant growth and complexity of biomedical research and behavioral research since the publication of the first COI regulations in 1995.
- Deepening relationships and interdependency of academic researchers and industry.
  - Financial support of biomedical research from 1994 to 2003 rose from $37.1 billion to $94.3 billion;
  - NIH invests over $31.2 billion annually in medical research.

Moses, H et al, JAMA; 2005; 294:1333-1342

http://www.nih.gov/about/budget.htm#note; Excluding the $10 billion appropriated to NIH for short-term purposes in 2009 under the American Restoration and Recovery Act (ARRA).

Era of Increased Regulation

- PHS Issues Regulations on COI in Research (FDA regs in 1999)
- HHS Guidance Financial Interests & Human Subjects Protection
- PPACA Physician’s Sunshine Provisions

PhRMA Code on Interactions with Healthcare Professionals (as of 2008)

Grassley, OIG, Dr. Nemeroff, etc.

Commercial Support for Accredited CME, 1998–2010

- Commercial Support
- Other sources

HHS Final Regulations on Objectivity in Research

PPACA Physician’s Sunshine Provisions
Why Should You Care?

A Review of the Physician Payment Sunshine Provisions

PPACA Physician’s Sunshine Provisions

- Manufacturers to report any payments to physicians or teaching hospitals above $10 unless an exception applies
- Broad definition of payment
- Manufacturers must report any ownership/investment interests by a physician or his/her immediate family
- This provision applies to pharmaceutical companies, biotech firms and medical device manufacturers that have products which are eligible for payment by Medicare, Medicaid or the Children’s Health Insurance Program (CHIP).

PPACA Physician’s Sunshine Provisions

Information required for reporting to HHS

<table>
<thead>
<tr>
<th>Consulting fees</th>
<th>Non-consulting compensation</th>
<th>Honoraria</th>
<th>Gift</th>
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<tbody>
<tr>
<td>Entertainment</td>
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<td>Travel (incl. destination)</td>
<td>Education</td>
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<tr>
<td>Research</td>
<td>Charitable contribution</td>
<td>Royalty or license</td>
<td>Ownership or investment interests</td>
</tr>
<tr>
<td>Direct compensation for serving as faculty or speaker for a medical education program</td>
<td>Any other payment or other transfer of value as defined by the Secretary</td>
<td></td>
<td></td>
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PPACA Physician’s Sunshine Provisions

- Information required for reporting to HHS (posted online) includes contact information and form, nature and amount of payment:
- Name, specialty, address, and National Provider Identifier of recipient
- Amount and date of payment or any other transfer of value
- Cash, in-kind-items, stock/options, dividends, ownership interests, etc.
- Nature of payments

On May 3rd CMS announced data collection would begin no sooner than January 1, 2013.

At some future date, manufacturers will post the collected information on a publicly available internet website that is searchable with downloading functionality.

A good place to check out: ProPublica “Dollars for Docs” website: >$760 Million in payments

Looking to the future, when the Physician Payment Sunshine Act goes into effect, you and your physicians will feel pressure to explain the payments that are reported by industry.

ProPublica “Dollars for Docs” Website
On August 23, 2011, the Department of Health and Human Services ("HHS") published a final rule ("Final Rule") on financial conflicts of interest ("FCOI"). Institutions must be in full compliance with all of the regulatory requirements no later than August 24, 2012.
Overview of the Final Rule

What is a Significant Financial Interest?
- any payment or equity interest over $5,000 within a rolling 12 month period, regardless of whether its related to specific PHS funding.
- SFIs can be that of the investigator, her/his spouse or dependent children.

What is a Financial Conflict Of Interest?
- a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

What are the Institutional Responsibilities under these regulations?
- Maintain an up-to-date, written, policy on financial COI and make it available via a publicly accessible Web site.
- Inform each Investigator of the COI policy, the responsibilities regarding disclosure of significant financial interest (SFI), and require each Investigator to complete COI training at least every 4 years.
- Take reasonable steps to ensure sub-recipients comply with financial COI regulations.
- Designate an institutional official to solicit and review disclosures of SFI.
- Require disclosures at least annually or within 30 days of discovering or acquiring a new SFI.
- Provide guidelines on how the institutional official determines that a financial COI is a SFI related to PHS-funded research.
- Take actions to manage financial COIs.
- Provide initial and ongoing financial COI reports to PHS.
- Maintain records of disclosure, their review, determinations, and any subsequent actions for at least 3 years.
- Establish enforcement mechanism to sanction Investigators who are noncompliant.
- Require investigator disclosures no later than the time of application for PHS funds.
- Certify compliance with these regulations in each PHS application.
Overview of the Final Rule

Institutions have additional disclosure obligations under the final rule:

- Institutions shall ensure public access to disclosed significant financial interests which are determined to be Financial Conflicts of Interest via a publicly accessible Web site or written response to any requestor.
- Institutions have 5 business days to respond to requestors.

Overview of the Final Rule

Institutions must have a process in place to manage Conflicts of Interest

- Upon determination that a SFI is a FCOI related to PHS funded research, institutions must develop and implement a management plan that shall specify the actions that have been, and shall be, taken.

Managing Conflicts of Interest

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing research);
- Disclosure of financial conflicts of interest to participants;
- Appointment of an independent monitor capable of being measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- Severance of relationships that create financial conflicts.
Implications of the Final Rule

- The NIH final rule foreshadows trends in management of Conflicts of Interest
  - Compliance-focused – Organizations must have adequate policies and mechanisms in place to review, identify and manage conflicts
  - Transparency – By requiring not only the posting of updated policies on a publicly accessible website, but also mandating the public disclosure of Significant Financial Interests, NIH is requiring organizations to track, monitor and disseminate information of public value and interest.

Conflicts of Interest in Research
IRS and the Form 990
Conflicts of Interest and Your Fiduciary Responsibility

IRS and the Form 990

IRS and the Form 990

The IRS is interested in financial remuneration...
- Tax exempt organizations must disclose reportable compensation of certain employees.
- Tax exempt organizations must report compensation information for its Officers, Directors, Trustees, Key Employees and Highest Compensated Employees.
  (Thresholds are over $100,000 or $150,000 depending on the role of the employee.)
- Reportable compensation is from the organization itself and related organizations (parent company, subsidiary or sponsor).
- Tax exempt organizations must report compensation on Form 990 for the calendar year ending within the organization’s fiscal year.


IRS and the Form 990

The IRS is interested in Real or Potential Conflicts of Interest...
- Some examples might include:
  - A board member or key employee may be affiliated with a business partner
  - A family member may have a relationship with the organization
  - A board member or a key employee may have a business relationship with another board member
  - A board member or key employee makes decisions that directly or indirectly affect him or her in positive or preferential manner
  - The organization might provide loans, grants, or other financial assistance to board members, officers, or key employees


Conflicts of Interest in Research

Conflicts of Interest and Your Fiduciary Responsibility

Conflicts of Interest in Research

IRS and the Form 990

Conflicts of Interest and Your Fiduciary Responsibility
Conflicts of Interest and Your Fiduciary Responsibility

Every healthcare organization is at risk for Conflicts of Interest related to:

- **Purchasing**
  - Pharmaceutics and Therapeutics Committee – how are you making sure that events, licenses, hips, etc., are not being selected based on hidden payments?
  - U.S. Senate Committee on Finance, Staff Report on Cardiac Stent Usage at St. Joseph Medical Center, Dec. 2010
  - Vendor Gifts – 2 South Florida Physicians paid fines of $65,000 and $57,000 for providing gifts of Miami Dolphins tickets and shirts.

- **Nepotism**
  - UCI Medical Center says it is investigating whether nepotism rules were violated when it hired three relatives of the hospital’s interim chief executive.
  - Bonus payments and hiring questions raised at William Beaumont Medical Center
  - “My brother owns Acme Office Supply, and I tell ALL my employees to buy their supplies from there!”

Conflicts of Interest and Your Fiduciary Responsibility

Every healthcare organization is at risk for Conflicts of Interest related to:

- **Physician Relationships**
  - Stark Law prohibiting self-referrals
  - Anti-Kickback law
    - Medical Staff Incidental Benefits can not exceed $31.00/month
    - Government focus on “fair market value” for rents, other arrangements

- **Board Relationships**
  - “Hospital did business with firms linked to CEO, board members”
  - “I can get a great home mortgage if I just bring part of the Hospital’s business to First National”

COI Management Challenges
COI Management Challenges

Institutions must:

- Create mechanisms to solicit and collect disclosures, and review and report on Conflicts of Interest.
- Establish mechanisms to respond to requests for public disclosures.
- Develop systems to process requests in accordance with the regulations.
- Create processes to compare their information with documented disclosures by industry, and explain any discrepancies.

A Case Study: Via Christi Health

Via Christi Health
Tone at the Top
- Fiduciary Duties
- Corporate Responsibility Program
- Conflict of Interests (COI) Policy
Conflict of Interests Disclosure
- Evolution of Process and Tools
- COI Disclosure & Management System
Via Christi Health

**Our Mission**
Inspired by the Gospel and our Catholic tradition, we serve as a healing presence with special concern for our neighbors who are vulnerable.

**Our Core Values**
- Human Dignity
- Stewardship
- Excellence

 Via Christi Health

- 10,000+ employees
- 300+ physicians and 115+ mid-level providers
- 1,100+ medical staff members
- 12 fully/partially owned or managed hospitals
- 16 owned or managed senior villages and programs
- Home health and home medical services
- Ambulatory surgery and imaging centers

 Via Christi Health

- Physician Visits: 680,299
- Long-term & Residential Care Days: 548,000
- Acute Care Patient Days: 220,559
  - Inpatient Admissions: 47,721
  - Beds in Service: 1,163
- Outpatient Services: 679,068
- Home Health Visits: 51,317
- Operating Revenues: $1.09 billion

Fiscal Year 2011
Via Christi Health

$82 million Community Benefit
- $45.3 million Charity Care
- $19.8 million Unpaid Costs of Medicaid services
- $16.9 million other community benefit

Fiscal Year 2011

Tone at the Top

Fiduciary Duty of Loyalty
- Good faith
- Best interests of the non-profit corporation - its charitable mission

IRS Form 990
- 275 Board and Committee members
- 291 Other ‘Interested Persons’
Tone at the Top

Board-level Conflict of Interests Policy

- Team: Corporate Responsibility, Governance, Legal
- Audit Committee accountability
- Annual COI Disclosure
- Ongoing duty to disclose: ‘continuous obligation’

Tone at the Top

Board-level Conflict of Interests Policy

- ‘Interested Persons’
  - Board members
  - Key Employees
  - Others: Exercise influence over corporation; Commit organizational resources >$10,000
- Disclosure management and reporting
COI Disclosure Evolution

- Paper
- FY 2007-09: Contract Management module
- FY 2010: Survey Monkey interim solution
- FY 2011: COI-SMART
  - 275 Board and Committee members
  - 291 Other ‘Interested Persons’

Integrated System

- Ease of use for respondents = critical
  - Organizational information available, e.g., board members & senior management; related organizations; policy requirements and definitions
  - Submission of respondent information based on making a disclosure
- Efficiency for administrators & reviewers
  - Questionnaire set-up
  - Tracking questionnaire status
  - Review process; disclosures/no disclosures
  - Communications contained within system
- Reporting

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<td>Subsequent Years</td>
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Estimate based on 600 respondents; assume 5% mailed
COI Disclosure and Management
System: Preparation

Preparation

Work Team
- Corporate Responsibility
- Finance
- Governance
- Human Resources
- Information Technology

Final Submission Date = ‘public’ due date
Close Date = no more entries possible
Security Profiles:

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<tr>
<td>Reviewer</td>
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## Preparation

- **Roles:**
  - Board / Board Committee Member
  - Employee
  - Medical Director / Administrative Physician
  - Lead Investigator (Research)

- **Department Designations**
  - Assign Reviewers based on Respondent Role, Department, or Facility

## Datasets

- **Roles**
- **Demographics**

## Data Uploads

- Secure upload directly from HRIS; automated
- Online Board Portal export to CSV; Incorporated file of additional ‘interested persons’; secure upload

## Permitted Values

- Enhanced capture of discreet information re: disclosures
Email Templates

COI Disclosure and Management System: Implementation

Questionnaire Opened

Email sent from the system
- Brief instructions with link to the online system
- Set unique password
Henry Ford Health System (HFHS), a non-profit integrated health care delivery and insurance system, recognizes and supports interactions with industry that serve to advance the delivery of health care services. However, we recognize that these interactions can at times create potential “conflicts of interest” and have designed HFHS policy, including specifically, guidance regarding workforce interactions with vendors, to ensure that these interactions support the best interest of HFHS.

Managing the risks associated with potential conflicts of interest begins with establishing a culture of transparency. This disclosure process is designed to serve as a tool for identifying situations that could create potential conflicts of interest, documenting them, and where necessary, establishing plans to manage the risk.

Your disclosure questions are based on your personal roles and responsibilities at HFHS. On the next screen you will see your profile which includes your name and other identifying information. Your role(s) have been pre-assigned and are indicated with a checkmark. You can add additional roles as you may find appropriate. However, you cannot eliminate any preassigned roles. Once you have reviewed your profile you will need to choose the appropriate button to save your profile and start your questionnaire.
Discussion

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