Clinical Trial Fraud and the False Claims Act

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Overview

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- **Federal Dollars**
- **False Claims Act and Proposed Amendments**
- **False Claims Act and Clinical Trials**
- **Preventive Steps**

Federal Dollars

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- **Nonprocurement Programs**
  - **Research Grants**
- **Medicare Coverage**

Medicare Coverage

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Medicare National Coverage Determinations Manual
Chapter 1, Part 4 (Sections 200 – 310.1)
Coverage Determinations

Table of Contents
(Rev. 74, 09-07-07)

310.1 ROUTINE COSTS IN CLINICAL TRIALS *(Effective July 9, 2007)*

(Rev. 74, Issued: 09-07-07, Effective: 07-09-07, Implementation: 10-09-07)

Effective for items and services furnished on or after *July 9, 2007*, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

False Claims Act

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- **Elements**
  - **Applies to 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" or**
  - **"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[.]" 31 U.S.C. §§3729(a)(1)-(2).**
- ***Allison Engine***
  - **The Court held that "a §3729(a)(2) claim must prove that the defendant intended that the false record or statement be material to the Government's decision to pay or approve the false claim."**

False Claims Act and Clinical Trials

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- **Responsible Parties:**
  - **Sponsors**
  - **CROs**
  - **IRBs**
  - **Clinical Investigators**
  - **Agents/Employees of All of the Above**

False Claims Act and Clinical Trials

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- The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).

- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.

- Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

False Claims Act and Clinical Trials

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The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;

2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;

3. The trial does not unjustifiably duplicate existing studies;

4. The trial design is appropriate to answer the research question being asked in the trial;

5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;

6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and

7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

False Claims Act and Clinical Trials

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- False statements in grant applications to NIH.
- False statements in progress reports and annual reports.
- Plagiarism.
- No IRB approval or inadequate IRB oversight.
- Omission of data.
- Not recording AEs.
- No or inadequate Informed Consent.
- "Gift" authorship.
- Failure to publish negative results.
- Failure to disclose a conflict of interest.
- Inadequate researching of a topic before beginning new research.
- Failure to post on clinicaltrial.gov

False Claims Act and Clinical Trials

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***United States ex rel Gross v. AIDS Research Alliance,* 415 F.3d 601 (7th Cir. 2005)**

- **Gross was a patient in an NIH-funded trial.**
- **Alleged significant violations of the protocol, Good Clinical Practices recordkeeping requirements, and failure to obtain proper informed consent.**
- **Alleged that annual filings to NIH were therefore false certifications.**
- **Seventh Circuit affirmed the dismissal because the relator did not allege "why any particular statement caused the government to keep the funding spigot open."**

Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria.

False Claims Act and Clinical Trials

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- **State Enforcement – Criminal**
  - **Drs. Borison and Diamond (1998)**
    - **Claimed to sponsors that research would be done under the auspices of Medical College of Georgia and the Veterans Administration when it was not.**
    - **Millions paid and diverted by clinical investigators.**
    - **Sentenced to 15 and 5 years respectively in state prison.**
    - **FDA debarment.**

False Claims Act and Clinical Trials

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- **Proposed Amendments**
  - **The False Claims Act Correction Act of 2007 (H.R. 4854):**
  - **Would repeal the requirement of presentment of a false or fraudulent claim to a government employee, redefining the offense as presentment of a false or fraudulent claim for *Government money or property* irrespective of who receives the claim.**

False Claims Act and Clinical Trials

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- **What Does the Future Hold?**
  - **Explosion of Clinical Trials**
  - **More Use of CROs**
  - **More Foreign Trials Intended for US Submission**

Foreign Clinical Trials

We will review the extent to which drug manufacturers use foreign clinical trials to support new drug applications (NDA) submitted to FDA. Section 505(i) of the FDCA and regulations at 21 CFR pt. 312 provide for FDA oversight of clinical trials of new drugs. Sponsors may submit data from foreign clinical trials provided that they meet criteria set forth in 21 CFR § 312.120 related to the qualifications of clinical investigators and participating sites. FDA is prohibited from disqualifying foreign trial data if the trials are conducted in accordance with ethical principles acceptable to the world community. FDA officials interviewed for a 2007 OIG report

Preventive Steps

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- **Select Qualified Investigators**
- **Monitor Sites**
- **Ensure Compliance with IND Requirements and Protocol**
- **Report Safety Information to FDA and Clinical Trial Investigators**
- **Report Investigator Misconduct to FDA**

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