Conflicts of Interest: Addressing the latest updates

April 19, 2010

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• Address emerging issues such as self disclosure and false claims act revisions
• Maintain physician monitoring through the development of process and controls
Understand new regulations and principles related to physician conflicts of interest

Conflicts of Interest headlines

**Wall Street Journal**
Chair of Cleveland Clinic Foundation Innovations Contract not Renewed
• Potential failure to disclose financial gains related to device company

**OIG Publication**
More Conflicts of Interest Problems for NIH
• Report dated November 2009
• National Institute of Health (NIH) isn’t paying close attention to management of potential Conflict of Interest for those receiving NIH funds

**Wall Street Journal**
Emory Psychiatrist Cited in Conflict of Interest
• Payments for promotional talks — previously unreported

**Milwaukee Journal-Sentinel**
Hunts Ghosts, Badgers, and Health care conflicts of Interest
• Ghost written medical articles downplayed risks of therapy

**New York Times**
Crackdown on Doctors who Take Kickbacks
Where do Conflicts of Interest begin?

- A Conflict of Interest (COI) is 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
  - Secondary interests:
    - Financial gain
    - Professional achievement
- Why have COI policies?
  - Maintain integrity
  - Maintain public confidence

COI guidance

- Various organizations have developed guidance on Conflicts of Interest including:
  - National Institute of Health (NIH)
  - Public Health Services (PHS)
  - AAME
  - Association of American Universities
- Recent guidance:
  - PhRMA
  - Advanced Medical Technology Association
COI examples — Where does it end?

• Referral and Arrangement Conflicts of Interest
  – Referral issues and arrangements governed by Stark
  – Consulting arrangements
  – Sample and gifts
  – Ghost writing
  – Purchasing discounts
• Research Conflicts of Interest
  – Institutional Conflicts of Interest
  – Research support
• Medical education Conflicts of Interest
• Board/director positions

COI types

• Individual Conflicts of Interest
  – Easier to identify
• Institutional Conflicts of Interest
  – Research conducted by institution could affect an investment holding by such institution or patent the institution licenses
  – Financial relationship by senior officers within the industry
Policy survey

Survey conducted by AAMC regarding Conflict of Interest (COI) policy inclusion language:

- 68% use the PHS standard for COI ($10,000), 27% use lower, and one used FDA threshold

Nonfederally related financial interests:

- 61% include equity and non-publicly traded companies regardless of percentage
- 64% include equity and non-publicly traded companies regardless of estimations as to value
- 38% include royalty income above a certain threshold
- 33% include royalty income regardless of amount
- 64% include non-royalty payments not directly related to reasonable costs for research
- 81% permit research with a significant financial interest to conduct human subject research when compelling circumstances exist

AAMC — U.S. Medical School Policies on Individual Financial Conflicts of Interest (Susan Ehringhaus, J.D. & David Korn, M.D. - 2004

Management of COI survey

Results of study which depict policies recommendations when a COI exists:

- Reduction of significant financial interest (SFI) — 83%
- Elimination of SFI — 83%
- Monitoring of research project — 87%
- Disclosure of SFI to human subjects in consent form — 51%
- Regular audits — 51%
- Involvement of patient rep in subject recruitment — 22%
- Involvement of patient rep during consenting and enrollment — 26%
- Use of internal/external data safety monitoring boards — 54%

AAMC — US Medical School Policies on Individual Financial Conflicts of Interest (Susan Ehringhaus, J.D. & David Korn, M.D. - 2004
PhRMA publishes revisions and updates related to COI

- **PhRMA Code on Interactions with Healthcare Professionals** — (Updated to enhance voluntary code, effective January 2009)

- **The PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results** — (Revised principles which build on 2004 revision effective, October 2009)
  - Greater transparency in reach — provide summaries of all interventional trials
  - Enhance disclosure standards in published research of all financial and personal relationships

AAMC Reports — Medical Education Conflicts of Interest

- AAMC “Task Force” report related to examining benefits and pitfalls associated with industry funding of medical education — recommendations below:

| Summary of AAMC Study (published 2008), A Selected Policy Language Compendium |
|-------------------------------|----------------------------------|
| Gifts                         | Prohibit acceptance of gifts     |
| Pharmaceutical Samples        | Central management               |
| Site Access by Pharma Reps    | Restrict non-patient care and nonpublic areas, education should be faculty supervised, structured group settings. |
| Site Access by Device Mfg Reps| Only if reps are credentialed, consent by patient, student interaction under faculty supervision. |
| Continuing Medical Education  | Central CME office, develop audit programs to assure compliance with Accreditation Council for Continuing Medical Education standards including content validation and audits. |
| Industry-Sponsored Programs   | Full transparency and disclosure by their personnel to the centers, payments only at FMV, no attendance of non-ACCME programs. |
| Industry-Sponsored Scholarships and Other Education | Received centrally by the administration of the AMC, no quid pro quo involved. |
| Food                          | Exception food permitted in ACCME accredited programs, otherwise not permitted. |
| Professional Travel           | None other than for legitimate reimbursement or contractual as described above. |
| Orthomolecular                | None other than for legitimate reimbursement or contractual as described above. |
| Purchasing                    | Policies to describe any conflicts of interest by individuals when making purchases. |
IOM Report — COI in Medical Research, Education and Practice

- Institute of Medicine warns that conflicts can undermine the integrity of medicine
- Committee recognized collaborations with industry can be beneficial. However...
  - Researchers should not conduct research involving human participants if they have a financial interest in the outcome of the research; for example, if they hold a patent on an intervention being tested in a clinical trial
  - The only exception should be if an individual’s participation is judged to be essential for the safe and appropriate conduct of the research
- Biggest concerns include:
  - Failing to evaluate and respond to risks posed when financial stake exits
  - Failing to publish negative results from industry funded trials timely
  - Failing to disclose financial relationships with industry to research institutions and sponsors

Source: Institute of Medicine Report — April 2009

IOM Report Cont. — Overview of Recommendations

- The general policy adopts COI policies and standardizes and develops reporting criteria for disclosure practices
- The medical education policy reforms relationships. Education requirements for COI and financing systems for continuing medical education
- The medical practice policy reforms industry relationships and interactions with physicians
- The clinical practice guidelines that restrict industry funding and create incentives for reducing COI in clinical practice settings
- The institutional COI policies create board-level responsibility, require the development of a research agenda, and provide incentives to create and implement COI policies
New AAHRPP standards — Research Conflicts of Interest

New AAHRPP standards (effective March 2010)
• Human research programs —
  – functioning institutional financial conflict of interest policy
  – special procedures for the close sharing of information with sponsors
  – assurances that any research not performed in U.S. meets equivalent protections provided to research subjects here
• Enforces strong institutional and individual research level
• New standard addresses I.6 requirements:
  – “The organization has and follows written policies and procedures to ensure that research is conducted so that financial conflicts of interest are identified, managed, and minimized or eliminated.”
  – “Disclosure or reporting policy defining with types of financial interests must be reported, so that the organization is able to identify those financial interests that are significant and meet the definition of financial conflict of interest.”

OIG Report — How grantees manage COI in research funded by the NIH

• Common types of conflicts
  – Equity ownership
  – Inventing technology
  – Consulting
  – Holding positions with outside companies
• Managing financial conflicts
  – Disclose financial relationships
  – Certification of primary commitment and abiding by institutional financial COI
  – Most rely on researcher’s discretion to determine significant financial relationships
• Challenges
  – Conflicts are not verified
  – Consistent and complete policies and procedures not in place
  – Conflicts not uniformly reported
  – Lack of documentation to support oversight of conflicts
  – No requirement to report to NIH any financial interests institutions have with outside companies
OIG Report Cont.: Recommendations for NIH

- Require institutions to collect information on all significant financial interests held by researchers and not those deemed by researchers to be reasonably affected by the research
- Collect information on specific amounts of equity and compensation from researchers
- Develop guidance to verify researcher’s financial interests
- Ensure institutions are providing adequate oversight of subgrantee compliance with COI regulations
- Ensure that institutions are maintaining proper documentation as outlined in the financial COI regulations
- Take appropriate action against researchers who do not follow appropriate regulations
- Increase oversight to ensure that financial COI are reported and managed
- Develop regulations that address institutional financial COI

Disclosure of Financial Relationships (DFRR)

- Designed to assess financial relationships and self-referrals
  - Direct ownership in hospital (stock for self or immediate family)
  - Indirect ownership in hospital (group payments)
  - Payments made to hospital by direct owners
  - Payments made to hospital by indirect owners
  - Compensation arrangements — (rentals, personal service, recruitment)
  - Other compensation arrangement
- The DFRR was enacted in the Deficit Reduction Act and is mandated.
- The initial 500 hospitals selected will be comprised of 290 hospitals who did not respond to CMS’ initial voluntary request
**Physician Payment Sunshine Act**

- Introduced in 2009 — Requires manufacturers and group purchasing organizations with annual revenues over $100 million to disclose to the Secretary of Health and Human Services quarterly, payments to physicians with a cumulative value of over $100
- If passed, the first report will be due on March 31, 2011, and is required to include anything of value related to marketing, education, a specific covered drug, device, biological, or medical supplies
- Reporting of physician ownership interests in private companies will also be required
- Reporting of physician research interests will be required, but may be delayed
- Reporting requirements are very comprehensive and inadvertent failure to report will result in penalties from $1,000–$10,000 for each payment not reported with a cap of $150,000/year

**Recent Settlements — Transparency Number 1**

Illegally marketing of drug products:
- **Eli Lilly** — $1.4 million fine
- **Pfizer** — $2.3 million fine

Must publicly post all payments made to doctors who serve in consulting or speaking roles

Other companies have agreed as well (Merck, Cephalon, GlaxoSmithKline, and Medtronic)
Address emerging issues, such as self-disclosure and false claims act revisions

False Claims Act Revisions

Fraud Enforcement and Recovery Act of 2009
- Violation to improperly keep money owed to the government
- Applies to government subcontractors
- Strengthens protection against retaliation towards whistleblowers
False Claims Act Revisions —
“OIG Approved” State False Claims Acts

- California
- Georgia
- Hawaii
- Illinois
- Indiana
- Massachusetts
- Michigan
- Nevada
- New York
- Rhode Island
- Tennessee
- Texas
- Virginia
- Wisconsin

COI and False Claims (cont.)

Other State-level Activities
- Disclosure requirements - Drug Manufacturers remuneration to physicians
  - Minnesota
  - Vermont
  - Maine
  - West Virginia
  - District of Columbia
Self-disclosure protocol

OIG Open Letter — March 24, 2009
• Revises OIG Self-Disclosure Protocol
• No more self-disclosures for Stark-only violations
• Kickback violations $50,000 or more only

COI and False Claims Act Nexus

Conflicts of interest may be a violation of an individual’s fiduciary duty, a violation of policy, may create an appearance of impropriety

... OR ...

Could be a violation of the Anti-Kickback Statute or Stark regulations, which are often pursued as False Claims Act cases
COI and False Claims Act Nexus (cont.)

Cases and Scenarios

• December 2008 — Condell Health Network agreed without litigation to pay $36 million as a result of filing false claims for reimbursement related to leases of medical office space at rates below fair market value; improper loans to physicians; and hospital reimbursement to doctors who performed patient services without required written agreements

• August 25, 2009 — Covenant Health agreed to pay the United States $4.5 million to resolve allegations that it violated the False Claims Act by paying compensation to five physician employees that exceeded the fair market value of the services provided by those physicians

• October 15, 2009 — McAllen Hospitals signs a Corporate Integrity Agreement and agrees to pay $27.5 million to settle claims that it violated the False Claims Act, the Anti-Kickback Statute, and the Stark Statute between 1999 and 2006, by paying illegal compensation to doctors in order to induce them to refer patients to hospitals within the group

OIG Perspective: Financial arrangements may be problematic if they:

• Skew clinical decision-making

• Increase costs to government health care programs or beneficiaries

• Increase risk of overutilization

• Create quality of care risk
Maintain physician monitoring through the development of process and controls

COI Risk Mitigation Strategies

Recent risk mitigation strategies:
- Banning all Gifts
- Public Disclosure of Conflicts/Financial Relationships
- No drug samples or centralized location
- No stock or unlimited fees for sitting on biotech and pharma boards
COI Policy Elements

Policy criteria:
• Are the policy and objectives defined?
• Is the policy directed at the most important conflicts?
• Is the policy comprehensive and accessible?
  – Does it address institutional (e.g., patent, license as a company) and individual conflicts?
• Does the policy indicate accountability and responsibility for monitoring and enforcing?
  – Do you have a committee to oversee COI?
• Does the policy apply to equally?

Key Processes and Controls

Conflicts of interest
• Disclosure process for Boards, Leadership, Management, Medical Staff, and anyone with Hiring or Purchasing Authority or Influence
• Objective review of disclosures
• Process for disclosure upon promotion or change in circumstance
• Contract Management System/Process
• Contract Approval Process
• Fair Market Value Assessments
• Documented Business Need
• Checklist to assess Independent Contractor versus Employee
• COI Disclosure Physician Arrangements
Key Processes and Controls (cont.)

• Background and Sanctions checks
• Duties Clearly Defined
• Documentation of Services Provided
• Process in Place to ensure Payments Consistent with Contract Terms
• Routine reviews of Contracts to Ensure Compliance with Policies and Procedures
• Gift Tracking

Conclusion

• Conflicts of Interest can create many risks, both financial and from a compliance perspective.

• Policies and processes should be in place to capture and manage the identification and disclosure of potential conflicts.

• The newly redesigned IRS Form 990 requests a description of how tax-exempt healthcare organizations monitor and enforce their conflict of interest policies.

• For these tax-exempt organizations, identifying and developing effective policies and processes will be more even important going forward.

• For all providers, arrangements with physicians need to be carefully managed and monitored utilizing audit and review methodologies.
Questions? Comments?

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