FRAUD AND ABUSE RISKS OF CONDUCTING CLINICAL RESEARCH TRIALS

Clinical Trials: Emerging Legal Threats
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FOCUS ON RECENT FRAUD AND ABUSE ENFORCEMENT IN:

- Grant Applications and Use of Grant Funds
- Clinical Research Trials

CIVIL FALSE CLAIMS ACT ("FCA") 31 U.S.C. §3729

- Liability for Certain Acts-Any person who-
  - knowingly presents, or causes to be presented, to an officer or employee of the United States Government... a false or fraudulent claim for payment or approval;
  - knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; ...

CIVIL FALSE CLAIMS ACT (cont.)

- Knowing and Knowingly means:
  - Has actual knowledge of the information;
  - Acts in deliberate ignorance of the truth or falsity of the information; or
  - Acts in reckless disregard of the truth or falsity of the information.

CIVIL FALSE CLAIMS ACT (cont.)

- Sanctions
  - Up to $11,000 per claim
  - Treble damages
  - Potential exclusion from federal healthcare programs (Medicare, Medicaid, NIH, etc.)

THE QUI TAM PROVISIONS OF THE FALSE CLAIMS ACT (31 U.S.C. §3730)

- Case brought by a private individual (a “whistleblower”)
- In the name of and in behalf of the United States government
- Filed under seal and in camera while the DOJ investigates merits for civil or criminal prosecution and considers whether to intervene
- In standard case, where government intervenes, qui tam relator (plaintiff) receives between 15% and 25% of the proceeds of settlement. (25% to 30% where government does not intervene.) (31 U.S.C. §3730(d)(1))
- Reasonable attorneys’ fees and costs also recoverable

WHO ARE THE QUI TAM RELATORS?

- Physicians
- Researchers
- Lab assistants
- Auditors/consultants
- Sales representatives
- University officials
- Disgruntled employees and former employees
- Disgruntled spouses

FCA CASES IN THE CONTEXT OF RESEARCH

- False certifications in grant applications
- False statements in use of grant funds
- Failure to make complete disclosures
- False statements in reporting use of grant monies or research results
- False statements in allocation of costs
- Fraudulent Medicare billing
- Double billing a grant and other federal payment program (Medicare)
- Omission of material facts on grant applications
- Failure to disclose industry funding

WHAT DOES NOT LEAD TO FCA LIABILITY

- Citation of published article
- Statement that is literally true
- Disagreement over scientific methodology
- Scientific errors
- Failure of research system to reveal an error
- Data immaterial to government's decision to fund research

RELATIONSHIP OF INVESTIGATION BY THE OFFICE OF RESEARCH INTEGRITY ("ORI") TO THE FCA

- Findings of ORI not entitled to preclusive effect in FCA case, where ORI did not conduct a hearing and parties had no opportunity to litigate the issues.
- Level of intent required for the ORI to proceed with an administrative action is intentional falsification, a higher level of intent than required under the False Claims Act.
- Claim may be actionable under the FCA that is not actionable under ORI regulations for research misconduct. (*See, Milam* case.)

RELATIONSHIP OF MEDICARE, FDA BILLING RULES TO THE FCA

- Prior to submitting claim for payment under Medicare or FDA billing rules, be sure claim complies with particular rule for specific treatment and/or research circumstance
  - If claim is not in compliance with billing rules, claim could be a false or fraudulent claim for payment or approval under the FCA

RELATIONSHIP OF MEDICARE, FDA BILLING RULES TO THE FCA (cont'd)

- Review accuracy of facts and circumstances set forth in:
  - Research application
  - Medical records of research subjects
  - Results reported in research trials
  - If records submitted are not accurate, they could be construed as a false record submitted to secure a false or fraudulent claim for payment

ANTI-KICKBACK STATUTE
42 U.S.C. §1320a-7b(b)

- Whoever knowingly or willfully solicits or receives any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind-
  - in return for referring an individual to a person for the furnishing or any item or service for which payment may be made in whole or in part under a Federal health care program; or
  - in return for purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal health care program,
  - shall be guilty of a felony, fined not more than $25,000 or imprisoned for not more than 5 years or both.

POTENTIAL KICKBACKS IN CLINICAL RESEARCH

- Award of clinical trial to Key Opinion Leader or Top Prescriber
  - Does funding encourage investigator to prescribe drug or device being tested?
  - Was this the intent?
- Payments to researchers/recruiters or subjects of the study inconsistent with fair market value for services rendered and/or costs
- Seeking of reimbursement for clinical supplies or devices

ADDITIONAL AREAS OF KICKBACK RISK

- Payment of consultants, speakers above FMV for services rendered or speaking engagements
- Providing value to influence research, expenditures, reporting, other
  - Free travel
  - Fine dining
  - Free tickets to sports, theatre, golf and other country club outings
  - Other items of value

USE OF THE FALSE CLAIMS ACT TO ENFORCE RESEARCH GRANT ACCOUNTING RULES

- Indictment of Former Dean, University of Louisville
  - On October 22, 2008, a former Dean from the University of Louisville and a colleague were indicted on charges of conspiracy to commit money laundering, mail fraud and tax evasion for allegedly taking a total of $2.3 million in grant funds from the University of Rhode Island. In furtherance of the scheme, a non-profit organization was created for the purpose of siphoning off grant funds.

- Settlement of False Claims Act case by officials from cancer research institute in New York state
  - On January 11, 2007 the former President, officers and directors of a cancer research institute settled for $3.2 million a case alleging misuse of federal grant funds involving fraudulent requests for reimbursement seeking payment for expenses not related to the terms of the grants. Both outside auditors and financial services providers paid significant amounts for civil claims arising from their advice to the institute. In 2008, Institute CFO entered into a plea agreement after admitting he lied to federal agents during the investigation.

- St. Louis University School of Public Health settlement of False Claims Act case
  - The whistleblower, former Dean of St. Louis University School of Public Health, filed suit in May 2005 alleging that faculty from the school overstated their time spent on grants from the CDC, and this resulted in the inflation of supplemental income to these faculty members through the grants. In July 2008, the School paid $1 million and agreed to yearly auditing to settle the case.

- Cook County Hospital settled False Claims Act case by former investigator
  - Hospital and an associated non-profit institute paid $5.5 million to settle a 1997 qui tam action alleging that they submitted false claims under a research grant from National Institute on Drug Abuse. False claims alleged included inflation of number of research subjects ("ghost subjects") and misrepresentation about randomization of the study. In related case, the United States Supreme Court determined that the local county government, which received the federal funds, can be sued in a qui tam action under the False Claims Act. *Cook Co., Illinois v. United States ex rel. Janet Chandler*, 538 U.S. 119 (2003).

- Yale University settles False Claims Act and common law claims for $7.6 million
  - Included in the allegations in this case were assertions that from 2000 to 2006, Yale researchers allegedly transferred costs to federal grant accounts to which the costs were not allocable. It was alleged that this was done rather than returning the funds to the government, as the grants were near expiration and monies remained in the accounts. Researchers also allegedly submitted reports showing 100% time charged to the federal grants when the researchers were actually spending time on work not related to the grant that they would not otherwise have been paid for. The case was settled in December 2008.

CLINICAL TRIAL BILLING

CMS Issues Clarification of Medicare Payment for Routine Costs in a Clinical Trial (Sept. 29, 2008; revised Jan. 7, 2009)

(http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0822.pdf)

- Payments for routine costs in a clinical trial are outlined in Chapter 16, Section 40, of the Medicare Benefit Policy Manual
  - Medicare Standard: Medicare will not pay for services or items provided freely, which no one has a legal obligation to pay for or provide.
  - OIG has advised that Medicare allows hospitals to waive collection of charges to uninsured patients of limited means and this will not violate the Anti-Kickback Statute. Nonetheless, waivers of co-pays must be carefully reviewed and justified.

Research Sponsor Payments for Routine Costs in Clinical Trials Must be Analyzed in Conjunction with Payments to Medicare Beneficiaries

- If research sponsor agreement provides that sponsor will pay for routine costs if there is no reimbursement from patient or insurer, Medicare payment cannot be made, and beneficiary cannot be charged.
- Research sponsor may pay for routine costs for indigent non-Medicare patients based on financial need. If this payment is made, Medicare beneficiary may be charged, if all other patients are charged (whether their insurance pays or not).
- Research sponsor may pay for Medicare co-payments and deductibles in clinical trials, but this possibly could pose fraud and abuse problems.

OIG Advisory Opinion 8-11 (Sept. 17, 2008)

Issue: Whether cost-sharing obligations for Medicare beneficiaries participating in a federally sponsored clinical trial could be waived without a violation of the fraud and abuse laws (in particular, the Anti-Kickback Statute)?

Response: Yes, in spite of the OIG's general dislike of blanket waivers.

Analysis: All OIG Advisory Opinions are limited to the particular facts and circumstances of the case presented, and cannot be relied upon by any other than the parties requesting the opinion. In this case of a long-term randomized controlled trial, both CMS and NIH sponsored the research and closely monitored the trial, there was no specific industry involvement and the cost-sharing waiver could enhance the likelihood of success of the trial.