OFFICE OF INSPECTOR GENERAL WORK PLAN

FISCAL YEAR 2006
MEDICARE HOSPITALS

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Medicare Hospitals – Areas of Focus for OIG Work Plan 2006

- Adjustments for Graduate Medical Education Payments
- Payments for Observation Services versus Inpatient Admissions for Dialysis Services
- Medical Education Payments for Dental and Podiatry Residents
- Nursing and Allied Health Education Payments
- Inpatient Prospective Payment System Wage Indices
- Inpatient Rehabilitation Facilities Payments
- Inpatient Hospital Payments for New Technologies
- Inpatient Psychiatric Hospitals
- Inpatient Rehabilitation Payments – Late Assessments
- Long Term Care Hospital Payments
- Critical Access Hospitals
- Organ Acquisition Costs
- Rebates Paid to Hospitals
- Coronary Artery Stents
- Outpatient Outlier and Other Charge-Related Issues
- Outpatient Department Payments
- Unbundling of Hospital Outpatient Services
- “Inpatient Only” Services Performed in an Outpatient Setting
- Diagnosis-Related Group Coding
- Hospital Reporting of Restraint-Related Deaths
Medicare Hospitals – Area of Focus

Added to OIG Work Plan 2006

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- Inpatient Psychiatric Hospitals
- Outpatient Department Payments
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Medicare Hospitals – Areas of Focus
Continued from OIG Work Plan 2005

- Medical Education Payments for Dental and Podiatry Residents
- Nursing and Allied Health Education Payments
- Inpatient Prospective Payment System Wage Indices
- Inpatient Rehabilitation Facilities Payments
- Long Term Care Hospital Payments
- Critical Access Hospitals
- Organ Acquisition Costs
- Rebates Paid to Hospitals
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Deleted From OIG Work Plan 2005 and Not Included in OIG Work Plan 2006

- Quality of Improvement Organization Mediation of Beneficiary Complaints
- Graduate Medical Education Voluntary Supervision in Non-hospital Settings
- Postacute Care Transfers
- Inpatient Outlier and Other Charge-Related Issues
- Consecutive Inpatient Stays
- Level of Care in Long-Term Care Hospitals
- Outpatient Cardiac Rehabilitation Services
- Lifetime Reserve Days
Office of Inspector General
Office of Investigations ("OI")

- OI Conducts Investigations of Fraud and Misconduct and Health Care Fraud
- Identifies Systematic Weaknesses in Vulnerable Program Areas and Recommends Management, Regulatory and Legislative Corrective Action
- Provides Investigative Assistance in Criminal and Civil False Claims, Civil Money Penalty and Exclusion Cases
- Responds to Thousands of Complaints of Health Care Fraud from Various Sources, including "Whistleblowers"
- Provider Self-Disclosure Program
- False Claims and Anti-Kickback Violations
Office of Inspector General
Office of Legal Counsel ("OCIG")

- Resolution of Civil False Claims Act cases and negotiation of Corporate Integrity Agreements ("CIA")
- Providers compliance with Corporate Integrity Agreements
- Industry Guidance: Advisory Opinions and Fraud Alerts
- Development of regulations, including safe harbors to the Anti-Kickback Statute
- Enforcement of the Civil Money Penalty and Exclusion Statutes
- Enforcement of the Patient Anti-Dumping Statute
Overview

- The Anti-Kickback Statute
- The Stark Law
- The False Claims Act
- Recent Trends in OIG and DOJ Enforcement
I. The Anti-Kickback Statute

42 USC § 1320a-7b(b)(2)

It is unlawful to knowingly and willfully offer or pay any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend 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.
The Anti-Kickback Statute

- What it All Means? – Prohibits anyone from purposefully offering, soliciting, or receiving anything of value to generate referrals for items or services payable by any Federal health care program.

- 42 States and D.C. have enacted anti-kickback statutes
Purpose of the Law

- Prevent the corruption of medical decision-making
- Prevent the over utilization of items or services
- Prevent unfair competition
Elements

- Remuneration
- Offered, Paid, Solicited, or Received
- Knowingly & Willfully
- To Induce or In Exchange for Federal Program Referrals
Remuneration

- Anything of value
- “In-cash or in-kind”
- Paid directly or indirectly
- Examples: cash, free goods or services, discounts, below market rent, relief of financial obligations
Offered, Paid, Solicited, or Received

- Different Perspectives – Payors and Payees
- “It Takes Two to Tango”
- Old Focus: Payors Subject to Prosecution
- New Focus: Payees (usually doctors)
To Induce Federal Program Referrals

- Any Federal health care program
- A nexus between payments and referrals
- Covers any act that is intended to influence and cause referrals to a Federal health care program
- One purpose test
Knowingly & Willfully

- The Anti-Kickback law requires that the individual have a particular “state of mind”, acting with knowledge and purpose when committing the offense.

- This “Knowingly & Willfully” requirements has been interpreted differently by the various Circuit Courts:
  - 9th Circuit: Must have knowledge of the Anti-Kickback Statute and have specific intent to violate the statute.
  - 8th Circuit: Mere knowledge that the conduct was “wrongful” satisfies the “Knowingly & Willfully” standard.
  - 11th Circuit: Must show that one acted with an intent to “disobey or disregard” the law.
Fines and Penalties

The Government may elect to proceed:

Criminally:
- Felony, Imprisonment up to 5 Years & a fine up to $25,000, or both
- Mandatory exclusion from participating in Federal health care programs
- Brought by the DOJ

Civilly:
- Violation is based on express or implied certification of compliance with violations of the Anti-Kickback and Stark Statutes
- Penalties are same as under False Claims Act (more later)
- Controversial, yet expanding use of the FCA

Administratively:
- Monetary penalty of $50,000 per violation & assessment of up to three times the remuneration involved
- Discretionary exclusion from participating in Federal health care programs
- Brought by the OIG
Exceptions and Safe Harbors

- Many harmless business arrangements may be subject to the Statute
- Approximately 24 exceptions ("Safe Harbors") have been created by the OIG
- Compliance is voluntary
- Must meet all conditions to qualify for Safe Harbor protection
- Is substantial compliance enough?
Guidance on the Anti-Kickback Statute

- Advisory Opinions from the OIG
  - A party may request advice on the law, concerning 1) remuneration within the meaning of the law, 2) whether they are meeting one of the law’s exceptions or safe harbors, or whether their arrangement warrants the imposition of a sanction
  - Recent Advisory Opinions on Gainsharing Arrangements

- Fraud Alerts and Special Advisory Bulletins

- Preamble to the Safe Harbor Regulations

- Compliance Program Guidance’s

- www.oig.hhs.gov
The Stark Law

- Section 1877 of the Social Security Act, 42 U.S.C. 1395nn
- The law is complicated and consists of the original statute (Stark I) and the amended provisions (Stark II)
- Most Stark II regulations went into effect in 2002, but some are still pending
The Stark Law

- A prohibition on physician self-referrals
- If a physician (or immediate family member) has a direct or indirect financial relationship (ownership or compensation) with an entity that provides designated health services ("DHS"), the physician cannot refer the patient to the entity for DHS and the entity cannot submit a claim for the DHS, unless the financial relationship fits in an exception
Penalties

- Nonpayment of claims
- Civil Money Penalties of $15,000 for each service rendered plus an assessment of three times the amount claims
- Penalty of up to $100,000 for “Circumvention Scheme”
- Don’t forget FCA liability
Difference Between Anti-Kickback Statute and the Stark Law

- Physician referrals only
- No “knowingly and willfully standard” – Strict liability
- Involves Designated Health Services (“DHS”)
Types of Designated Health Care Services (DHS)

- Clinical laboratory
- Physical therapy
- Occupational therapy
- Radiology and Imaging Services (MRI, CAT Scan, Ultrasound)
- Radiation therapy & supplies
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services
What is a Financial Relationship

- Nearly any type of investment or compensation agreement between the referring physician and the DHS entity will qualify as a financial arrangement under the Stark law.

- Examples:
  - Stock Ownership
  - Partnership Interest
  - Rental Contract
  - Personal Service Contract
  - Salary

- Compensation agreements can be direct or indirect:
  - Exceptions for certain indirect compensation arrangements.
Exceptions

- Compliance is Mandatory
- Types of Exceptions:
  - In-office ancillary services
  - Personal physician services by member of Group Practice
  - Pre-paid health plan
  - Certain publicly traded securities
  - Rural provider (investment interests)
  - Hospital ownership (must be in the “whole” hospital)
  - Rental of office space and equipment
  - Bona fide employment
  - Personal services arrangement
  - Physician recruitment
  - Fair market value payment by physicians
Additional Exceptions
Added in January 2004

- Fair Market Value compensation arrangements
- Academic medical center arrangements
- Implants provided in an ASC (Implants are DHS, but are not included in the bundled Medicare ASC payment)
- EPO and other dialysis-related drugs furnished in or by an ESRD facility
- Preventing screening tests, immunizations, and vaccines
- Eyeglasses and contact lenses following cataract surgery
- Non-monetary compensation up to $300
- Medical staff incidental benefits provided by a hospital
- Risk sharing arrangements
- Compliance training
- Indirect compensation arrangements
The False Claims Act

31 U.S.C. § 3729, the False Claims Act ("FCA") sets forth seven bases for liability. The most common ones are:

1. Knowingly presenting, or causing to be presented, to the government a false or fraudulent claim for payment

2. Knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid

3. Conspiring to defraud the government by getting a false or fraudulent claim allowed or paid

4. Knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the government.
Elements of an FCA Offense

- The Defendant must:
  - Submit a claim (or cause a claim to be submitted)
  - To the government
  - That is false or fraudulent
  - Knowing of its falsity
  - Seeking payment from the Federal treasury
  - Damages (maybe)
Knowing & Knowingly

- No proof or specific intent to defraud is required
- The government need only show person:
  - Had “actual knowledge of the information”; or
  - Person acted in “deliberate ignorance” of the truth or falsity of the information; or
  - Person acted in “reckless disregard” of the truth or falsity of the information
Penalties

1) Civil penalty of no less than $5,500 and no more than $11,000 per false claim

2) Three times the amount of damages which the government sustained
Investigative Guidelines

- Were false claims submitted by a provider with knowledge of their falsity?
  - Was there actual or constructive notice of the rule or policy on which a potential case would be based?
  - Was the rule or policy clear?
  - Does the size of the false claim support inference of knowledge or inference of mistake?
  - What plans did the provider make to adhere to the rules?
  - Are there any past remedial efforts?
  - Did the provider receive guidance by program agents on the issue?
  - Have there been previous audits to the provider of same or similar billing errors?
Qui Tam Actions & Government Intervention

- A private person ("Relator") may bring a False Claims Act action under the *qui tam* provisions of the FCA - The Whistleblower
- Government may intervene in a suit brought by Relator
- The relationship between Relator and government
FCA Statistics

- If the government intervenes and obtains recovery, the Relator receives between 15% and 25% of the proceeds.
- Since 1986, of all of the *qui tam* actions filed, the average yearly intervention rate has been about 25% (approximately 300-400 cases).
- About $1.5 billion of the $1.7 billion in health care FCA recoveries in FY ’03 were from whistleblowers.
- Recoveries have increased (higher penalties and publicity).
- Whistleblower protection is provided to those that take lawful actions in furtherance of the *qui tam* suit, including investigation, initiation, testimony for, or assistance in the action.
Role of the OIG in FCA Cases

- May assist in the investigation
- Settles as client agency on behalf of HHS
- Permissive exclusion authority
- May waive exclusion authority in exchange for Corporate Integrity Agreement
  - Monitoring and Annual Reports
  - Successor Liability
Types of FCA Cases

- Unbundling (billing single service as if one service)
- Services not rendered
- Billing for items or services that are not covered
- Upcoding
- Duplicate billing
- Submitting false or inflated cost reports
- Quality of Care ("standard of care claims" or "worthless claims")
- Research Grand and Clinical Trial fraud
- Actions under the Food, Drug & Cosmetic Act
  - Misbranding & adulteration of drugs and promotion of off label use
- False Claims Act cases based on violations of the Stark Law and/or the Anti-Kickback Statute ("Tainted Claims")
Trends in Government Enforcement

- Health care fraud enforcement continues as a priority and includes anything whistleblowers may target
- Medicare Reform Act – Expansion of prescription drug benefit – new fraud opportunities
- Corporate liability and compliance
- Quality of Care
- Stark Law and Anti-kickback violations
Hot Topics

- Physician recruitment
- Medical directorships
- Joint ventures
- Pharma and medical device marketing
- Clinical research
- Quality of Care
Corporate Liability, Compliance and Governance

- HIPPA ’96 and corporate scandals
- The new era of corporate responsibility
- Sarbanes-Oxley Act of 2002
- United States Sentencing Guideline Amendments of 2004
- Department of Justice principles of Federal prosecution of business organizations
Sarbanes-Oxley and the Sentinel Effect on Health Care Organizations

- **Public Companies** – Governance and integrity of reporting financial information
- **Private Companies** – Fiduciary obligations and shareholder derivative liability
- **Not-for-Profit Organizations** – Fiduciary obligations and Attorney General oversight
- Caremark Decision
Sentencing Guideline Amendments Raise the Stakes for Business Organizations

- Codification of principles of Caremark Decision
- Oversight and responsibility of the Board of Directors and high level personnel of the organization
- Board knowledge about the content and operation of the compliance program to prevent and detect violations of the law
- Board exercises reasonable oversight with respect to implementation and effectiveness of the compliance program
- Risk assessment as an essential component of design implementation of an effective compliance program
- Assessment of likely compliance risks given an organization’s business activities
United States Sentencing Guideline Amendments and Department of Justice Principles of Federal Prosecution of Business Organizations

“Cooperation” or “Unconditional Surrender”

- Voluntary disclosure and self-reporting as quasi mandatory function of cooperation
- Cooperation in investigating business organizations own wrongdoing
- Effects charging decision against business organization
- Effects scope of liability for business organization
- Effects sentence under Sentencing Guidelines
- Business organization’s cannot run the risk of failing to have an effective compliance and governance program
- Failure to detect and prevent wrongful conduct will result in consequences for any business organization in current compliance environment
The End