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Conflicts of Interest Issues in Physician Practice Settings

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CONFLICTS OF INTEREST

- “Conflicts of interest occur when physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician’s roles are or will be compromised.”
 - JAMA, January 25, 2006, Vol 295, No. 4
 - Financial Gain
 - Academic Gain
 - Other Personal Gain



Conflict . . . Schmonflict
So what



Conflicts of Interest for Physicians

- I. Headlines – Who's Concerned about Physician Conflicts of Interest
- II. Conflict of Interest Laws and Authorities
- III. Tips to success and how to start



Who Cares About Conflicts of Interest

- 2007 Highlights
 - Physician Payments Sunshine Act of 2007
 - Introduced by Sen. Grassley, Sept 2007
 - Calls for Quarterly reporting of all payments to physicians by Manufacturers of drug, devices & medical supplies
 - State Laws
 - Maine
 - Minnesota
 - Vermont
 - District of Columbia



Who cares about Physician Conflicts

- National Media Groups
 - *Wall Street Journal*, Your Doctor's Business is Your Business, Nov. 20, 2007
 - *New England Journal of Medicine*, Doctors and Drug Companies – Scrutinizing Influential Relationships, Nov. 1, 2007
 - Also see, *NEJM*, Financial Conflicts of Interest in Physicians' Relationships with the Pharmaceutical Industry — Self-Regulation in the Shadow of Federal Prosecution, Oct. 28, 2004
 - *New York Times*, Psychiatrists, Children and Drug Industry's Role, May 10, 2007
 - *New York Times*, Is Your Doctor Tied to Drug Makers, July 2, 2007
 - USA Today
 - Denver Post
 - Houston Chronicle
 - Pioneer Press
 - St. Petersburg Times
 - Des Moines Register
 - Countless Others



Conflict of Interest - Outcomes

- **NIH Scientist Pleads Guilty in Accepting \$285,000 from Pfizer**

Washington Post, Saturday, December 9, 2006;

- A senior government scientist who was a focus of a congressional probe into conflicts of interest in medical research admitted in federal court yesterday that he improperly failed to disclose payments of \$285,000 he received as a consultant for the pharmaceutical manufacturer Pfizer Inc.
- Sunderland, 55, admitted to entering consulting agreements with the drugmaker beginning in 1998 without receiving the required approval in advance or disclosing his income after the fact. Sunderland was paid as a consultant on two projects in which his department was collaborating with Pfizer on research to identify chemical warning signs of Alzheimer's disease.



Conflict of Interest - Outcomes

- **“Ties to Industry Cloud a Clinic's Mission”**

- Dr. Eric J. Topol, a cardiologist, has been perhaps the most public face of the prestigious Cleveland Clinic Foundation, a prominent medical center regarded as one of the nation's best. . . In the last month, he has been demoted and the clinic's image has been tarnished in what has become an unusually public dispute pitting him against the clinic's chief executive, Dr. Delos Cosgrove. . . But his demotion has drawn attention to the mounting tensions between the clinic's research mission and its deep ties to the businesses that finance that research.

- New York Times, Dec. 17, 2005



Conflict of Interest - Outcomes

- **Tap Pharmaceuticals & Medical Conflicts of Interest**
 - The probe began when the medical director for pharmacy programs at Tufts Health Plan in Massachusetts alerted the U.S. Attorney in Boston that he had been offered a \$65,000 "educational grant," to be used for any purpose, to switch the plan from Zoladex to Lupron, as well as the opportunity to be reimbursed by the government at a price higher than that paid to TAP. Ultimately, TAP also was charged with giving physicians trips to expensive golf and ski resorts, free consulting services, medical equipment and forgiveness of debt.
- \$875 million



Conflict of Interest - Outcomes

- Malpractice Trial
- <plaintiff atty> "Doctor – when you decided to use [insert drug or machine here] to treat my client, did you inform them that you were paid \$X,000 last year by that company to participate in seminars about their products?"



Conflict of Interest Issues

- What types of Conflicts of Interest arise in non-institutional health care settings such as physician practices or other
- What formal and informal guidance is available for physicians and other health care providers in the area of conflicts of interest
- Conflict of Interest? So what . . . How to get buy in from stakeholders



Types of Conflicts

- **Ordinary Financial Conflicts** – placing financial self interest in the place of medical or clinical decision making
- **Self-dealing**: The individual makes decisions that financially or materially affect the individual or family member at the expense of the organization.
- **Accepting benefits**: In the individual's role, accepts substantial gifts, bribes, services, or other significant benefits that may be perceived to influence the purchaser's or provider's decision.
- **Influence peddling**: The individual accepts benefits in exchange for exerting influence or giving preferential treatment to the giver of the benefit.
- **Using confidential information**: The individual uses confidential information acquired because of organizational work for private gain.
- **Post-relationship Favors**: Confidential information that has been gained in the individual's role is used for private advantage after leaving the organization.
- **Conflicts of Commitment** – shared or mutually exclusive organizational commitments



Resources on Physician Conflicts of Interest Policies

- **AMA (AMA code of ethics)**
 - <http://www.ama-assn.org/ama/pub/category/2498.html>
 - <http://www.ama-assn.org/ama/pub/category/5689.html>
- **NIH**
 - <http://grants1.nih.gov/grants/policy/coi/index.htm> (NIH guide for conflicts of interest in NIH supported institutions)
- **PhRMA**
 - http://www.phrma.org/code_on_interactions_with_healthcare_professionals/
- **ACP**
 - http://www.acponline.org/ethics/ethics_man.htm?hp (American College of Physicians Ethics Manual)
- **AAMC, Task Force on Financial Conflicts of Interest in Clinical Research**
 - <http://www.aamc.org/research/coi/coiresults2003.pdf>
 - June 2007 AAMC Symposium



Medical Organization Scrutiny

- In 2002, three leading professional organizations — the American Medical Association,¹ the American College of Physicians,² and the Accreditation Council for Continuing Medical Education, ³ — issued or revamped guidelines regarding physicians' interactions with drug companies.
 - **New England Journal of Medicine, Volume 351:1891-1900, October 28, 2004, Number 18, Financial Conflicts of Interest in Physicians' Relationships with the Pharmaceutical Industry — Self-Regulation in the Shadow of Federal Prosecution, David M. Studdert, LL.B., Sc.D., M.P.H., Michelle M. Mello, J.D., Ph.D., M.Phil., and Troyen A. Brennan, M.D., J.D., M.P.H.**
 - **Emergence of Conflicts of Interest Involving Pharma Companies**
 - **"Anti-Kickback" Law**
 - **Conflicts of Interest and the Lupron Case**
 - **Responses of the Industry and the Medical Profession**
 - **Guidance of the Office of the Inspector General**

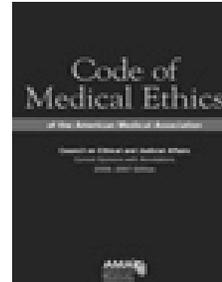


American Medical Association

AMA Code of Medical Ethics

E-8.03 Conflicts of Interest: Guidelines

- Under no circumstances may physicians place their own financial interests above the welfare of their patients. The primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. For a physician to unnecessarily hospitalize a patient, prescribe a drug, or conduct diagnostic tests for the physician's financial benefit is unethical. If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit.



American Medical Association

Various Categories of Guidance & Opinions on Conflict of Interest Issues

- E-8.03 Conflicts of Interest: Guidelines
- E-8.031 Conflicts of Interest: Biomedical Research
- E-8.0315 Managing Conflicts of Interest in the Conduct of Clinical Trials
- E-8.032 Conflicts of Interest: Health Facility Ownership by a Physician
- E-8.035 Conflicts of Interest in Home Health Care
- E-8.051 Conflict of Interest Under Capitation
- E-8.054 Financial Incentives and the Practice of Medicine
- E-8.06 Prescribing and Dispensing Drugs and Devices
- E-8.061 Gifts to Physicians from Industry
- E-8.062 Sale of Non-Health-Related Goods from Physicians' Offices
- E-8.063 Sale of Health-Related Products from Physicians' Offices



PhRMA Guidance



This Code is to reinforce our intention that our interactions with healthcare professionals are to benefit patients and to enhance the practice of medicine.

The Code is based on the principle that a healthcare professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the healthcare professional's medical knowledge and experience.

"Ethical relationships with healthcare professionals are critical to our mission of helping patients by developing and marketing new medicines."



American College of Physicians

- **OVERRIDING PRINCIPLES**

- The physician must seek to ensure that the medically appropriate level of care takes primacy over financial considerations imposed by the physician's own practice, investments, or financial arrangements.
- Trust in the profession is undermined when there is even the appearance of impropriety.
- Physicians must disclose their financial interests in any medical facilities or office-based research to which they refer or recruit patients.

– ACP Ethics Manual, 2005, 5th Edition



American College of Physicians

- The acceptance of individual gifts, hospitality, trips, and subsidies of all types from the health care industry by an individual physician is strongly discouraged. The acceptance of even small gifts has been documented to affect clinical judgment and heightens the perception (as well as the reality) of a conflict of interest.
- In addition to applying the Royal College of Physicians' standard and asking "Would I be willing to have this arrangement generally known?", physicians should also ask "What would the public or my patients think of this arrangement?"; "What is the purpose of the industry offer?"; "What would my colleagues think about this arrangement?"; and "What would I think if my own physician accepted this offer?"

- ACP Ethics Manual, 2005, 5th Edition



Stark and Anti-kickback Rules

- Federal rules that regulate the referral patterns of physicians based upon the financial relationships that they maintain
- Fundamental issue being addressed by these two federal laws is the conflict of interest between a physician's financial self-interest and the best interest of the patient – are they always the same?



Stark and Anti-kickback Rules

- The basic concept of the Stark Law is simple. Certain items and services, including hospital services and many ancillary items and services, are “designated health services.”
- If a physician (or an immediate family member) has a financial relationship with an entity, the physician cannot refer a designated health service to the entity, and the entity cannot bill for the designated health service, unless an exception applies.
- Violation can result in severe financial penalties, exclusion and potential False Claims Act liability.



Stark and Anti-kickback Rules

- Exceptions to the Stark rules relate primarily to situations where adequate safeguards exist against such financial self-interests outweighing a physician’s medical judgments:
 - Lease Exception
 - FMV Exception
 - Personal Services Exception
 - Employment Exception
 - Group Practice Exception



Stark and Anti-kickback Rules

- The anti-kickback statute prohibits the knowing and willful offer or payment of remuneration to induce referrals, or in return for purchasing or recommending the purchase of any item or service that may be paid for by a federal health care program.
- A violation of the anti-kickback statute is a felony. In addition, the OIG may impose civil money penalties or exclude a person or entity from participation in any federal or state health care program for violating the anti-kickback statute.
 - 42 U.S.C. §§ 1320a-7a(a)(7) and 1320a-7(b)(7).



OK

OKAY

OK

Ok, ok already!!!! So now what?



Management of Conflicts

<drum roll please . . .>

- 1. Develop Standards – what do you believe
- 2. **GET PHYSICIAN BUY IN – NEED A CHAMPION (with encouragement from Compliance)!!!!!!!!!!!!**
- 3. Create a Process and Forms to Identify Conflicts
- 3. Develop a system to measure compliance
- 4. How does the group review & analyze conflicts?
- 5. Determine if reporting is necessary ---
 - To patients
 - To other group members or owners
 - To others 'stakeholders'



Conflicts -- What is unique about physicians?



Why is managing physician conflicts be a challenge?

- Most physician groups have very informal oversight processes
 - Do not go through some of the same formal processes that institutions do with their Boards
- Individual physicians sometimes negotiate small side arrangements to speak or review data or respond to email offers
- More de-centralized management than corporate boards
- Reluctance to ask questions they don't want to know the answer to.



Standard of Conduct - Sample

Conflict of Interest -- Conduct Standards

- Each of us shall refrain from engaging in any action, activity or transaction that would create an actual or potential conflict of interest with respect to our work-related responsibilities. Conflicts exist where actions or activities result in an improper personal gain or advantage to an individual, improperly influence business judgment or the performance of business activities, or give rise to divided loyalty
- We shall not use improperly or for personal gain any confidential information belonging to the practice that has not been released to the general public.
- No one may work (as an employee, independent contractor or otherwise) for a company that is in competition with or provides supplies or services to the company unless authorized in writing by the Practice President or Compliance Officer.



Standard of Conduct - Sample

Conflict of Interest -- Conduct Standards

- Each of us shall promote competitive procurement in the selection of suppliers, subcontractors and vendors based on objective criteria, including quality, technical excellence, price, delivery, service and maintenance of adequate inventory and make procurement decisions based on the supplier's ability to meet our needs.
- Each of us shall report any actual or perceived conflicts of interest to the Practice President or Compliance Officer
- No waiver of this conflict of interest provision may be granted without the expressed approval of the Practice President and the Compliance Officer.



Clinical Research & Physician Conflicts

- Protecting Subjects, Preserving Trust, Promoting Progress — Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research ASSOCIATION OF AMERICAN MEDICAL COLLEGES, Task Force on Financial Conflicts of Interest in Clinical Research, OCTOBER, 2002
 - **Rebuttable Presumption that Financially Interested Individuals May Not Conduct Human Subjects Research.**
 - **Affirmation of Institutional Policies on Intellectual Property and Publication Rights**
 - **Prohibition on Payments for Results.**
 - **Significant Financial Interests in Research:**
 - Consulting fees, honoraria, gifts or other emoluments, or "in kind" compensation from a financially interested company that in the aggregate have in the prior calendar year exceeded the de minimis amount established in PHS regulation (presently \$10,000), or are expected to exceed that amount in the next twelve months.
 - Equity interests, including stock options, of any amount in a non-publicly-traded financially interested company (or entitlement to the same).
 - Equity interests (or entitlement to the same) in a publicly-traded financially interested company that exceed the defined de minimis amount.
 - Royalty income or the right to receive future royalties under a patent license or copyright, where the research is directly related to the licensed technology or work
 - Any non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research.
 - Service as an officer, director, or in any other fiduciary role for a financially interested company, whether or not remuneration is received for such service.



Organizational Champion to help achieve buy in

SENIOR PHYSICIAN LEADERSHIP!

This conflicts of interest process must be an organizational commitment

-- if the president or senior leaders don't practice what they preach or believe in the standards, any policy of the best intent will be destined for failure.



Disclosure Process

- If a Conflict Management plan is a new program, determine who should be included – all physicians and senior management levels
 - Query: Can general employees be addressed with a simple policy plus compliance training
 - Some recommend same process for all
- New Physicians and Managers should complete a Disclosure Statement
- Disclosure must include all relevant conflict risk areas – disclosure forms can provide checklists of potential risk areas to serve as a reminder of routine issues



Disclosure Review Process

- Appoint a small review committee responsible for review of all Disclosure Forms submitted
- May need input from
 - Chief Administrator
 - Compliance and/or Legal
 - Possibly HR and/or Purchasing
- Additional process for Disclosures by member review committee
- Annual Updates



Review Process and Procedure

- Routine Conflict – Generally Acceptable
 - Conflicts or potential conflicts that do not compromise or give the appearance of compromising the interests of the organization and have a minimal personal financial impact
 - Do not compromise patient care
 - Examples:
 - Medical Director Agreements compensated at FMV
 - Uncompensated Board Positions on Non-Profit Boards, such as ACS, Hospice, Hospital
 - Prior relationship with a vendor of the business



Review Process and Procedure

- Routine Conflicts – But Requiring Examination and Possible Action
 - Conflicts that compromise or have the potential to compromise the interests of the organization in favor of personal financial gain or interests

 - May possibly compromise patient care decision

 - May be acceptable with disclosure and isolation of conflicted issues when necessary

 - Examples:
 - Ownership interest in an ancillary service provider
 - Certain paid speaking or sponsorship situations
 - Moonlighting



Review Process and Procedure

- Conflict Disclosures that are generally NOT acceptable, but could be with proper disclosure and management
 - Generally these are not permissible. These are conflicts where either the appearance of conflicts or the personal benefits arising from a conflict are detrimental to the organization or patient

 - Might be approved with independent oversight or various monitoring plans.

 - May place financial or other self-interests above patient care decisions

 - Examples:
 - Awarding substantial contracts based on nepotism or other undisclosed self-interest

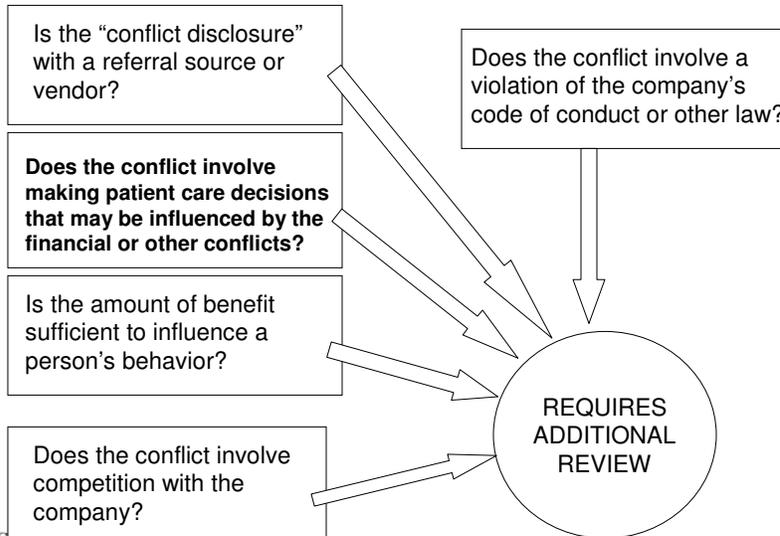
 - Serving on a paid pharma speaker bureau speaker while simultaneously serving as a principal investigator for a controversial new device or drug



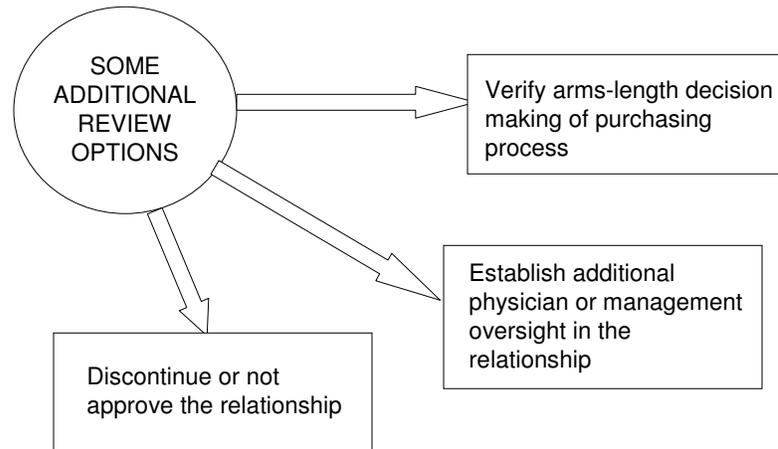
When do you need to look behind the curtain of a conflict disclosure?



Conflict Review – Additional Oversight Questions



Conflict of Interest Additional Review Procedures



Other Conflict Review Options

- Verify bona-fide services are required/provided
- For Research related relationships – is the relationship a legitimate research project or just a paid trip
- Aggregate limits of outside relationships – either number of relationships or limits of compensation
- Require ALL compensation paid to the group and shared rather than retained by an employee or physician – tends to decrease outside deals.

Unique Problems with Physicians

- How do you handle:
 - Nobody will take on this issue
 - “everyone’s in on it”
 - Chronic Abuser –
 - “what are you going to do – fire me?”
 - So who makes the hard decisions
 - No committee help to enforce violations



Management of Conflicts of Interest in Physician Practices

QUESTIONS?

