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Healthcare Enforcement

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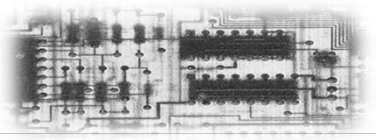
Enforcement

- **Ongoing scrutiny from many sources …**
  - **MAC** – Medicare Administrative Contractors
    - Processes Part A and Part B claims; conducts post-payment reviews
  - **RAC** – Recovery Audit Contractors
    - Identifies both overpayments and underpayments; receives a percentage of improper payments collected from providers
  - **ZPIC** – Zone Program Integrity Contractors
    - Investigates Medicare claims; initiates administrative sanctions including payment suspension and overpayment determinations
  - **MIC** – Medicaid Integrity Contractors
    - Identifies Medicaid overpayments, fraud, emerging risk areas

Enforcement

- **Ongoing scrutiny from many sources …**
  - **Prepayment analysis**
    - "Pattern matching" technology used by credit card industry
      - Searches for suspicious patterns; segments claims by group; compares practitioners with their peers
  - **Post-payment data mining**
    - Software that reacts to rules for detecting known payment scams



Enforcement

- **Ongoing scrutiny from many sources …**
  - **HEAT – Health Care Fraud Prevention and Enforcement Action Team**
    - Medicare Fraud Strike Force – DOJ / OIG Interagency Effort
      - Currently operates in 9 cities (including Houston)
      - 77 convictions; $161 M in recoveries (Apr. – Sept. 2011)
  - **Special U.S. Attorneys Program**
    - Details OIG Special Agents to the DOJ's Criminal Division, Fraud Section
  - **Medicaid Fraud Control Units**
    - Funded with federal grant dollars ($194 M in 2010)
    - 9,710 Medicaid fraud investigations and 1329 convictions in 2010

Source: OIG Semiannual Report to Congress (Apr. - Sept. 2011)

Enforcement

- **Department of Justice (DOJ) – FY 2011**
  - 1,235 new prosecutions (healthcare)
    - Up 69% over 2010; up 96% over 2001
  - $2.4 B False Claims Act recoveries (healthcare)
- **Office of Inspector General (OIG) – FY 2011**
  - 614 criminal and 381 civil actions
  - $ 5.2 B in recoveries
  - 2,708 exclusions

5 Sources: Trac Report, Record Number of Federal Healthcare Prosecutions Filed in FY 2011; DOJ Press Release (Dec. 19, 2011); OIG Semiannual Report (Apr. - Sept. 2011)

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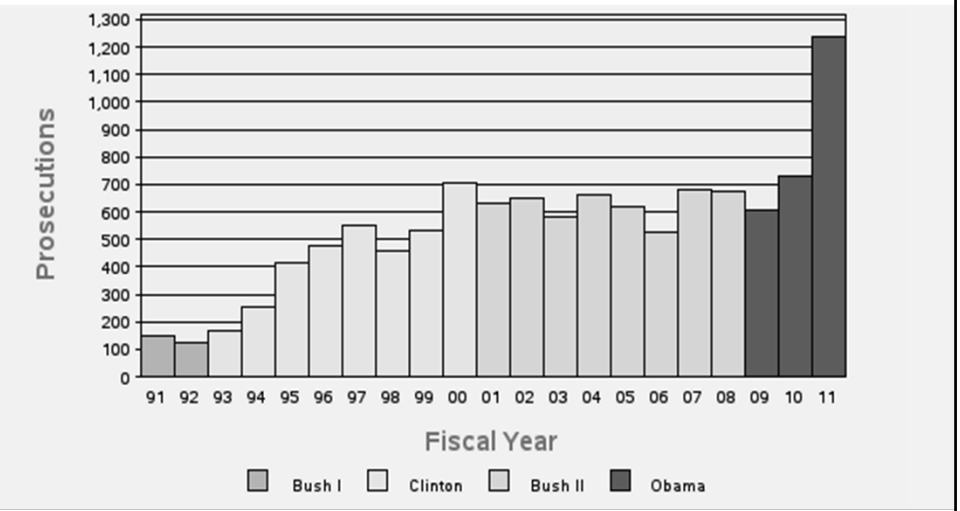
Criminal Healthcare Fraud Prosecutions 1991-2011



6 Sources: Trac Report, Record Number of Federal Healthcare Prosecutions Filed in FY 2011

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False Claims Act

- **The prohibition (31 U.S.C. Section 3729)**
  - Imposes civil liability on a person who
    - Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
    - Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
    - Conspires to commit an FCA violation
    - And more . . .

False Claims Act

- "Knowing" or "knowingly" means that the person
  - has actual knowledge of the information;
  - acts in deliberate ignorance of the truth or falsity of the information; or
  - acts in reckless disregard of the truth or falsity of the information

False Claims Act

- **Damages**
  - $5,500 to $11,000 for each claim filed
  - Treble (3x) damages to the federal government
  - Program exclusion
  - Burden of proof
    - Preponderance of evidence notwithstanding the fact that damages are quasi criminal in nature

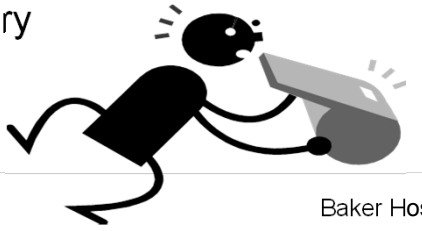
False Claims Act

$100,000 Liability Example

Defense Contractor	(12 Claims/Yr.)	Provider	(2000 Claims/Yr.)
Triple Damages	$300,000	Triple Damages	$300,000
Penalty	$132,000	Penalty ($11,000 x 2,000)	$22,000,000
Total Recovery	**$432,000**	**Total Recovery**	**$22,300,000**

False Claims Act

- **Whistleblower or "qui tam" actions**
  - "Use a rogue to catch a rogue"
  - Actions brought on behalf of the federal government by a private party having direct knowledge of the fraud
  - Whistleblowers or *qui tam* "relators" may receive up to 30% of recovery



Enforcement Trends

- Overpayments
- Conflicts of interest; Stark Law; Anti-Kickback Statute
- Medical necessity
- Individual liability

Overpayments

- **"Overpayment"**
  - Any money received or retained to which the person is not entitled to, after applicable reconciliation
- **Affordable Care Act provisions**
  - An overpayment must be reported and returned 60 days after being "identified" or by the date any corresponding cost report is due
    - Applies to all federal programs—not just Medicare and Medicaid

 Source: Patient Protection and Affordable Care Act, Section 6407

Overpayments

- **Fraud Enforcement & Recovery Act (FERA)**
  - Imposes FCA liability for retaining money owed to federal government *regardless of whether a false claim exists*
- **President's Memo on Improper Payments**
  - 2010 directive to federal agencies requires expanded use of "payment recapture audits"
- **OIG FY 2012 Work Plan**
  - Mentions the term "overpayment" 37 times

Conflicts of Interest

- **Physician Payment Sunshine Act**
  - Affordable Care Act provision (Section 6002) requires annual tracking / reporting of financial relationships between physicians and drug and device manufacturers

Anti-Kickback Statute

- **Affordable Care Act amendments make it easier for government to support AKS causes of action**
  - A person need not have actual knowledge of the AKS nor specific intent to commit an AKS violation
  - Clarifies that an AKS violation constitutes a false claim

16 Source: Patient Protection and Affordable Care Act, Sections 6402, 10606

FCA Enforcement Actions

- **Medtronic ($23.5 M)**
  - Whistleblower action alleges Medtronic used post-market studies and device registries as vehicles to pay participating physicians illegal kickbacks to implant Medtronic pacemakers and defibrillators (Dec. 2011)
  - Whistleblowers received $3.6 M

FCA Enforcement Actions

- **McAllen Hospital d/b/a South Texas Health System ($27.5 M)**
  - Allegations include financial relationships with physicians to induce referrals
  - "Improper financial relationships between health care providers and their referral sources can corrupt a physician's judgment about the patient's true healthcare needs." *DOJ Press Release*

Stark Law / FCA Enforcement Actions

- **Drakeford v. Tuomey**
  - Employed surgeons to provide services at outpatient surgical center
  - Payments not commercially reasonable and in excess of fair market value
  - Trial jury found Stark violation and awarded $45 M, but no violation of FCA
  - New trial granted on FCA issue
  - Fourth Circuit appeal

Stark Law / FCA Enforcement Actions

- **Singh v. Bradford**
  - Hospital leased nuclear camera from cardiologists
    - Fixed lease payment for nuclear camera, noncompete, and space in physician's office
  - Court held:
    - Fixed payment varied based on volume / value of referrals because appraisal for noncompete based on expected revenue from physicians' referrals
    - Payments were in excess of FMV
  - Arrangement violated Stark, but not FCA or AKS

Medical Necessity

- **AHA survey of RAC denials (Oct. 2011)**
  - "Medically necessary" = top reason for complex review denials cited by 93% of hospitals surveyed
    - Percentage of medical necessity denials involving care that was provided in the wrong setting – *not because the care was medically unnecessary*
      - **85% for 1-day stays**
      - 51% for greater than 1-day stays

N = 2,127 hospitals participated in the survey

 Source: American Hospital Association, RACTrac Survey, Second Quarter 2011 (Oct. 5, 2011) Baker Hostetler

Medical Necessity

- **Kyphoplasty initiative**
  - Hospitals agree to settle with government for approximately $38 M to resolve allegations related to claims for Kyphoplasty procedures
    - Specific allegations involve the furnishing of Kyphoplasty on an inpatient basis when the service should have been furnished on an outpatient basis
    - Whistleblower action by two former employees of the device maker

Reference: "14 Hospitals Pay $11.9 Million to Settle Kyphoplasty Cases," Modern Healthcare Daily Dose (Feb. 7, 2012)

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Individual Liability

- **Risks associated with non-compliance**
  - U.S. v. Caputo
    - "Corporate compliance officers are very much today's corporate 'fire personnel.' They are often the company's 'first responders' and must focus on both proactive and reactive efforts to be effective."

Individual Liability

- **"Hospital exec. charged in $116 million Medicare scam"**
  - Riverside General Hospital
  - "Dr. Khan"; Assistant Administrator
  - Kickbacks to patients and recruiters
  - Mental health services

Source: Houston Chronicle (Feb. 8, 2012)

Individual Liability

Individual Liability

- **Remarks by HHS IG Daniel R. Levinson**
  - "OIG is focused on holding **Responsible Corporate Officials** accountable for health care fraud" [emphasis added]
    - "Liability as a responsible corporate officer does not turn upon a corporate officer's approval of wrongdoing, but rather on whether the officer had, **by reason of his or her position in the corporation**, responsibility and authority to either prevent, or promptly correct, the violation at issue, and the officer failed to do so. United States v. Park, 421 U.S. 658, 673-674 (1975)."

Source: Highlights of the Keynote Address Delivered By Daniel R. Levinson at the Health Compliance Association Annual Compliance Institute (Apr. 19, 2010)

OIG Permissive Exclusion 2010 Guidance

- **Factors OIG considers in determining whether to impose exclusion**
  - "… if the evidence supports a finding that an **owner** knew or should have known of the conduct, OIG will operate with a presumption in favor of exclusion."
  - "…when there is evidence that an **officer or managing employee** knew or should have known of the conduct, OIG will operate with a presumption of exclusion."

 Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act at http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf

OIG Permissive Exclusion 2010 Guidance

- **Factors OIG considers when evaluating an individual's role in a sanctioned entity**
  - What is / was the person's position and degree of managerial control or authority?
  - Did the misconduct occur within his / her chain of command?
  - Did he / she take steps to stop or mitigate the ill effects of the misconduct?
  - Did he / she disclose the misconduct to federal and state authorities?

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Exclusion Actions
Owners, Officers and Managers

- **Dinkel v. Inspector General (July 2011)**
  - ALJ upheld 8-year exclusion of the owner / president of a diagnostic imaging company
    - Allegations include 9,500 false claims / 30 mos. for venography injections not performed resulting in $1.7 M in improper payment
  - ALJ found that Dinkel
    - Had a duty "to do more than delegate to others the responsibility for establishing which codes should be utilized for filing claims," and
    - "His failure constituted reckless indifference to the propriety of the claims he caused to be presented"

Exclusion Actions
Owners, Officers and Managers

- **Dinkel v. Inspector General, cont'd**
  - ALJ rules 8-year exclusion "reasonable" because:
    - Dinkel "chose not to know whether what he was doing was right" and "was utterly indifferent to the consequences of his actions"
    - "The damage to the integrity of the programs is no less in the case of reckless indifference to the truth than it is with deliberate fraud"
    - "A reckless individual may be just as untrustworthy as a calculating criminal"

Exclusion Actions Owners, Officers and Managers

- **Pleasant Care**
  - Owner / Chair of a 29-facility nursing home chain sued by the California AG for substandard patient care receives permanent exclusion even though no judgment or finding of liability was made against the owner
- **Purdue Frederick (Friedman v. Sebelius)**
  - District Court upheld 12-year exclusion of the President / CEO, General Counsel and Chief Scientific Officer, all of whom pled guilty to drug misbranding
    - "Plaintiff's served as 'responsible corporate officers'" and had the "responsibility and authority to either prevent or to promptly correct" the misconduct

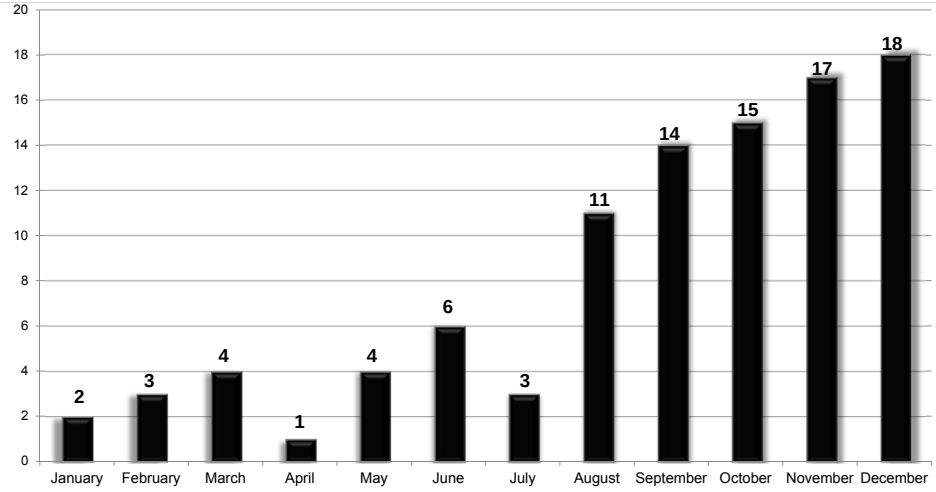
Enforcement Actions Owners, Officers and Managers

- **Synthes, Inc. (U.S. v. Norian Corp.)**
  - Four Synthes medical device company executives receive prison sentences for conspiring to conduct unauthorized clinical trials of Norian's surgical bone cement products
    - President of North America – 8 mos. prison, 3 mos. probation, $100,000 fine
    - President of Spine Division – 8 mos. prison, 3 mos. probation, $100,000 fine
    - Sr. VP of Operations – 8 mos. prison, 4 mos. probation, $100,000 fine
    - Director of Regulatory and Clinical Affairs – 5 mos. prison, $100,000 fine

Enforcement Actions Owners, Officers and Managers

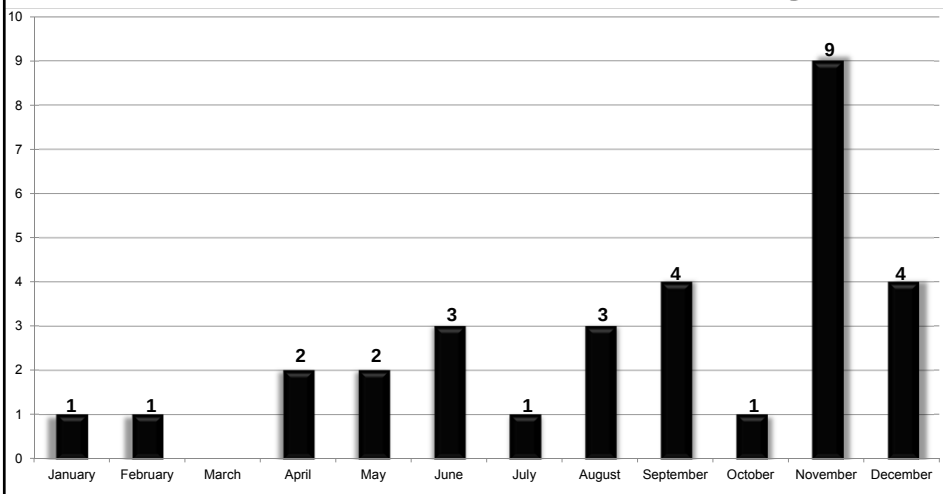
- **U.S. v. Duran**
  - Co-owners of a company operating partial hospitalization programs are sentenced to respective 50 and 35 year prison terms for $205 M kickback scheme that involved:
    - Kickbacks to patient recruiters, assisted living facilities and half way houses for “ineligible patients”
    - Doctoring patient files and therapist notes in an effort to hide the scheme
    - “Robo-signing” patient charts when the supervising therapist (who also was an owner) did not see or treat the patients
  - 50-yr. jail sentence = longest for Medicare fraud in history

2011 Enforcement Actions* “Owner”



* Includes civil and criminal enforcement actions
Source: http://oig.hhs.gov/fraud/enforcement/criminal/index.asp

2011 Enforcement Actions* "Executive, Officer, Manager"



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Source: http://oig.hhs.gov/fraud/enforcement/criminal/index.asp

Compliance Programs

- **Federal Sentencing Guidelines**
  - To have an effective compliance program under the Guidelines, an organization must exercise due diligence to prevent and detect criminal conduct and otherwise promote an organizational culture that encourages ethical conduct and commitment to compliance with the law

Compliance Programs

- **OIG Compliance Guidance**
  - Compliance Officer / Compliance Committee
  - Policies and Procedures
  - Training and Education
  - Effective Lines of Communication / Hotlines
  - Disciplinary Action / Background & Exclusion
  - Internal Investigations and Corrective Action
  - Auditing and Monitoring

Compliance Programs

Healthcare Reform Law

Mandatory Compliance Programs

- Providers and Suppliers participating in Medicare and Medicaid are required to implement a compliance program with core elements as a condition of enrollment.

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