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"Clinical Research Enforcement Initiatives and False Claims Act Update Relevant to Academic Medical Centers"

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Gary W. Eiland, Partner
King & Spalding
Houston, Texas

What We'll Cover

- Compliance and Enforcement Authority Post-FERA and PPACA
- Enforcement Actions, Qui Tam Litigation and AMC Settlements
- Clinical Research Compliance Risks
- Enforcement Initiatives and Cost Settlements
- Internal Compliance and Minimizing FCA Risks

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Compliance and Enforcement Authority Post-FERA and PPACA

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The FCA is the Fraud Enforcement Vehicle of Choice

- Recent efforts made by the DOJ's Health Care Fraud Prevention and Enforcement Action Team ("HEAT"), FCA's public disclosure bar and other fraud enforcements helped FY 2010 fraud recoveries.
  - $2.5 B in health care fraud recoveries
  - $4.6 B in FCA recoveries
  - $2.3 B in lawsuits under FCA's *qui tam* provisions
  - Since 1986, more than $27 B in recoveries

Press Release, Dep't of Justice, Department of Justice Recovers $3 Billion in False Claims Cases in Fiscal Year 2010 (Nov. 22, 2010)

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The FCA is the Fraud Enforcement Vehicle of Choice

- But see Senator Charles E. Grassley letter to DHHS Secretary Kathleen Sebelius and Attorney General Eric H. Holder, Jr. (Dec. 17, 2010)
- Are DOJ and DHHS using increased federal funding wisely, efficiently, and promptly to combat healthcare fraud?
- Requested significant statistical data from DOJ and DHHS

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Qui Tam Relators

- The federal False Claims Act is a *qui tam* statute, meaning that private citizens ("relators") may file complaints alleging violations of the FCA under seal on behalf of the U.S. Government and receive up to 30% of any amount recovered by the Government.
- Once a whistleblower files a suit, the Department of Justice must decide whether to "intervene" (i.e., take over and prosecute the suit).
- If the government does not intervene, the case is unsealed and the whistleblower may proceed on his/her own with some Government monitoring.

31 U.S.C. § 3730(b) 6

Public Disclosure Bar Evolution

- In 1943, Congress amended the FCA to jurisdictionally bar "parasitic relators" by prohibiting suits based on information in the Government's possession.
- In 1986, Congress revised the jurisdictional bar to encourage *qui tam* suits by removing the Government possession concept. Nevertheless, it sought to balance encouraging true whistleblowers with preventing parasites, so it added the "Public Disclosure Bar."
- March 23, 2010, PPACA sought to make it easier for DOJ & relators to avoid the operation of the Public Disclosure Bar.

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PPACA Changes — "Public Disclosure"

- **No longer stated in terms of a jurisdictional bar.**
  - More vigilance required early; must be in an answer or dispositive motion or may be waived.
- **The court is not required to dismiss a relator's action if the Government opposes a defendant's motion to dismiss.**
- **Revision of the definition of "publicly disclosed":**
  - Information only from "Federal" proceedings "in which the Government or its agent is a party";
  - Information only from a "Federal report, hearing, audit or investigation";
  - "News media" remains the same.
    - No definition of "news media"
    - Consider press release regarding overpayment refunds and self-disclosures

§ 10104(j), Effective March 23, 2010 8

Redline of Changes to Public Disclosure Bar

(A) ~~No~~**The** court shall ~~have jurisdiction over~~**dismiss** an action **or claim** under this section ~~based upon~~**, unless opposed by** the ~~public disclosure of~~**Government, if substantially the same** allegations or transactions **as alleged in the action or claim were publicly disclosed--**

(i) in a **Federal** criminal, civil, or administrative hearing**, in which the Government or its agent is a party;**

(ii) in a congressional, ~~administrative, or Government Accounting~~**Government Accountability** Office**, or other Federal** report, hearing, audit, or investigation~~,~~**;** or

(iii) from the news media,

unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

§ 10104(j), Effective March 23, 2010 9

Redline of Changes to Public Disclosure Bar

(B) For purposes of this paragraph, "~~,~~original source~~,~~" means an individual who ~~has direct and independent knowledge of~~ **either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government** the information on which ~~the~~ allegations **or transactions in a claim** are based**, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions,** and **who** has voluntarily provided the information to the Government before filing an action under this section ~~which is based on the information~~.

§ 10104(j), Effective March 23, 2010 10

PPACA Changes — "Original Source"

- **PPACA modifies the original source requirement:**
  - Only requires a relator to have "knowledge that is independent of and materially adds to the publicly disclosed allegations," which omits the prior requirement that the knowledge be "direct and independent of . . . the information on which the allegations are based."
  - "Independent knowledge" and "materially adds" are undefined.

§ 10104(j), Effective March 23, 2010 11

Public Disclosure Bar

- **Goldberg v. Rush University Medical Center**
  - Allegations:
    - FCA violations by billing Medicare and Medicaid for procedures done by residents who were not supervised by faculty physicians.
  - PATH audit initiative constituted prior public disclosure
  - Resolution: The Northern District of Illinois dismissed FCA action based upon the public disclosure bar and relators were not original sources
  - FCA filed by former employee & a faculty member

Goldberg v. Rush Univ. Medical Ctr., No. 04 C 4584 (N.D. Ill. Nov. 2, 2010); Adam Robison, *Federal Court Dismisses FCA Action Against Teaching Hospital and Faculty Physicians Finding Allegations Publicly Disclosed Through Government's PATH Initiative*, http://www.kslaw.com/News-and-Insights/PublicationDetail?us_nsc_id=4190 12

Expanded Definition of "Claim"

- The Fraud Enforcement and Recovery Act of 2009 (FERA) modified 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,**…"

31 U.S.C. § 3729(b)(1)(2) 13

Expansion of FCA Liability for Retention of Overpayment Obligation

- This may be the single most significant development for the healthcare industry
- The FERA amendments to the FCA in 2009 expanded liability for overpayments by amending section 3729(a)(7).
- Previously, a "false claim, record, or statement" was required to violate the FCA. Now, "knowing" and "improper" concealment or avoidance of an obligation is sufficient.
- Under FERA, if one knowingly and <u>improperly</u> retains an overpayment from the Government, there is potential liability.
- "Improperly" is not defined

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Expansion of FCA Liability for Retention of Overpayment Obligation

- The FERA amendments added a definition of "obligation" to mean: "an established duty, whether or not fixed, arising from . . . the retention of any overpayment."
- The FCA's requirement to report and return overpayments is linked to the new definition of "obligation" in the statute.

§ 6402, Effective March 23, 2010 ; 31 U.S.C. 3729(b)(3) 15

FERA Legislative History – Cost Report Reconciliations

- The FERA Committee Report notes that this provision is not intended to capture interim retention of an overpayment permitted by a reconciliation process so long as it is not the product of any willful act to increase interim payments to which the entity is not entitled
- "This would include reconciliation processes established under statutes, regulations, and rules that govern Medicare, Medicaid, and various research grants and programs."

155 Cong. Rec. H 5260, 5268 (daily ed. May 6, 2009);
S. Rep. No. 111-10, at 15 (March 23, 2009) 16

Overpayment Obligation – 60 Day Time Period

- PPACA states:
  - Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of section 3729 of such title.
- This section does not add a new liability provision to the FCA but stipulates with only limited detail the procedural steps and time period to report and return an identified overpayment obligation in order to avoid potential FCA liability.

§6402; 31 U.S.C. 3729(b)(3) 17

Overpayment Obligation – 60 Day Time Period

- PPACA provides a 60-day deadline for **reporting and returning** overpayments.
- The deadline is the later of:
  - (A) the date which is 60 days after the date on which the overpayment was identified;
    or
  - (B) the date any corresponding cost report is due, if applicable.
- Effective for overpayments "identified" as of the March 23, 2010 PPACA enactment date
  - Initial reports would have been due on May 22, 2010

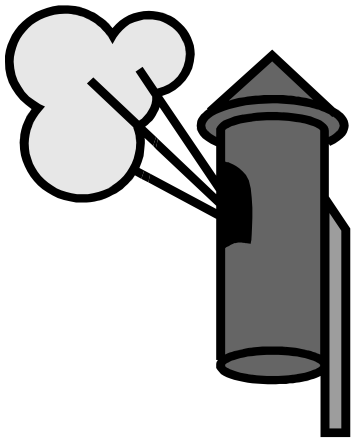
§ 6402, Effective March 23, 2010 18

Implications for Academic Medical Centers 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 identified?
  - The OIG Provider Self-disclosure Protocol suggests disclosure within 60 days of determining credible evidence of overpayment

OIG Provider Self-disclosure Protocol, 63 Fed. Reg. 58399 (Oct. 21, 1998) 19

Enforcement Actions, Qui Tam Litigation and AMC Settlements



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Recent FCA settlement affecting AMCs

- LSU Health Sciences Center-Shreveport
  - **Allegation:**
    - LSUHSC routinely submitted claims to Medicare on behalf of teaching physicians who were not actually present for the procedures as required
  - Settlement:
    - LSUHSC paid $706,779 but denied liability
    - 3-yr Certificate of Compliance Agreement
  - Whistleblowers:
    - A teaching physician and an orthopedic head nurse
- Per DOJ Press Release, LSUHSC submitted the Part B claims to Medicare and divided reimbursements between hospital & teaching physicians.

www.usdoj.gov/usao/law (July 1, 2009) 21

Recent FCA settlement affecting AMCs

- Kaiser
  - **Allegation:**
    - Improperly billed Medicare and Medicaid over a 7-year period for services the company claimed were provided by teaching physicians
  - Settlement:
    - $3.75 M
  - Kaiser voluntarily disclosed the misconduct

http://www.dailymail.com/ap/ApTopStories/200912041003 (Dec. 4, 2009) 22

Recent Settlements

Detroit Medical Center

- **Allegations:**
  - Engaged in improper financial relationships with referring physicians
  - Office leases, medical director, and other agreements without written and executed agreements for the entire term ("gap arrangements")
  - FMV issues; excess "business courtesies;" signage; and advertising and biographical materials
  - Employed physicians E&M coding issues

DOJ Press Release, December 30, 2010 23

Recent Settlements

Detroit Medical Center (cont.)

- **Background**:
  - One of first self-disclosures involving suspect physician financial arrangements subsequent to Sept. 9, 2010 CMS Stark Law Self-Disclosure Protocol
  - Resolved in record time to facilitate closing of sell of Detroit Medical Center to Vanguard Health System
- **Settlement**:
  - $30 Million
  - No admission of liability or imposition of CIA or CCA

DOJ Press Release, December 30, 2010 24

Senate Finance Committee Statement

- Maryland cardiologist accused of implanting nearly 600 unnecessary stents
- The relationship between the cardiologist and Abbott Laboratories, the manufacturer of the stents, was put into question. The company paid for events held by the cardiologist and hired him as a consultant once he was relieved of his duties at St. Joseph Medical Center (Towson, MD)
- Medicare paid $3.8 million for the alleged improper stent implantations.

Sarah Barr, Doctor's Improper Stent Implantations Cost Medicare Millions, Finance Probe Reveals, BNA's Healthcare Daily Report (Dec. 8, 2010). 25

Kyphoplasty Investigation

Kyphoplasty Services

- **Allegations:**
  - Hospitals billed Medicare (2000-2008) for short stay inpatient kyphoplasty procedures
  - Services should have been billed as less costly and more clinically appropriate outpatient procedures
- **Settlement:**
  - Seven hospitals in six states agreed to pay U.S. $6.3 million
  - This settlement follows the 18 other kyphoplasty-related Medicare claim settlements reached in 2009 and 2010
  - And the $75 million settlement in May 2008 with Medtronic Spine LLC, corporate successor to Kyphon Inc.
- Investigations continuing under initial qui tam case filed in W.D. NY and in other copy-cat qui tam actions

Georgeann Edford, *The DOJ Initiative on Kyphoplasty*, Aspen Reimbursement Advisor, Aug. 2010, 1-2, 6-12.
DOJ Press Release, January 4, 2011 26

ICD Investigation

- The DOJ is conducting investigations into billing compliance related to implantable cardiac defibrillators ("ICDs").
- Medicare reimbursement to a hospital for a ICD implantation ranges from $40,000 to $50,000.
- Medicare investigative course of action:
  - Initially served CIDs; now using less formal "cooperative approach" to facilitate review and discussion of questioned ICD claims
  - Assessment of patient procedures under NCD
  - Compliance with new Medicare claims process which came into effect August 2010.
  - Extensive review of documents related to billing, coding, payments, reimbursement, etc.
  - Subpoenas to ICD manufacturers

Dennis M. Barry, *Investigation of Hospital Billing for Implantable Cardiac Defibrillators (ICDs),* King & Spalding Health Headlines, Apr. 26 2010, http://www.kslaw.com/News-and-Insights/PublicationDetail?us_nsc_id=2435; Beverly F. Lorell, *CMS Coverage Criteria for Implantable Cardiac Defibrillators,* Aspen Reimbursement Advisor, Jan. 2011, at 1-2, 8-12.

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Other Enforcement Issues – Off-Label Use

- **Settlements**
  - Pfizer (Bextra) ($2.3 B) (2009)
  - Eli Lilly settlement (Zyprexa) ($1.4 B) (2009)
  - Serono (Serostim) ($704 M) (2005)
  - Pfizer (Genotropin) ($35 M) (2007)
  - Otsuka Pharmaceutical Co. Ltd. (Abilify) ($4 M) (2008)
  - Allergan Inc., (Botox) ($600 M) (2010)
  - Novartis Pharmaceuticals Corp. (Trileptal) ($422.5 M) (2010)
  - Elan Corp. PLC, (Zonegran) ($203.5 M) (2010)
  - Forest Laboratories Inc. (Lexapro and Celexa) ($313 M) (2010)

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Clinical Research Compliance Risks

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CMS/OIG Clinical Research Focus

- **FY 2011 OIG Work Plan initiatives:**
  - Review college and university compliance with select cost principles
  - Review colleges and universities recharge centers compliance with cost rate schedule standards
  - Review data in clinical trials monitored by the Data and Safety Monitoring Boards (DSMB)
  - Analyze the scope of grantee compliance with NIH policies of multisite clinical trials

HHS, Office of Inspector General Work Plan 2011 30

CMS/OIG Clinical Research Focus

- **November 2009 OIG Report:**
  - 90% of grantee institutions rely solely on researcher discretion to determine whether their financial interestes must be reported
  - Majority of grantees do not have policies or procedures addressing subcontractee compliance with federal conflicts rules
  - Grantee institutions do not routinely verify information submitted by researchers
  - Grantee institutions rarely reduce or eliminate researchers‘ financial conflicts of interest

"How Grantees Manage Conflicts of Interest in Research Funded by the National Institutes of Health," OEI-03-07-00700, November 2009

CMS/OIG Clinical Research Focus

- **OIG Recommendations:**
  - Oversight of grantee institutions should be increased to ensure conflicts of interest are reported and managed appropriately
  - Grantee institutions should be asked to provide details to NIH of how conflicts of interests are managed, reduced, or eliminated
  - Grantee institutions should be required to collect information on <u>all</u> significant financial interests, not just those deemed relevant by researchers
  - NIH should develop regulations addressing institutional financial conflicts of interest

"How Grantees Manage Conflicts of Interest in Research Funded by the National Institutes of Health," OEI-03-07-00700, November 2009

Clinical Research Compliance

- Risks of non-compliance: 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

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Clinical Research Compliance

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

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Clinical Research Compliance Challenges and 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

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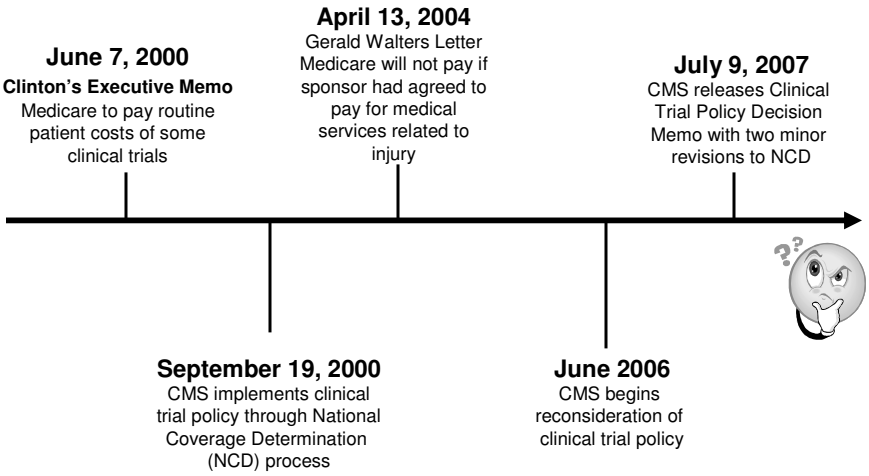
CMS Clinical Research Policy



http://www.cms.hhs.gov/ClinicalTrialPolicies/ 36

CMS Clinical Research Policy

September 27, 2007
Food and Drug Administration Amendments Act of 2007; includes several new requirements affecting clinical trials

September 29, 2008
MLN Matters SE0822 "clarifies" Medicare payment of routine costs associated with clinical trials

July 19, 2007
CMS announces Second Reconsideration Of newly renamed "Clinical Research Policy"

October 17, 2007
Final Decision Memorandum on Clinical Research Policy maintains the status quo

January 7, 2009
MLN Matters SE0822 is reissued to further clarify Medicare payment issues

http://www.cms.hhs.gov/ClinicalTrialPolicies/ 37

Medicare Secondary Payor / No Legal Obligation to Pay Issues

- CMS interpretation in April 2004 Gerald Walters 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
- Upshot: CMS believes Medicare is payor of last resort, not clinical trial sponsor, when sponsor guarantees payment for injury-related 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

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Medicare Secondary Payor / No Legal Obligation to Pay Issues

- Clarification of Medicare Payment for Routine Costs in a Clinical Trial (Sept. 29, 2008)
- Question:
  - If a research sponsor says in writing that they will pay for routine costs if there is no reimbursement from ***any insurance company*** (including Medicare), does that fall into the "free of charge" category?

CMS Transmittal SE0822 (Sept. 29, 2008) 39

Medicare Secondary Payor / No Legal Obligation to Pay Issues

- Answer:
  - 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 after denials
    - Medicare payment cannot be made
    - Beneficiary cannot be charged

CMS Transmittal SE0822 (Sept. 29, 2008) 40

Medicare Secondary Payor / No Legal Obligation to Pay Issues

- 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) 41

Medicare Secondary Payor / No Legal Obligation to Pay Issues

- 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
- If a research sponsor offers to pay cost-sharing amounts owed by non-indigent beneficiaries, could be fraud and abuse

CMS Transmittal SE0822 (Sept. 29, 2008) 42

Medicare Secondary Payor / No Legal Obligation to Pay Issues

- CMS clarifies September 2008 guidance in revised version of MLN Matters SE0822
  - 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) 43

Medicare Secondary Payor / No Legal Obligation to Pay Issues – New Reporting Obligation

- Medicare Secondary Payor law: "business . . . professional entity 'deemed' to have a 'self-insured plan' if it carries its own risks, whether by failing to obtain insurance or otherwise"
- Section 111 of Medicare, Medicaid, and SCHIP Extension Act of 2007
  - Imposes an affirmative duty on entities including tort defendants to report the resolution of any claim or action brought by a beneficiary
  - Provides stiff penalties for failure to report – up to $1,000 a day per claimant
  - Potential prosecution for the submission or causing the submission of false claims in violation of federal False Claims Act
  - Entities must determine the status of all plaintiffs with whom claims are settled on or after January 1, 2010

(42 U.S.C. 1395y(b)(2)(A)(ii) (amended by MMA § 301(b)(1)) 44

Medicare Secondary Payor

- Clinical trial "sponsors" payment reporting obligations
  - Required by Medicare Secondary Payer ("MSP") law
- Medicare become a secondary payor, if a sponsor agrees to pay for injuries related to clinical trial related injuries
- If elected sponsor never makes payment for research related injuries, Medicare will make payment.

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2005 OIG Draft Compliance Program Guidance

- OIG's *Draft Compliance Program Guidance for Recipients of PHS Research Awards*
  - Provides recipients of research awards from HHS agencies with a framework for development and implementation of effective compliance programs
  - Promotes adherence to Federal rules and regulations
  - Provides information on the benefits and suggested components of a comprehensive, well-managed compliance program
  - Subsequently withdrawn in deference to multi-agency initiative on clinical research compliance guidance

70 Fed. Reg. 71312 (Nov. 28, 2005) 46

2005 OIG Draft Compliance Program Guidance

- Multi-Agency Initiative on Clinical Research Compliance Guidance
  - Launched by National Science and Technology Council (NSTC) to expand on OIG's efforts to provide voluntary compliance guidelines for recipients of Federal research funding from all agencies across the Federal Government
  - Research Business Models Subcommittee was reportedly collecting information on "priority areas" and developing "best practice" policies to facilitate efforts to promote and streamline research compliance

http://oig.hhs.gov/publications/docs/press/2006/ResearchCPG-finalrelease06072006.pdf (June 7, 2006)

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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)

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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
    - **<u>Self-Disclosure Issues:</u>**
      - Improperly billed sponsor and Medicare for $670,000 in physician and hospital cancer research services that were not reimbursable as routine care costs under the NCD
      - Violations were attributed to an 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)

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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 Agmt (CCA)

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

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National Coverage Determination

- **U. of Alabama at Birmingham**
  - **<u>Allegations:</u>**
    - 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
  - $3.39 M settlement
  - 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)

2005 OIG Draft Compliance Program Guidance – Risk Areas

- **Examples of risk areas that have come to the OIG's attention**
  - 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
- **Not intended to be an exhaustive list**

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) 53

2005 OIG Draft CPG – Risk Areas

- **Allocating charges among 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 research projects banking or trading award funds among themselves

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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

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Institute for Cancer Prevention

- **<u>Allegations:</u>**
  - Drawing down federal grant money to pay bills ineligible for reimbursement under grants
- **Settlement: $2.3 M**
- **Developments:**
  - 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

Press Release, Dep't of Justice, *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)

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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 57

Mayo Foundation

- **<u>Allegations:</u>**
  - Improper cost transfers from overspent grants and internal cost centers to under spent 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"
- **$6.5 M settlement**
- **Whistleblower = former accounting associate**

U.S. ex rel. Long v. Mayo Foundation, No. CV02-522-ADM/SRN (D. Minn. settlement announced May 26, 2005) 58

Harvard/Beth Israel Deaconess Medical Center

- **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
- $2.4 M settlement

www.taf.org/settlements/harvard.pdf, March 16, 2004 59

Yale University

- **Allegations:**
  - Researchers "spent down" remaining grant funds near expiration dates via improper cost transfers
  - Yale submitted time and effort reports that charged 100% to federal grants when researchers were actually engaged in unrelated work
- **Settlement:**
  - $7.6 M ($3.8 M for actual damages, $3.8 million for punitive damages)

http://newhaven.fbi.gov/dojpressrel/2008/nh122308.htm 60

Improperly Allocating Costs and Charges to Award Projects

- **Other Reported Investigations and Settlements**
  - Weill Medical College of Cornell University ($4.3 M, June 2005)
  - University of Alabama at Birmingham ($3.39 M, Apr. 2005)
  - East Carolina University – OIG Audit ($2.3 M at risk, Aug. 2004)
  - 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)

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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

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Time and Effort Reporting

- **Reporting Rules**
  - Must "reasonably reflect the activity for which employees are compensated by the institution"
  - Must be confirmed after the fact by "responsible persons with suitable means of verification"
  - Must use independent internal evaluations to ensure compliance
  - Reports must be prepared for:
    - faculty and professional staff -- at least every 6 months
    - other employees -- monthly

Office of Management and Budget Circular A-21, Section J.10 (May 10, 2004) 63

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

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Time and Effort Reporting

- Reported Investigations and Settlements
  - Yale University ($7.6 M, Dec. 2008)
  - 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)
  - Northeastern University ($5.5 M, June, 2003

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Time and Effort Reporting

- **Johns Hopkins University**
  - **<u>Allegations:</u>**
    - Overstated percentage of effort; falsely reported Time and Effort of employees who did not work on grants
    - Failed to maintain adequate compliance mechanisms to reconcile proposed effort commitments with actual effort
  - Settlement: $2.6 M
  - Whistleblower = office supervisor

U.S. ex rel. Grau v. Johns Hopkins University, No. 99-1448 (D. Md. Feb. 26, 2004) 66

Time and Effort Reporting

- **East Carolina University**
  - **OIG Audit: $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 (August 2004) 67

Sub-Recipient Monitoring

– *"Sub-recipient monitoring may be an important risk area for those institutions that rely on subcontracts to fulfill the purposes of a PHS award."*

-- 2005 Draft OIG Compliance Program Guidance for Recipients of PHS Research Awards

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Sub-Recipient Monitoring

- **Boston University** audit of sub-grant management
  - **Allegations:**
    - 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
  - OIG recommendations:
    - Comply with Federal and University 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 $11,234 received from NIH for inappropriate cost transfers
  - The University maintained that all costs that it claimed under the subaward were reasonable, allocable, and allowable

http://oig.hhs.gov/oas/reports/region1/10601500.htm (Sept. 28, 2006) 69

Indirect Cost Rate Issues

- **University of Connecticut**
  - **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
  - **$2.5 M settlement**
  - 500 Federal Grants (1997-2004) involved

DOJ Press Release: http://www.usdoj.gov/usao/ct/Press2006/20060109.html 70

Indirect Cost Rate Issues

- **New York University Medical Center**
  - **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) 71

Indirect Cost Rate Issues

- **NYU 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
  - **$15.5 M settlement**
  - 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) 72

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 73

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 74

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
  - Resolved by restatement of Financial Status Reports and repayment to NIH

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Internal Compliance and Minimizing FCA Risks

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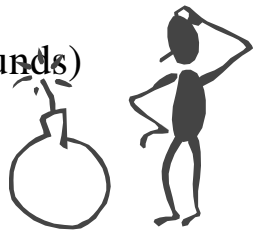
What Does the Future Hold - Mandatory Compliance Programs

- PPACA makes compliance plans mandatory for certain providers
  - Nursing homes first
  - HHS will select the additional types of providers required to have such programs
  - HHS "shall establish core elements" of the programs and determine the timeline for implementation

§ 6402(h)(1) 77

Assessing and Minimizing Risks

- **Three C's: Compliance, Compliance, and Compliance**
- Obtain OIG/CMS Advisory Opinions in appropriate circumstances
- Proactively self-disclose identified errors and overpayments (with refunds)
- Avoid or minimize the negative publicity



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Questions

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CLINICAL RESEARCH ENFORCEMENT INITIATIVES AND FALSE CLAIMS ACT UPDATE RELEVANT TO ACADEMIC MEDICAL CENTERS[1]

By
Gary W. Eiland
King & Spalding

I. False Claims Act Update

A. The FCA is the Fraud Enforcement Vehicle of Choice

According to the Department of Justice, $27 billion has been recovered by the government under the False Claims Act since 1986. The 2010 fiscal year, had the largest recovery, $2.5 billion was in health care fraud recoveries. Under the qui tam provision, $2.3 billion, with $385 million going to relators. Under the False Claims Act, $4.6 billion was recovered along with $1.6 billion recoveries from pharmaceutical and medical device industries.

U.S. Department of Justice Press Release: Department of Justice Recovers $3 Billion in False Claims Cases in Fiscal Year 2010 (Nov. 22, 2010) at http://www.justice.gov/opa/pr/2010/November/10-civ-1335.html.

B. PPACA Changes - "Public Disclosure"

The Patient Protection and Affordable Care Act revised the definition of "publicly disclosed," in its effort to make it easier for the Department of Justice and relators to avoid the operation of the Public Disclosure Bar. The court is not required to dismiss a relator's action if the Government opposes a defendant's motion to dismiss.

§10104(j), Effective March 23, 2010

C. Public Disclosure Bar

An "original source" can bring an FCA case even where there has been a public disclosure. An "original source" is an individual who has direct and independent knowledge of the information on which the allegations are based, and has voluntarily provided the information to the Government before filing an FCA action.

E. Expanded Definition of "Claim"

[1] Mr. Eiland gratefully acknowledges the contribution of James Rodgers in preparing this outline and accompanying PowerPoint presentation.

FERA modified 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…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…"

This provision is, in part, a response to the Custer Battles case, 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. The District Court's decision in Custer Battles was reversed on April 10, 2009 by the Fourth Circuit – before the passage of FERA.

31 U.S.C. § 3729(b)(1)(2); U.S. ex rel. DRC, Inc. v. Custer Battles, LLC, 376 F.Supp.2d 617 (E.D. Va. 2005)

F. 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. "Knowingly" is defined in the FCA as "a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required." "Improperly" is not defined. Senator Jon Kyl (R-AZ) stated that "knowingly and improperly" requires "improper motives or inherently improper means." "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."

G. Legislative History: Cost Report Reconciliations

The Committee Report notes that this provision is not intended to capture interim 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. 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."

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

H. Overpayment Obligation - 60 Day Time Period

The Patient Protection and Affordable Care Act provides a 60-day deadline for reporting and returning overpayments. The deadline is the later of: (a) the date which is 60 days after the date on which the overpayment was identified; (b) the date any correspondence cost report is due, if applicable. The overpayment obligation came into effective as of March 23, 2010.

§6402, Effective March 23, 2010

II. Enforcement Actions, Qui Tam Litigation and AMC Settlements

A. Recent FCA Settlements Affecting Academic Medical Centers

LSU Health Sciences Center-Shreveport was alleged to have routinely submitted claims to Medicare on behalf of teaching physicians who were not actually present for the procedures as required. LSUHSC paid $706,779 to settle the allegations, but denied liability. As part of the settlement, LSUHSC entered into a 3-year Certificate of Compliance Agreement. The whistleblowers in the suit were a teaching physician and an orthopedic head nurse. According to the Department of Justice Press Release, LSUHSC submitted the Part B claims to Medicare and divided reimbursements between hospital and teach physicians.

U.S. Attorney's Office, Western District of Louisiana, Press Release: LSU-Shreveport Medical School to Pay $700,000.00 to Settle Federal Fraud Suit Involving Never-Performed Services By Orthopedic Teaching Physicians, (July 1, 2009).

Kaiser paid $3.75 million to settle allegations that it had improperly billed Medicare and Medicaid over a 7-year period for services the company claimed were provided by teaching physicians. Kaiser voluntarily disclosed the misconduct.

http://www.dailymail.com/ap/ApTopStories/200912041003 (Dec. 4, 2009).

B. Detroit Medical Center

Detroit Medical Center was alleged to have violated the False Claims Act, the Anti-Kickback Statute and the Stark Statute by engaging in certain improper financial relationships with referring physicians. Alleged “gap arrangements” existed regarding office leases, medical director and other agreements without written and executed agreements for the entire terms and certain potential excess "business courtesies" were identified. Detroit Medical Center became aware of the suspect arrangements during the preparation for the sale of its facilities to Vanguard Health Systems, Inc. The government and Detroit Medical Center reached a $30 million settlement, resolving the self-disclosure in record time to facilitate the closing of the sell to Vanguard Health Systems, Inc.

U.S. Department of Justice Press Release: Detroit Medical Center Pays U.S. $30 Million to Settle False Claims Act Allegations (December 30, 2010) at http://www.justice.gov/opa/pr/2010/December/10-civ-1484.html.

C. Senate Finance Committee

The Senate Finance Committee reviewed the case of a Maryland cardiologist implanting unnecessary stents into almost 600 patients. The committee’s report expressed concern over the relationship between the cardiologist and Abbott Laboratories, the manufacture of the stents. Medicare went on to pay $3.8 million for the alleged improper stent implantations.

Sarah Barr, Doctor’s Improper Stent Implantations Cost Medicare Millions, Finance Probe Reveals, BNA’s Healthcare Daily Report (Dec. 8, 2010).

D. Kyphoplasty Investigation

Seven hospitals in six states allegedly billed Medicare (2000-2008) for short stay inpatient kyphoplasty procedures. The services should have been billed as less costly and more clinically appropriate outpatient procedures. The settlement follows 18 other kyphoplasty-related Medicare claim settlements reached in 2009 and 2010 and the 2008 settlement with Medtronics Spine LLC, the corporate successor to Kyphon. Investigations are continuing under the initial qui tam case filed in the Western District of New York and in other copy-cat qui tam actions.

Georgeann Edford, The DOJ Initiative on Kyphoplasty, Aspen Reimbursement Advisor, Aug. 2010, 1-2, 6-12.; DOJ Press Release, January 4, 2011.

E. ICD Investigation

The Department of Justice is conducting investigations into billing compliance related to implantable cardiac defibrillators (“ICDs”). The Medicare reimbursement to a hospital typically ranges from $40,000 to $50, 000. Medicare’s course of action in handling the ICD investigations initially began using CIDs but has changed to a "cooperative approach" in the more recent phases of the investigation. The DOJ communication asks for the hospital's cooperation in assessing patient procedures under the national coverage decision ("NCD"),

reviewing compliance with the new Medicare claims process instructions, analyzing documents related to billing, payments, and reimbursement. It has been reported that the DOJ also issued subpoenas to ICD manufacturers.

Dennis M. Barry, Investigation of Hospital Billing for Implantable Cardiac Defibrillators (ICDs), King & Spalding Health Headlines, Apr. 26 2010, http://www.kslaw.com/News-and-Insights/PublicationDetail?us_nsc_id=2435.

Beverly F. Lorell, CMS Coverage Criteria for Implantable Cardiac Defibrillators, Aspen Reimbursement Advisor, Jan. 2011, at 1-2, 8-12.

F. Other Enforcement Issues - Off-Label Use

Pfizer (Bextra) ($2.3 B) (2009): 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. The $2.3 Billion settlement is the largest settlement ever reached by the DOJ for improper off-label marketing practices. Pfizer executive pled guilty to charges she instructed 100 sales representatives to promote Bextra for uses rejected by FDA.

U.S. Attorney's Office District of Massachusetts, Press Release: Justice Department Announces Largest Health Care Fraud Settlement In Its History (Sept. 2, 2009) at http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Sept2009/Pfizer.html.

Eli Lilly (Zyprexa) ($1.4 M) (2009): illegally marketed one of its antipsychotic drugs (Zyprexa) for unauthorized use in patients vulnerable to risky side effects.

U.S. Department of Justice Press Release: Eli Lilly and Company Agrees to Pay $1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa (Jan. 15, 2009) at http://www.justice.gov/opa/pr/2009/January/09-civ-038.html.

Serono (Serostim) ($704 M) (2005): 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; and, offering financial incentives to doctors who prescribed the drug in certain amounts.

U.S. Department of Justice, Press Release: Serono To Pay $704 Million for the Illegal Marketing of Aids Drug (Oct. 17, 2005) at http://www.justice.gov/opa/pr/2005/October/05_civ_545.html.

Pfizer (Genotropin) ($35 M) (2007): alleged improper marketing of the synthetic human growth hormone Genotropin; illegally offering kickbacks to a pharmacy benefit manager.

United States v. Pharmacia & Upjohn Company, Inc., No. 07-cr-10099-RGS (D. Mass. *information filed* 4/2/07), http://news.bna.com/hdln/HDLNWB/split_display.adp?fedfid=7387769&vname=hcenotallissues&wsn=531802000&searchid=13374194&doctypeid=1&type=date&mode=doc&split=0&scm=HDLNWB&pg=0.

Otsuka Pharmaceutical Co. Ltd (Abilify) ($4 M) (2008): causing the submission of false claims for Abilify (an anti-psychotic drug) by marketing the drug to physicians and in long-term care facilities as a treatment for dementia-like psychosis in pediatric and geriatric patients without FDA approval (FDA only approved drug for bipolar disorder and schizophrenia in adults).

U.S. Attorney's Office District of Massachusetts, Press Release: Otsuka To Pay More Than $4 Million To Resolve Off-Label Marketing Allegations Involving Abilify (Mar. 27, 2008) at http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Mar2008/OtsukaSettlementPR.html

Allergan Inc. (Botox) ($600 M) (2010): Allergan plead guilty to charges of unlawful promotion of its product, Botox, for uses not approved as safe and effective by the Food and Drug Administration.

U.S. Department of Justice Press Release: Allergan Agrees to Plead Guilty and Pay $600 Million to Resolve Allegations of Off-Label Promotion of Botox (Sept. 1, 2010) at http://www.justice.gov/opa/pr/2010/September/10-civ-988.html.

Novartis Pharmaceuticals Corp. (Trileptal) ($422.5M) (2010): alleged off-label promotion of the epilepsy drug (Trileptal) and paid kickbacks to get doctors to prescribe the drug.

U.S. Department of Justice Press Release: Novartis Pharmaceuticals Corp. to Pay More Than $420 Million to Resolve Off-label Promotion and Kickback Allegations (Sept. 30, 2010) at http://www.justice.gov/opa/pr/2010/September/10-civ-1102.html.

Elan Corp. PLC, (Zonegran) ($203.5 M) (2010): Elan Corporation, PLC agreed to pay over $203.5 million to resolve the illegal promotion of sales and marketing of the epilepsy drug Zonegran.

U.S. Attorney's Office District of Massachusetts, Press Release: Pharmaceutical Companies To Pay $214.5 Million To Resolve Allegations Of Off-Label Promotion Of Epilepsy Drug (Dec. 15, 2010) at http://www.justice.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Dec2010/ELANstlmntPR.html.

Forest Laboratories Inc. (Lexapro and Celexa) ($313 M) (2010): the pharmaceutical company agreed to pay $313 M to settle qui tam allegations that it promoted drugs, Lexapro and Celexa, for off-label pediatric use and paid kickbacks to physicians who promoted the use of the drugs.

United States v. Forest Pharmaceuticals Inc. (D. Mass., settlement 9/15/10). http://news.bna.com/hdln/HDLNWB/split_display.adp?fedfid=17794546&vname=hcenotallissues&wsn=497447500&searchid=13375039&doctypeid=1&type=date&mode=doc&split=0&scm=HDLNWB&pg=0.

III. Clinical Research Compliance

A. 2011 OIG Work Plan Initiatives

The HHS Office of Inspector General's Work Plan for 2011 states the following initiatives: review college and university compliance with select cost principles; review college and university recharge centers compliance with cost rate schedule standards; review data in clinical trials monitored by the Data and Safety Monitoring (DSMB); analyze the scope of grantee compliance and NIH policies of multisite clinical trials.

HHS, Office of Inspector General Work Plan Fiscal Year 2011 at http://www.oig.hhs.gov/publications/workplan/2011/

B. November 2009 OIG Report

In a report issued in November 2009, "How Grantees Manage Conflicts of Interest in Research Funded by the National Institutes of Health," the OIG reported that 90 per cent of grantee institutions rely solely on researcher discretion to determine whether their financial interests must be reported, and the majority of grantees do not have policies or procedures addressing subcontractee compliance with federal conflicts rules. The OIG also reported that grantee institutions do not routinely verify information submitted by researchers, and rarely reduce or eliminate researchers' financial conflicts of interest.

Among the report's recommendations: NIH oversight of grantee institutions should be increased to ensure conflicts of interest are reported and managed appropriately; grantee institutions should be asked to provide details to NIH of how conflicts of interest are managed, reduced, or eliminated; grantee institutions should be required to collect information on all significant financial interests, not just those deemed relevant by researchers; and the NIH should develop regulations addressing institutional financial conflicts of interest.

"How Grantees Manage Conflicts of Interest in Research Funded by the National Institutes of Health," OEI-03-07-00700, November 2009.

C. The Risks of Clinical Research Non-Compliance

An institution's non-compliance with clinical research standards compromises not only the financial and operational viability of current trials, but may result in (1) a loss of funding and draw down privileges for future research activity, (2) a risk of fines and penalties imposed by oversight agencies, (3) settlement costs and/or damages arising from actions under the Federal and State False Claims Act, and

(4) diminution of the AMC's reputation in the medical and scientific communities.

An individual's non-compliance may result in (1) loss of Principal Investigator ("PI") status, (2) debarment, suspension, and exclusions, and (3) criminal and/or civil sanctions.

D. Status of Multi-Agency Clinical Research Compliance Guidance

In announcing that it had withdrawn its November 2005 draft compliance program guidance for HHS research grants, the HHS, Office of Inspector General stated that it would be collaborating with the National Science and Technology Council's (NSTC) Committee on Science (COS) as part of an inter-agency plan to create compliance guidelines for recipients of Federal research monies. According to the OIG Press Release, the Research Business Models (RBM) Subcommittee of the White House Office of Science & Technology will establish the multi-agency initiative, to expand upon the OIG's efforts to provide guidance in its "Draft Compliance Program Guidance for Recipients of PHS [Public Health Service] Research Awards," published November 28, 2005 in the Federal Register. The RBM Subcommittee was reportedly collecting information on "priority areas" and developing "best practice" policies to facilitate a "coordinated effort" across agencies in promoting and streamlining research compliance.

HHS, Office of Inspector General Press Release: NSTC Launches Government-wide Initiative Based on OIG Draft Guidance for HHS Research Grants (June 7, 2006); Research Business Models Subcommittee Home Page at http://rbm.nih.gov/index.htm.

E. The Evolution of CMS' National Coverage Determination

Executive Memorandum – The question of Medicare coverage in the context of clinical trials when items or services that are not experimental are furnished as part of the clinical trial was addressed by CMS with the publication of a national coverage determination ("NCD") on September 19, 2000. The NCD implemented a June 2000 Executive Memorandum by President Clinton ordering Medicare to cover routine health care costs of beneficiaries in clinical trials.

Coverage Policy—Clinical Trials, Final National Coverage Decision (Sept. 19, 2000) at http://www.cms.hhs.gov/ClinicalTrial Policies/; Medicare Claims Processing Manual (Pub. 100-4), ch. 32, § 69.1.

Gerald Walters Letter - In April 2004, in response to an inquiry, Medicare stated that it will not make payments for injuries received as a result of participation in a clinical trial if the trial sponsor states in its consent documentation that it would.

The April 14, 2004 letter can be found on the internet at http://op.bna.com/hl.nsf/id/rkun-783hav/$File/Lutz.letter.pdf

Revised Clinical Trial Policy - In June 2006, CMS initiated the first reconsideration of its clinical trial policy. On July 9, 2007, the Clinical Trial Policy Decision Memo was released by CMS, making only two minor revisions to the National Coverage Decision, and renaming it "Clinical Research Policy"

HHS Centers for Medicare and Medicaid Services, National Coverage Determination for Routine Costs in Clinical Trials (310.1), Publication No. 100-3 (July 9, 2007) at http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=310.1&ncd_version=2&basket=ncd%3A310%2E1%3A2%3ARoutine+Costs+in+Clinical+Trials

Second Reconsideration of Clinical Research Policy - After announcing a second reconsideration of its clinical research policy, CMS issued a final decision On October 17, 1007, making no changes to the July 9, 2007 CTP policy. CMS noted that the Food and Drug Administration Amendments Act of 2007, enacted on September 27, 2007, established several new significant requirements for clinical trials. Accordingly, CMS is continuing to review the Act and is coordinating with other HHS components to avoid duplicative or inconsistent instructions.

HHS Centers for Medicare and Medicaid Services, Decision Memo for Clinical Trial Policy, CAG-00071R2 (Oct. 17, 2007); Final Decision for Clinical Trial Policy, Q's and A's, at http://www.cms.hhs.gov/determinationprocess/downloads/id210qa.pdf.

Medlearn Matters 0822 - On September 29, 2008, CMS issued MLN Matters SE0822, purportedly clarifying rules for Medicare payment of routine costs associated with clinical trials. The Medlearn article addressed the following question: If a research sponsor says in writing that they will pay for routine costs if there is no reimbursement from any insurance company (including Medicare), does that fall into the "free of charge" category? SE0822 stated if routine costs are furnished gratuitously, without regard to a beneficiary's ability to pay and without expectation of payment from another source, then Medicare payment cannot be made and the beneficiary cannot be charged. Similarly, if private insurers deny routine costs and the provider does not pursue non-Medicare patients, Medicare payment cannot be made and the beneficiary cannot be charged. If routine costs are not billed to indigent non-Medicare patients, but are billed to all other patients with the financial means to pay, then a legal obligation to pay exists and Medicare payment may be made. In this situation, the provider should bill the non-indigent beneficiary for co-payments and deductibles, but may waive payment for those with financial hardship.

CMS Transmittal SE0822 (Sept. 29, 2008)

MLN Matters SE0822 Clarified - CMS issued a revised version of MLN Matters SE0822, in which it confirmed Medicare payment may be made, provided that patients in the trial who have means to pay are billed. The revised SE0822 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)

F. Medicare Secondary Payor Law

Medicare Secondary Payor Law -- "business…professional entity 'deemed' to have a 'self-insured plan' if it carries its own risks, whether by failing to obtain insurance or otherwise."

Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 imposes an affirmative duty on entities including tort defendants to report the resolution of any claim or action brought by a beneficiary, provides stiff penalties for failure to report – up to $1,000 a day per claimant, warns of potential prosecution for the submission or causing the submission of false claims in violation of federal False Claims Act, and states that entities must determine the status of all plaintiffs with whom claims are settled on or after January 1, 2010.

(42 U.S.C. 1395(b)(2)(A)(ii) (amended by MMA § 301(b)(1))

G. National Coverage Determination

Rush University Medical Center ($1 M) - Rush University Medical Center (Rush) agreed to pay $1 million to the federal government to settle allegations of improper billing to the U.S. for physician and hospital outpatient care in connection with clinical trial services. The settlement, which was among the first related solely to the NCD on Clinical Trials, resulted from a voluntary self-disclosure by Rush to the DOJ of information obtained during an internal investigation. Specifically, Rush had improperly billed Medicare for $670,000 in services associated with cancer research that were not reimbursable as routine care costs under the NCD on Clinical Trials. The violations were attributed to an absence of "synchronization of the Medicare rules, the compensation arrangements with the sponsors, and the financial discussion in the patient's informed consent." As part of the corrective action, Rush established a centralized Research & Clinical Trials Administration Office responsible for coordinating documents and information from all departments in order to develop a single standardized billing guidance. Rush also implemented a requirement that all clinical trials receive a coverage analysis. Under terms of the settlement, Rush refunded the overpayments and paid a 50 percent penalty. In addition, Rush entered into a three-year Certification of Compliance Agreement (CCA) with OIG.

Press Release, Rush University Medical Center, Rush Settlement with Government May Help Clarify Billing Requirements for Medicare Patients in Research Studies (Dec. 8, 2005); Settlement Agreement dated Dec. 8, 2005; Certification of Compliance Agreement dated Dec. 8, 2005.

University of Alabama at Birmingham ($3.39 M) - The University of Alabama at Birmingham (UAB) agreed to pay the government $3.39 million to settle two separate false claims suits that alleged the University improperly billed Medicare and the NIH for research costs. UAB allegedly overstated the percentage of work effort that researchers devoted to the grants and falsely reported the time and effort of employees who did not work on the grants. UAB also was alleged to have falsely billed Medicare for researcher's time spent on patient care when no patients had actually been seen, and to have double-billed Medicare for clinical research trial services that were also billed to sponsor of the grants. The two whistleblowers, UAB's Research Compliance Officer and an academic physician at UAB, received $395,000.

United States ex rel. Gober v. University of Alabama at Birmingham, No. 01-cv-00977-VEH (N.D. Ala. settlement reached Apr. 14, 2005); United States ex rel. Meythaler v. University of Alabama at Birmingham, No. 04-00112-VEH (N.D. Ala. settlement announced Apr. 14, 2005).

H. Improper Billing of Costs and Charges to Award Projects

Requirements for claiming costs and charges to award projects stem from both external and internal standards. Externally, grant awards are conditioned on adherence to procedures mandated by the National Institutes of Health (NIH) (or other awarding entity) and the Office of Management and Budget (OMB). Internally, institutions should have established policies and procedures for managing grants awards and claims, and implement compliance controls to ensure conformity with all relevant guidelines. Examples of inappropriate activity include: end of year transfers or 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 refunding unused grant proceeds; PI's on different research projects banking or trading award funds among themselves; mischarging federal grants; inflating research grant costs; differentiating direct costs versus indirect costs versus cost sharing; cost transfers; charges incurred by employees unauthorized to work on the project; and inadequate accounting policies and internal controls.

Institute for Cancer Prevention ($2.3 M) - New York-based Institute for Cancer Prevention and its former President Daniel Nixon agreed to pay $2.3 million to resolve civil False Claims Act charges arising from alleged unlawful receipt and use of federal grant money between 2002 and 2003. Specifically, the company was charged with *drawing down $5 million of federal grant money to pay bills ineligible for reimbursement under its federal grants*, according to the Department of Justice press release. The company previously paid $4M in a settlement involving similar allegations for the period between 1991 and 1994.

The Department of Justice announced January 2, 2008 that the former Chief Financial Officer Roy Victor of the Institute for Cancer Prevention 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. After audits revealed improper use of federal grant money, the Institute repaid grant funds and agreed to implement necessary procedures to prevent further fund misuse. However, Victor attempted to "conceal the improper requests for grant funds," according to the DOJ press release.

Department of Justice Press Release, *U.S. Settles Civil Charges Against Former President of the Institute for Cancer Prevention, and Other* Related *Parties*, (Jan. 11, 2006) at http://newyork.fbi.gov/dojpressrel/pressrel07/execcivilcharges011107.htm

Department of Justice Press Release, *Ex-CFO of Institute for Cancer Prevention Pleads Guilty in White Plains Federal Court to Obstruction of Justice* (Jan. 2, 2008) at http://newyork.fbi.gov/dojpressrel/pressrel07/execcivilcharges011107.htm.

U.S. ex rel. Long v. Mayo Foundation ($6.5 M) - The Mayo Foundation agreed to pay $6.5 million to resolve allegations that Mayo improperly transferred costs among federal grant awards. *Mayo was alleged to have inappropriately charged the government for costs unrelated to research sponsored by the grants and to have improperly transferred research costs from overspent grants and internal Mayo cost centers to underspent grants*. The government also alleged, "Mayo had an accounting system unable to monitor and manage charges made to federal grant awards in the manner required by federal law." The whistleblower, a former accounting associate for Mayo, received $1.3 million.

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

Harvard University and Beth Israel Deaconess Medical Center Settlement ($2.4 M) - Harvard University and Beth Israel Deaconess Medical Center (BIDMC) agreed to pay $2.4 million to the federal government to resolve allegations that the institutions submitted false claims to the federal government in connection with four grants awarded to Harvard University by the NIH. Combined with a partial settlement reached in 2002 of $850,188, Harvard's total payment to the government for a series of related allegations is over $3.25 million. The investigation was prompted by the *voluntary disclosure* of information by Harvard and BIDMC regarding the results of an internal audit. Harvard and BIDMC are alleged to have improperly charged $1.9 million for a variety of salary and equipment expenses to four NIH grants. The allegations included the following:

> • *Harvard/BIDMC allegedly billed the government for a number of unallowable expenses, including salaries of researchers who did not work on the grants, did not meet citizenship requirements, or did not spend at least 75 percent of their time on the grants;*

• *salary expenses of the principal investigator charged to the grant were in excess of the budgeted amount;*

• *supply and equipment expenses charged were incurred in connection with projects unrelated to the grants;*

• *additional expenses were incurred by researchers who were not eligible or did not work on the grant; and*

• *expenses were incurred for research animals that were used for unrelated projects or used by researchers not eligible to work on the grants.*

Under terms of the settlement, Harvard paid just over $1.3 million and BIDMC paid slightly under $1.1 million.

Settlement Agreement dated Mar. 16, 2004 is available at http://www.taf.org/settlements/Harvard.pdf (2004); Press Release, United States Dep't of Justice, District of Massachusetts, Harvard and Beth Israel Deaconess Medical Center Pay $2.4 Million to Settle Allegations of False Claims to NIH (June 17, 2004).

Yale University ($7.6 M) - Yale University agreed to pay $7.6 million to settle allegations its researchers "spent down" remaining grant funds near expiration dates via improper cost transfers, and that Yale submitted time and effort reports that charged 100% to federal grants when researchers were actually engaged in unrelated work. Of the $7.6 million, half was for actual damages, the other half for punitive damages.

http://newhaven.fbi.gov/dojpressrel/2008/nh122308.htm

I. Time and Effort Reporting

According to the Office of Management and Budget Circular's "reporting rules" reports must "reasonably reflect the activity for which employees are compensated by the institution," must be confirmed after the fact by "responsible persons with suitable means of verification," and must use independent internal evaluations to ensure compliance. Reports must be prepared for faculty and professional staff at least every six months, and for other employees on a monthly basis.

Office of Management and Budget Circular A-21, Section J.10 (May 10, 2004)Proposed effort v. available effort v. charged effort v. documented effort

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

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% consistence; examine material differences

U.S. ex rel. Grau v. Johns Hopkins University ($2.6 M) - Johns Hopkins University agreed to pay $2.6 million to resolve allegations that the University knowingly overstated the percentage of effort that the researchers were able to devote to the grants and the percentage of effort that personnel had actually worked on applications for the grants. The suit also claimed that the University applied erroneous fringe benefit rates to the grants. The whistleblower, an office supervisor at the medical center, received $439,582.

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

East Carolina University Audit ($2.3M at risk) - An OIG audit of costs claimed for reimbursement by East Carolina University (ECU) under a contract from the National Library of Medicine (NLM) found that of the $4,070,528 claimed by ECU for reimbursement over a four-year period, only $1,718,140 was allowable. $565,820 of the remainder was recommended for financial adjustment and $1,786,568 was set aside for adjudication by NLM due to inadequate documentation by the University. The OIG found that ECU charged the contract for salaries, wages, and fringe benefits of employees who had been instructed to falsely certify that they were devoting effort to the NLM contract and for the salaries, wages, and fringe benefits of clerical and administrative personnel whose duties did not apply directly to the project. NLM also was charged for equipment that was never used for project operations, as well as for payments to firms having business relationships with the former co-principal investigator even though the services were either not rendered or were unrelated to the project. OIG asserted that ECU lacked adequate internal and management controls, had not implemented an effort reporting system adequate to comply with the requirements of OMB Circular A-21 and had instead "relied upon an incomplete, inconsistent system that was subject to frequent errors and could easily be manipulated." Time and effort reports prepared by ECU employees were based on inconsistent methods (e.g., some reported based on a percentage of time and effort, others reported number of hours worked, and some did not report at all). Additionally, key personnel were found to have failed to implement procedures to correctly report and compute the costs of paid leave; there were no procedures in place to compare the time and effort reported for each employee to the approved funding levels for the contract; there was no requirement for timely submission of

employee effort reports to the contract administrator; and there was no procedure to reconcile the reported time and effort to ECU's actual payroll distribution.

HHS Office of Inspector General, Audit of Costs Claimed for Reimbursement by East Carolina University Under National Library of Medicine Contract No. N01-LM-9-3541 – September 30, 1999 Through September 30, 2003, Report No. A-04-04-01001 (Aug. 3, 2004) at http://oig.hhs.gov/oas/reports /region4/40401001.htm

J. Sub-recipient Monitoring

"Sub-recipient monitoring may be an important risk area for those institutions that rely on subcontracts to fulfill the purpose of a PHS award." -- 2005 Draft OIG Compliance Program Guidance for Recipients of PHS Research Awards

A 2006 Boston University audit involved sub-grant management. The OIG investigated two salary cost transfers totaling $7,196 that were not authorized or adequately supported, and found over $4,000 in indirect costs that were unallowable. The OIG also cited Boston University for failure to submit a final invoice to the prime grantee within 45 days of the end of the budget period.

OIG recommended the University: comply with Federal and University requirements to ensure that cost transfers are properly authorized and documented; establish controls to ensure that final invoices are submitted promptly; and work with the prime grantor to resolve the $11,234 received from NIH for inappropriate cost transfers.

The University maintained that all costs that it claimed under the sub-award were reasonable, allocable, and allowable.

http://oig.hhs.gov/oas/reports/region1/10601500.htm (September 28, 2006)

K. Which Indirect Cost Rate Is Applicable to Continuing Grants?

Colleges and universities are subject to OMB Circular A-21 which states: "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." OMB Circular A-21 Section G.7.

Hospitals are subject to SHHS Guide OASC-3 which states: ". . . indirect costs will be awarded using the latest established indirect cost rate applicable to the period of performance of the award." OASC-3 Section I at 5. Although the quoted text of OASC-3 Section I could be interpreted to reference the indirect cost rates as of the grant award, OASC-3 Section I also provides: "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." OASC 3 Section I at 2. This if further clarified in OASC-3

Section IV, Exhibit D-1, n (8): "…indirect cost rates established for the period in which direct expenditures are actually made are applied to those expenditures."

There was a recent self-disclosure matter by a hospital operating within a state university system. The hospital's self-disclosure to the NIH concerned the use of incorrect, indirect cost rates on NIH grants over multiple years. The matter was resolved by restatement of FSRs and repayment to the NIH.

University of Connecticut ($2.5M) - University of Connecticut agreed to pay the government $2.5 million to settle allegations that it failed to utilize proper basis for setting and updating billing rate structure, failed to follow federal law for calculating how extra compensation is paid to faculty working on grant-supported research, and failed to provide University cost sharing and matching where appropriate. 500 Federal grants from 1997-2004 were involved.

http://www.usdoj.gov/usao/ct/Press2006/20060109.html (January 9, 2006)

U.S. ex rel. Emmanuel Roco v. NYU Medical Center ($15.5 M) - New York University agreed to pay the government $15.5 million to settle allegations that the NYU Medical Center submitted false claims in connection with indirect costs related to federally sponsored research. NYU is alleged to have:

- inflated its indirect cost rate information by submitting substantially lower dollar figures for voluntary cost sharing than those reflected in internal documents and consultants' reports;

- submitting duplicate claims for the same utility costs in its research-related indirect cost proposals and in institutional cost reports submitted for Medicare reimbursement; and

- submitting duplicate claims for certain environmental services costs through separate indirect cost proposals from NYU Medical Center and New York University.

The settlement also resolved allegations related to the inclusion of certain unallowable expenses (e.g., entertainment costs, capital interest); overstated costs (e.g., housekeeping expenses based on budgeted expenses rather than actual costs); inconsistent allocation of direct and indirect costs of certain activities and departments; and use of an outdated space survey that resulted in over-allocation of costs. The settlement followed a three-year investigation. The whistleblower, a former NYU finance employee, received $1.5 million.

United States ex rel. Emmanuel Roco v. NYU Medical Center, No. 93-8012 (DC SNY Apr. 7, 1997).

IV. Internal Compliance and Minimizing FCA Risks

A. Assessing and Minimizing Risks

The three C's to assessing and minimizing risks are compliance, compliance and compliance. It is essential to obtain the Office of Inspector General (OIG) and Centers for Medicare & Medicaid Services (CMS) Advisory Opinions, proactively self-disclose any identified errors and avoid the negative publicity.