

Research Compliance

Legal Discussion Panel

October 20, 2009

Gary W. Eiland
King & Spalding LLP
Houston, TX

Lisa Murtha
Sonnenschein, Nath & Rosenthal, LLP
Washington DC

Gabriel Imperato
Broad and Cassel
Fort Lauderdale, FL

Juliann Tenney
University of North Carolina
Chapel Hill, NC

Risks and Enforcement Initiatives



Clinical Research Compliance

- Risks of non-compliance to institutions
 - Diminution of institution's reputation in medical, scientific communities
 - Loss of funding and draw down privileges
 - Risk of fines and penalties
 - Settlement costs and/or damages arising from FCA actions
 - Shut down of research operations

3

Clinical Research Compliance

- Risks of non-compliance to individuals
 - Loss of PI status
 - Debarment, suspension, and exclusion
 - Criminal and/or civil sanctions

4

CMS/OIG Clinical Research Focus

■ 2010 OIG Work Plan initiatives:

- Review National Institute of Health (NIH) internal controls over research grant award process
- Review selected NIH grantees to determine whether they have capacity to manage and account for federal funds and to operate in accordance with Recovery Act requirements
- Determine whether NIH has a system in place to ensure grantees capture and report necessary financial, economic, and grant/contract data

CMS/OIG Clinical Research Focus

■ 2010 OIG Work Plan initiatives (cont.):

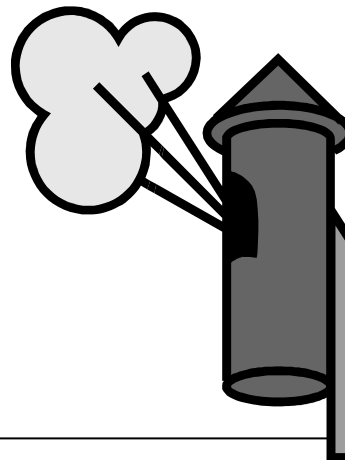
- Review extent to which DSMBs monitor data in clinical trials in accordance with NIH policies
- Review college and university compliance with select cost principles
- Continue to determine extent to which institutions receiving NIH grants have financial interests that could be affected by the research

Research Enforcement Risks

- **Billing**
 - CMS National Coverage Determination Policy
 - Billing Coordination
- **Grant Management**
 - Allocation of charges to award costs
 - Cost transfers
 - Effort Reporting
 - Indirect Cost Rates
 - Training grants
 - Subrecipient award monitoring
- **Scientific Misconduct, Financial Conflicts of Interest, and Informed Consent Improprieties**

7

False Claims Act Update



8

The FCA is the Fraud Enforcement Vehicle of Choice

- \$21 billion recovered by the Gov't since 1986
- \$1.34 billion recovered in FY 2008
 - \$1.12 billion in health care cases
- FY 2009 will break records with off-label settlements
 - \$1.4 billion Eli Lilly settlement (Zyprexa)
 - \$2.3 billion reserve by Pfizer (Bextra)

9

Fraud Enforcement and Recovery Act of 2009 (FERA)

- The statute modifies existing federal criminal, securities, and money laundering laws and increases funding available to combat mortgage fraud and predatory lending.
- Section 4 of the Act modifies the False Claims Act to clarify the scope of its application, which FERA's sponsors thought had "been undermined by court decisions."

Public Law No. 111-21 (May 20, 2009)

10

Overview of FERA's Changes to the FCA

- Clarification of the applicability of the FCA to claims submitted to government contractors and grantees
- Expanded definition of "claim"
- Materiality requirement ("natural tendency" test)
- Expansion of false claim liability for certain retentions of overpayments
- Partially retroactive effective date (which may be subject to constitutional challenges)
- Procedural amendments
- Pending legislation could add more changes to FCA

11

Application of FCA to Claims Made to Contractors and Grantees

- The legislation removes the prior FCA language requiring a false claim to be presented to "an officer or employee of the United States Government or a member of the Armed Forces of the United States."
- The statute also removes the language "by the Government," "to get," and "getting" in response to U.S. Supreme Court's reading of an intent requirement into certain provisions of the FCA.

12

Redline of Revisions to Sections 31 U.S.C. 3729 (a)(1) and (a)(2)

(a) LIABILITY FOR CERTAIN ACTS.—~~Any~~

(1) ~~IN GENERAL.~~—Subject to paragraph (2), any person who—

- ~~(1A)~~ knowingly presents, or causes to be presented, to ~~an officer or employee of the United States Government or a member of the Armed Forces of the United States~~ a false or fraudulent claim for payment or approval;
- ~~(2B)~~ knowingly makes, uses, or causes to be made or used, a false record or statement material to ~~get~~ a false or fraudulent claim paid or approved by the Government;

S.386 "Fraud Enforcement and Recovery Act of 2009"

13

Impact on *Allison Engine* and *Totten*

- These changes are intended to overturn the decisions in *Allison Engine* (Supreme Court 2008) and *Totten* (D.C. Cir. 2004).
- Where there is no presentment of a claim to the Government, *Allison Engine* held that an FCA plaintiff is required to prove that "a defendant must intend that the government itself pay the claim" for there to be a violation.
- *Totten* held that a claim submitted to Amtrak was not a claim presented to the Government because Amtrak is a federal grantee.

14

Allison Engine – Healthcare Litigation

- At the time FERA was enacted, litigants had filed briefs contending that since various contractors actually pay claims in the Medicare and Medicaid systems, there could be no “presentment” to a federal official as required by *Allison Engine*.
- FERA’s legislative history makes clear Congress was aware of these arguments in healthcare cases.

15

Retroactive Application

- FERA explicitly makes the change to Section (a)(2) retroactive to June 7, 2008, two days before the decision in *Allison Engine*.
- The retroactive nature of this provision provides defendants with potential constitutional challenges for imposing punitive civil liability, e.g. Due Process and Ex Post Facto Clause.

16

Materiality Test

- Codified “materiality” requirement that had been recognized by several courts.
- Defined “material” as whether the claim was “capable of influencing” or had “natural tendency to influence” the government’s payment decision.
- Rejected the more defendant-favorable “outcome materiality” test that asked whether the government *actually* relied on the information. (Minority view)

17

Expanded Definition of “Claim”

- FERA modifies the definition of “claim” to include:
“any request or demand...for money or property and **whether or not the United States has title to the money or property**, that –

(ii) is made to a contractor, grantee, or other recipient, **if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest,...**”

18

Expanded Definition of “Claim”

- This provision is, in part, a response to the *Custer Battles* case (E.D. Va. 2005), in which a jury verdict in favor of the whistleblower was overturned because the funds at issue were Iraqi funds under the control of the United States Government.

19

Expansion of FCA Liability for Retention of Overpayments

- This may be the single most significant development for the healthcare industry.
- Previously, a “false record or statement” was required to violate the FCA. Now, “knowing” and “improper” concealment or avoidance of an obligation is sufficient.

20

Redline of Revision to “Reverse” FCA Provision

31 U.S.C. 3729 (a)(1)(G):

(~~7~~G) knowingly makes, uses, or causes to be made or used, a false record or statement material to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

21

New Definition of “Obligation”

- “Obligation,” which was previously undefined, is defined by FERA as:

“[A]n established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the **retention of any overpayment.**”

22

Legislative History – Cost Report Reconciliations

- The Committee Report notes that this provision is not intended to capture simple retention of an overpayment permitted by a reconciliation process so long as it is not the product of any willful act to increase payments to which the entity is not entitled.

S. Rep. No. 111-10, at 15

23

Legislative History – Cost Report Reconciliations

- Representative Dan Maffei (D.-N.Y.) echoed this point on the House floor during consideration of S. 386. Maffei noted:

“[T]he drafting problem we faced was avoiding language that would impose liability on research institutions or hospitals for holding on to overpayments at a time when the applicable rules would allow them to do so pending repayment through the normal process. This would include reconciliation processes established under statutes, regulations, and rules that govern Medicare, Medicaid, and all sorts of other various research grants and programs.”

155 Cong. Rec. H 5260, 5268 (daily ed. May 6, 2009) 24

Legislative History – Cost Report Reconciliations

- “Moreover, any action or scheme created to intentionally defraud the Government by receiving overpayments, **even if within the statutory or regulatory window for reconciliation**, is not intended to be protected by this provision. Accordingly, any knowing or improper retention of an overpayment as required by statute or regulation – including relevant statutory or regulatory periods designated to reconcile cost reports, but excluding administrative and judicial appeals – would be actionable under this provision.”

S. Rep. No. 111-10, at 15 (Emphasis added.)

25

Implications for Healthcare Entities to Consider

- Retention of funds during reconciliation period?
- Internal discovery of an overpayment without voluntary disclosure?
- How quickly must one act? When is an overpayment considered determined?

26

Proposed Health Reform Bill

- The House version of the health reform bill, America's Health Choices Act of 2009, provides at section 1641:
 - If a person knows of an overpayment, that person must:
 - Report and return the overpayment, and
 - Provide notice in writing to the entity to which the overpayment was returned of the reason for the overpayment.
 - The overpayment must be returned within 60 days "after the date the person knows of the overpayment."
 - Retention of the overpayment more than 60 days creates an "obligation" as defined in the FCA.

H.R.3200, "America's Health Choices Act of 2009"

27

Implications for Healthcare Entities to Consider

- What if no proactive audits or effective compliance plan – reckless w/out actual knowledge?
- Credit balance policies?
- Internal audits, including pre-RAC?
- Stark?

28

Procedural Changes

Expanded use of Civil Investigative Demands

- FERA permits the Attorney General to delegate authority for issuance of civil investigative demands, which allow requests for documents, interrogatories, and the taking of sworn testimony.
- Authority previously was vested solely in the Attorney General.

29

Procedural Changes

Government Permitted to Share CID Information with Relators and States

- FERA explicitly allows the Government to share information from CIDs with Relators.
- This could have the potential to permit Relators' use in attempting to satisfy Rule 9(b) with this information.
- The seal will not preclude the federal government from sharing the complaint, any other pleadings, or the written disclosure with any state or local government entity named as co-plaintiff.

30

Additional Potential Changes to the FCA

- False Claims Act Clarification Act and the False Claims Act Correction Act of 2009:
 - Would allow only the Government, not the defendant, to invoke public disclosure bar
 - Would eliminate requirement for relators to plead fraud with specificity under FRCP 9(b)
 - Would expand statute of limitations to 8 or 10 years
 - Would permit government employees to serve as relators (would resolve current circuit split)
- Amendment to Senate Health Reform Bill — Floor of 3x damages up to 6x damages for “Payments made by, through, or in connection with a Gateway.”

S. 458 “False Claims Act Clarification Act”
H.R.1788 “False Claims Act Correction Act of 2009”

31

Recent Compliance & Enforcement Matters

32

Pharmaceuticals and Medical Devices

- **Off-Label Promotions**

- Eli Lilly

- **Allegations:**

- Criminal and civil charges:
 - Illegally marketed one of its antipsychotic drugs (Zyprexa) for unauthorized use in patients vulnerable to risky side effects

- **Settlement:**

- \$1.4 billion, plus 5-year CIA with OIG
 - Criminal fine of \$515 M
 - Forfeit assets of \$100 M
 - \$800 M to resolve civil allegations

Dept. of Justice Press Release No. 09-038 (January 15, 2009)

33

Pharmaceuticals and Medical Devices

- **Off-Label Promotions**

- Pfizer

- **Allegations:**

- Improper marketing of Bextra painkiller and other drugs to treat acute surgical pain
- Bextra, intended to treat arthritis, was recalled in 2005 due to links to cardiovascular problems, skin infections, and other side effects

- **Settlement:**

- Proposed \$2.3 Billion settlement announced 1/27/09
- Agreement not yet approved in Federal court
- If approved, would be largest ever settlement of improper off-label marketing practices

- Pfizer executive pled guilty to charges she instructed 100 sales representatives to promote Bextra for uses rejected by FDA

Financial Times, "Pfizer to pay a record fine for off-label promotion practice" (Jan. 28, 2009)

Boston Business Journal, "Drug sales exec pleads guilty in Bextra case" (March 30, 2009)

34

Pharmaceuticals and Medical Devices

■ Off-Label Promotions – Has the Tide Changed?

□ Pfizer

■ **Allegations:**

- Promoted Lipitor in an off-label manner

■ **District Court's Ruling:**

- Violation of FDA regulations does not translate into an FCA claim
 - “It is the false *certification* of compliance which creates liability when certification is a pre-requisite to obtaining gov't benefit”
- Relator did not identify:
 - Any false claims
 - Any doctors prescribing Lipitor after reading marketing materials
 - Any pharmacists filling any such prescription

U.S. ex rel. Polansky v. Pfizer Inc., No. 04-cv-0704-ERK-SMG
2009 WL 1456582 (E.D.N.Y. May 22, 2009)

35

Pharmaceuticals and Medical Devices

■ Off-Label Promotion or Free Speech?

□ Actimmune

■ **Allegations:**

- Press release and T-shirts promoted off-label use

■ **Defendant argued:**

- Press release contained scientific speech
- Neither press release nor t-shirt qualify as “drug label”

■ **Court ruled:**

- Press release constitutes “labeling”
- First Amendment does not protect fraud
 - Speech appeared in press release, not a peer-reviewed publication
 - Speech referred to specific commercial product
 - Communication was disseminated for commercial benefit

U.S. v. Harkonen (N.D.Cal. 6-3-2009) No. C 08-00164 MHP

36

Pharmaceuticals and Medical Devices

■ Off-Label Promotions

- **Serono (\$704 M)** - Resolving alleged illegal schemes to promote, market, and sell AIDS drug Serostim, including:
 - Submission of false claims that were medically unnecessary, off-label use, and/or induced by kickbacks
 - Provision of unapproved computer software to boost increase in diagnosis of AIDS wasting condition
 - Offering financial incentives to doctors who prescribed the drug in certain amounts
- **Pfizer (\$35 M)** – alleged improper marketing of the synthetic human growth hormone Genotropin; illegally offering kickbacks to a pharmacy benefit manager

U.S. v. Harkonen (N.D.Cal. 6-3-2009) No. C 08-00164 MHP

37

FCA Settlement – Alleged Physician Kickbacks

Bayer Healthcare

■ **Allegations:**

- Paid kickbacks to induce diabetic suppliers to convert their patients to Bayer supplies
- Caused those suppliers to submit false claims
- Kickbacks were disguised as payments for advertising

■ **Settlement:**

- \$97.5 million and CIA w/ OIG

Dept. of Justice Press Release 08-1050 (November 25, 2008)

38

Billing Issues



39

2005 OIG Draft Compliance Program Guidance – Risk Areas

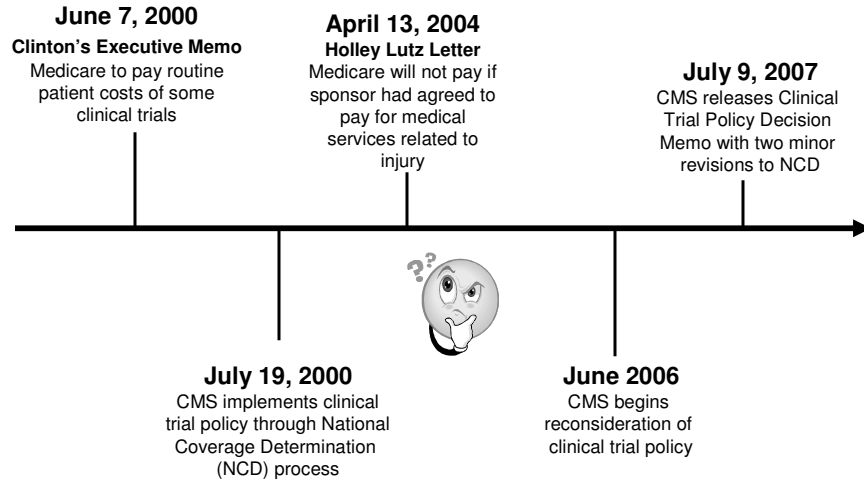
■ Synchronizing with Medicare rules

“A problem related to the ... charging of both award funds and Medicare and other health insurers for performing the same service.

This is clearly improper and has subjected institutions to fraud investigations.”

70 Fed. Reg. 71312 (Nov. 28, 2005) 40

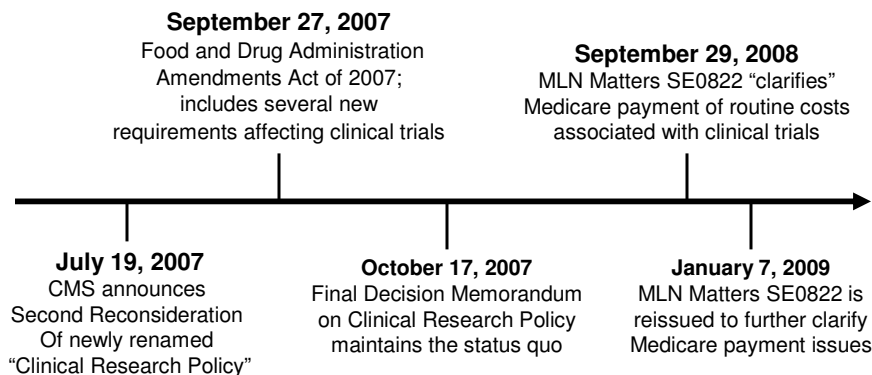
CMS Clinical Research Policy



<http://www.cms.hhs.gov/ClinicalTrialPolicies/>

41

CMS Clinical Research Policy



<http://www.cms.hhs.gov/ClinicalTrialPolicies/>

42

CMS Clinical Research Policy

- CMS Pub 100-04; Transmittal 1418; Change Request 5805 (January 18, 2008)
- New HCPCS Modifiers when Billing for Patient Care in Clinical Research Studies
 - Modifier Q0 replaces QA and QR for investigational clinical services in an approved clinical research study

43

CMS Clinical Research Policy

- Modifier Q1 replaces QV for routine clinical services in an approved clinical research study
 - Covered outside of clinical research study
 - Used for direct patient management within study
 - Do not constitute investigational clinical services
- Modifier Q0 replaces QA and QR for investigational clinical services
 - Items/services being investigated within study
 - May include items/services approved or unapproved under Medicare
- Effective Date: January 1, 2008
Implementation Date: April 7, 2008

CMS Pub 100-04; Transmittal 1418; Change Request 5805 (January 18, 2008)

44

CMS Clinical Research Policy

- CMS Pub 100-20; Transmittal 310; Change Request 5790 (January 18, 2008)
- Voluntarily Including 8-Digit Clinical Trial Number on Medicare Claims
 - Providers requested to voluntarily report the number assigned by the Nat'l Library of Medicine Clinical Trials Data Bank when a new study is registered by a sponsor or investigator
- Effective Date: April 1, 2008
Implementation Date: April 7, 2008

CMS Pub 100-20; Transmittal 310; Change Request 5790 (January 18, 2008)

45

National Coverage Determination

- **Rush University Medical Center**
 - **\$1 M settlement**
 - Among the first settlements related solely to the Medicare national coverage determination (NCD) on clinical trials
 - **Self-Disclosure Issues:**
 - Improperly billed Medicare for physician and hospital outpatient cancer research services as routine care costs under the NCD
 - Violations attributed to absence of *“synchronization of the Medicare rules, the compensation arrangements with the sponsors, and the financial discussion in the informed consent”*

Press Release, Rush Univ. Med. Ctr., Rush Settlement with Government May Help Clarify Billing Requirements for Medicare Patients in Research Studies (Dec. 8, 2005)

46

National Coverage Determination

■ **Rush University Medical Center (cont.)**

- Corrective action
 - Establish Research & Clinical Trials Admin. Office
 - Centralized office responsible for coordinating documents and information from all departments so as to develop single standardized billing guidance
 - Require a coverage analysis for clinical trials
 - Refund Medicare overpayments *plus* 50% penalty
 - 3-year Certification of Compliance Agreement

Press Release, Rush Univ. Med. Ctr., Rush Settlement with Government May Help Clarify Billing Requirements for Medicare Patients in Research Studies (Dec. 8, 2005)

47

National Coverage Determination

■ **U. of Alabama at Birmingham**

- **\$3.39 M settlement**
- **Allegations:**
 - Falsely billed Medicare for clinical research trials that were also billed to the sponsor of the research grants
 - Falsely billed Medicare for researcher's time spent on patient care when no patients had been seen
- Whistleblowers = Compliance officer, academic physician

U.S. ex rel. Gober v. UAB, No. 01-cv-00977-VEH (N.D. Ala. settlement announced 4/15/2005); *U.S. ex rel. Meythaler v. UAB*, No. 04-00112-VEH (N.D. Ala. settlement announced 4/15/2005)

48

Medicare Secondary Payer Issues

- Medicare Secondary Payer law (42 U.S.C. 1395y(b)(2)(A)(ii) (amended by MMA § 301(b)(1)):
“business . . . professional entity ‘deemed’ to have a ‘self-insured plan’ if it carries its own risks, whether by failing to obtain insurance or otherwise”
- CMS interpretation in April 2004 letter: Statement by trial sponsor that it would “pay for medically necessary services” to treat injuries related to clinical trial if patient’s insurance will not cover considered “insurance” for primary payment responsibility

49

Medicare Secondary Payer Law

- Upshot: CMS believes Medicare is payer of last resort, not clinical trial sponsor, when sponsor guarantees payment for patient care
- Requires careful language in trial agreements and in discussions with clinical trial participants
- Need CMS or Congress to clarify whether policy reflected in April 2004 letter is consistent with Congressional intent of Medicare Secondary Payer law

50

CMS Clinical Research Policy

- Clarification of Medicare Payment for Routine Costs in a Clinical Trial (MLN Matters SE0822)
 - If routine costs are furnished gratuitously (without regard to beneficiary's ability to pay & without expectation of payment from another source)
 - Medicare payment cannot be made
 - Beneficiary cannot be charged
 - If private insurers deny routine costs and provider does not pursue non-Medicare patients
 - Medicare payment cannot be made
 - Beneficiary cannot be charged

CMS Transmittal SE0822 (Sept. 29, 2008)

51

CMS Clinical Research Policy

- Clarification of Medicare Payment for Routine Costs in a Clinical Trial (cont.)
 - If routine costs are not billed to indigent non-Medicare patients, but are billed to all other patients with financial means to pay
 - Legal obligation to pay exists
 - Medicare payment may be made
 - Provider should bill non-indigent beneficiary for co-payments and deductible, but may waive payment for those with valid financial hardship

CMS Transmittal SE0822 (Sept. 29, 2008)

52

CMS Clinical Research Policy

- Clarification of Medicare Payment for Routine Costs in a Clinical Trial (cont.)
 - If a research sponsor offers to pay cost-sharing amounts owed by non-indigent beneficiaries, could be fraud and abuse
 - Nothing in Federal anti-kickback statute prohibits hospitals from waiving charges to uninsured patients of limited means, provided the waiver is not linked to generation of business payable by a Federal health care program

CMS Transmittal SE0822 (Sept. 29, 2008)

53

CMS Clinical Research Policy

- CMS clarifies September 2008 guidance in revised version of MLN Matters SE0822
 - Removes provisions contained in prior version
 - Confirms that Medicare payment may be made provided patients in the trial who have means to pay are billed
 - Makes clear that CMS does not approve arrangements where Medicare co-pays are not collected from non-indigent beneficiaries

CMS Transmittal SE0822 (January 7, 2009)

54

Medicare Secondary Payer Law

- Section 111 of Medicare, Medicaid, and SCHIP Extension Act of 2007
 - Requires on or after the first day of the calendar quarter that is 18 months after enactment of Act (*i.e.*, by July 1, 2009)
 - Submission of certain information by, or on behalf of applicable plans, including self-insurance
 - Determination of whether a patient is entitled to Medicare benefits
 - Information, including patient identity, and other information deemed necessary for coordination of benefits to the HHS Secretary
 - Failure to meet reporting requirement is subject to civil monetary penalty of \$1000 per day of noncompliance
 - Potential prosecution for the submission or causing the submission of false claims in violation of federal False Claims Act

55

Grant Management



56

2005 OIG Draft Compliance Program Guidance (CPG)

■ Risk areas

- **Examples of risk areas that have come to the OIG's attention**
 - Reporting of financial support from other sources
 - Properly allocating charges to award projects
 - Time and effort reporting
- **Not intended to be an exhaustive list**
 - For example, subrecipient monitoring may be an important risk area for those institutions that rely on subcontracts to fulfill the purposes of a PHS award

57

2005 OIG Draft CPG – Risk Areas

- **Failure to accurately and completely report support from other sources**
- **Financial certification of the PHS award application**
 - False, fictitious or fraudulent statements or claims could subject PI/Program Director and the applicant organization to criminal, civil or administrative penalties

58

FCA Decision – 3rd Circuit Court of Appeals

- **Held a medical researcher and the University of Pittsburgh subject to FCA penalties for failing to disclose information about sources of research support on NIH grant applications**

“...industry funding is relevant for assessing conflicts of interest, how much time an applicant has to devote to the requested NIH grant, and how the research fits within a broader research program...a reasonable NIH grant applicant would know that the NIH regards the information as important.”

U.S. ex rel. Cantekin v. University of Pittsburgh, 192 F.3d 402 (3d Cir.1999)

59

2005 OIG Draft CPG – Risk Areas

- **Allocating charges to award projects**
 - Examples of inappropriate activity
 - End of year transfers of direct costs on various research awards from overspent accounts to under spent accounts, with the purpose of maximizing federal reimbursement, and in some cases avoiding the refunding of unused grant proceeds
 - PIs on different projects banking or trading award funds among themselves

60

Improperly Allocating Costs and Charges to Award Projects

- Mischarging federal grants
- Inflating research grant costs
- Differentiating direct costs v. indirect costs v. cost sharing
- Cost transfers
- Charges incurred by employees unauthorized to work on project
- Inadequate accounting policies and internal controls

61

Improperly Allocating Costs and Charges to Award Projects

- **Institute for Cancer Prevention**
 - Allegations:
 - Drawing down federal grant money to pay bills ineligible for reimbursement under grants
 - Developments:
 - January 11, 2006: \$2.3 M Settlement
 - January 2, 2008: Former CFO Roy Victor pleaded guilty to obstruction of justice for repeatedly lying to federal agents concerning false statements used by the Institute in obtaining research grants from the federal government

DOJ Press Release: *U.S. Settles Civil Charges Against Former President of the Institute for Cancer Prevention, and Other Related Parties*, (Jan. 11, 2006); *Ex-CFO of Institute for Cancer Prevention Pleads Guilty in White Plains Federal Court to Obstruction of Justice* (Jan. 2, 2008)

62

Improperly Allocating Costs and Charges to Award Projects

■ Other Reported Investigations and Settlements

- University of Chicago (June 2006)
- Weill Medical College of Cornell University (\$4.3 M, June 2005)
- Mayo Foundation (\$6.5 M, May 2005)
- University of Alabama at Birmingham (\$3.39 M, Apr. 2005)
- East Carolina University – OIG Audit (\$2.3 M at risk, Aug. 2004)
- Harvard/Beth Israel Deaconess Medical Center (\$2.4 M, June 2004)

63

Improperly Allocating Costs and Charges to Award Projects

■ Other Reported Investigations and Settlements (cont.)

- Johns Hopkins University (\$2.6 M, Mar. 2004)
- Northwestern University (\$5.5 M, Feb. 2003)
- Thomas Jefferson University (\$2.6 M, May 2000)
- Beth Israel Deaconess Medical Center (\$920 K, Apr. 1999)
- New York University Medical Center (\$15.5 M, Apr. 1997)

64

University of Chicago

- Cost transfers: “*after-the fact reallocation of costs, either labor or non-labor, to a federally funded award/grant*”
- OIG found
 - Procedures for cost transfers at the University were not always followed. Several transfers:
 - Lacked required documentation explaining how error occurred; or,
 - Lacked proper authorization form for University oversight and approval.
- No fine assessed

HHS, OIG “*Audit of Cost Transfers Funded Under NIH Grants at the University of Chicago*” (A-05-05-00047) June 16, 2006

65

Mayo Foundation

- **\$6.5 M settlement**
 - **Allegations:**
 - Improper cost transfers from overspent grants and internal cost centers to underspent grants
 - Inappropriately charged grant for costs unrelated to research sponsored by the grant
 - “Mayo had an accounting system unable to monitor and manage charges made to federal grant awards in the manner required by federal law”

Whistleblower = former accounting associate

U.S. ex rel. Long v. Mayo Foundation, No. CV02-522-ADM/SRN (D. Minn. settlement announced May 26, 2005)

66

Harvard/Beth Israel Deaconess Medical Center

■ **\$2.4 M settlement**

□ **Allegations:**

- Harvard/BIDMC improperly billed 4 NIH grants \$1.9 M over 5-yr period

□ **Examples of alleged inappropriate activity**

- Salaries inappropriately paid for researchers who did not work on the grants
- PI salary charged to grants in excess of budgeted amounts
- Supply and equipment expenses incurred for projects unrelated to the grants
- Additional expenses incurred
 - By researchers who were not eligible to work on or who did not work on the grant
 - For research animals used for unrelated projects

www.taf.org/settlements/harvard.pdf

67

2005 OIG Draft CPG – Risk Areas

■ **Time and effort reporting**

□ **Examples of inappropriate activity**

- A researcher separately reports to 3 awarding agencies that he intends to spend 50% of his time on each of the 3 awards
- An institution reports to the awarding agency that 70% of a researcher's time would be spent on an award when 50% of the researcher's time would be spent on clinical responsibilities

68

2005 OIG Draft CPG – Risk Areas

■ Time and effort reporting (cont.)

□ Accurate and consistent treatment of institutional based salary (IBS)

- IBS serves as the denominator in calculating the proportion of an employee's activity that is allocated to a particular federal award
- Typically includes only non-clinical work –
 - However, certain institutions include clinical work based on an expansive definition of the "institution" for cost reporting purposes
 - Correct salary allocation is critical

69

Time and Effort Reporting

- Proposed effort v. available effort v. charged effort v. documented effort
 - Relationship between research effort reporting and Medicare time studies and time allocations
- Objectives:
 - Research: Allocate individual physician effort and salary related costs to specific grants
 - Medicare: Identify portion of aggregate physician compensation costs to be claimed as allowable "Part A" teaching and administrative service costs
- Procedures:
 - Research: "Effort" report = total effort in relevant period
 - Medicare: Two week per quarter or one week per month "snapshot" of physician activities
- Compliance Issues:
 - Unrealistic to expect 100% consistency
 - Examine material differences

70

Time and Effort Reporting

- Reported Investigations and Settlements
 - University of Alabama at Birmingham (\$3.39 M, Apr. 2005)
 - Johns Hopkins University (\$2.6 M, Mar. 2004)
 - Northwestern University (\$5.5 M, Feb. 2003)
 - East Carolina University – OIG Audit (\$2.3 M at risk, Aug. 2004)
 - Florida Int'l University – OIG Audit, subsequent Investigation (\$11.5 M, Feb. 2005)
 - Yale University – OIG Audit (\$193,779 at risk, Feb. 2006)
 - Northeastern University (\$5.5 M, June, 2003)

71

Time and Effort Reporting

- **Johns Hopkins University**
- **\$2.6 M settlement**
 - **Allegations:**
 - Overstated percentage of effort; falsely reported T/E of employees who did not work on grants
 - Failed to maintain adequate compliance mechanisms to reconcile proposed effort commitments with actual effort
 - **Whistleblower = office supervisor**

U.S. ex rel. Grau v. Johns Hopkins University, No. 99-1448 (D. Md. Feb. 26, 2004)

72

Time and Effort Reporting

- East Carolina University
- **OIG Audit (Aug. 2004): \$2.3 M at Risk**
 - Interim audit of costs claimed for reimbursement over a 4-year period under a National Library of Medicine (NLM) contract
 - **OIG Findings included: inappropriate charges for salaries wages and fringe benefits**
- **Specific OIG Findings**
 - T/E reports based on inconsistent methods (% of T/E; hours worked; others)
 - No requirement for timely submission of T/E reports
 - No procedure to reconcile T/E reported to actual payroll distribution
 - No procedure to compare T/E reported to approved funding levels

<http://oig.hhs.gov/oas/reports/region4/40401001/htm>

73

Sub-recipient Monitoring

- Referenced as risk area in 2005 OIG draft CPG
- **Reported Investigations and Settlements**
 - Boston University Audit (Sept. 28, 2006)
 - **Sub-grant management:**
 - Two salary cost transfers totaling \$7,196 not authorized or adequately supported
 - Over \$4,000 indirect costs unallowable
 - Failure to submit final invoice to prime grantee within 45 days of the end of the budget period

<http://oig.hhs.gov/oas/reports/region1/10601500.htm>

74

Indirect Cost Rate Issues

- Reported Investigations and Settlements
- University of Connecticut (\$2.5 M)
 - **\$2.5 M settlement**
 - **Allegations:**
 - Failure to utilize proper basis for setting and updating billing rate structure
 - Failure to follow federal law for calculating how extra compensation is paid to faculty working on grant-supported research
 - Failure to provide University cost sharing and matching where appropriate
 - **500 Federal Grants (1997-2004) involved**

DOJ Press release, <http://www.usdoj.gov/usao/ct/Press2006/20060109.html>

75

Indirect Cost Rate Issues

- Reported Investigations and Settlements
- **New York University Medical Center**
 - \$15.5 M settlement
 - **Allegations:**
 - NYU falsely inflated indirect cost rate information by submitting
 - Substantially lower dollar figures for voluntary cost sharing than those reflected in internal documents and consultants' reports
 - Duplicate claims for the same utility costs and certain environmental services costs
 - Unallowable expenses for entertainment costs and capital interest
 - Overstated costs for housekeeping expenses based on budgeted expenses rather than actual costs

U.S. ex rel. Emmanuel Roco v. NYU Medical Center, No. 93-8012 (D.C. S. NY Apr. 7, 1997)

76

Indirect Cost Rate Issues

- **New York University Medical Center (cont.)**
- **Additional allegations**
 - Inconsistent allocation of direct / indirect costs
 - Over-allocation of costs
 - Use of outdated space survey
 - Failure to verify that grant was not charged for effort that was separately compensated by another entity
- **Whistleblower = Former hospital finance employee**

U.S. ex rel. Emmanuel Roco v. NYU Medical Center, No. 93-8012 (D.C. S. NY Apr. 7, 1997)

77

Indirect Cost Rate Issues

- **Boston University**
- Claimed \$11,234 in salary and costs that did not comply with Federal regs and the terms of the subaward
 - Salary cost transfers were
 - Not supported by certified time and effort reports
 - Not properly authorized, explained, or supported
 - Made 85 days after the deadline specified in the subaward
- **OIG recommendations:**
 - Comply with requirements to ensure that cost transfers are properly authorized and documented
 - Establish controls to ensure that final invoices are submitted promptly
 - Work with the prime grantor to resolve the money received from NIH for inappropriate cost transfers

OIG Audit "Review of Subaward Costs Claimed by Boston University on NIH Grant Number 5 U01 HL066582-04 and 3 U01 HL066582-04S1 From August 1, 2003, Through July 31, 2005," (A-01-06-01500) 78

Which Indirect Cost Rate Applies to Continuing Grants?

- Colleges and Universities:

- OMB Circular A-21:

- *Federal agencies shall use the negotiated rates for F&A costs in effect at the time of the initial award throughout the life of the sponsored agreement*

<http://rates.psc.gov/fms/dca/c&u.html>

79

Which Indirect Cost Rate Applies to Continuing Grants?

- Hospitals:

- SHHS Guide OASC-3:

- *...indirect costs will be awarded using the latest established indirect cost rate applicable to the period of performance of the award*
 - *When a grant or contract period does not coincide with the hospital's fiscal year, two indirect cost rates are used, one for each of the hospital's fiscal years in which the award is performed.*
 - *...indirect cost rates established for the period in which direct expenditures are actually made are applied to those expenditures.*

<http://rates.psc.gov/fms/dca/hospital.html>

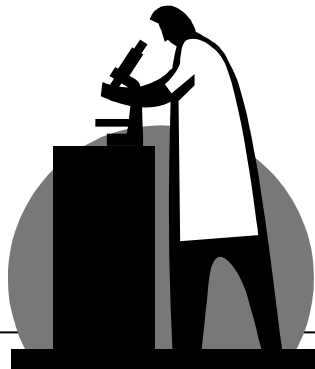
80

Indirect Cost Rate Issues

- Recent NIH Self-Disclosure Matter:
- Self disclosure to the NIH concerning the use of incorrect, indirect cost rates on NIH grants over multiple years

81

Scientific Misconduct, Financial Conflicts of Interest, and Informed Consent Improprieties



82

Quality Improvement and Human Subject Research

- Determination by HHS Office of Human Research Protection (OHRP) raises important issues
 - July 19, 2007 OHRP issued “Determination Letter” to Johns Hopkins University
 - Faulted JHU for conducting non-exempt human research (quality improvement assessment/research) without
 - Institutional Review Board (IRB) approval
 - Informed Consent

83

Quality Improvement and Human Subject Research

- Factual Background:
 - Keystone: ICU Project
 - Grant from Agency for Healthcare Research and Quality to develop and implement intervention to improve quality and safety of ICU healthcare services
 - OHRP received a complaint about Keystone after publication of results of a successful intervention to reduce bloodstream infections

84

Quality Improvement and Human Subject Research

■ Factual Background (cont.)

- JHU described project as “research” involving human subjects in AHRQ grant application
- project involved testing an intervention, not just collection of study data or medical records/documents
- data, medical records/documents collected and studied did not exist until after “research” proposed to IRB

85

Quality Improvement and Human Subject Research

- OHRP found that QI study was human subject research under 45 CFR 46.101 and 46.102
 - Not “exempt” under 45 CFR 46.101(b)(4)
- Follow-up response from JHU
- Press criticism from noted surgeon and commentator, Dr. Atul Gawande (12/10/07 article in The New Yorker and 12/30/07 op-ed in the New York Times)
- Ultimately, OHRP allowed the QI assessment to proceed as a “non-research” activity
 - Confusion remains about OHRP policy and actions

[http://www.newyorker.com/reporting/2007/12/10/071210fa_fact_gawande:](http://www.newyorker.com/reporting/2007/12/10/071210fa_fact_gawande)
http://www.nytimes.com/2007/12/30/opinion/30gawande.html?_r=1&oref=slogin

86

Quality Improvement and Human Subject Research

■ Lessons Learned:

- Analyze QI interventions against OHRP regulatory requirements
 - 45 CFR §§ 46.101 - 46.103
- Consider exemptions and expedited IRB review
 - <http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc95-02.htm>
- Analyze QI interventions against OHRP Research Engagement Guidance
 - <http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm>

87

Enforcement Trends

■ FDA Warning Letters

- West Jefferson Medical Center IRB (Feb. 25, 2008)(Division of Scientific Investigations)
 - IRB failed to excuse an IRB member from participating in the initial review of a project in which the member had a conflicting interest
 - Failed to develop and maintain certain policies
 - Failed to determine at time of initial review whether studies involving children were in compliance with Additional Safeguards for Children in Clinical Investigations. See 21 CFR 56.109(h)

88

Enforcement Trends

- FDA Warning Letters (cont.)
 - Center for Spinal Disorders (July 3, 2007)(Center for Devices and Radiological Health, Office of Compliance)
 - Failure to adhere to informed consent requirements
 - Failure to conduct investigation in accordance with the study agreement, the investigational plan and applicable FDA regulations
 - Some subjects didn't meet inclusion criteria (age)
 - Adverse device effects not reported to sponsor or to IRB

89

Scientific Misconduct, Financial Conflicts of Interest, and Informed Consent Improprieties

- Other Reported Investigations and Settlements
 - University of Pennsylvania and Children's Nat'l Medical Center (\$1 M, 2005) (Jesse Gelsinger case)
 - Grimes v. Kennedy Krieger Institute (private settlement)
 - University of Minnesota (\$32 M)

90

OIG Compliance Guidance

- 1991 Report: “*Promotion of Prescription Drugs through Payment and Gifts*”
- 1992 Report: “*Prescription Drug Promotion Involving Payments and Gifts: Physicians’ Perspectives*”
- 1994 Fraud Alert: Drug industry marketing practices
- 1996 letter: Physician investment in medical device companies is subject to close scrutiny and “regular” rules about investments by referral sources
- 2003 CPG for pharmaceutical manufacturers
- 2008 OIG Report: NIH does not receive sufficient information to provide an accurate count of COI incidents, the nature of the COIs reported, or how they were managed; NIH should obtain this information from grantees

91

Scientific Misconduct; Financial Conflicts of Interest; and Informed Consent Improprieties

- **Continued Prevalence of Financial Relationships Between Industry and Academic Institutes:**
 - Eric G. Campbell, PhD, et al., *Institutional Academic–Industry Relationships*, 298 JAMA 1779 (2007)
 - David M. Studdert, et al., *Financial Conflicts of Interest in Physician’s Relationships with the Pharmaceutical Industry – Self-Regulation in the Shadow of Federal Prosecution*, 351 NEJM 1891-1900 (2004)

92

HHS Guidance

- HHS, *Financial Relationships and Interest in Research Involving Human Subjects: Guidance for Human Subject Protection* (61 Fed. Reg. 15,456, March 31, 2003)
- HHS, OIG, *National Institutes of Health: Conflicts of Interest in Extramural Research* (OEI-03-06-00460, January 17, 2008)

93

NIH Standards

- NIH grantee institutions must have a written policy to address COI
 - Policy for identifying COI, as well as managing, reducing or eliminating identified COI
 - Grantee must certify compliance before funds are spent
 - Regulations: 42 CFR Part 50, Subpart F
- Findings of OIG Report (January 2008) -- NIH: Conflicts of Interest in Extramural Research
 - NIH did not receive sufficient information to provide an accurate count of COI incidents, the nature of the COIs reported, or how they were managed

94

Recent NIH Action – Emory University

- Allegations:
 - Emory University psychiatry professor did not report \$1.2 M in payments from Glaxo for research into Glaxo drugs
 - Emory failed to take action after conducting internal inquiry
- Committee led by Sen. Grassley investigated
- NIH Response:
 - For all future NIH awards, Emory must submit an institutional assurance of compliance that includes:
 - List of every participating Investigator
 - Assurance that for each Investigator, a Report of Financial Interests in Research is on file
 - “Investigator” = Any individual in the grant budget or any person whose biographical sketch is in the application
 - Description of the financial interest and actions taken by Emory to manage, reduce, or eliminate conflict of interest

www.pharmalot.com/2008/10/nih-requires-emory

95

FDA Standards

- Applications to the FDA relating to new drugs, biological products and devices must disclose completely, or include certifications concerning, the financial interests of all clinical investigators:
 - Compensation affected by the outcome of the study
 - Significant equity interest in the sponsor (ownership, stock options, or similar interests)
 - Proprietary interest in the tested product (patent, trademark, copyright, licensing agreement)
 - Significant payments by the sponsor (research grant, equipment, consultation fees, honoraria)

96

IRB Issues

- Regulations: Requirement to assure that IRB members who review research have no COI
- DHHS Guidance for Institutions, Investigators and IRBs (2004): Non-Binding
 - Questions for consideration: Does the research involve financial relationships that create actual or potential COI? Do methods for management of the COI adequately protect human subjects?
 - Potential action to manage COI: Establish conflict of interest committee to define and manage institutional and individual COI, determine disclosure to patients

97

AAMC: Recent Major Developments

- February 2008: Joint Report of the Association of American Medical Colleges (AAMC) and the Association of American Universities (AAU)
 - Reporting and managing financial conflict-of-interest in human subjects research
 - Refinements of principles presented in 2001, 2002
 - "Time is of the essence" in fully implementing comprehensive COI programs in research
 - Covers institutional and individual COI
- June 2008: AAMC Task Force Report
 - Industry gifts/funding of medical education, with broad implications for clinical research and practice of medicine

"Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research"; "Industry Funding of Medical Education: Report of an AAMC Task Force"

98

Industry Guidance

- Pharmaceutical Research and Manufacturers of America (PhRMA), *Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results* (June 2004):
 - Protecting research participants
 - Conduct of clinical trials
 - Ensuring objectivity in research
 - Disclosure of clinical trial research
- PhRMA Statement on Clinical Trial Integrity (April 2008):
 - Essential that clinical trials be conducted as ethically as possible
 - Unfair to suggest manufacturer-sponsored trials inherently biased
 - Trial data should be made available to all healthcare stakeholders

<http://www.phrma.org/files/Clinical%20Trials.pdf>

PhRMA Press Release: "PhRMA Statement on Clinical Trial Integrity" (April 14, 2008)

99

Implications of Recent Developments

- Consider review and modification of policies that
 - Foreshadow FDA responses to OIG report including compliance required of
 - Sponsors, and Investigators as Sponsors
 - IRBs
 - Investigators
- Prepare for new AAMC standards for managing relationships and COI disclosure in clinical studies, as well as education

100

Address COI Now!

- Given the spotlight placed on COI, every institution involved in human subject research should develop and implement policies and procedures for identifying, disclosing, managing and monitoring COI
- The particular plan adopted may vary depending on the size, resources and risk-profile of the institution, but institutions who delay the inevitable are at risk

101

Where is an Institution to Begin?

- Adapt to your setting --
 - Definition of COI; covered persons under the policy
 - Identify your areas of vulnerability for COI
 - Systems for collecting an accessible database of COI disclosures, monitoring management plans
 - COI committee membership and jurisdiction
 - COI management plan ideas, monitoring techniques
 - Bring together needed participants: Who do you need at the table?
 - Educate all stakeholders

102

Where is an Institution to Begin?

- The AAMC-AAU Report contains helpful information to use as a starting point:
 - Appendix A: Model Policy on Institutional Conflict of Interest in Human Subjects Research
 - Appendix B: Analyzing Cases Involving Potential Conflicts of Interest in Human Subjects Research -- Template and Compendium of Cases
 - Appendix C: Definition of Financial Interests in Research
 - Appendix D: Institutional Policies and Practices on Consulting -- Topics and Questions to Consider
- Many research institutions have revisited and publicized their COI policies

103

Provider Industry Response

- **Adoption of comprehensive conflict-of-interest policies**
 - Stanford School of Medicine (<http://med.stanford.edu/coi/>)
 - Disclosure of even "*de minimus*" conflicts; closer scrutiny of more significant financial interests
 - Cleveland Clinic (<http://www.clevelandclinic.org/aboutus/pdf/COI.pdf>)
 - Disclose existing, potential, and past personal interests "that may result in a Conflict of Interest"
 - SMDC Health System
 - Limits access to clinics by drug company representatives
 - "Clean Sweep" roundup of drug trinkets
(Steve Karnowski, *Minn. Health System Purges Drug Trinkets*, Hartford Courant (Jan. 19, 2008) at http://www.courant.com/news/health/ats-ap_health11jan19_0_3850677_story)
 - Univ. of Southern California Keck School of Medicine
 - Maintain a "culture of ethics"; provide guidelines for interaction with industry
(http://www.imapny.org/usr_doc/Policy_Regarding_RelationshipsUSC7.pdf)
 - Duke University School of Medicine
 - COI reporting through interactive, online reporting form
(http://medschool.duke.edu/wysiwyg/downloads/COI_Policy_2008_01_10_FINAL.pdf)

104

Merck CIA (February 2008)

- **Mandatory policies and procedures must address:**
 - Consultant arrangements entered into with health care professionals (speaker programs, speaker meetings, advisory board meetings, training programs, colloquiums, roundtables and forums) to assure such arrangements and related events are used for legitimate and lawful purposes
 - Funding of grants (including educational grants)
 - Sponsorship or funding of research
 - Assurance that individuals do not receive financial incentives for the improper promotion, sale and marketing of Merck's products

105

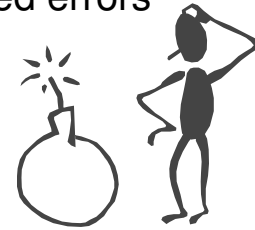
Cephalon CIA (September 2008)

- **Allegation:** Cephalon marketed drugs for uses not approved by the DFA
- **Resolution:** Cephalon paid \$425 M and entered into 5-year Corporate Integrity Agreement with the OIG
- **The CIA requires Cephalon to post payments made to doctors on its web site**

U.S. Dept. of Justice Press Release, Sept. 29, 2008 106

Assessing and Minimizing Risks

- Three C's: Compliance, Compliance, and Compliance
- Obtain OIG/CMS Advisory Opinions in appropriate circumstances
- Proactively self-disclose identified errors
- Avoid the negative publicity



107

Questions



108