

Physician Health Care Fraud and Compliance

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Sean R. McKenna, Assistant U.S. Attorney
Northern District of Texas
Dallas Division

This Presentation Provides General Legal Information and Should not be Construed as Legal Advice. Persons Wishing such Advice Should Seek Legal Counsel Concerning Specific Fact Situations that Confront Them. Opinions Expressed Herein or Otherwise are Those of the Speaker and do not Necessarily Reflect the Views of the United States Attorney's Office for the Northern District of Texas or the United States Department of Justice.

Outline of Presentation

- Introduction
- Health Care Fraud Enforcement Agencies and Efforts
- Physician Financial Relationships
- Investigations
- False Claims
- Questions

Compliance “Jeopardy”

Enforcement	Financial Relationships	Investigations	False Claims
\$100	\$100	\$100	\$100
\$200	\$200	\$200	\$200
\$300	\$300	\$300	\$300
\$400	\$400	\$400	\$400
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Enforcement \$100

**This Federal Agency is Committed to
Combating Health Care Fraud.**

What is the Department of Justice (DOJ)?

Health Care Fraud and DOJ

- Strategic Goal Continues to be Dismantlement of Criminal Enterprises Engaging in White-Collar Crime, Including Health Care Fraud
- “Main” Justice is Located in Washington, DC
 - Pursue Separate and Joint Criminal and Civil Health Care Fraud Prosecutions
 - No Geographic Limitations on Jurisdiction
 - Organized into Distinct Components
 - Criminal Fraud Section - HIPAA
 - Civil Frauds Section of Commercial Litigation Branch - HCA
- United States Attorneys’ Offices
 - Located Within 93 Separate Federal Judicial Districts
 - Conduct Criminal and Civil Prosecutions along with Debt Collection Activities
 - Limited Geographic Jurisdiction
 - Most Health Care Fraud Cases Resolved by U.S. Attorneys’ Offices

Enforcement \$200

These Two Entities are the Primary Health Care Fraud Enforcement Agencies for the Federal Government.

What are DOJ and the Office of Inspector General for Health and Human Services (OIG)?

DOJ Enforcement Efforts

- Obtained \$605 Million in Health Care Fraud Judgments and Settlements in 2004
- \$1.51 Billion Returned to the Medicare Trust Fund in 2004
- \$99 Million Transferred to CMS in 2004
- Prosecutors Filed 395 Indictments in Health Care Fraud Cases and Convicted 459 Defendants in 2004
- Opened 868 New Civil Health Care Fraud Matters and Intervened or Filed Complaints in 269 Civil Cases in 2004

OIG Enforcement Efforts

- The OIG Reported Savings of \$35.4 Billion in Implemented Recommendations and Other Actions to Strengthen the Medicare and Medicaid Programs in FY 2005
- The OIG Obtained 537 Criminal Convictions in FY 2005
- The OIG Entered into 262 Civil Settlements in FY 2005
- The OIG Collected \$1.6 Billion in Recoveries and Fines in FY 2005
- The OIG Imposed 3,806 Program Exclusions Against Direct and Indirect Providers in FY 2005

Enforcement \$300

Health Care Compliance Resources Available to Physicians Include These Government Publications.

What are OIG Advisory Opinions, Compliance Guidance Programs, and Semi-Annual and Work-Plan Reports?

Enforcement Related Information

- CMS/Program Safeguard Contractor Sponsored Education and Training
- Government Websites and Statistics
- Advisory Opinion Process
- Compliance Program Guidance
- OIG Work Plans and Audit Reports
- GAO Reports
- Published Corporate Integrity Agreements
- Comments to Proposed and Preambles to Final Anti-Kickback Safe Harbors
- Provider Self-Disclosure Protocol

Enforcement \$400

Daily Double

Enforcement \$500

These are Three of the Top Sources of
Federal Health Care Fraud Cases.

What are Referrals from Law Enforcement,
Qui tam Suits, and Competitor
Complaints?

Sources of Health Care Fraud Cases

- Referrals from Law Enforcement Agencies
 - Federal Bureau of Investigation
 - Offices of Inspector Generals
 - Defense Criminal Investigative Service
- Qui tam Suits Filed Under the Civil False Claims Act
- Competitor Complaints
- Referrals from Program Safeguard Contractors
- DOJ/CMS Working Groups or Task Forces
- Anonymous and Hotline Complaints

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Financial Relationships \$100

These Two Federal Statutes Limit Financial Relationships of Health Care Providers.

What are the Anti-Kickback Statute and “Stark” Law?

The Anti-Kickback Statute and Stark Law

- Increasingly Bases for Civil False Claims Act Cases
- The Anti-Kickback Statute
 - Criminal Statute Covering all Persons
 - Remuneration can be Anything of Value
 - Fair Market Value is the Critical Inquiry in Several Safe Harbors
 - Generally, Compliance with Safe Harbor Means Less Risk
- The Stark Law
 - Civil Statute Covering Physicians and Family Members
 - Remedy is Disallowance of Improperly Paid Claims
 - Commercially Reasonable Under Fair Market Value Exception Requires Arrangement to Further a Legitimate Business Interest

Financial Relationships \$200

Can a Hospital be Prosecuted and/or Sued for Paying Physicians for Medical Director Duties if that Physician Refers Medicare and Medicaid Patients to the Hospital for Treatment and Diagnostic Testing.

What is Yes, if “One Purpose” of the Payments are to Induce Patient Referrals?

“The Government Must Prove Beyond a Reasonable Doubt That Only One Purpose for the Offering or Paying of a Remuneration was to Induce the Referral of an Individual to a Person for any Item or Service for Which Payment may be Made in Whole or Part Under a Federal Health Care Program.

The Government Need Not Prove all of the Purposes, or Even the Primary Purpose of the Remuneration, but Only That a Purpose of the Offering or Paying of the Remuneration was to Induce a Referral.

It is Not a Defense that There Were Other Reasons for the Offering or Payment of a Remuneration if You Find Beyond a Reasonable Doubt that One Purpose for the Offering or Payment was to Induce the Referral.”

Financial Relationships \$300

This Marketing Practice is Again Making News.

What are “Free” Lunches?

Free Lunches as Marketing?

- The OIG and Drug Industry Recognize the Marketing of Products can be Problematic
 - *Final OIG Compliance Guidance for Pharmaceutical Manufacturers*, April 2003
 - *Code on Interactions with Healthcare Professionals*, PhRMA, July 2002
- *Drug Makers Pay for Lunch as They Pitch*, Stephanie Saul, New York Times, July 28, 2006
 - “Incredibly Effective in Lifting Pharmaceutical Sales. . .”
 - “Currency that Buys Access to Doctors’ Offices for Drug Representatives”
 - “Good Time to Sit Around and Talk About the Clinical Properties of [] Drug and Disease Categories”

Financial Relationships \$400

This Potentially Problematic Arrangement Involves Two Competitors Jointly Furnishing Health Care Services to Federal Health Care Program Beneficiaries.

What are Contractual Joint Ventures?

Contractual Joint Ventures

- Usually Arrangement Between Providers to Cooperate in Furnishing Health Care Services or Creation of New Legal Entity
 - Hospital Creating DME Subsidiary and Contracts with Existing DME Supplier
- Implicate the Anti-Kickback Statute but no Specific Safe Harbor is Applicable to Contractual Joint Ventures
 - Discount Safe Harbor Protection Unavailable if There is no “Arms Length Transaction”
- Indicia of Suspect Contractual Joint Ventures:
 - New Line of Business that is Already Provided to Owner’s Patients
 - Serves Captive Referral Base or Owner’s Existing Patients
 - Little or No Bona Fide Risk to Owner
 - Manager/Supplier is Really Competitor
 - Most Substantive Services Provided by Manger/Supplier
 - Remuneration Generated Depends on Value/Volume of Referrals
 - Exclusivity of Arrangement

Financial Relationships \$500

**This Guidance Addresses Recipients' Use of
and Accountability for Federal Research
Grants.**

**What is Formerly the OIG's Draft Compliance
Guidance Program for Recipients of Public
Health Service Research Awards?**

Compliance Guidance for Research Awards

- Basis for Forthcoming Voluntary Compliance Guidance for Recipients of all Federal Research Funding
- Several Elements of Compliance Program are Mitigating Factors in Debarment Proceedings
- Seeks to Ensure Proper Grant Compliance and Administration
 - Identify and Correct Unlawful and Unethical Conduct
 - Encourage Employees to Report Problems, Initiating Internal Inquiry, and Implement Corrective Action
 - Minimize Financial Loss to the Institution and Government
 - Reduce the Possibility of Audits or Investigations Regarding Unallowable Costs or Fraud

Research Awards (continued)

- Time and Effort Reporting
 - In June 2005 Weill Cornell Medical College Paid \$4.4 Million to Settle Allegations that it Improperly Used NIH Funds
 - In February 2003 Northwestern Paid \$5.5 Million to Settle Allegations that it Spent Less Time on NIH Projects than Reported
- Proper Allocation of Charges to Projects
 - 2005 Survey by HealthPartners Research Foundation and the University of Minnesota
 - 50% of 3,300 Scientists Surveyed Spent Research Funds Designated for One Project on a Different Project
 - June 2006 OIG Audit of University of Chicago Regarding Cost Transfers of NIH Grant Funds
- Reporting of Financial Support from Other Areas
 - *Medical Journal Says it was Again Mislead*, AP, New York Times, July 12, 2006
 - 11 of 13 Authors Failed to Disclose Ties to Drug Companies When Study Originally Published

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Investigations \$100

These are Two Initial Decisions that Occur
Before Health Care Fraud Cases are
Prosecuted by the Government.

What are Review of the Allegations and
Determination How to Proceed?

Government's Initial Determinations

- Review Complaint
 - What are Allegations of Fraud?
 - Is DOJ Involvement Appropriate?
 - Contact Agency Representative
- Civil, Criminal, Administrative or Combination
 - Parallel Proceedings
 - Is there Harm to Federal or Private Health Care Programs?
 - Determine if Program/Agency has Issued Guidance/Instructions
- Scope and Nature of the Investigation
 - Involvement of Agent and AUSA
 - Federal and/or State
- Assemble Investigative Team
 - Agents and/or Auditors
 - Agency Counsel
 - Retain Litigation Consultant

Investigations \$200

These are Three Investigative Techniques Used
by the Government in Civil, Criminal, and
Administrative Investigations.

What are Subpoenas, Warrants, and Claims
Samples?

Investigative Tools

- Search and Arrest Warrants
- Surveillance
- Subpoenas
 - Authorized Investigation Demand (HIPAA)
 - Inspector General
 - Grand Jury
 - Civil Investigative Demand
- Requests for Information
- Interviews
- Statistically Valid Random Samples
- Medical Reviews
- Consultants and Experts

Investigations \$300

These are Three Elements of Common Investigative Plans Used by the Government in Health Care Fraud Cases.

What are Requests of Claims, Interviews, and Issuance of Subpoenas?

Health Care Fraud Investigations

- Request Claims History, Sample, and/or Medical Review
- Interviews
 - Former Employees of Physician
 - Current Employees of Physician
 - If Represented, First Inform Counsel for Employer
- Issue Subpoenas or Requests for Information
 - Evidence of “Knowledge”
 - Organization and Structure
 - Policies and Practices
 - Supporting Documents for Remuneration Paid to Physician
- Review and Analyze Relevant Documents
 - Claims Data, Rules/Guidance, and Medical Records
 - Agreement or Contracts with Physician
 - Internal/External Correspondence
 - Compliance and Educational Materials

Investigations \$400

These are Three of the Goals of a Parallel Health Care Fraud Investigation.

What are Indictment and Conviction of Culpable Persons, Civil Recoveries from Responsible Persons and Entities, and Preservation of a Defendant's Assets to Pay Fines, Penalties, and Restitution?

Goals of Parallel Fraud Investigations

- Joint Operation/Cooperation Between Law Enforcement Agencies
- Indictment and Criminal Conviction of Culpable Company, Owners, Employees, and Individual Health Care Providers
- Freeze Assets Belonging to Criminal and Civil Defendants
- Seize and Forfeit Proceeds of Health Care Fraud
- Suspend Target Companies and Providers
- Civil False Claims Act Recoveries from Responsible Persons and Entities
- Exclude Criminal Targets and Selected Civil Subjects from Participation in Federal Health Care Programs

Investigations \$500

These are Two Benefits of an Effective Compliance Program.

What are Deterrence and Detection of Fraud and Reductions in Possible Civil, Criminal, and Administrative Liability?

Benefits of Compliance

- Helps Ensure that Provider is Properly Paid
- Recognition of High Risk and/or Problem Areas
- Effective Compliance Programs Likely Prevent and Deter Health Care Fraud and Abuse
- Elimination or Reduction of Potential Civil, Criminal, and Administrative Liability
- Avenue for Employee Grievances and Complaints
- Demonstrated Commitment to Compliance may Help Mitigate Penalties and/or Punishment

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False Claims \$100

This is the Primary Statute Used to Combat Health Care Fraud Against the United States.

What is the Civil False Claims Act (FCA)?

Civil False Claims Act

- Majority of FCA Cases are Qui tam Actions
 - Qui tams Resulted in Recoveries of \$1.3 Billion in FY 2003
- Generally, Persons who Knowingly Make or Present, or Cause to be Made or Presented, a False or Fraudulent Claim or Statement for Payment to the Government
 - Not Intended to Punish Mere Negligence
- “Knowingly” is Defined as:
 - Actual Knowledge
 - Acting in Deliberate Ignorance, or Reckless Disregard of the Truth or Falsity of the Information on the Claim
 - No Specific Intent to Defraud is Required
- Violators are Subject to Penalties of \$5,500 - \$11,000 per False Claim, Treble Damages, and Costs

False Claims \$200

This Prohibition or Law is a Basis for Provider Liability Under the Civil False Claims Act.

What is the Physician Self-Referral Prohibition or “Stark” Law?

Stark Law Violations Under the FCA

- Tenet Healthcare Corporations, Paid \$22.5 Million to Resolve Allegations that One of its Facilities Improperly Billed Medicare for Referrals Provided by Doctors with whom the Hospital had Prohibited Financial Arrangements
- Settlement is the Largest FCA Recovery from a Single Hospital for Alleged Violations of the Stark Law due to the Hospital's Failure to Comply with Specified Exceptions for Financial Relationships

False Claims \$300

These are Three Common Criminal Statutes
Used by the Government to Prosecute Health
Care Fraud.

What are the Health Care Fraud, Wire Fraud,
and Mail Fraud Statutes?

Criminal Health Care Fraud Provisions

- False Claims, 18 U.S.C. § 287
- Conspiracy, 18 U.S.C. § 371
- Health Care Theft or Embezzlement, 18 U.S.C. § 669
- Mail Fraud, 18 U.S.C. § 1341
- Wire Fraud, 18 U.S.C. § 1343
- Fraud Injunction Statute, 18 U.S.C. § 1345
- Health Care Fraud, 18 U.S.C. § 1347
- The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)
- Illegal Retention of Federal Funds, 42 U.S.C. § 1320a-7b(a)(3)

False Claims \$400

This Generic Term is Used to Characterize a Health Care Provider's Intentional or Knowing Failure to Disclose on a Medicare/Medicaid Cost Report any Discount or Rebate that Affects that Provider's Reimbursement.

What is "Fraud"?

Notable FCA Settlements

- Schering Sales Corporation Paid the United States and 50 State Medicaid Programs \$293 Million to Settle Allegations of Fraudulent Drug Pricing
 - Allegations Were Schering Failed to Report to Medicaid its True Best Price and Discounts for Claritin
 - Agreed to a Corporate Integrity Agreement with the OIG
- SmithKline Beecham Corporation Paid the United States \$149 Million to Settle Allegations of Inflated Drug Pricing
 - Allegations Included SmithKline's Use of Fraudulent and Inflated Prices for Antiemetic Drugs Zofran and Kytril
 - Agreed to Additional 5 years to Existing Corporate Integrity Agreement

False Claims \$500

True or False: Providers who Disclosure Federal Health Care Program Overpayments are Always Required to Enter into Corporate Integrity Agreements.

What is False?

Self-Disclosure of Overpayments

- Affirmative Obligation to Repay Funds
 - Potential Criminal Liability Under 42 U.S.C. § 1320a-7b(a)(3)
- OIG Self-Disclosure Protocol
 - 295 Total Submissions, 60 Recoveries, 63 Settlements, and \$104.2 Million Paid by Providers
 - St. Joseph Mercy-Oakland Agreed to Pay \$4 Million to Resolve Liability for Allegedly Improper Financial Arrangements with Physicians and Physician Groups to Induce Patient Referrals
 - St. Francis Hospital, Inc. Agreed to Pay \$9.5 million to Resolve Liability for Allegedly Significant Error Rates and Documentation Lapses Within its Home Health, Hospice, and DME Medicare Claims
 - Cedar Oaks Care Center, Inc. Agreed to Pay \$92,232.74 to Resolve Liability for Allegedly Employing an Individuals Excluded from Participation in Federal Health Care Programs

Questions