A DISCUSSION WITH THE OIG

MICHAEL J ARMSTRONG
REGIONAL INSPECTOR GENERAL FOR AUDIT SERVICES

STEPHEN J CONWAY
DIRECTOR, ADVANCED AUDIT TECHNIQUES

ROBERT K DECONTI
CHIEF, ADMINISTRATIVE & CIVIL REMEDIES BRANCH
Office of Inspector General

- Who we are
- What we do
Independence
Organizational Structure

- 5 Components
  - Office of Audit Services
  - Office of Evaluations and Inspections
  - Office of Investigations
  - Office of Counsel to the Inspector General
  - Office of Management and Policy
Interdisciplinary Approach

- OIG
- Providers
- CMS Contractors
- DOJ
- Law Enforcement
- State Agencies
Arsenal

- Laws
- Data
- Advanced analytical tools
- Special Initiatives
Laws
Statutorily Authorized

- IG Act
  - Access to all records and information
  - Issue subpoenas
  - Exclude providers from federal healthcare programs
  - Assess Civil Monetary Penalties
- Affordable Care Act
Healthcare Data
Program Outlays

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Medicare/Medicaid Statistics

- Nearly $1 trillion Medicare and Medicaid combined outlays for CY 2011
- Estimated 49 million Medicare beneficiaries
- Estimated 56 million Medicaid recipients
- Over 4.5 billion claims per year to Medicare and Medicaid
- 4.5 million claims processed by Medicare daily and paid within 30 days
Providers/Suppliers

- Nearly 3 million providers nationwide
  - 8,300 Hospitals
  - 39,000 Outpatient Facilities
  - 15,000 Skilled Nursing Facilities
  - 10,000 Home Health Agencies
  - 3,400 Hospices
  - 104,000 Durable Medical Equipment Suppliers
  - 131,000 Pharmacies
  - 1.7 Million Physicians/Suppliers
OIG Components
Office of Audit Services
# Reports

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OAS Audits

- Financial
- Performance Audits
Audit Techniques

- Risk analysis
- Computer matching
- Statistical sampling
- Medical review
OAS Audits

- Result in
  - Financial adjustments
  - Program Savings
  - Improved Internal Controls
Initiatives

- Hospital
- Home Health Agencies
- Hospice
- End-Stage Renal Disease
- Physician Services
Focus of OAS Audits

- Data Driven
- Enhanced Analytics
- Posted Results
- Management Involvement
- Be Proactive
Office of Evaluation and Inspections (OEI)

- Conducts national evaluations of HHS programs from a broad, issue-based perspective.
- The evaluations incorporate practical recommendations and focus on preventing fraud, waste or abuse and encourage efficiency and effectiveness in HHS programs.
Notable Work Products

- Vulnerabilities in FDA's Oversight of State Food Facility Inspections
- Few Adverse Events in Hospitals Were Reported to State Adverse Event Reporting Systems
- Medicare Atypical Antipsychotic Drug Claims For Elderly Nursing Home Residents
- Vaccines For Children Program: Vulnerabilities In Vaccine Management
Improperly Stored Vaccines
Office of Investigations
Office of Investigations (OI)

- Conducts criminal, civil and administrative investigations of fraud and misconduct related to HHS programs, operations and beneficiaries.
How Fraud is Detected

- Hot-Line Complaints
- Referrals From Contractors
- Audits
- Whistleblowers (Qui Tam)
- Data Mining
Data Mining
Data Matching

- Developed in-house data matching applications to identify improper payments or program savings

- Matches have included
  - Inpatient to Outpatient - DRG Payment Window
  - Medicare Part B to Outpatient - Physician Place of Service
  - Inpatient to Inpatient - Acute Care Transfers
## Trend Analysis

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Social Networking
Sophisticated Data Mining

- Anomaly Detection
- Clustering Analysis
- Time Sequencing
- Association Rules
- Predictive Modeling
What Data Can Reveal

- Over-utilization of services in very short-time windows
- Patients simultaneously enrolled in multiple states
- Geographic dispersion of patients and providers
- Patients traveling large distances for controlled substances
- Billing for “unlikely” services
- Pre-established code pair violation
- Up-coding claims to bill at higher rates
Medical Identity Theft

- Medical identity theft occurs when someone steals your personal information (like your name, Social Security number, or Medicare number) to obtain medical care, buy drugs, or submit fake billings to Medicare in your name.

- Medical identity theft can disrupt your life, damage your credit rating, and waste taxpayer dollars.

- The damage can be life-threatening to you if wrong information ends up in your personal medical records.
Compromised Number Project

- A repository and searchable database of all compromised Medicare beneficiary identification numbers (Health Insurance Claim Numbers) and provider identification numbers (National Provider Identifiers) used to bill or order Medicare services.
Compromised Number Project

- To date, the CMS has identified
  - 5,134 compromised providers & suppliers, and
  - 284,152 compromised beneficiaries.
Office of Counsel to the Inspector General
Office of Counsel to the Inspector General (OCIG)

- Provides timely, accurate and persuasive legal advocacy and counsel
- Offers advice and representation on HHS programs and operations, employment, administrative law issues, and criminal procedure;
- Imposes program exclusions and civil monetary penalties on health care providers;
- Represents OIG in the global settlement of cases arising under the civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidance; and
- Renders advisory opinions on OIG sanctions and issues fraud alerts and other industry guidance.
OCIG

- **Advisory opinions** – provide meaningful advice on the application of the anti-kickback statute and other OIG sanction statutes in specific factual situations.

- **Exclusions** - authority to exclude individuals and entities from Federally funded health care programs

- **Civil Monetary Penalties** – authority to assess penalties for a variety of behavior (false claims, kickbacks, etc.)
Corporate Integrity Agreements - negotiates corporate integrity agreements (CIA) with health care providers and other entities as part of the settlement of Federal health care program investigations arising under a variety of civil false claims statutes. Providers or entities agree to the obligations, and in exchange, OIG agrees not to seek their exclusion from participation in Medicare, Medicaid, or other Federal health care programs.
Compliance Guidance - developed a series of voluntary compliance program guidance documents directed at various segments of the health care industry, such as hospitals, nursing homes, third-party billers, and durable medical equipment suppliers, to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements.
Exclusion
OIG Exclusion Authorities

HHS OIG Exclusion

- 20 statutory bases for exclusion in section 1128 of SSA
- 4 bases for mandatory exclusion – 1128(a)
  - Convictions for specified types of crimes
- 16 bases for permissive exclusion
  - Derivative (e.g., conviction, loss of license)
  - Affirmative (initiated by OIG)
- Convictions = Exclusion (almost always)
- Civil = CIA (sometimes exclusion)
Exclusion of individuals - civil cases
  - False Claims -- 1128(b)(7)
  - Poor quality care – 1128(b)(6)(B)

Corporate Integrity Agreements
  - Certifications by members of management and board
    - Reviewed area of responsibility
    - In compliance OR non-compliance being addressed
Case Examples

Marc Hermelin (2010)

- Owner (and former executive) of Ethex Corporation, a wholly owned subsidiary of K-V Pharmaceutical Company

- Ethex pled guilty to felony criminal charges after it failed to inform FDA about manufacturing problems that led to the production of oversized morphine tablets.

- Excluded for 20 years under section 1128(b)(15)
Case Examples

Michael Dinkel (2012)

- Owner of Drew Medical, a diagnostic imaging services provider.
- OIG alleged Dinkel caused the submission of $1.6M in false claims for venography procedures that were not provided as claimed. Issued Exclusion Notice.
- HHS Departmental Appeals Board upheld 8-year exclusion.
Case Examples

Dr. Rakesh Nathu (2012)

- Paid $5.7 million to resolve the excessive billing of CPT codes
- After FCA settlement, OIG pursued permissive exclusion under 1128(b)(7).
- Agreed to a 5-year exclusion agreement.
Case Examples

Mississippi Physician Cases (2010 – 2012)

- Physical therapy companies bribed with sham medical director fees in exchange for allowing the use of their provider numbers in a PT fraud scheme
- OCIG focused on the physicians who participated in the scheme
- CMPL settlements with 9 physicians who have collectively paid over $630,000.
- Alert posted
Affordable Care Act

- § 6402 of ACA requires reporting and repayment of overpayments within 60 days of identification (or due date of next cost report, if applicable)

- Violations actionable under FCA

- CMS proposed regulation
Travel Advisory System

HOMELAND SECURITY ADVISORY SYSTEM

SEVERE
SEVERE RISK OF TERRORIST ATTACKS

HIGH
HIGH RISK OF TERRORIST ATTACKS

ELEVATED
SIGNIFICANT RISK OF TERRORIST ATTACKS

GUARDED
GENERAL RISK OF TERRORIST ATTACKS

LOW
LOW RISK OF TERRORIST ATTACKS
OIG’s Exclusion System

- Exclusion
- Unilateral Monitoring
- Corporate Integrity Agreement
- Low Priority
- Do Nothing
**Demand exclusion in settlement or litigate exclusion**

- Strongest evidence
- High damages
- Patient harm
- Focus on individuals
Unilateral Monitoring

- OIG seeks CIA
- Provider refuses CIA
- No exclusion release
- Exclusion?
- OIG will monitor using OIG tools
Corporate Integrity Agreement

Contract between OIG and Provider

- Compliance Infrastructure
- Independent Review Organization
- Reporting
- Sanctions for Breaches
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<td>2. No patient harm</td>
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<td>3. No egregious facts</td>
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<td>4. Not a priority for OIG to seek exclusion or CIA</td>
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<td>5. No Release (Express Reservation)</td>
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• Provider has self-disclosed misconduct and cooperated with Government to resolve the matter.
Self-Disclosure Protocol

Average Length of Time in OIG Self-Disclosure Protocol (In Months)

- 2008: 18.66 months
- 2009: 16.21 months
- 2010: 13.17 months
- 2011: 10.47 months
OIG Webinar
Work Plan Webinar

- Coming this Fall
- Q&A on OIG’s 2013 work plan
- Check on our website for details
  - www.oig.hhs.gov
Questions?