

**Epstein Becker & Green, P.C.**




**Contracting With Research Sites  
And Investigators:  
A Fraud And Abuse Primer**

Presented by:  
Elizabeth A. Lewis

**[www.ebglaw.com](http://www.ebglaw.com)**

# Checklist for Compliance: Contracting Guidelines

 Evaluate purpose/scientific value of proposed research project

 Develop research budget

- FMV Evaluation
- Contemplate allocation/return of excess funding
- No profits
- Time records/documentation
- Limit to appropriate number of investigators/sites
- No payments directly to investigators/sites
- No incentives to increase subject participation

# Checklist for Compliance: Contracting Guidelines

## Identify Potential Investigators/Sites

- Beware of cumulative relationships
- Develop qualification criteria (don't limit to high prescribers)
- Limit to appropriate number of investigators/sites
- No incentives for participation

# Checklist for Compliance: Contracting Guidelines

## Require Written Documentation

- Meet safe harbor requirement

## Require Financial Conflict of Interest Disclosures

- Meet industry guidelines

## Research Meetings must be Modest, Limited, have Scientific Purpose and not be Promotional




# Checklist for Compliance: Contracting Guidelines

- 📄 Require Appropriate Written Documentation of Research
- 📄 Establish Appropriate Monitoring Systems for Billing Federal Health Care Programs
- 📄 Establish Monitoring and Checks and Balances for Contract Compliance

# Legal/Regulatory Framework For Compliance Checklist

- 📄 Federal Anti-kickback Statute
- 📄 Federal False Claims Act
- 📄 Physician Self Referral Law
- 📄 Industry Guidelines on Conflict of Interest
- 📄 AMA Guidelines

# Contracting Guidelines: Legal Basis

-  Evaluate Purpose
-  Develop Research Budget
-  Identify Potential Investigators

# Legal/Regulatory Guidelines: Federal Anti-kickback Statute

 It is a felony to:

- knowingly and willfully:
- solicit or receive any remuneration (bribes, kickbacks, rebates)
- directly or indirectly
- overtly or covertly
- in cash or in kind
- in return for:
  - referring an individual to a person for the furnishing or
  - arranging for the furnishing of an item/service; or
  - purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering any good, facility, service or item
- for which Medicare or a state health care program may pay

# Federal Anti-kickback Statute

- Violators may be subject to the following penalties:
  - \$25,000 for each offense
  - Imprisonment for up to 5 years
  - Exclusion from the Medicare, Medicaid and/or other Federal and State health care programs
  - Civil monetary penalties

# Federal Anti-kickback Statute

It is significant to note that civil monetary penalties are widely applied to:

- Any individual entity that furnishes items or services that are reimbursable under the programs is subject to exclusion from the programs, *regardless* of whether that individual or entity directly presents a bill to the program.
- Pharmaceutical manufacturers are indirect providers.

# Federal Anti-kickback Statute: Special Fraud Alert

- 📄 Aug. 1994 Special Fraud Alert on Prescription Drug Marketing Schemes
- 📄 Identifies provision of substantial payments for de minimis research as problematic
- 📄 Investigation warranted if research has questionable scientific value or lacks scientific pursuit

# Contracting Guidelines: Legal Basis

 Require Written Documentation

# Federal Anti-Kickback Statute

- Congress has adopted exceptions to the Federal Anti-Kickback Statute.
- Congress also has given HHS authority to issue “Safe Harbor” regulations to describe financial arrangements that fall outside of the Anti-Kickback Statute.
- Compliance with a Safe Harbor should offer protection against liability under the Anti-Kickback Statute.
- Conduct outside the Safe Harbors must be analyzed based on the “*facts and circumstances*” to determine whether a violation exists.

# Personal Services and Management Safe Harbor

## Requirements:

- signed, written document
- specifies services
- part-time vs. full-time
- at least one-year term
- aggregate compensation set in advance, fair market value, not based on referrals
- a legal activity
- commercial reasonableness

# Contracting Guidelines: Legal Basis

 Require Written Financial Conflict of Interest Disclosure

# Industry Guidelines: Conflict of Interest

## Consensus Statement on Conflict of Interest Policies for Academic Institutions

- Developed by NIH-funded medical schools in January 2001
- Purpose is to clarify, strengthen and add structure to institutional conflict of interest policies governing collaboration between faculty and industry


# Industry Guidelines: Conflict of Interest

- 📄 Written policy on financial interests related to research
- 📄 Application to all involved
- 📄 “Financial Interest” includes fees, gifts, honoraria, consulting arrangements, equity interests, stock options, directorships, special relationships with potential for personal material gain
- 📄 Disclosure Required

# Contracting Guidelines: Legal Basis

 Require Meetings

# Industry Guidelines: AMA Guidelines

 Provides guidance on research related travel

- genuine research purpose
- payment only of “reasonable expenses”
- no exotic location
- modest hospitality only
- meeting must be appropriate size to accomplish research purpose, no larger
- not for promotional purposes

# Industry Guidelines: AMA Guidelines

## Definition of “Genuine Research Purpose”

- valid study protocol
- recruitment of physicians with appropriate expertise/qualifications
- recruitment of appropriate number of physicians

# Contracting Guidelines: Legal Basis

 Billing Federal Health Care Programs

# Federal False Claims Act (“FCA”)

- FCA prohibits:
  - A person from “knowingly” submitting claims or making false record or statement in order to be paid from the federal government
- FCA defines “knowingly” to mean that a person:
  - Has actual knowledge of information
  - Acts in deliberate ignorance of the truth/falsity of information
  - Acts in reckless disregard of the truth/falsity of information
- Violators of the FCA:
  - Civil penalty for each claim of \$5,000-\$10,000 plus three times the amount of damages to the federal government.