

CONFLICTS OF INTEREST AND CONFLICTS OF COMMITMENT

2012 YEAR IN REVIEW

T9:Tuesday, October 2, 2012

CONFLICT OF INTEREST

- What is a potential conflict of interest?

Broadly defined, a *potential conflict of interest* encompasses ties that may or may appear to improperly bias an individual's or organization's judgment

CONFLICT OF COMMITMENT

- What is a potential conflict of commitment?
- Broadly defined, a *potential conflict of commitment* encompasses situations in which external relationships or activities may or may appear to interfere or compete with the mission, or with the ability or willingness to perform one's responsibilities fully and impartially

WHY USE THE WORD *POTENTIAL*?

- Because a lot depends upon the circumstances
 - For example, if an employee discloses an external tie and steps are then taken to remove the chance of bias (e.g., removing the employee from certain decisions), the potential conflict has been eliminated

WHY *POTENTIAL*?

- Another example...
 - An employee accepts a gift from someone outside the employee's organization and then makes an allegedly unbiased decision about using the services of the company which is the source of the gift. But the *appearance* of bias, regardless of anything else, creates a *potential* COI

NEW COI POLICIES

- 42 CFR Part 50 Subpart F (grants and cooperative agreements)
- 45 CFR Part 94 (contracts)
 - http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm
 - Revised Final Rule published on 8-25-11
 - <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

2011 REVISED FCOI REGULATION

- Revised regulations on *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors*
- Implementation by August 24, 2012
- Applies to each Notice of Award issued subsequent to compliance dates of final rule

RECENT HHS REGULATION CHANGES

- Shift from Investigator's to Institution's responsibility
- Disclosure expanded to external activities related to “Institutional Responsibilities” rather than Conflicts of Interest
- Disclosure of “Significant Financial Interest” \$\$ threshold lowered
- Mandatory training
- Disclosure of Reimbursed and Sponsored Travel
- Public disclosure
- Increased compliance oversight

NEW PHS REGULATION: WHO IS COVERED?

- National Institutes of Health (NIH)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Agency for Healthcare Research and Quality (AHRQ)

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NEW PHS REGULATION: WHO IS COVERED? (2)

- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)

WHO IS COVERED?

- Each Institution that applies for or receives PHS/NIH grants or cooperative agreements for research
 - Domestic, foreign, public, private (not Federal)
- Any Investigator, as defined by the regulation, planning to participate in or participating in the research
- When an individual, rather than an Institution, is applying for or receives PHS/NIH research funding
- SBIR/STTR Phase II applicants/awardees
(Phase I SBIR/STTRs are exempt)

INSTITUTIONAL RESPONSIBILITIES

- Establish standards
- Maintain an up-to-date, written, enforced policy and make policy publicly accessible
- Maintain records of all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures
- Certify in each application for funding

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INSTITUTIONAL RESPONSIBILITIES (2)

- Require that each Investigator complete FCOI training
- Take necessary actions to manage FCOIs of its Investigators, including those of subrecipient Investigators
- Flowdown to subrecipients
- Respond to Non-compliance

TRANSPARENCY AND OBJECTIVITY

- **For Immediate Release** **May 29, 2012**
- Grassley questions new federal grant to research physician who was previously suspended
 - Senator calls on the National Institutes of Health to set tone for disclosure, accountability
- WASHINGTON – Senator Chuck Grassley is asking the National Institutes of Health to explain why it has awarded a \$400,000 medical research grant to a physician who it banned from NIH funding in recent years for failing to disclose a \$1.2 million financial relationship with a major pharmaceutical company while leading a \$9 million federal study involving that drug company's blockbuster depression drug Paxil

INSTITUTIONAL CONFLICT OF INTERESTS

- There has developed a significant literature regarding individual conflict of interests
- Consideration of institutional conflict of interests is less mature
- The AAMC definition of "Institutional Conflict of Interest" includes financial interests that might affect – or reasonably appear to affect – institutional processes for the conduct, review, or oversight of human subjects research..."

OTHER COMPETING INTERESTS

- Peer recognition
- "Publish or perish"
- Enthusiasm and boundless optimism
- Competition for limited grants, labs, support

REGULATORS BEGINNING TO FOCUS ON MORE THAN ECONOMIC CONFLICTS

- Report (OEI-03-09-00480)
 - 01-10-2011
 - Institutional Conflicts of Interest at NIH Grantees
- FAR Case 2011-001
 - Implements section 841 of the NDAA for FY 2009 (Pub. L. 110-147)
 - **Report Due 8/15/2012 (6th ext.)**
 - **Report Due 9/26/2012 (7th ext.)**

MEDICAL INDUSTRY TIES OFTEN UNDISCLOSED IN JOURNALS

- New York Times
 - Tuesday, September 14, 2010
 - Twenty-five out of 32 highly paid consultants to medical device companies in 2007, or their publishers, failed to reveal the financial connections in journal articles the following year

BIAS IN BIOMEDICAL RESEARCH

- Physician Payment Sunshine Act: Senate Aging Committee Roundtable September 12th, and Letter from Stakeholders to CMS Requesting 180 Days for Implementation
 - Sunshine Act disclosure requirements already delayed for almost a year.
- Standards for Developing Trustworthy Clinical Practice Guidelines (CPGs)
 - Institute of Medicine - March 2011
 - STANDARD 2 - Management of conflict of interest (COI)

UNIVERSITY OF TEXAS COMPOUNDS CONFLICT QUESTION IN REVIEW OF GAS REPORT

- New York Times
 - August 22, 2012
 - By Andrew C. Revkin
 - University of Texas initiated an independent review, of the report from its Energy Institute ... ordered after the Public Accountability Initiative ... pointed out previously undisclosed financial ties between a leader of the report, Charles Groat, and a drilling company.

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UNIVERSITY OF TEXAS COMPOUNDS CONFLICT QUESTION IN REVIEW OF GAS REPORT (2)

- New York Times - August 22, 2012
 - By Andrew C. Revkin
 - ... the same watchdog group pointed out that the announced leader of the independent review, Norman Augustine, a past presidential science and technology adviser and leader of important technical assessments for NASA and Congress, is receiving substantial payments from ConocoPhillips for past service on the board of directors.

AFFORDABLE CARE ACT

- Expands COI and other “transparency” requirements
 - VI. Transparency and Program Integrity
 - Physician Payment Sunshine Act
 - Medicare & Medicaid Fraud & Abuse
 - Elder Justice Act
 - Nursing Home Transparency
 - Patient Centered Outcomes Research Institute

OVERVIEW OF SECTION 6002 OF PPACA

- Section 6002 of the Patient Protection and Affordable Care Act implements the “Physician Payments Sunshine Act”
 - Requires pharmaceutical and medical device manufacturers to report payments and other transfers of value furnished to physicians and teaching hospitals
 - First introduced by Senators Charles Grassley and Herb Kohl in 2007, and introduced annually thereafter in various forms

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OVERVIEW OF SECTION 6002 OF PPACA (2)

- Designed to encourage greater transparency in the relationships between life sciences companies and physicians
 - Allow consumers to identify potential sources of bias
 - Provides the federal government with a means of identifying potential kickbacks and other improper financial relationships
 - Deters conflicts of interest in research and education
 - Due to the enforcement risk, potentially deters manufacturers from paying remuneration in excess of fair market value to a referral source – query as to whether this will reduce the cost of healthcare
- Regulations were to be issued no later than October 2011– STILL PENDING

NATURE OF REPORTABLE PAYMENTS

A transfer of value includes:

- Consulting fees
- Compensation for services other than consulting
- Honoraria
- Gifts
- Entertainment
- Food
- Travel

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NATURE OF REPORTABLE PAYMENTS (2)

A transfer of value includes (*continued*):

- Education
- Research
- Charitable contribution
- Royalty or license
- Current or prospective ownership or investment interest
- Direct compensation for serving as faculty or speaker for medical education program
- Grant
- Any other transfer of value

EXCLUDED PAYMENTS AND TRANSFERS OF VALUE

- Transfer of anything of value less than \$10, unless aggregate annual amount per covered recipient exceeds \$100; for calendar years after 2012, the dollar amounts shall be increased by the same percentage as the percentage increase in the CPI for all urban consumers for the 12-month period ending with June of the previous year
- Product samples
- Educational materials for patients' use/benefit
- Loan of a covered device for a short-term trial period, not to exceed 90 days

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EXCLUDED PAYMENTS AND TRANSFERS OF VALUE (2)

- Items or services provided under a contractual warranty, including the replacement of a covered device
- Discounts
- In-kind items used for the provision of charity care
- Dividends or other profit distribution forms
- Several others related to covered recipients when not in the context of their professional capacity (e.g., as a patient, legal proceeding)

INDIRECT PAYMENTS

- In the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer shall disclose that payment or other transfer of value under the name of the covered recipient.
- Payment or other transfer of value “does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.”
 - Referred to as the “marketing research exclusion”

STARK LAW

- Prohibits referrals (and any related billing) of “Designated Health Services” (DHS) by a physician to an entity in which the physician or an immediate family member has a financial interest (compensation/ownership)

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STARK LAW (2)

- Violations often arise when physician is not an employee of the hospital – any contracts for research services must take into account the Stark law exceptions or risk the ability to refer DHS to the hospital (even for DHS unrelated to the research)

RECENT ENFORCEMENT/ SETTLEMENT ACTIONS

- Company made payments to physicians through clinical trials to induce physicians to prescribe off-label
- Company promoted psychiatric drug for unapproved uses by recruiting physicians to author articles about studies physicians did not conduct
- Paying illegal remuneration to health care professionals recruited to conduct studies for unapproved uses
- Investigator quoted in magazines promoting an IND

SETTLEMENTS

- Criminal and civil fines ranging from \$24M to \$600M
- CIAs with specific obligations addressing research-related activities
- Payments to be disclosed consistent with payments under Section 6002 of ACA
- Public disclosure of results, post-marketing commitments
- Exclusion

ORGANIZATIONAL CONFLICTS OF INTEREST (OCIs)

- Definition of OCI
- Application of FAR 9.5 – “impaired objectivity” analysis
- Personal Conflicts of Interest

WEAPON SYSTEMS ACQUISITION REFORM ACT (WSARA), 2009

- Section 205 –“OCIs in the Acquisition of Major Weapon Systems (MWS)”
 - Mandates DFAR Supplement (DFARS) revision to address OCIs in the acquisition of Major Weapon Systems
 - DOD must be advised by a Federally Funded Research and Development Center (FFRDC) or other independent source re: systems architecture and engineering
 - Systems Engineering and Technical Assistance (SETA) contract clause to bar contractor or affiliate from direct financial interest in development or construction of MWS or any component

WSARA

- Requires fair, objective make/buy decisions by primes on MWS
- DOD must establish an OCI Review Board
 - Resulted in DFAR 209-571 (29 December 2010) addressing OCIs in systems engineering and technical assistance (SETA) work provided by Major Defense Acquisition Programs (MDAPs).

FAR SUBPART 3.11

PERSONAL COI FOR CONTRACTOR EMPLOYEES

- ACQUISITION FUNCTIONS

- Took effect December 2, 2011
- The new Rule requires contractors to screen/prevent personal conflicts of interest when supporting Government acquisition functions

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FAR SUBPART 3.11

PERSONAL COI FOR CONTRACTOR EMPLOYEES - ACQUISITION FUNCTIONS (2)

- Also requires contractors to prohibit “covered employees” from utilizing non-public information for personal gain and to obtain from them non-disclosure agreements prohibiting the dissemination of such information
- “Covered employees” include the contractor's employees who perform an "acquisition function *closely associated with inherently governmental functions.*

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FAR SUBPART 3.11

PERSONAL COI FOR CONTRACTOR EMPLOYEES - ACQUISITION FUNCTIONS (3)

- Examples include: (1) financial interests of employee and family members, *e.g.*, compensation, business and real estate investments, stock ownership, intellectual property interests; (2) employment and financial relationships, including seeking or negotiating prospective employment; and (3) gifts.

Q&A

- Questions
- Comments

Thank you for your participation!

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