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

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Risks and Enforcement Initiatives



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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

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Clinical Research Compliance

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

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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

CMS/OIG Clinical Research Focus

■ November 2009 OIG Report:

- 90% of grantee institutions rely solely on researcher discretion to determine whether their financial interests 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

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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 all 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

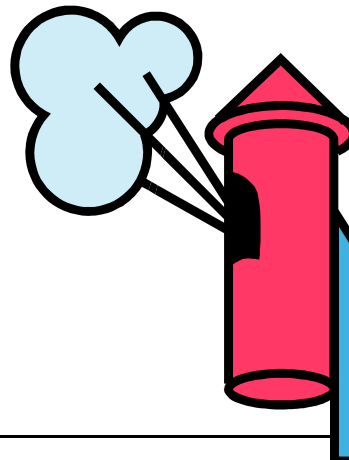
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Research Enforcement Risks

- 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

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False Claims Act Update



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The FCA is the Fraud Enforcement Vehicle of Choice

- More than \$24 B recovered by Gov't under FCA since 1986
- Settlements have become very large
 - Pfizer in September 2009 -- \$2.3 Billion
- "Healthcare has accounted for the lion's share of fraud settlements and judgments" under the FCA
- 515 criminal actions and 387 civil actions in FY 2009
- According to Senator Charles Grassley, more than 1,000 *qui tam* cases are awaiting an intervention decision by the government

HHS OIG Semiannual Report to Congress, Fall 2009;
Dept. of Justice Press Release (11/10/08)

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President Obama's FY 2011 Budget

- Requests \$1.7 B for HHS to combat healthcare fraud and abuse
 - HHS would receive \$561 million in Health Care Fraud and Abuse Control discretionary funding, an increase of \$250 million over FY 2010 funding
- Funds expansion of Medicare Strike Force Teams
- Supports investments in technology and techniques that would allow for data analysis and data-sharing "with unprecedented speed"
- Estimated \$9.9 B over 10 years in savings from recoveries and prevention

www.stopmedicarefraud.gov/healthcarefraud_factsheet.html

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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)

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Overview of FERA's Changes to the FCA

- Clarifies the applicability of the FCA to claims submitted to government contractors and grantees
- Partially retroactive effective date (which is subject to constitutional challenges)
- Codifies and defines materiality requirement ("natural tendency" test)
- Expands definition of "claim"

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Overview of FERA's Changes to the FCA

- Expands "Conspiracy" subsection to cover all elements within FCA
- Procedural amendments strengthen DOJ's authority
- Expands false claim liability for certain retentions of overpayments
- Pending legislation could add more changes to FCA

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FCA Sections/Subsections Subject to Effective Date Provisions

FCA Section	Date Provision
Subparagraph (B) of subsection 3729(a)(1) of title 31	Shall take effect as if enacted on June 7, 2008, and apply to all <i>claims</i> under the FCA pending on/after that date
Section 3731(b) of title 31	Shall apply to cases pending on the date of enactment*
Section 3733 of title 31	Shall apply to cases pending on the date of enactment*
Section 3732 of title 31	Shall apply to cases pending on the date of enactment*

*Date of enactment was May 20, 2009

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Redline of Revisions to Section 31 U.S.C. 3729 (a)(1)

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

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

- ~~(A)~~ 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;
- ~~(B)~~ 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~~;

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.

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.

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Allison Engine – Healthcare Litigation

- Litigants had filed briefs contending that since various contractors actually pay claims under the Medicare and Medicaid programs, 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
- FERA explicitly makes the change to Section (a)(1) retroactive to June 7, 2008, two days before the decision in *Allison Engine*

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Retroactive Application

- Litigation about the retroactive effect of FERA has already begun
 - *U.S. v. Science Applications International Corp.*
 - Distinction between “case” and “claim”
 - D.C. District Court rejected Gov’t argument that FERA applied retroactively to all *cases*
 - Payments were made before retroactive application date, so no *claims* existed on date of enactment
 - *U.S. ex rel. Carter v. Halliburton Co.*
 - Court permits retroactive application of FERA amendment because case was pending on retroactive date
- Constitutional challenges will likely continue

United States v. Science Applications International Corp., No. 04-1543, 2009 WL 2929250 (D.D.Ⓔ Sept. 14, 2009); *U.S. ex rel. Carter v. Halliburton Co.*, 2009 WL 2240331 (E.D. Va. 2009)

Materiality Test

- FERA 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)

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Expanded Definition of “Claim”

- FERA modifies the definition of “claim”:
Money or property is to be spent or used on the Government’s request or interest, and the Government:
 - Provides or has provided any portion of the money or property requested or demanded; or
 - Will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded
- Confirms FCA is applicable to downstream recipients of federal money or property

31 U.S.C. § 3729(a)(2)

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Expanded Definition of “Claim”

- 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

U.S. ex rel. DRC, Inc. v. Custer Battles, LLC, 376 F.Supp.2d 617
(E.D. Va. 2005)

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Expanded “Conspiracy” Liability

- Previously, conspiracy subsection applied only “to get a false or fraudulent claim allowed or paid”
- Under FERA, conspiracy liability is expanded to include conspiracies to commit a violation under any substantive portion of the FCA:
 - (3C) ~~conspires to defraud the Government by getting a false or fraudulent claim allowed or paid~~commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
- Essentially, any conspiracy to violate FCA liability provisions is actionable

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Procedural Changes

Expanded Use of Civil Investigative Demands

- FERA permits the Attorney General to delegate authority for issuance of civil investigative demands (CIDs)
- Prior to FERA, the AG was required to personally approve issuance of CIDs
- Responding to U.S. Chamber of Commerce concerns about delegated authority, the AG’s office:
 - did not commit to limiting CID authority to the AAG level
 - acknowledged that CIDs will be used with more frequency in FCA cases

Letter from Honorable Tony West, Assistant Attorney General,
Civil Division, August 25, 2009.

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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

31 U.S.C. § 3733(a)(1); 31 U.S.C. § 3732

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Procedural Changes

Relation back of Gov't complaints in intervention

- A new or amended gov't complaint relates back to the filing date of the original relator complaint, so long as the gov't claims arise out of the conduct or occurrences set forth in the initial complaint or claims the relator attempted to plead
- Apparent intent to overturn Second Circuit decision in *U.S. ex rel. Cosens v. Baylor Univ. Medical Center*
 - Based on unique procedural history of this case, 2nd Circuit held Gov't may not rely on relation back provisions for statute of limitations purposes when calculating time by which it must file its complaint in intervention because defendant is not given timely and sufficient notice of allegations

31 U.S.C. § 3731(c); *U.S. ex rel. Cosens v. Baylor Univ. Medical Center*, 284 F.3d 263 (2d Cir. 2006)

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.

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Redline of Revision to “Reverse” FCA Provision

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

~~(7G)~~ 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.

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Expansion of FCA Liability for Retention of Overpayments

- “Knowingly” is defined in the FCA:
 - *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:
“Knowingly and improperly” requires “improper motives or inherently improper means”

31 U.S.C. § 3729(b)

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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.**”

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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

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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) 34

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.)

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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 determined?
 - 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)

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Implications for Academic Medical Centers to Consider

- What if no proactive audits or effective compliance plan – reckless disregard without actual knowledge?
- Credit balance policies?
- Internal audits, including pre-RAC?
- Stark?

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Executive Order No. 13520

- In response to a GAO report, President Obama issued an executive order requiring the Secretary of the Treasury to publish:
 - Names of entities that have received the greatest amounts of improper payments
 - Matters that have been or may be referred to the DOJ would not be published
 - Contractors who receive significant overpayments, but knowingly fail to disclose these overpayments to the Government
 - Only if publication would not interfere with ongoing criminal or civil investigations

Executive Order 13520 (Nov. 20, 2009)

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Executive Order No. 13520

- The Order requires within 6 months:
 - Establishment an Internet-based method of collecting information from the public regarding suspected improper payments
 - For the federal programs with the highest dollar value or number of improper payments:
 - Establish semi-annual targets for reducing improper payments within these programs
 - Implement reporting requirements for agencies operating these programs

Executive Order 13520 (Nov. 20, 2009) 39

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)

S. 458 "False Claims Act Clarification Act"; H.R.1788 "False Claims Act Correction Act of 2009" 40

Additional Potential Changes to the FCA

- 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 Affordable Health Choices Act of 2009", at §1641

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Additional Recent Anti-Fraud Legislation

- "Fighting Medicare Payment Fraud Act of 2009"
 - Introduced by Sen. Chuck Grassley (R-Iowa)
 - Would give the Secretary of Health and Human Services (HHS) authority to extend Medicare's time period for paying claims from 30 days to 365 days if fraud, waste, or abuse seems likely
 - HHS would be required to use the additional time to conduct more detailed reviews of questionable claims
 - Referred to Senate Committee on finance 11/16/09

S.2774, "Fighting Medicare Payment Fraud Act of 2009"

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Additional Recent Anti-Fraud Legislation

- **“Prevent Health Care Fraud Act of 2009”**
 - Introduced by Sen. George LeMieux (R-Fla.)
 - Originally introduced by his predecessor, Sen. Martinez
 - Calls for establishment of the Office of Deputy Secretary for Healthcare Fraud Prevention within HHS
 - Would implement real-time analysis and audits of claims data to pinpoint billing patterns that could indicate fraud or abuse
 - Referred to Senate Committee on 10/29/09
 - Companion bill introduced in the House on 12/8/09

S.2128, “Prevent Health Care Fraud Act of 2009”; H.R.4222 “To provide for the establishment of the Office of Deputy Secretary for Health Care Fraud Prevention” 43

Additional Recent Anti-Fraud Legislation

- **“Health Care Fraud Enforcement Act of 2009”**
 - Introduced by Sen. Ted Kaufman (D-Del.)
 - Provides that a person “need not have actual knowledge” or “specific intent to commit” to be subject to criminal punishment for healthcare fraud
 - Increases penalties for healthcare fraud
 - Expands definition of a “Federal health care offense” to attempts and conspiracies to commit fraud that relate to healthcare benefit programs
 - Would make false claims for benefits under a federal healthcare program subject to criminal liability as well as civil fines of \$5,000 to \$10,000 plus treble damages
 - Referred to Senate Judiciary Committee 10/28/09

S.1959 “Health Care Fraud Enforcement Act of 2009” 44

Additional Potential Changes to the FCA

- “The Strengthening Program Integrity and Accountability in Health Care Act”
 - Introduced by Sen. Grassley
 - Would make revisions to the FCA beyond those contained in FERA:
 - Two-year statute of limitations for retaliation claims
 - Revision of the Public Disclosure Bar to prevent dismissal of a relator when such dismissal is opposed by the Government
 - Revision of the “original source” exception to permit relators to proceed *“if the relator reported the fraud to the Government before the [public] disclosure or if the relator provides information to the Government that ‘materially adds’ to the publicly disclosed information”*

S. 2964, “The Strengthening Program Integrity and Accountability in Health Care Act” (Jan. 28, 2010) 45

Additional Potential Changes to the FCA

- “The Strengthening Program Integrity and Accountability in Health Care Act” (cont.)
 - Includes various health care fraud prevention methods from the now-stalled health care reform bills:
 - Requirement to report and return overpayments within 60 days after the date identified or the date a corresponding cost report is due, after which time an “obligation” arises that may lead to liability under the FCA
 - Expansion of Civil Monetary Penalties Section of the Social Security Act to cover various actions, including the failure to return an overpayment
 - Increased funding for program integrity and healthcare fraud prevention
 - Expansion of the Recovery Audit Contractor Program to Medicare Parts C and D by December 2010

S. 2964, “The Strengthening Program Integrity and Accountability in Health Care Act” (Jan. 28, 2010) 46

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

www.usdoj.gov/usao/law (July 1, 2009) 47

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) 48

Medicare Clinical Research Coverage Issues



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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) 50

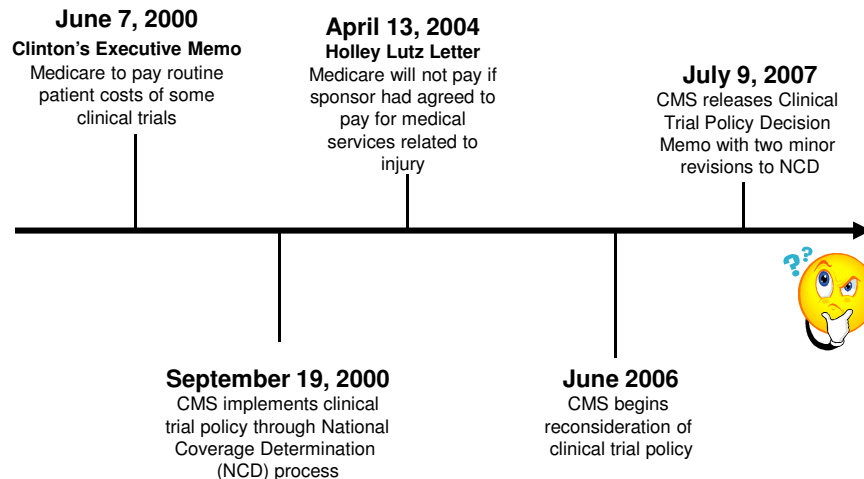
2005 OIG Draft Compliance Program Guidance

- **Multi-Agency Initiative on Clinical Research Compliance Guidance**
 - Launched by National Science and Technology Council to expand on OIG efforts to provide voluntary compliance guidelines for recipients of Federal research funding from all Federal agencies
 - Research Business Models Subcommittee assessment of the Guidance was suspended, but reconvened in late 2009
 - HHS has asked NIH to release another request for information in order to revise current regulations
 - Subcommittee assessment is on hold until NIH process concludes

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

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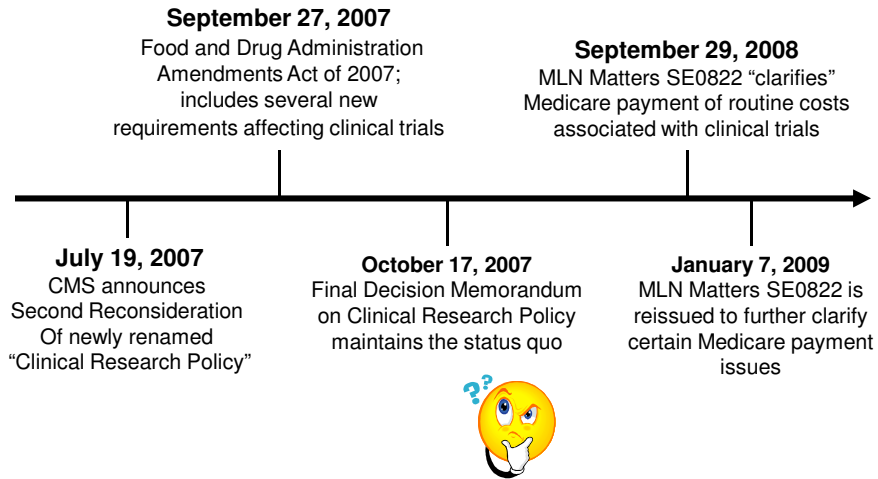
CMS Clinical Research Policy



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

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CMS Clinical Research Policy



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

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Medicare Secondary Payor / No Legal Obligation to Pay Issues

- CMS interpretation in April 2004 Holley Lutz 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?

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

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

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

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)

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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))

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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) 61

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 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**

- **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
- \$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)

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Grant Management



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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**

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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)

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2005 OIG Draft CPG – Risk Areas

- **Allocating costs and 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

- **Allegations:**
 - 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

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)

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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

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Mayo Foundation

- **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”
- **\$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)

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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

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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>

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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)

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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**
 - **Allegations:**
 - 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)

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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)

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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)

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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>

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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)

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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)

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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>

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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>

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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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Questions



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