Physician Conflicts of Interest

Physician Practice Compliance Conference
October 17-19, 2010
Health Care Compliance Association
Paul Belton, Sharp HealthCare

Physician-Conflicts of Interest

Objectives

✔ Background
✔ Recent Enforcement Activity
  • Industry Activity/Efforts
  • State and Federal Legislation
✔ Balancing of Relationships
  • Risk or Benefit to the Organization
✔ What should Organizations do before the Government Steps In
  • Challenges and Recommendations
Conflicts of Interest

Definition:

A conflict of interest occurs when an individual or organization has a financial or other interest that has the potential to interfere with their professional judgment, objectivity, or ethical responsibilities.

- Conflicts of interest are difficult, if not impossible, to avoid in medicine.

Conflicts of Interest

IOM

Definition:

A circumstance that creates a risk that professional judgment or actions toward a primary interest will be unduly influenced by a secondary interest.

- Primary interests
  - Welfare of patients
  - Integrity of research
  - Quality of medical education
- Secondary interests
  - Financial gain
  - Professional advancement (name and reputation)
Conflict of Interest
Sharp HealthCare

A conflict occurs when an individual’s personal interest interferes in any way with his/her professional obligation to the Sharp Medical Staff, affiliates, and patients such that an independent observer might reasonably question whether the individual’s professional actions or decisions are determined by considerations of personal gain, financial or otherwise.

Facts & Issues

Fact:
Dr. Nemeroff, earned more than $2.8 million in consulting arrangements with drug makers from 2000 to 2007.
Facts & Issues

**Issue:**
Failed to report at least $1.2 million of that income to Emory University and violated federal research rules.
(Becomes poster boy for conflict of interest)

Facts & Issues

**Fact:**
Dr. Nemeroff, signed a letter dated July 15, 2004, promising Emory administrators that he would earn less than $10,000 a year from GlaxoSmithKline to comply with federal rules.
Issue:
On that very same day, Dr. Nemerof was at the Four Season’s Resort in Jackson Hole, earning $3,000 of what would become $170,000 in income from that company - 17 times the figure he had agreed on.

Fact:
Dr. Melissa DelBello of University of Cincinnati told university officials that from 2005 to 2007 she earned about $100,000 from eight drug makers.
Facts & Issues

**Issue:**
AstraZeneca alone paid Dr. DelBello $238,000 during that time frame.

Facts & Issues

**Fact:**
- Dr. Joseph Biederman, a renowned child psychiatrist at Harvard Medical School, and a colleague, Dr. Timothy E. Wilens, had reported to university officials earning several hundred thousand dollars each in consulting fees from drug makers from 2000-2007.
Facts & Issues

**Issue:**
When in fact they had earned at least $1.6 million each.

“After questioning about 20 doctors and research institutions, it looks like problems with transparency are everywhere.”

“The current system for tracking for tracking financial relationships isn’t working.”

- *Senator Charles Grassley*
Physician-Conflicts of Interest

The publicity surrounding these cases and others that followed have created a sense of urgency on the part of organized medicine, academia, and government to define, identify, and manage conflicts that interfere with the delivery of cost effective, evidence-based medicine.

Physician-Conflicts of Interest

An extremely volatile area .....that is drawing intense interest...

- Congress
- Media (WSJ, NYT, LAT)
- Accrediting Bodies
- Patient Advocacy Groups
- Medical Specialty/Professional Societies
- Government Agencies (OIG, CDC, FDA, NIH)
- Academic Medical Schools (AAMC, AAU)
- Academic Associations
Medtronic Discloses Pay to Doctors

BY THOMAS M. BOSTOCK

Medtronic Inc., which makes medical devices, disclosed that it sent payments of more than $1 million to surgeons and other medical professionals in the first quarter, the first time the Minneapolis company has provided such details.

The move by the voluntary disclosure shows how Medtronic is stepping ahead of competitors like Abbott Laboratories, Johnson & Johnson, and the Boston Scientific Corp. in disclosing payments to doctors.

Medtronic’s chief executive, Mark Mahlke, said in an interview that the company has been more transparent than its peers, and that the disclosure was prompted by a request for comment by The Wall Street Journal.

The disclosure shows how doctors receive payments from the company for their work, and how those payments may influence the decisions of patients and doctors.

The company’s move follows a new federal law that requires doctors and hospitals to disclose payments for their work.


Tipping their hand

AAMC wants physicians to disclose conflicts of interest to patients

"The AAMC has asked us to come up with a plan for how we can disclose conflicts of interest to our patients," said Dr. Markideas, the head of the AAMC’s Department of Medical Education.

The AAMC is working with the National Institutes of Health and other organizations to develop a plan for how doctors can disclose their financial interests to patients.

The AAMC’s plan would require doctors to disclose any financial relationships with companies that make medical devices and to report any financial interests in medical journals and other publications.

The AAMC’s plan also includes a requirement for doctors to disclose any financial interests in companies that make medical devices, and to report any financial interests in medical journals and other publications.

The AAMC’s plan is one of several initiatives that aim to improve the transparency of medical research and to reduce conflicts of interest.

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Physician-Conflicts of Interest

An extremely challenging issue...
- Managing
- Reducing
- Eliminating
- Nature and amount of information that should be reported and disclosed
- Who (individual, government or institution) should bear the responsibility for monitoring and managing potential COIs
- Extent to which government regulation oversight and verification responsibility

Physician-Conflicts of Interest

A new frontier in health care risk...
- Significant shift in perceptions, policies, and practices over the last several years
- Wholesale changes (forthcoming) in attitudes and behavior of physicians and the industry at large.
- Underlying “theme” of transparency to physicians, as well as the efforts being undertaken by institutions to require disclosure of potential conflicts
- Manage any that are uncovered
- Profound effect on the ability of a typical organization to manage risk
Physician-Conflicts of Interest

- **Conflicts can arise in a variety of contexts:**
  - Profit incentives to commercialize products that had successful clinical trials;
  - Questionable clinical trial results;
  - Corrupt data;
  - Purchase of drugs and devices based on commercial influence; and
  - Industry support for school, residency and continuing medical education (CME) programs.

Physician-Conflicts of Interest

- **Conflicts can be subtle and often hard to detect:**
  - What may appear to be an appropriate arrangement between a researcher and a drug manufacturer may actually raise potential COI issues that could taint the results of a clinical trial.
Physician-Conflicts of Interest

- Crux of the debate regarding systems for detecting and reporting potential COIs has centered on:
  - Physicians
  - Researchers
  - Institutions
  - Degree of responsibility for reporting and managing COIs amend the extent government regulation should place oversight and verification on Federal agencies

- If COIs are undetected and/or not properly dealt with
  - Damage reputations
  - Raise public concerns about integrity
  - Patients may suffer potential harms:
    - Subject to unnecessary risk
    - Deprived of beneficial therapies
    - Unsafe or ineffective drugs or devices may enter U.S. market
    - Patients may receive inferior therapies
    - Waste limited Medicare/Medicaid dollars
Historical Financial Conflict of Interest (FCOI) Regulations

- 42 CFR Part 50 Subpart F (PHS-funded grants and cooperative agreements).
- 45 CFR Part 94 (PHS-funded contracts).
- These regulations are aimed at ensuring that the design, conduct, or reporting of research funded under NIH grants, cooperative agreements and contracts will not be biased by any conflicting financial interest of the investigators responsible for the research.

(The regulations went into effect on October 1, 1995)

Historical Financial Conflict of Interest - Definitions

- SFI: Anything of monetary value, including but not limited to:
  - De minimis threshold of $10,000 for disclosure generally applies to payments or equity interests
    - Salary or other payments for services (e.g., consulting fees or honoraria)
    - Equity interests (e.g., stocks, stock options or other ownership interests)
    - Intellectual property rights (e.g., patients, copyrights and royalties from such rights)
- FCOI: A significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of NIH funded research.
Industry Efforts

Professional Associations

- Association of American Medical Colleges (AAMC) has taken a lead role in addressing conflicts.
- Working with the Association of American Universities
  - Issued recommendations in 2001 and 2002 addressing financial COIs
  - Formed an Advisory Committee in 2006
  - Published recommendations describing and urging the adoption of consistent COI policies in 2008
    - Prohibit gifts of any size
    - Ban food provided by industry
    - Restrict industry access to physicians
    - Distribute free product samples through a central repository

Industry Efforts

Dozens of Medical Schools have taken these recommendations, and transformed the culture of their organizations.
- Boston University
- University of Massachusetts
- Yale
- University of Pennsylvania
- Universities of Michigan, Wisconsin, Chicago and the entire University of California system
- Stanford has limited CME funding by drug makers
- Cleveland Clinic is publicly reporting business relationships of any of its 1800 staff MD’s and scientists have with drug and device makers
Potential Issues: Institution

- **Policy Issues**
  - Institutional policy does not comply with the regulation
  - Officials do not follow the policy consistently
- **FCOI Identification**
  - SFIs are not correctly identified as conflicts
- **FCOI Management**
  - Planned strategy is not sufficient to manage, reduced or eliminate conflict
  - Implementation of management plan is not enforced
- **Reporting to the NIH**
  - FCOI is identified and managed, reduced or eliminated but not reported to the NIH or not reported in a timely manner

Environmental Factors

- Since the existing rules were promulgated in 1995:
  - Biomedical and behavioral research has grown in complexity
  - Interactions among Government, research institutions, and the private sector have increased
  - Public scrutiny has grown
- All these factors have raised the question whether a more rigorous approach is required to strengthen
  - Investigator disclosure,
  - Management of financial conflicts, and
  - Federal oversight
    - As a result, and to ensure the highest standards of integrity, an Advanced Notice of Proposed Rulemaking (ANPRM) was issued in May 2009 soliciting comments on potential changes to the existing rules.
Federal Engagement in COI

- Bayh Dole requires translation from bench to bedside.
- MedPac addresses COI concerns based on effect on Medicare costs.
- FDA has extensive requirements for COI.
- NIH publishes COI regulations for comment.
- Senator Grassley’s “Sunshine Act” now included in health reform.
- Six states require disclosure of payments to providers.

States requiring disclosure of payments to physicians

- Vermont, Maine, West Virginia, and DC all require disclosure but not in a public database.
- Minnesota and Massachusetts have public data bases but they are not searchable.
- Practical value is limited.
**States Requiring Disclosure**

- Many state and local governments have enacted rules to increase transparency and minimize undue influence in health care, for example:
  - **Massachusetts:** Pharmaceutical and Medical Device Manufacturer Conduct statute (Mass Gen. L. c. 111N).
    - Effective July 1, 2009, the Massachusetts Code prohibits payment for outside meals, entertainment or recreational items of value (i.e., theater tickets, sporting events, concerts, etc.) or non-educational gifts, including complimentary items such as pens and coffee mugs.
    - Effective July 1, 2010, The Massachusetts Code will require companies to disclose of all payments to providers of at least $50
  - **Vermont:** An Act Relating to the Marketing of Prescribed Products Act no. 59.
    - Effective July 1, 2009, the law in Vermont prohibits companies from paying for any food, entertainment, travel subscription, advance, service, or anything else of value provided to a health care provider.
    - Annual required disclosure of all payments by companies to providers with prescribing authority.

**MedPac Report to Congress: Medicare Payment Policy, 2009**

- Concern is for both overt and subtle commercial effect.
- At least some interactions associated with rapid prescribing of newer, more expensive drugs and request for addition to hospital formularies.
- Influence over medical education may skew information received by students and practitioners.
MedPac Report to Congress, 2009
Public Reporting of Physician Financial Relationships

One purpose of establishing a national reporting system [for pharma, device and biological companies] to post payments to providers is “encouraging physicians to reflect on the propriety of their relationships with industry...”

Reality Check:
Report Card

- An interesting player in the COI discussion has been the American Medical Students Association (AMSA).
- Ranked all United States Medical Schools on the basis of their conflicts of interests policies.
- Of approximately 130 schools, only nine earned an “A” (7%) and 36 a “B” (28%).
- Gives us an indication of the progress that needs to be made.
2007 and Senator Grassley makes news

- Senator Grassley focuses on conflicts in academic medicine—waste of public dollars for funding research.
- Stanford, Emory, Harvard and many more AMCs received the first of the “Grassley letter” series, and the on-going discussions with the Senator and with the press continue.
- Ghostwriting, medical journals, IRBs, the NIH—the net is broad and the publicity continues.
Physician Payment Sunshine Act
2009-Grassley-Kohl

- Over two years, Senator Kohl conducted four oversight hearings exploring relationships (MD vs. industry).
- Focusing on CME, drug reviews, medical device payments (consulting), relationships.
- Introduces Physician Payments Sunshine Act.
  - Manufacturers of drugs, devices, and biologics required to disclose publicly a wide range of payments and gifts to physicians.

Industry Efforts

- In January 2009, the Pharmaceutical Research and Manufacturers of America (PhRMA), which represents leading pharmaceutical and biotech companies, released the newest version of its voluntary "Code on Interactions with Healthcare Professionals."
  - The code went further than ever before...prohibits the giving of gifts, entertainment, even pens and other small promotional items, to physicians.
  - Also in 2009, the industry group AdvaMed, which represents medical device manufacturers, implemented a "Code of Ethics" with similar prohibitions.
Industry Efforts

- In April 2009, the Institute of Medicine (IOM), of the National Academies of Science published a comprehensive analysis titled “Conflict of Interest in Medical Research, Education and Practice.”
  - The 392 page report provides sixteen recommendations, some aimed at providers, some at industry and some at government.

Relationships-Balancing Risk

- Maintaining objectivity in research and prevent the introduction of bias in federally supported research.
- Integrity of scientific research compromised?
- Even the appearance of a conflict can undermine public trust.
- Can’t afford to take chances.
Relationships-Balancing Risk

- Integrity
  - Institution
  - Investigator
  - Data
  - NIH
- Transparency
- Universities and professional organizations have been tightening their policies.

Leaders of the NIH are finally considering seriously an idea they have rejected for years: public disclosure of grantees’ financial arrangements that may create conflicts of interest.
Relationships-Risk or Benefit

- 52% of researchers had relationships with industry; 41% said that relationship contributed to their most important research.
- Average investigator receives $33,417 annually from industry. (JAMA, Sept. 2009)
- One analysis found researchers were five times more likely to find favorable results in research when they had a financial tie to the drug company sponsoring the research. (Clinical Trial in Psychiatry, Oct. 2005)

Relationships-Risk or Benefit

- Physicians, like the general public, have an optimistic bias; YOU might be swayed, but not me.
- Gifts and interactions with Pharma, reported in numerous publications, show significant differences in prescribing patterns for drugs, favorable comments on company product.
Recent Enforcement Activity

- May, 20, 2010 The National Institutes of Health proposed new guidelines to prevent financial conflicts,
  - Long sought by watchdogs of scientific research.
  - Affects more than 40,000 researchers.
  - Comes amid rising concern about influence of pharmaceutical industry and other private-sector interests on scientific research.

Recent Enforcement Activity
NIH New Guidelines

- Will reduce from $10,000 to $5,000 minimum payment to report.
- Mandate that universities, colleges, research institutes, etc., that employ researchers who receive NIH funding monitor compliance with the new reporting requirement.
- Funding information has to be posted on a publicly accessible Web site.
- Violators could lose their funding.
Major Proposed Changes to the Regulations

- **Significant Financial Interest (SFI)**
  - Minimum threshold of $5,000 generally applies to payments and/or equity interests.
  - Includes any equity interest in non-publicly traded entities.
  - Exclusions include income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies or institutions or higher education.

- **Investigator Disclosure**
  - All SFIs related to investigator's institutional responsibilities.
  - Institutions responsible for determining whether SFIs relate to PHS-funded research and are FCOI.

- **Institutional Management**
  - Institutions must have a management plan, which may include reducing or eliminating the FCOI.

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Major Proposed Changes to the Regulations

- **Reporting to PHS Awarding Component (NIH)**
  - Current requirements, along with
  - Value of the financial interest.
  - Nature of FCOI, e.g., equity, consulting fees, travel reimbursements, honoraria, and description of how FCOI related to PHS-funded research.
  - Key elements of the institution’s management plan.

- **Public Notice**
  - Before spending funds for PHS-supported research, an institution shall post on a publicly accessible website information on certain SFIs that the institution has determined are related to the PHS-funded research and are FCOI.

- **Scope**
  - Includes SBIR/STTR Phase I applications.

- **Investigator Training**
  - FCOI training required for investigators before engaging in PHS-funded research, and every two years thereafter.
Senator Grassley’s Comments

- “Disclosure of financial relationships and the resulting accountability have been sorely lacking in Federally sponsored research.”
- “Letting the sunshine in and making information public is basic to building people’s confidence in medicine. And with the taxpayer funding that’s involved, people have a right to know.”
- “Public trust and public dollars are at stake.”

Challenges of COI in Community Hospital Setting

- Need to address all the same concerns as AMCs.
  - Manage COI to ensure integrity of research, trust of the community and safety and well being of subjects.
  - Same pitfalls in failing to manage COI – damage reputation, government enforcement, injury or death to subject.
- Usually comes up through financial assessment of whether research is covering costs.
Challenges of COI-Community Hospital Setting

Challenges
- Unknown to hospital
- Push-back from CI on hospital knowing financial terms of CI’s arrangement
- Stark, AKS, not-for-profit risks created when CIs do not pay hospital for services to CI’s research subjects that are covered by per capita or other payments by Sponsor to CI

Recommendations
- MS Bylaws: include requirement of disclosure of research to IRB
- Withhold approval absent disclosed information (recognize adds a challenge of CI taking study elsewhere)
- Require services agreement whereby CI pays for research related services. Consider research CDM, above costs, to avoid further compliance risks

Challenges of COI-Community Hospital Setting

Challenges
- IRB hesitant to review/consider financial information
- IRB Members hesitant to deny approval for colleagues
- Effectively managing COI once they are identified

Recommendations
- Remind IRB this creates HSP risks, therefore COI of payment should be considered
- IRB training (recognizing it is difficult enough to staff IRBs)
- Set a threshold of financial interest that must be identified
- Create system to review disclosed interests, COIC or subcommittee (likely to include Finance physician ethics/compliance
- Require disclosure of interest to patients/human subjects
- Preclude physician from consenting process
Challenges of COI-Community Hospital Setting

Challenges
- Maintaining perspective on Sponsor dollars in the aggregate
- Designated responsibility to approve institutional participation in research (either direct or with CI contract)
- Identifying all persons within Hospital who have a financial relationship with sponsors of research when those relationships may be outside of research

Recommendations
- Residual Fund Balance policy
- Identify Finance person to ensure costs covered and keep eye on aggregate funds
- Financial disclosure forms for Board, Management, those with purchasing power or influence, e.g., physicians on P&T Committee, IRB, employees in SPD.

Challenges of COI-Community Hospital Setting
New Disclosure Requirements

The Patient Protection and Affordable Care Act (PPACA) of 2010 (Healthcare reform act)
- Section 6002 of the Healthcare Reform Bill "Transparency Reports and Reporting Physician Ownership or Investment Interests" (originally The Physician’s Payment Sunshine Act proposed by Senators Grassley and Baucus in 2009.
- Beginning in 2012, any payments or transfer of value of $10 or more (to single provider totaling $100 or more within a year) must be reported to the Department of Health and Human Services (HHS) March 31, 2013 for posting on a public, searchable website the following September.
- Companies must report.

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<tr>
<th>Consulting Fees</th>
<th>Research</th>
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<tr>
<td>Education</td>
<td>Charitable Contribution</td>
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<td>Gifts</td>
<td>Royalties/License</td>
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<td>Entertainment</td>
<td>Ownership/Investment Interest</td>
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<td>Food</td>
<td>Direct compensation for serving as faculty or as a speaker for medical education program</td>
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<tr>
<td>Travel</td>
<td>Any other payment or transfer of value as defined by the Secretary</td>
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Other COI Requirements

- Not-for-profit organizations are required to have COI policies.
  - Organizations which are 501c 3 tax exempt must state that they have written conflict of interest policies per Form 990 find that Part VI, Section B, Line 12.
    - The IRS encourages charitable organizations to require its directors, trustees, officers and others covered by the policy to disclose, in writing, known financial interests that the individual, or a member of the individual's family, has in any business entity that transacts business with the charity in order to assure sound management and governance.

What Organizations Should Do

- Audit your current conflict of interest policies.
  - Establish greater collaboration with Research Dept.
  - Review/audit COI questions on research applications.
  - (Sponsors often don’t explain why they were unable to obtain financial information, from all clinical investigators.
  - Require researchers to provide specific amounts of equity or compensation on their financial disclosure forms.
What Organizations Should Do

- Consider adopting a stronger policy.
  - Strengthen by engaging physicians and researchers
- Establish COI policies that require disclosure and management of both individual and institutional financial ties to the industry.
- Create conflict of interest committees to evaluate these ties. (If necessary, a board-level committee should deal with conflicts at the institutional level.)
- Ensure a process to identify when an institutional official has a financial relationship.

What Organizations Should Do

- Standardize the content, format and procedures for disclosing financial relationships physicians have with industry.
- Consider restrictions regarding gifts, including meals from companies, presentations or articles whose content is controlled by industry; meetings with sales representatives; and use of drug samples.
- Council on Government Relations (COGR) has created a toolkit, "Approaches to Developing an Institutional Conflict of Interest Policy," which is available on its website (www.cogr.edu/files/publications_Conflicts.cfm.)
What Organizations Should Do

- Establish a Culture
  - Once an institution defines institutional conflict of interest, it must ensure that it protects the impartiality and integrity of the research through an active culture of enforcement and management of the policy.
  - Recognize that the institutional policy is only as strong as the various committees or senior officers responsible for developing and monitoring management plans to handle conflicts.

- Consider segregation of individuals involved in research policy from all decisions regarding institutional investments
- Consider that institutions have a rebuttable presumption against conducting research if there is a conflict of interest
- Recognize that institutions consistently must apply its COI policy throughout the institution. (this is critical as the consistent application of policies guards against bias)
Summary

- Recognize that institutional conflicts of interest exist.
- Establish an environment of vigilance against the appearance of institutional COIs.
- Identify such conflicts in a timely manner.
- Manage such conflicts to ensure the impartiality of the research.
- Utilize guidance from AAMC, AAU, and COGR to restructure and create COI policies.

What can we expect?

- Congressional scrutiny, both directly and indirectly by reviews of individual physicians will continue-and increase with headlines.
- Physician payment disclosure may provide a usable database.
- Management and mitigation of COI will be more closely reviewed by NIH and other groups.
  - Expectations of verification of information
  - Audits of documentation for oversight of conflicts
  - More definitive management plans with audits
- Clinical COI will increasingly require disclosure and better standards for meaningful disclosure are needed.
Conclusion

- In difficult economic times, hospitals, medical schools, and physicians rely on the good will and trust of the public more than ever.
- Organizations that ignore the potential damage that conflicts of interest can do to their reputations do so at their own risk.
- We need to study the issues, and take measures to protect patient, the industry and our institutions.