Three Lines of Defense against Conflict of Interest

HCCA Research Compliance Conference
June 5, 2016
Bill Sacks, Rebecca Scott, and Andrew Hill

AGENDA

- Introductions / Housekeeping
- The Evolution of Conflicts of Interest as a Management Concern
  - Research related: NIH/PHS Regulations
  - IRS related: Form 990, the Board and "Key Employees"
  - Internal Policy: Fiduciary Responsibility
- Overview of the “Three Lines of Defense”
- Applying Three Lines of Defense to Conflicts of Interest Management
- One AMC’s Lessons
**Conflicts of Interest in Research and Healthcare**

Evolution of the Concept
(Bill)

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**The Evolution of Thought on COI**

**1980’s**

- 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

1990’s

- 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

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The Evolution of Thought on COI

1990’s

- 1999 Jesse Gelsinger case
- Informed Consent Issues
- Conflict of Interest Issues

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The Evolution of Thought on COI

2000’s

JAMA The Journal of the American Medical Association

- “Physicians and the Pharmaceutical Industry; Is a Gift Ever Just a Gift?”
  (Wazana, A., January 2000)
- “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 Drug Makers’ Pay
October 4, 2008

The New York Times

- Dr. Charles Nemeroff
- Chair of Psychiatry, Emory University
- Paid >$2.8 Million by Drug Companies
- From 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
November 24, 2008

The New York Times

- 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

COI in The News

Study: Doctors often fail to disclose company payments
September 13, 2010

“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.”
COI in The News

Health Guideline Panels Struggle with Conflicts of Interest
November 2, 2011

The New York Times

“In all, about 20 of the three panels’ members, including some co-chairmen, have been advised that they should not vote on crucial issues as they prepare to issue the health guidelines next year — because they are too closely connected to industries with a keen interest in the panels’ recommendations.”

Lax Policing of Doctor and Pharmacy Conflicts Is Found in Medicare Coverage Decisions
March 5, 2013

The New York Times

“Deciding which drugs will be covered by Medicare can influence huge amounts of spending, but government officials do little to police conflict of interest among doctors and pharmacists who make those decisions, federal investigators said Monday.”
COI: Increased Regulation

- 1995: PHS Issues Regulations on COI in Research (FDA regs in 1999)
- 2004: HHS Guidance Financial Interests & Human Subjects Protection
- 2008: Grassley, Dug, Dr. Nemeroff etc.
- 2010: PPACA Physician’s Sunshine Provisions
- 2012: PHS NAPRM to Expand COI Regulations
- 2014: HHS Final Regulations on Objectivity in Research
- Implementation of the Physician Payment Sunshine Act Provisions of the ACA

Overview of the NIH Final Rule

- On August 23, 2011, the Department of Health and Human Services ("HHS") published a final rule ("Final Rule") on financial conflicts of interest ("FCOI")
- The Final Rule became effective September 26, 2011.
- Institutions had to be in full compliance with all of the regulatory requirements:
  - Immediately upon making its investigator FCOI policy publicly accessible, but
  - No later than August 24, 2012
COI - PHS Funded Research

42 CFR Part 50 Subpart F continued
Overview of the NIH Final Rule

Institutions must:

- Take actions to manage Financial COIs.
- Maintain records of disclosures, their review, determinations, and any subsequent actions for at least 3 years.
- 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 NIH Final Rule

42 CFR Part 50 Subpart F continued
Institutions must:

- Maintain an up-to-date, written, policy on financial COI and make it available via a publicly accessible website.

- Inform each investigator of the COI policy, her/his responsibilities regarding disclosure of significant financial interests (SFI), and require each Investigator to complete COI training at least every 4 years.

- Require disclosures at least annually or within 30 days of discovering or acquiring a new SFI.
COI - PHS Funded Research

Overview of the NIH Final Rule

Institutions have new 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 website or written response to any requestor.
- Institutions have 5 business days to respond to requestors.

Overview of the NIH Final Rule

- The underlying principles and ethics are not new.
- Transparency is enhanced.
- The rules are more specific and complex.
- Thresholds are lower and the net is cast wider.
- Your processes (work process flows, Standard Operating Procedures) may need to be revised.
- You may need to utilize Information Systems solutions.
Overview of the NIH Final Rule

Who is an Investigator?

- Project Director and/or Principal Investigator
- Any other person, regardless of title or position, who is responsible for the
  - design, conduct, or reporting of research funded by the PHS, or
  - proposed for such funding, including persons who are sub-grantees, contractors, collaborators, or consultants.

Overview of the NIH Final Rule

What is a SFI?
The new regulations define Significant Financial Interest (SFI) as:

- Any remuneration or equity interest that exceeds $5,000 (when aggregated over 12 months) that reasonably appears to be related to the Investigator’s institutional responsibilities.
- Regardless of whether its related to specific PHS funding.
- SFIs can be that of the investigator, her/his spouse or dependent children.
Overview of the NIH Final Rule

What is a Financial COI?

The new regulations define Financial Conflict of Interest (FCOI) as a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Implications of the “Sunshine” Database

Open Payments

Creating Public Transparency of Industry/Physician Financial Relationships

The Official Website for Open Payments (the Sunshine Act)

- Applicable manufacturers of covered drugs, devices, biologicals, and medical supplies to report payments or other transfers of value made by these entities to healthcare providers or teaching hospitals.
- Applicable manufacturers and applicable group purchasing organizations (GPOs) to report to CMS certain ownership or investment interests held by physicians or their immediate family members.
- Applicable GPOs to report to CMS payments or other transfers of value made to physician owners or investors if they held ownership or an investment interest at any point during the reporting year.

Important Information

Physician and Teaching Hospital Registration in the Open Payments System

Physicians and teaching hospital representatives can register in the Open Payments system. Visit the Physician page in Teaching Hospital page for more information.

View the instructional videos on Physician and Teaching Hospital Registration and Physician and Teaching Hospital Review and Dispute to learn how to register in the Open Payments system and nominate individuals to perform actions on your behalf, as well as how to dispute, affirm, initiate, and follow disputes in the system. You can also download instructional PEPs from the Downloads section, below.
Implications of the “Sunshine” Database

- The database is receiving significant publicity
- Local media will devour the data
- Some hospitals will be surprised by what is revealed
- Some patients will begin to ask questions
- Direct payments from industry to physicians may be reduced next year
- Hospitals will want to get a handle on this information going forward

Implications of the Open Payments Database

- CMS training slides say “physicians, principal investigators, and teaching hospitals” should log in via 2 step process
  1. Register with the CMS Enterprise Identity Management Portal
     a. National Provider Identification (NPI) number
     b. Medical License Number
  2. Request Access to Open Payments App

- What about PI’s who aren’t MD’s?
- No “institutional reviewer” function
COI - IRS and the Form 990

The Form 990 is essentially a “non-tax” return.

- The Government wants to ensure that non-profit organizations are acting in a manner that justifies their tax-exempt status
- Ensure that no Board member, key employee, significant donor, or top management official receives any undue benefit from their relationship with the non-profit.
- Ensure compensation is appropriately determined
- Ensure COI Policies and Procedures are in place


COI - Fiduciary Responsibility

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

- Purchasing
  - Pharmaceuticals and Therapeutics Committee – (How are you making sure that stents, knees, 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.)
  - Vendor Gifts – (2 South Florida Physicians paid fines of $65,000 and $57,000 for providing gifts of Miami Dolphin tickets and meals)
COI - Fiduciary Responsibility

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

- 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!”

COI - 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 tied to its CEO, board members”
  - “I can get a great home mortgage if I just bring part of the Hospital’s business to First National”
Three Lines of Defense

Managing COI Risk
(Rebecca)

Origin Story
  - Institute of Internal Auditors’ Position Paper of 2013 (IAA)
  - European Confederation of Institutes of Internal Auditing (ECIIA)
  - Federation of European Risk Management Associations (FERMA)
  - Weick and Sutcliff’s “Managing the Unexpected: Resilient Performance in an Age of Uncertainty” of 2011

Evolution
- Criticism and reinterpretations (circa 2008-present)
  - Protiviti’s Five Lines of Defense model of 2013
  - Norman Marks’ “The Three Lines of Defense Model Is the Wrong Model” of 2015
The IAA Model

The Three Lines of Defense Model

Governing Body / Board / Audit Committee

Senior Management

1st Line of Defense
- Management Controls

2nd Line of Defense
- Internal Control Measures
- Financial Control
- Security
- Risk Management
- Quality
- Inspection
- Compliance

3rd Line of Defense
- Internal Audit
- External Audit

Adapted from ECIIA/FERMA Guidance on the 8th EU Company Law Directive, article 41

The Protiviti Model

1 Tone of the Organization
- Board Risk Oversight
- Executive Management

2 Business Unit Management and Process Owners

3 Independent Risk Management and Compliance Functions

4 Internal Assurance Providers
The First Line of Defense

- Management Controls
- Internal Control Measures
  - Operational managers own and manage risk
  - Policy and procedure
  - Education and training
  - Regulations/Procedures/Practices

The Second Line of Defense

- Management level risk management and compliance functions
  - Auditing and monitoring
  - Security
  - Quality
  - Risk Management
  - Legal
  - Inspection
  - First level guidance and remediation
Deming’s Model of Continuous Improvement (PDCA)

<table>
<thead>
<tr>
<th>Plan</th>
<th>Do it</th>
<th>Act to</th>
</tr>
</thead>
<tbody>
<tr>
<td>what is needed</td>
<td></td>
<td>improve performance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>that it works</td>
</tr>
</tbody>
</table>

The Third Line of Defense

- Internal Audit functions without undue influence

- Control oversight
  - Internal auditors
  - External auditors
  - Regulators

<table>
<thead>
<tr>
<th>FIRST LINE OF DEFENSE</th>
<th>SECOND LINE OF DEFENSE</th>
<th>THIRD LINE OF DEFENSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk Owners/Managers</td>
<td>Risk Control and Compliance</td>
<td>Risk Assurance</td>
</tr>
<tr>
<td>operating management</td>
<td>limited independence</td>
<td>• internal audit</td>
</tr>
<tr>
<td></td>
<td>reports primarily to management</td>
<td>• greater independence</td>
</tr>
<tr>
<td></td>
<td></td>
<td>reports to governing body</td>
</tr>
</tbody>
</table>
Applying Three Lines of Defense to Conflicts of Interest Management

Applying Three Layers to Risk Management

<table>
<thead>
<tr>
<th>Risk Area</th>
<th>Unit Controls</th>
<th>Compliance Controls</th>
<th>Internal/External Audits</th>
</tr>
</thead>
<tbody>
<tr>
<td>As Identified During Risk Assessment</td>
<td>What do the units do to help mitigate this risk?</td>
<td>What do you monitor to help mitigate this risk?</td>
<td>What type of audits exist to help mitigate this risk?</td>
</tr>
<tr>
<td>Conflict of Interest</td>
<td>▸ Educate personnel about COI policies.</td>
<td>▸ Open Payments database</td>
<td>▸ 10% of outside travel payments against Accounts Payable travel reimbursements.</td>
</tr>
<tr>
<td></td>
<td>▸ Report non-compliance to COI Manager.</td>
<td>▸ Annual COI disclosure</td>
<td>▸ Level 2 review of COI disclosures</td>
</tr>
<tr>
<td></td>
<td>▸ Report unauthorized vendors representatives and displays</td>
<td>▸ Purchasing and Pharmacy vendor registrations.</td>
<td>▸ 10% of “nothing to disclose”</td>
</tr>
<tr>
<td></td>
<td>▸ Advise personnel to contact Compliance with questions</td>
<td>▸ Research conflict database cross-check</td>
<td>▸ For cause investigations.</td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Develop Work Plan

<table>
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<td>As Identified During Risk Assessment</td>
<td>What do the units do to help mitigate this risk?</td>
<td>What do you monitor to help mitigate this risk?</td>
<td>What type of audits exist to help mitigate this risk?</td>
</tr>
<tr>
<td>Gifts/Industry influence</td>
<td>- Report vendors who are onsite without permission</td>
<td>- Open Payments Database</td>
<td>- Conflict Management Plan audit</td>
</tr>
<tr>
<td></td>
<td>- Educate staff to not accept gifts</td>
<td>- Annual disclosure review</td>
<td>- Data trends analysis</td>
</tr>
<tr>
<td>Reconciliation of payments for contractual agreements</td>
<td>- Follow business procedures to receive outside moneys for contractual obligations</td>
<td>- Request and review monthly report for outside payments made to faculty</td>
<td>- Develop strategy for on-site evaluation at contractual locations</td>
</tr>
<tr>
<td></td>
<td>- ?</td>
<td>- Spot-check contractual terms</td>
<td></td>
</tr>
<tr>
<td>Research misconduct</td>
<td>- Office of Research Integrity monitors data, receives and investigates reports</td>
<td>- Advise ORI and dept of any areas of concern based on Open Payments data</td>
<td></td>
</tr>
<tr>
<td>Undisclosed family relationships</td>
<td>- Notify Compliance of family relationships</td>
<td>- Monitor on annual disclosure form</td>
<td>- Randomly audit family relationships and industry ties</td>
</tr>
</tbody>
</table>

## Assessing Risk

**Risk Assessment Matrix (sample)**

<table>
<thead>
<tr>
<th>Controls</th>
<th>Occurrence</th>
<th>Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unlikely to occur</td>
<td>Somewhat likely</td>
</tr>
<tr>
<td>Good Controls</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate Controls</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weak Controls</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Controls</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Develop Overall Risk Table

#### FY 2016 Conflict of Interest Risk Table (sample)

<table>
<thead>
<tr>
<th>Risk</th>
<th>Location</th>
<th>New/Existing</th>
<th>Source</th>
<th>Controls</th>
<th>Risk Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician payment arrangements centralization and oversight</td>
<td>Enterprise</td>
<td>New</td>
<td>OIG, CMS</td>
<td>Poor</td>
<td>High</td>
</tr>
<tr>
<td>Practice plan centralization and oversight.</td>
<td>VP</td>
<td>Existing</td>
<td>Leadership</td>
<td>Poor</td>
<td>High</td>
</tr>
<tr>
<td>Very little faculty communication about COI or Sunshine</td>
<td>Enterprise</td>
<td>New</td>
<td>CMS, Internal</td>
<td>Poor</td>
<td>High</td>
</tr>
<tr>
<td>Not much support for cooperation from all healthcare colleges</td>
<td>Enterprise</td>
<td>New</td>
<td>Leadership</td>
<td>Poor</td>
<td>High</td>
</tr>
<tr>
<td>Contract compliance engagement</td>
<td>VP</td>
<td>Existing</td>
<td>Internal</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>Consistent and clear corrective action possibilities for failure to comply</td>
<td>Enterprise</td>
<td>Existing</td>
<td>7-Elements</td>
<td>Poor</td>
<td>Medium</td>
</tr>
<tr>
<td>Manager for whole process, not just one part of one college</td>
<td>Enterprise</td>
<td>New</td>
<td>Internal</td>
<td>High</td>
<td>Medium</td>
</tr>
<tr>
<td>Written policy/practice and training on conducting COI investigations</td>
<td>Compliance</td>
<td>Existing</td>
<td>7-Elements</td>
<td>Poor</td>
<td>Low</td>
</tr>
</tbody>
</table>

### Managing Identified Risk

#### Utilizing Technological Resources
(Andrew)
COI Technology Enablement

Electronic COI management systems can be used to simplify the COI reporting process for managers and researchers.

- Electronic conflict reporting options
- Centralization of management processes
- Integration with publicly reported databases

Selecting a COI Management Tool

Right-sizing your electronic solution

- Spreadsheet
- Home-grown database
- Outside vendor

Integration with current systems and processes

- Can legacy data be imported into the new system?
- Does the software need to “talk” to other systems within your organization?
- How will it adapt to your process/systems? Or vice versa?
Selecting a COI Management Tool

Some factors to consider

- Questionnaire design
- Questionnaire completion, tracking, and review
- Data searching and reporting
- Templates
- Management plans
- System requirements
- Security functions/user authorization
- Vendor reputation
- COST!!!!!!!!!!!!

UK HealthCare Gap Analysis

Starting point

- 1000+ faculty and staff across multiple colleges and departments
- Mixed healthcare and basic research faculty
- Decentralized COI management process
- Limited audit process
UK HealthCare Gap Analysis

Target

- Single, standardized data collection for all groups
- Sharing of reported data across colleges
- Streamlined reporting process for faculty and researchers
- Centralized database for reported conflicts and management plans
- Integration of data from Open Payments database
- Audit process for reported conflicts

UK HealthCare Vendor Requirements

- Technical support throughout the implementation and operations of the proposed solution
- Templates for management plans
- Levels of implementation support services available — e.g., telephone, onsite, etc.
- Implementation time frame (<120 days)
UK HealthCare Vendor Requirements

- Telephone support - which hours on which days.
- Average response time to telephone call? What percentage of calls are closed within 1 hour, 8 hours and 5 days?
- Project management and guidance of training material development
- On-line help/support availability
- Regular product updates and enhancements

UK HealthCare RFP Considerations

- Committee assignment
  - Executive champion
  - Faculty/staff representation
  - HR representation
- IT support
  - Level of involvement
- Fiscal year
  - Timeframe
  - Funding
- CMS’s Sunshine database launch/reliability
UK HealthCare Implementation

- Implemented January 2015
- College of Medicine launch March 2015
- Data collection complete May 2015
- First COI Committee meeting June 2015
- Well-received
- Requests for onboarding from new constituents (College of Nursing, College of Pharmacy, Continuing Medical Education department)

- Initial Challenge: Segregation of PHS COI management (VPR) vs. UKHC COI Compliance processes. Seek greater data aggregation.

UK HealthCare Update!

- Designated a COI Manager for UKHC

- Integration of healthcare COI reporting and VPR COI reporting
  - Merged two COI disclosure forms and processes into one
  - Three user roles drive who receives which questions to answer
  - Three types: investigator, healthcare faculty, healthcare faculty who are also investigators
- Launched March 4, 2016

- All faculty in the colleges of medicine, dentistry, nursing, pharmacy, and public health.
- All investigators at UK!!

- Mandatory annual PHS training is done and documented from within the system.
Integration Lessons Learned

- Understand gaps and differences in policies across departments
  - Example: travel reporting requirements

- Standardize definitions
  - If working with multiple reporting groups, this may require revisions to written policies, but make sure the message is consistent
  - What do we mean by “faculty” or “researcher”

- There will always be complaints from someone, so expect them
  - Focus on the positive results
  - Emphasize benefits to users

Questions

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