Gifts and Conflicts of Interest
2010 HCCA Compliance Institute
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Goals of the Presentation

- Provide brief overview of the gifts and conflicts of interest landscape
- Discuss hot compliance issues related to industry-provider relationships
- Understand the nexus between potential conflicts of interest (COI) and quality oversight
- Learn methods to detect undisclosed conflicts
- Answer your questions
Background: Law and Industry Guidance

- Federal and State Anti-Kickback Statutes and Stark
- States and Federal Claims Acts
- Prescription Drug Marketing Act
- State Pharmaceutical Disclosure Laws
- Forthcoming State Hospital Compliance Guidances
- OIG Compliance Program Guidance for Pharmaceutical Manufacturers
- PhRMA Code of Interactions with Health Care Professionals
- AdvaMed Code of Ethics
- AMA Opinion E-8.061 – Gifts to Physicians from the Industry
- American College of Physicians Position Paper – Physicians and the Pharmaceutical Industry
- American Association of Orthopedic Surgeons (Standards of Professionalism)
- Association of American Medical Colleges (AAMC) Task Force
- Internal Revenue Service – Form 990

Brief Timeline of Vendor COI Developments

- **2005-2007**: Medical schools, health systems begin to adopt more stringent gift policies (e.g., California, Minnesota, Penn, Pitt, Stanford, Yale, NYU, Mt. Sinai, HCA, Henry Ford)
- **Association of American Medical Colleges (AAMC)**, “The Scientific Basis of Influence and Reciprocity: A Symposium” (June 12, 2007)
- **AAMC**, “Industry Funding of Medical Education: Report of an AAMC Task Force” (June, 2008)
Emerging Medical COI and Gift Trends

- Proposed Federal Law: Physician Payment Sunshine Act
- Numerous Existing or Proposed State Gift Laws
  - Strict Disclosure Rules
  - Prohibits or limits Industry Food
  - Ban or limits Gifts
- Proposed Physician Disclosure Requirements for Industry Gifts (NJ)
- Healthcare Providers Prohibiting and/or capping Pharmaceutical Speakers Fees
- Institute of Medicine Report: Conflict of Interest in Medical Research, Education, and Practice, April 21, 2009
- Joint Commission Standard: LD.04.02.01
- IRS Form 990
- Increased Government COI Reviews

Examples of Gift AKS Settlements

- Several Large Industry *Qui Tam* AKS Related Settlements
  - Among other items, includes treating physicians to lavish resorts, entertainment, disguised educational grants, sham consulting arrangements, inflated speaking fees
- 2 South Florida Physicians (DME related)
  - Gifts, Miami Dolphin tickets, meals ($65,000 and $57,000)
- LinCare (DME Company) $10 million
  - Among other items, sporting and entertainment expenses, advertising expenses, meals, fishing trips, gift certificates
- Advanced Neuromodulation Systems (ANS) $2.95 million
  - Kickback allegations included conferences at resort locations, free dinners and gifts, educational grants and fellowships
Academia’s View on Vendor Gifts

- Accreditation Council for Graduate Medical Education (ACGME)
  - Mandates all members institute a vendor relationship policy
- American Medical School Association (AMSA)
  - PharmaFree Medical School Student Pledge: “…pledge to accept no money, gifts, or hospitality from the pharmaceutical industry…”
  - Ranks U.S. medical school’s policies on pharmaceutical company’s access and influence
  - [http://www.amsascorecard.org/](http://www.amsascorecard.org/)
- Association of American Medical Colleges (AAMC)
  - Formed a high-level task force to address vendor gift issues

Key Medical COI Articles

  - Pharma reps met with physicians on average 4 times a month
  - The present extent of physician-industry interactions appears to affect prescribing and professional behavior
  - Drug sponsored CME highlighted the sponsors’ drugs compared with other CME programs
  - Meetings with pharma reps were linked to physicians adding drugs to hospitals’ formulary
  - Physicians attending pharma presentations were linked to non-rational prescribing
  - Attending sponsored CME and accepting travel from pharma companies were linked to increased prescription rates of the sponsor’s medication
Key Medical COI Articles (continued)

  - Authors conclude conflicts of interest between vendors and physicians pose challenges to the principles of medical professionalism
  - Current controls and self-regulation will not satisfactorily protect patients
  - Calls for the elimination or modification of common practices
    - Small gifts
    - Pharmaceutical samples
    - CME
    - Funds for physician travel
    - Speakers bureaus
    - Ghostwriting
    - Consulting and research contracts

Key Medical COI Articles (continued)

  - Survey of 3,167 physicians in six specialties in 2003-04
  - Most physicians (94%) reported some type of relationship with pharmaceutical industry
  - 35% received reimbursement for costs associated with meetings or CME
  - 28% received payments for consulting, giving lectures, or enrolling patients in trials
  - Cardiologists were more than twice as likely as family practitioners to receive payments
Key Medical COI Articles (continued)

  - Compared publicly reported data on orthopedic manufacturers’ Web sites in 2007 to conflict of interest disclosures made by physicians at a 2008 industry annual meeting
  - Overall rate of disclosure was 71.2% (245 of 344 payments)
  - The rate of disclosure was 79.3% for directly related payments to the topic and 50% for indirectly related payments
  - Most common reasons for non-disclosure was that the payment was unrelated to topic of presentation and physician misunderstood the disclosure requirements
  - 11.1% reported that payment had been disclosed, but was mistakenly omitted from the program

Key Medical COI Articles (continued)

  - CME is a $2 billion per year business – less than half of its revenue from physician learners
  - Discusses the Neurontin case where Warner-Lambert sponsored CME activities that encouraged the use of Neurontin off-label indications
  - Discusses various approaches to eliminate commercial bias in CME and to eliminate commercial sponsorship
  - Suggests that a pooled-funding mechanism (i.e., prohibits donors to specify which programs their donations will fund) offers a promising solution
Other COI Articles of Note

- A Social Science Perspective on Gifts to Physicians from Industry, *JAMA* 2006; 290: 252-255, July 9, 2003
  - Bias is strong even when the stakes are small
  - Disclosures can only be effective if those informed can rationally discount the advice from physicians who disclosed a conflict of interest
- The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest, 34 *J. Legal Studies* 1-25 (The University of Chicago, January 2005)
  - Suggests that disclosures gives advisors “strategic reason and moral license to further exaggerate their advice”

Hot Industry-Healthcare Provider Collaboration Issues

- Co-Marketing Arrangements
  - Vendor/healthcare provider product/service advertisements
  - Vendor Patient General Education Brochures
  - Community Patient Education Events
  - Vendor Training Agreements
- Educational Grant Activities
- Speakers’ Bureaus
- Vendor FDA Related Training
- Scope of a Gifts and COI Policy
Implementation Tips for a COI Policy

- Try to Obtain Senior Management and Physician Leadership Support
- Data is King! – Medical Journal Articles
- Identify Compliance Champions
- Can’t Change Rome in a Day – Set Reasonable Expectations
- Town Hall Meetings – Give Stakeholders a Voice
- Create Educational Documents and Training
- Don’t Forget to Educate the Vendors

Quality Issues and Conflicts of Interest

One Place to Analyze

Who is Doing Your Clinical Research??

Clinical Research Organizations
Contract Research Organizations

Many different companies with different expertise
http://www.biore.org/dir/Companies/Contract_Research_Organizations/
WHY WOULD WE BE CONCERNED ABOUT WHO IS CONDUCTING YOUR CLINICAL RESEARCH?

Conflicts of Interest (corruption of medical judgment)

Money Flow

Interrelationships of Companies

Quality of Principle Investigators

Patient Care

HOW ARE HOSPITAL IRBs TOLD?

I was a member of a Hospital IRB for 8 ½ years

We were never informed (overtly) that someone other than the pharmaceutical, device, or healthcare organization (data collection) was doing the research study

We didn’t know what a Clinical (or Contract) Research Organization was…

Were they conducting research on our patients?

Was this disclosed?
WHY WOULD HOSPITAL IRBs WANT TO KNOW ABOUT CROs?

Is there any conflict of interest of the CRO to enroll patients quickly?

- How is the CRO compensated?
- What relationships does the CRO have with main researching party?
- Should they have any relationships other than conducting research?

Who is doing QA at the clinical sites?

IRB / COMPLIANCE QUESTIONS TO ASK

If the CRO is involved, did they have involvement in writing the Clinical Protocol?

- If so, should they be permitted to conduct, enroll, monitor the research?
- If the protocol is flawed, what is the consequence for future business?

If a CRO is involved, who is really the Principle Investigator (PI)?

- Does the CRO have physicians that are “ghost PIs” (remember ghost writers) for the pharmaceutical or device companies?
**COMPLIANCE OFFICER PERSPECTIVE**

Good Compliance Officers are taught to be skeptical…

Good Compliance Officer is taught to “look everywhere.”

Where is the Compliance function within a CRO?

Most time the skepticism is validated in future years.

$\textdollar$ and Egos!

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**CRO BUSINESS MODEL**

For-profit !!!

How are Senior Executives paid?

- Portion Salary, Stock, and Bonus
- Is this appropriate for Clinical Trials?

Research it Yourself?

“CROs stay in business by hitting the numbers, that is a big ethical no-no. They should never be reviewing anything in which they have a direct financial interest.” – Executive from a Center for BioEthics
WHAT ABOUT THE CRO PHYSICIAN?

Who are the physicians leading the study for a CRO?

- Are they in the proper specialty?
- Are they Board Certified?
- Where are they located?
- What Experience?
- Where did they train?
- Could they be credentialed at our hospital?

WHY WOULD IRBs WANT TO KNOW ABOUT CROs?

They are directing care for our patients!
BACK TO MY IRB EXPERIENCE

Would I have reviewed a project differently if I knew the PI functions were subcontracted to a CRO who had a non-Board Certified or Board Eligible Physician in charge of the day-to-day functions, including all adverse effects of the study?

YES!!

But, if I didn’t know I couldn’t ask the question.

CAUSE FOR CONCERN?

Majority of CROs probably have quality as top priority but do all – all of the time?

There is always fraud and corruption in every industry…

Consider the following:

1998 – 10 complaints to the FDA regarding clinical drug trial irregularities
2006 – 350 complaints to the FDA regarding clinical drug trial irregularities

Why the increase? Maybe because people are starting to look?
Example of a Problem

Conclusions

- Awareness of research challenges is important

- Compliance Professionals need to become engaged in IRB activities
  - Begin to ask questions and require answers

- Healthcare Compliance Officers need to understand the value and risk of CROs
Disclosure: Certifications and Questionnaires for COI

- **Certifications**
  - Used by organizations for select (mostly high-level) or all employees
  - Provide employees opportunity to report or certify they are not aware of any policy violations
  - Typically require employees to certify that they have read and are familiar with the conflicts of interest policy (and code of conduct)

- **Questionnaires**
  - Request employees to supply information and respond to more detailed questions

Identify Participants

Individuals who should complete disclosure on an annual basis
- are in leadership positions,
- influence purchasing decisions for products and services,
- own private practices or businesses that seek to do business with company,
- have commitments or relationships with competing organizations,
- have outside employment relationships with businesses that seek to do business with company or are competitors of company,
- work in targeted areas/departments, or
- previously had a conflict identified.
Solicit Disclosure
Targeted participants are notified by e-mail

From: Company Ethics and Compliance Office
Sent: Thursday, April 19, 2009 10:18 AM
To: Suzie Q Doe@hotmail.com
Subject: 2009 Company Conflicts of Interest Disclosure Statement

The Company Conflicts of Interest Policy is a Board of Trustees approved policy that requires annual disclosure of conflicts of interest through completion of a Statement of Disclosure of Outside Interests and Activities (Disclosure Statement). You have been identified either by your job description or responsibilities as an individual who must complete a Disclosure Statement for Fiscal Year 2007 (FY07).

Click on the hyperlink shown below to access your 2009 Disclosure Statement. After clicking the link, type the following username into the login box that appears. Then enter your password to access your Disclosure Statement. For security purposes your password will be provided in a separate email from Company@tractmanager.com.

Username: Suzie Doe
Please click here to complete your disclosure statement

All information must be completed to successfully submit the Disclosure Statement. All “yes” answers must have a complete explanation in the corresponding “Comments” box.

Additional Instructions:
Submit the Disclosure Statement by scrolling to the bottom of the form and clicking the “SUBMIT” button.

Track Completion of Disclosures

Participation Reporting

☐ Weekly system statistics during annual process
☐ Individuals who have not responded

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Financial aid chief signed ethics policy
UT official had claimed he wasn't aware of rules on conflicts of interest

Sunday, May 6, 2007
The Associated Press

AUSTIN – Before he acquired stock in a company whose subsidiary was placed on a preferred student lender list, the financial aid director at the University of Texas signed an ethics policy prohibiting financial conflicts. He said last month that he wasn't aware of conflict of interest regulations except for a provision requiring employees to notify the university about any outside work.

Auditing COI Processes

- Who conducts?
  - Interview individuals responsible for the process (Compliance and Ethics, Legal) and in high risk areas (Procurement, Contracting, Grants)
    - Who reviews questionnaires and to whom are results reported?
- Evaluate data collected from COI questionnaires
  - What are the most common types of conflicts reported?
  - Those who failed to disclose a conflict later identified?
  - Any consequences for those who did not complete the form?
Auditing the Processes, (Cont’d)

- Review targeted sample of COI questionnaires to assess the reporting and disclosure process
  - Interview respondents to get feedback
  - Is there documentation that support the disclosures being reviewed and investigated?
  - Were reported and identified conflicts resolved pursuant to company policy?
  - Resolutions to identified conflicts being followed?

Monitoring Techniques

- Build notification triggers into expense and gift reporting when thresholds are reached
- Develop trend and exception reports of entertainment data
- Require close review and accountability of expense reports by managers with approval authority
- Review helpline/hotline reports for calls alleging conflicts of interest, and questions concerning conflict policies
Identifying *Undisclosed* Conflicts

- Random and targeted audits of expense reports
- Interviewing and surveying the workforce
  - Perceptions of work environment and willingness to report misconduct
  - Awareness and understanding of conflict of interest policies and training received
- Including vendors/suppliers in a certification and disclosure process

Auditing for Compliance – The Giver

- Gift giving, entertainment expenses
  - Review expenditures, T&E reports in sensitive areas
  - Audit employees with highest expense reporting
  - Random spot audits of expense reports
Auditing for Compliance – The Receiver

- Receipt of gifts
  - Trace and validate the receipt of funds (grants, gifts, etc.) for appropriate use
  - Review pre-approvals and waivers for consistent application
  - Some organizations now asking suppliers to confirm that payments have not been made, or gifts given to their employees (variation of the holiday letter to suppliers)

Commonalities Between Employees and Vendors

Tests:

- Identify vendors and employees with common SSN and Tax ID #s
- Identify vendors and employees with common bank account #s
- Identify vendors and employees with common addresses

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Proactive Approaches: Data Analysis

Questions?

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