



Understanding the Focus of Healthcare Fraud Enforcers

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Overview

- The Enforcement Climate
- Understanding the Players
- Anatomy of An Investigation
 - Parallel Criminal/Civil Investigations
- Case Resolutions
 - Deferred Prosecution Agreements
- Practical Tips

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Enforcement Climate

This settlement “reflects our continuing effort to hold drug companies accountable for devising pricing schemes that deliberately seek to deny federal health care programs the same lower prices for drugs that are available to other commercial customers.”

- *Attorney General Michael B. Mukasey (Feb. 2008)*

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Enforcement Climate

“The Office of Inspector General has a strong record of pursuing violations in the Medicaid Drug rebate program and is working closely with Federal and State law enforcement to hold accountable pharmaceutical companies engaged in illegal practices resulting in Medicaid fraud.”

Inspector General Daniel Levinson, February 2008

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Recent Settlements

- Merck & Company (Feb. 2008)
- Bristol-Myers Squibb Company (Sept. 2007)
- King Pharmaceuticals (Oct. 2005)

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Merck & Company

- Feb. 2008
- \$650 million
- Five-year corporate integrity agreement
- Resolved two *qui tam* suits in E.D. Pa. and Louisiana
- Relators' share in excess of \$68 million
- Alleged violations of Medicaid Drug Rebate Program and Antikickback Statute

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Bristol-Myers Squibb Company

- September 2007
- \$515 million
- Five-year corporate integrity agreement
- Resolved seven *qui tam* suits in Mass. and S.D. Florida
- Relators' share of \$50 million
- Alleged violations of Medicaid Drug Rebate Program, Antikickback Statute, Food Drug and Cosmetics Act

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King Pharmaceutical

- Oct. 2005
- \$124 million
- Five-year corporate integrity agreement
- Resolved *qui tam* suit in E.D. Pa.
- Alleged violations of Medicaid Drug Rebate Program

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Enforcement Climate

- Government not just targeting large manufacturers, but also smaller companies
- *Qui tam* filings are the main source of pharmaceutical investigations
- Increasing geographic dispersion of cases (not just Boston and Philadelphia)
- Government actively training agents and attorneys nationwide on how to investigate these cases

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Enforcement Climate (cont.)

- Monetary Recoveries:
 - \$1.5 billion to Medicare Trust Fund
 - \$177.1 million for federal share of Medicaid
 - \$378.4 million disallowed by HHS
 - \$25.2 billion in Medicare savings “funds put to better uses”
 - \$8.48 billion in Medicaid savings

Source: *FY 2006 HCFAC Report (Nov. 2007)*

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The Players

- HHS
 - Office of Inspector General
 - Centers for Medicare & Medicaid Services
 - Food and Drug Administration
- DOJ
 - DOJ Criminal Fraud
 - DOJ Civil Fraud
 - EOUSA and the U.S. Attorney's Offices
 - Office of Consumer Litigation (FDCA) and others as appropriate
- State agencies (MFCU, Medicaid agency, etc.)



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OIG Role

- OI may investigate (or decline)
- Counsel's Office always involved in FCA cases (independent of OI involvement)
- Resource in case development
 - Initial Contact – coordinate with OGC/CMS
 - Investigation (subpoena authority)

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Office of Counsel to the Inspector General

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OIG Role (cont.)

- Qui tams – intervention/declination
- Represent HHS
- Sole Authority to Exercise Permissive Exclusion
 - 42 U.S.C. 1320a-7(b)(7)
 - Federal health care programs
- Exclusion waiver – AIG must waive in writing, often in exchange for CIA or other integrity measures



Exclusions as Part of Global Settlements

- Criminal
 - Advise on applicability of exclusion authorities
 - Can provide exclusion agreement to accompany plea
- Civil
 - Criteria for use of 42 U.S.C. § 1320a-7(b)(7)
 - Negotiated in FCA settlement or administrative litigation
 - Corporate integrity agreement (or CCA) in lieu of exclusion (November 20, 2001 Open Letter)

CMS's Role in Health Care Fraud Enforcement

- Primarily Program Integrity Group (headed by Kim Brandt) and HHS OIG (headed by Daniel Meron)
- Agreement with OIG regarding consultation on cases of interest
- Shared authorities (EMTALA, Stark)
- CMS remedies (e.g., payment suspension)
- Contractor referrals

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Health Care Fraud Enforcement at DOJ

- Civil - Commercial Litigation Branch. Joyce Branda, Director.
 - Michael Granston and Dan Anderson (Deputy Directors)
 - Major cases and national projects
 - Smaller cases often delegated to USAO
- Criminal Fraud. Kirk Ogrosky, Deputy Chief.

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U.S. Attorney's Offices

- EOUSA – National policy
 - Health Care Fraud Coordinator
 - ACE Coordinator

- Each USAO has:
 - Health Care Fraud Coordinators (Civil and Criminal)
 - Affirmative Civil Enforcement (ACE) Coordinator

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Competing Priorities Within the Government

- DOJ Civil: Monetary recovery

- DOJ Criminal: Egregious conduct

- OIG: Protection of FHCP

- CMS: Delivery of services to Medicare/Medicaid beneficiaries

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Funding Health Care Fraud Enforcement

- Deficit Reduction Act/Medicaid Integrity Program/MMA
- Health Care Fraud & Abuse Control Program
- DOJ 3% Funds (debt collection)
- Reimbursement to OIG for the “costs of conducting investigations and audits and for monitoring compliance plans when such costs are ordered by a court, voluntarily agreed to by the payor, or otherwise.” 42 U.S.C. § 1320a-7c(b).

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Health Care Fraud Enforcement Authorities

- False Claims Act
- Civil Monetary Penalties Law
 - False Claims
 - Kickback/Stark
- Federal Health Care Program Exclusions
- Criminal Statutes (e.g., False Statements)

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What Triggers an investigation?

- Qui Tam Complaints (“Avalanche” on pricing and kickbacks)
- CMS, CMS contractor, or OIG audit or data-mining
- National investigations
- Complaints to the OIG hotline
- Tips from competitors

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Anatomy of an Investigation: Investigative Tools

- OIG Subpoenas (most common)
- OIG Testimonial Subpoenas (CMP cases)
- HIPAA Subpoenas (AID), 18 U.S.C. § 3486
- Civil Investigative Demands
- Visits by the Fiscal Intermediary or Other Fraud Agent

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Investigative Tools (cont.)

- Grand Jury Subpoenas
- Search Warrants
- OIG Immediate Access Letter
- Other tools (Data-mining, covert investigations, trash runs, etc.; but not OIG site visits!)

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Parallel Investigations

- Criminal/civil/administrative
- Typically criminal goes first
- Cases where administrative has gone first – why?
- Assignment of agent may influence direction of investigation
- Sharing evidence

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Responding to Government Investigators

- Policies, Procedures and Training
- Designated contact person (Preferably attorney or compliance officer)
- Responding to Government Investigators
- Document retention/E-discovery issues
- Don't start your own shadow investigation (counsel should initiate to protect privilege)

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Responding to Government Investigators (cont.)

- Assert privileges
- Consider HIPAA and state law confidentiality requirements, but they don't typically bar federal agents
- Consider represented persons issues
- Document all communications with investigators

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FCA or CMP?

- False or Fraudulent Claims
 - Same elements and intent standard as FCA
- Kickback/Stark Violations
 - No explicit civil remedy
- Defendant – State or State entity
- Remedy – Exclusion
- Forum – ALJ – Jury appeal issues
- Small dollars
- CMP assessment can be higher than FCA damages

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How *Qui Tam* Mechanics Affect Government Focus

- Seal deadline drives government investigation of *qui tam* matters
- Must quickly determine whether allegations have enough merit to warrant government intervention in the case
- FCA provides for intervention decision within 60 days, but had been routinely extended by the courts
- Courts less tolerant of delay
- Ability of *qui tam* complaint to toll running of statutes of limitation called into question → DOJ requesting more tolling agreements

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Focusing on Intent

- Actual intent to defraud is required for acts such as conspiring to defraud, delivering less property to the government than indicated on the receipt, and delivering the receipt without knowing the information is true
- Most other acts, such as the submittal of a false claim, require the person to act knowingly. “Knowingly” is defined as:
 - acting with actual knowledge that the claim is false,
 - acting with deliberate ignorance of the truth or falsity of the information, or
 - Acting with reckless disregard of the truth or falsity of the information

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Consequences of Pending Government Investigations

- Need for internal investigation to determine potential liability (avoid submitting additional false claims or compounding the original problem)
- Need to Disclose (SEC, etc.)
- Medicare Payment Suspension

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Consequence of Pending Government Investigations (cont.)

- Pre-pay Review
- Asset Forfeiture - Assets Acquired
- Employee Whistleblower Retaliation Complaints

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Consequences of a Conviction

- Restitution
- Sentencing
- Criminal Fines
- Mandatory or permissive exclusion authorities may be triggered

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Consequences of a Settlement

- Settlement Payment
 - Usually a minimum of double damages (to recover expenses of investigation), but can be up to treble damages plus penalties
- Corporate Integrity Agreement and/or Deferred Prosecution Agreement or equivalents

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Case Resolution Issues

- Scope of Releases
- Relator's Share
- State/Federal coordination
 - NAMFCU teams
- Corporate Integrity Agreements
 - Complexity of reviews in pharma cases
- Deferred Prosecution Agreements

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Practical Tips on Case Resolutions

- Global settlements are possible; intergalactic settlements are not
- Negotiating with the government is not the same as negotiating with a private persons
- Recognize that the government attorneys have limited authority
- Some politics are inevitable
- Don't ignore the relator (the OIG, CMS, State X,)
- Settlement agreements and CIAs are public documents and are negotiated as such

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Questions?

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