

A Primer on Physician Health Care Fraud

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This presentation provides general legal information and should not be construed as legal advice. 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.

The Department of Health and Human Services' fiscal year 2008 budget request sought \$1.3 billion in resources and legislation to strengthen oversight and reduce improper payments in the Medicare and Medicaid programs

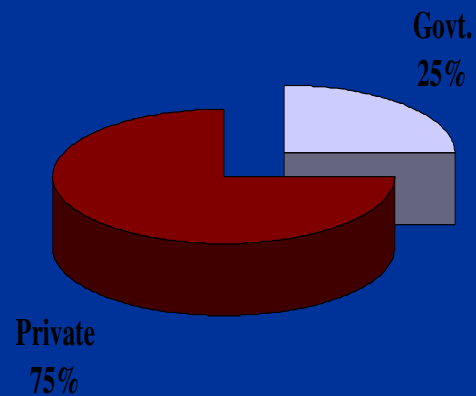
Secretary Mike O. Leavitt Before the
Committee on the Budget, United States
House of Representatives, July 17, 2007

Outline of Presentation

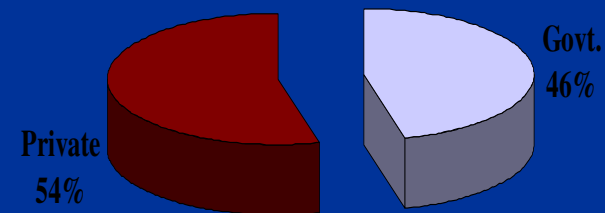
- Introduction to enforcement
- Health care fraud authorities
- Physician fraud and abuse risk areas
- Civil, criminal, and administrative settlements
- Questions

Federal & State Shares of American Health Care Expenditures

1960



2003



Health Care Fraud and DOJ

- DOJ strategic goal remains combating health care fraud in part through multidistrict investigations and multi-agency enforcement projects
- Criminal and Civil Divisions in Washington, DC
- 93 United States Attorneys' Offices
- Federal Bureau of Investigation

Enforcement Agencies

- Office of Inspector General, Department of Health and Human Services (OIG)
- Centers for Medicare and Medicaid Services (CMS)
- Quality Improvement Organizations
- Medicaid Fraud Control Units
- Local district attorneys

Health Care Fraud Statistics for 2006

- 523 criminal convictions
- 266 civil actions filed in federal court
- 3,425 program exclusions
- \$38.2 billion savings & expected recoveries

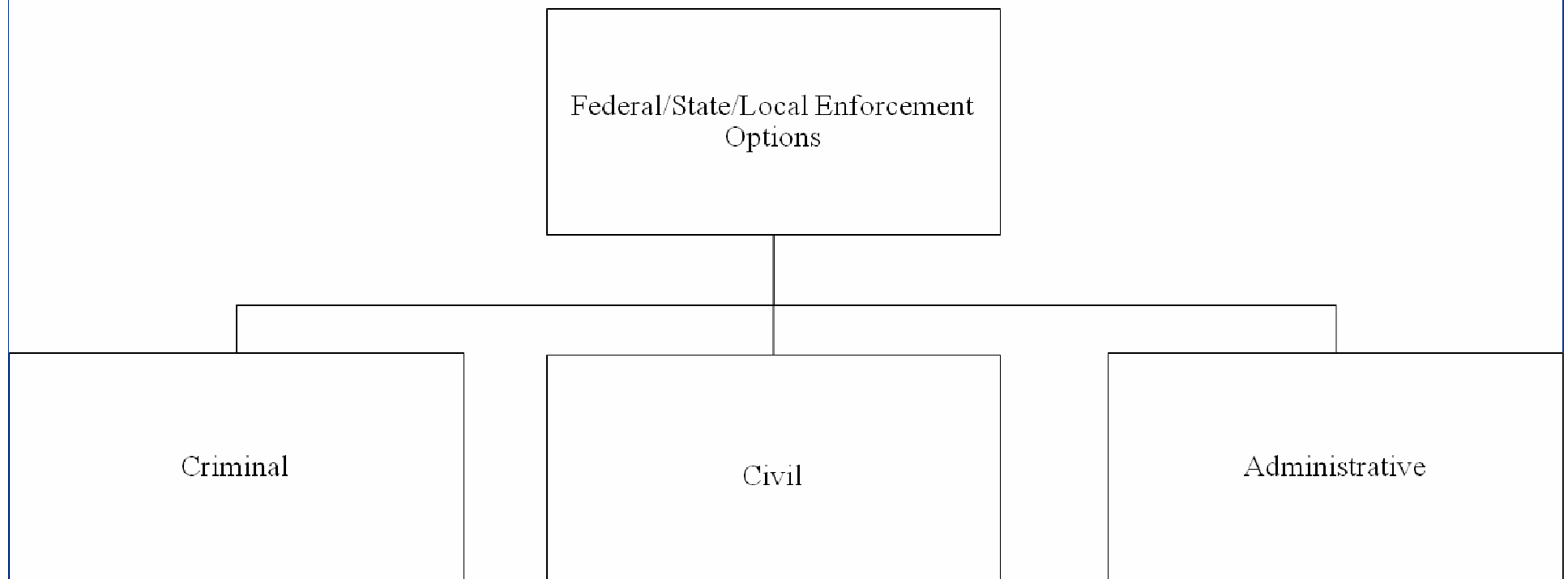
Government Enforcement Information

- OIG advisory opinions
- OIG compliance program guidance
- OIG work plans and audits
- Published OIG integrity agreements
- Comments/preambles to proposed/final anti-kickback safe harbors

Sources of Health Care Fraud Cases

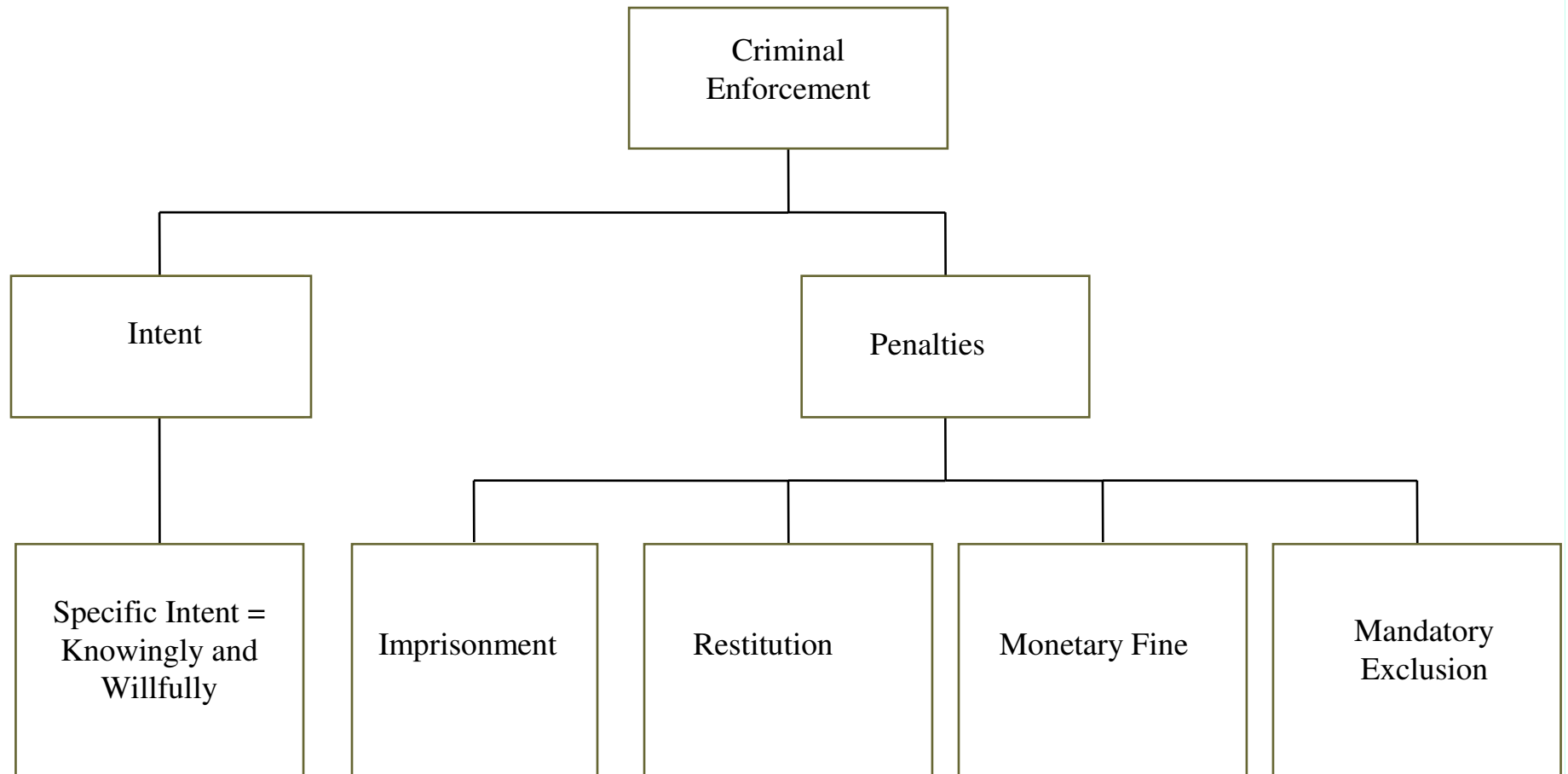
- Referrals from law enforcement agencies
- Qui tams under the False Claims Act (FCA)
- Initiatives, working groups, and task forces
- Anonymous or hotline complaints

Health Care Fraud Enforcement



*All diagrams from Lafferty's and McKenna's *The False Claims Act & Health Care Fraud*, HCCA's Annual Compliance Conference, April 23, 2007, Chicago, Illinois

Criminal Enforcement



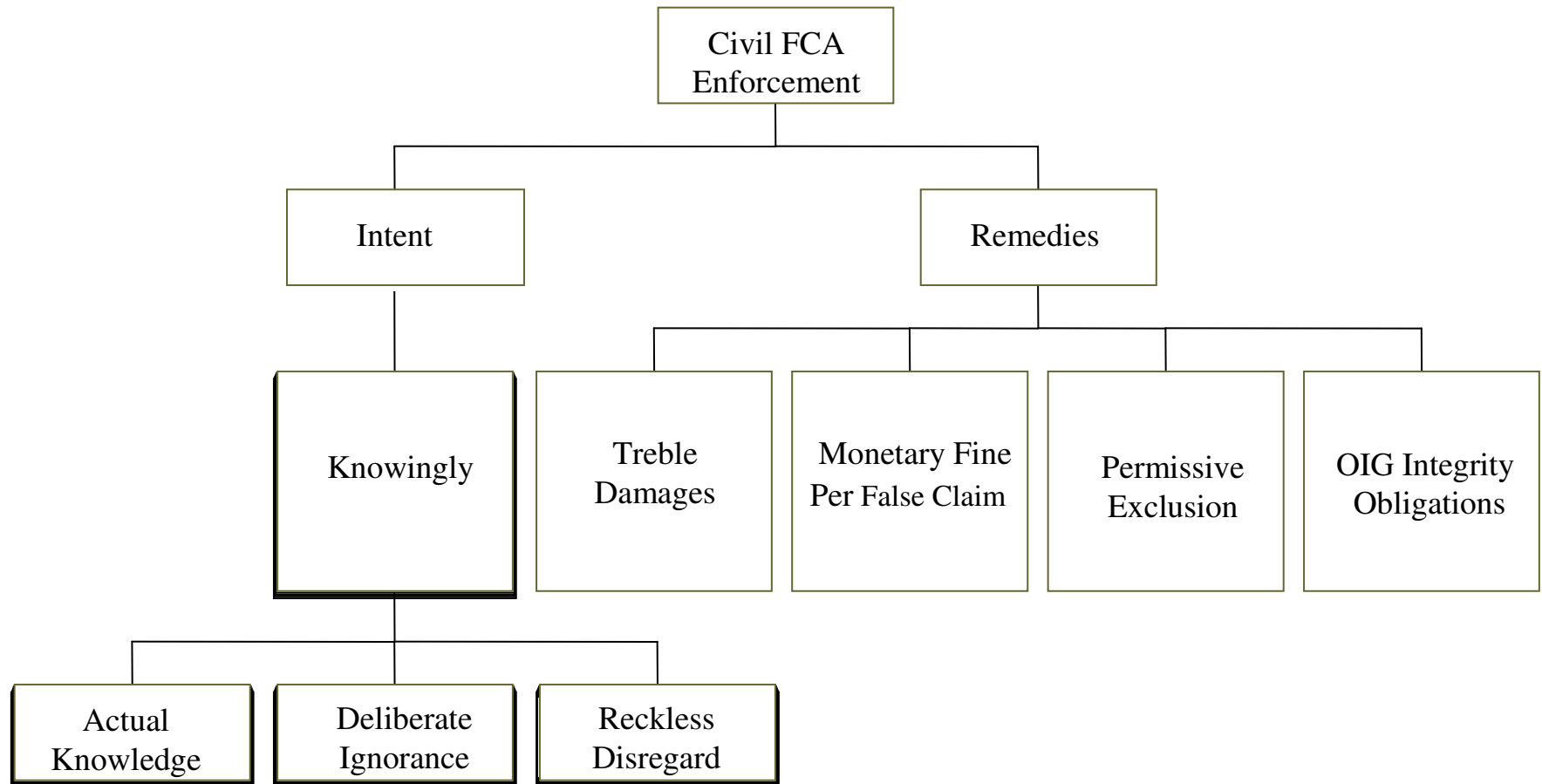
Health Care Fraud Statute

- Federal criminal statute for public AND private health care fraud, 18 U.S.C. § 1347
- Knowingly and willfully executes or attempts to execute a scheme or artifice to:
 - Defraud any health care benefit program; or
 - Obtain by false or fraudulent pretenses property under the custody/control of such a program in connection with the delivery or payment for items or services
- Maximum 10-years imprisonment, restitution, and fine

The Anti-Kickback Statute

- Criminal statute, 42 U.S.C. § 1320a-7b(b) - BUT
- Can form basis for FCA liability
- Remuneration can be anything of value
- Applies to providers and non-providers who recommend or arrange for health care items or services
- Greater compliance with safe harbor, generally means less risk

Civil Enforcement



Civil False Claims Act

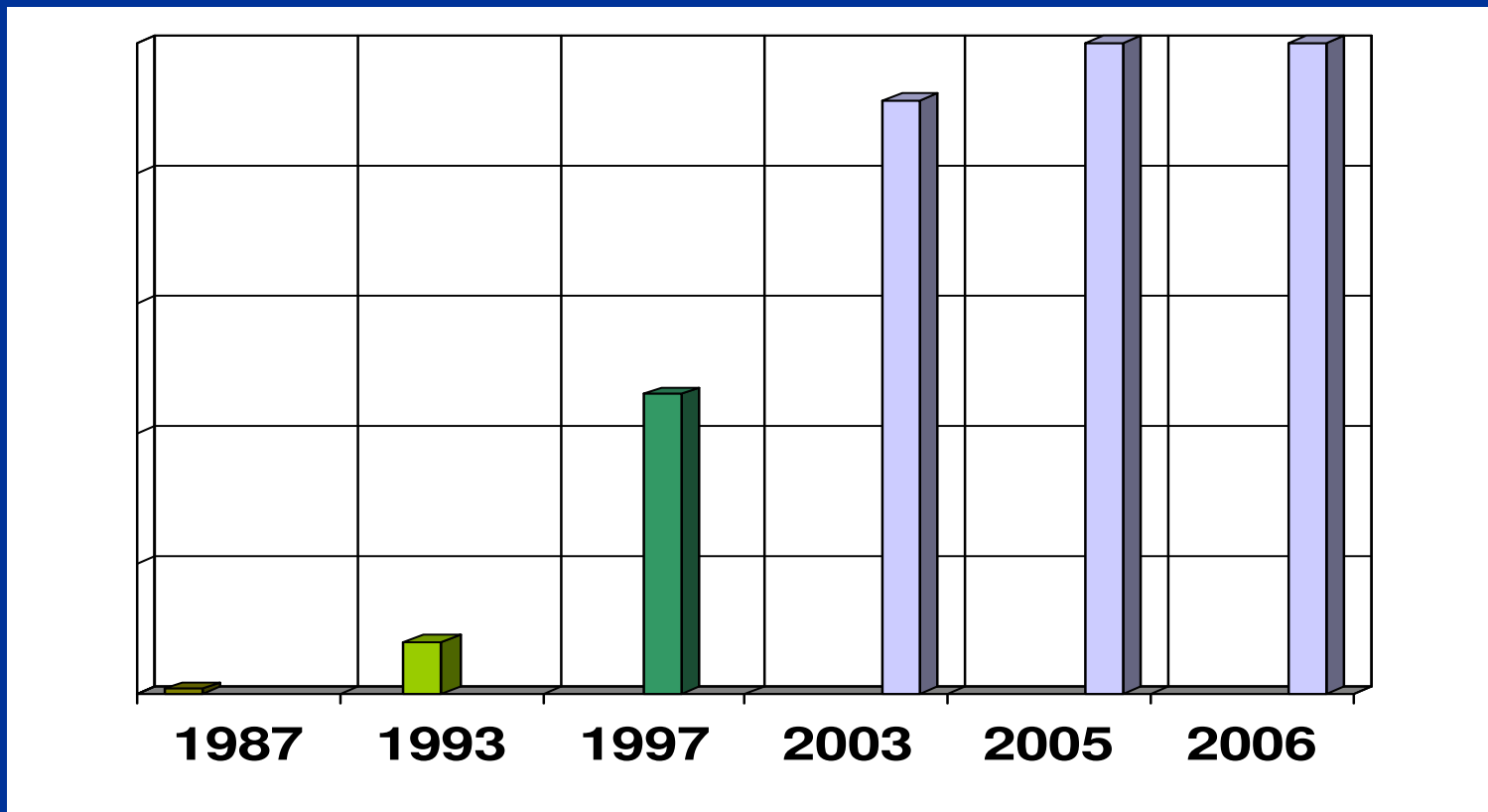
- False or fraudulent claim or statement submitted or caused to be submitted for payment to the government, 31 U.S.C. § 3729
- Must be “knowingly” submitted
 - Actual knowledge
 - Deliberate ignorance
 - Reckless disregard
 - No specific intent to defraud required

Civil False Claims Act Cont.

- Six year statute of limitations
 - Three years from date facts material are known or reasonably should have been known by official charged with responsibility to act
 - No more than 10 years after the date of the violation
- Violators subject to treble damages, a \$5,500 - \$11,000 penalty per false claim, and costs

Total Health Care Fraud Recoveries Under The FCA

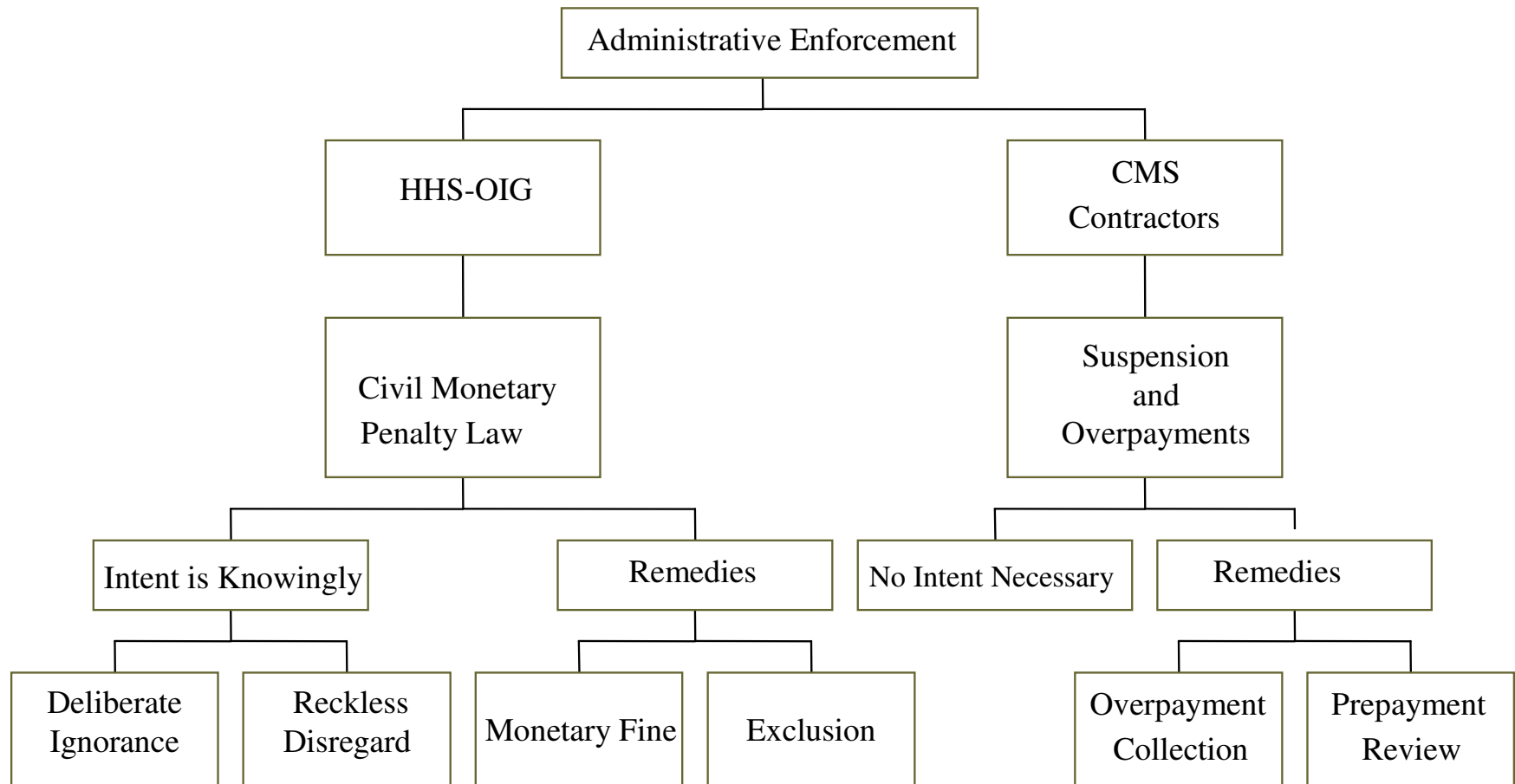
\$11.4 Million \$155.3 Million \$920.4 Million \$1.8 Billion \$1.1 Billion \$1.6 Billion



The Stark Law

- Civil statute, 42 U.S.C. § 1395nn
- Usual remedy is payment disallowance - BUT
- Can form basis for FCA or administrative liability
- Applicable only if physician or family member is involved
- To avoid violation, must fully satisfy exception (strict liability)

Administrative Enforcement



The Civil Monetary Penalties Law

- OIG administrative remedy, 42 U.S.C. § 1320a-7a(a)
- Permissive exclusion and money damages for specific violations, including payment or receipt of illegal kickbacks
- Generally mirrors FCA provisions
- OIG usually releases this authority in exchange for integrity obligations

Fraud and Abuse Risk Area #1

- Contractual arrangements
 - Equipment rental
 - Space leases
 - Medical directorships
- Physician incentives and payments
 - Recruitment packages
 - Investment opportunities
- Stark and anti-kickback implications
 - Fair market value or demonstrated need are critical
 - OIG advisory opinion could evaluate methodology for reaching fair market value

Risk Area #1 Enforcement Actions

- *United States v. Falks Woodland Pharmacy, Inc.*; No. 06-c-0389-C (W.D. Wis. April 2007) - Internet pharmacy paid \$300,000 to settle civil FCA allegations that it improperly filled controlled substance prescriptions without a legitimate patient-physician relationship
 - Patients filled out internet questionnaires which were then reviewed by physicians
 - No telephone or face-to-face contact with doctor
 - Issue is what constitutes the usual course of professional practice or treatment?

Risk Area #1 Enforcement Continued

- *United States ex rel. Marchese v. Cell Therapeutics, Inc.*; 2:06-cv-168-MJP (W.D. Wash. April 2007) - Company paid \$10.5 million to resolve civil FCA allegations that it illegally marketed to physicians an unapproved cancer drug for off-label use
 - Doctors allegedly were also paid illegal kickbacks of \$500-\$1,000 under sham consulting agreements to induce them to prescribe the drug for off-label use
 - Presentations on off-label uses were held at lavish restaurants or resorts

Risk Area #1 Enforcement Continued

- Proposed CMS rule that all physician-owned hospitals must disclose ownership to patients
 - 72 Fed. Reg. 24680 (May 3, 2007)
 - Physician-owned hospital means any hospital in which a physician has an ownership or investment interest
 - Physicians must notify patients that a list of physician-owners is available upon request
 - As condition of continued medical staff membership, physicians and hospitals must also disclose ownership interest to all patients referred to the hospital
 - Non-compliance could result in termination of the hospital's Medicare provider agreement

Fraud and Abuse Risk Area #2

- Submission of false claims
 - Upcoding and product substitution
 - Improper certifications of medical appropriateness
 - Services ordered or furnished by excluded providers
- Research or grant fraud
 - Time and effort reporting
 - Seeking reimbursement for unallowable costs
 - Use of awarded funds for other grants or projects
- Continued enforcement scrutiny
 - If institutional provider has problem, so does the individual practitioner

Risk Area #2 Enforcement Actions

- *United States v. Stokes*; No. 1:06-cr-0094-GJQ (W.D. Mich. April 2007) - Dermatologist convicted for his submission of false surgical claims that were upcoded to obtain higher reimbursement
 - Additional fraudulent claims included office visits misrepresented as necessary to treat patients for post-operative infections
 - Awaiting sentencing, maximum punishment is 10-years incarceration, restitution, \$250,000 fine, and \$100 mandatory special assessment

Risk Area #2 Enforcement Continued

- *United States v. Achille*; No. 1:06-cr-20496-KMM (S.D. Fla. April 2007) - Physician sentenced to 78-months imprisonment for his role in the submission of false Medicare claims for HIV treatment and medications that were not provided or medically necessary
 - Sentence increased by 2 years due to obstructive conduct, i.e., lying to investigators

Fraud and Abuse Risk Area #3

- Financial conflicts of interest
 - Off-label promotion of drugs or medical devices
 - Referral to specific health care providers
- Rebates and discounts
 - Billing for free samples
 - Marketing the spread
- Disclosure of potential physician conflicts of interests
 - Consumer outrage

Risk Area #3 Enforcement Actions

“A survey of medical experts who write guidelines for treating conditions like heart disease, depression and diabetes has found that nearly 9 out of 10 have financial ties to the pharmaceutical industry, and the ties are almost never disclosed.”

Stolberg, *New York Times*, February 6, 2002

94% of physicians report having at least one relationship with a drug or device company

Campbell, *et al.*, *A National Survey of Physician-Industry Relationships*, *New England Journal of Medicine*, April 26, 2007

Risk Area #3 Enforcement Cont.

“A New York Times/CBS News poll last month found that 85 percent of respondents thought it ‘not acceptable’ for doctors to be paid by drug companies to comment on prescription drugs. Eighty-five percent also said such payments would influence the decisions that doctors made about patient care.”

Harris and Roberts, *New York Times*, March 21, 2007

Risk Area #3 Enforcement Cont.

“Stanford University Medical Center will prohibit its physicians from accepting even small gifts like pens and mugs from pharmaceutical sales representatives under a new policy intended to limit industry influence on patient care and doctor education. . . [This policy] is part of a small but growing movement among academic medical centers. Yale and the University of Pennsylvania, for instance, have announced similar policies.”

Pollack, *New York Times*, September 6, 2006

Risk Area #3 Enforcement Cont.

“The pharmaceutical industry spends \$12 billion a year marketing to doctors, and much of that money is in the form of free samples delivered to doctors’ offices, often accompanied by lunch for the entire staff. When the University of Michigan health systems banned such lunches in 2005, they calculated that the lunches had been worth \$2.5 million a year.” (emphasis added)

Saul, *New York Times*, February 12, 2007

Risk Area #3 Enforcement Cont.

“Two of the world’s largest drug companies are paying hundreds of millions of dollars to doctors every year in return for giving their patients anemia medicines, which regulators now say may be unsafe at commonly used doses. Critics, including prominent cancer and kidney doctors, say the payments give physicians an incentive to prescribe the medicines at levels that might increase patients’ risks of heart attacks or strokes.”

Berenson, et al., *New York Times*, May 9, 2007

Risk Area #3 Enforcement Cont.

“Do you trust your doctor to prescribe the appropriate drugs for you?”

“Doctors receiving payment to RX a specific drug should be federally illegal—a blatant conflict of interest. RX should be made solely on the merits of the drugs—not bribes from drug companies. This is an outrage.”

“This is an outrage. I’m well aware of the ‘acceptable’ [sic] drug rep lunches, but this is so absurd and all financial and social ties between docs and drug companies should be stopped.”

Risk Area #3 Enforcement Cont.

“It’s disgusting to learn about this. One expects a doctor to be more concerned about a patient’s health than the profit that can be extracted from a patient. Doctors should at least disclose their monetary arrangements with the drug companies to their patients.”

Doctors Getting Paid to Prescribe, New York Times, May 9, 2007

<http://news.blogs.nytimes.com/2007/05/09/doctors-getting-paid-to-prescribe-drugs/?ex=1179374400&en=d228d96829eac4a5&ei=5070&emc=eta1>

Fraud and Abuse Risk Area #4

- Physician supervision
 - Direct personal supervision v. immediately available
 - State licensing restrictions on delegation
 - Patient care concerns
- Billing for services not provided as claimed
 - Who furnished the item or service?
 - Where was place of service?
 - Medically unreasonable or unnecessary?
- Most common allegation of physician fraud

Risk Area #4 Enforcement Actions

- *United States v. Stoddard*; No. 06-4252 (10th Cir. July 2007) - Physician sentenced to 12-months incarceration for submission of false claims involving hyperbaric oxygen therapies performed on Medicare patients without any physician supervision
- *New York v. Alonso, et al.*; No. 07-645 (N.Y. Sup. Ct. (Jan. 2007) - Dentist and wife indicted in part for their submission of false dental claims furnished while the dentist was out of the country

Fraud and Abuse Risk Area #5

- Contractor determinations
 - Suspension of payments
 - Pre and post payment reviews
 - Repayment of overpayments
- Investigator determinations
 - Credibility assessments
 - Obstruction of justice
 - Advice and input into prosecution or enforcement action

Risk Area #5 Enforcement Actions

- Criminal violation if fail to report material change in right to benefit, 42 U.S.C. § 1320a-7b(a)(3)
- *United States v. East Tenn. Heart Consultants*; (E.D. Tenn. Jan 2007) - First global resolution arising from failure to repay Medicare, Medicaid, private payors, and patients
 - Criminal pretrial diversion agreement under 18 U.S.C. §§ 1347 and 669
 - \$2.9 million federal, state, and private civil settlement
 - Restitution of \$1 million to over 11,200 patients
 - 5-year corporate integrity agreement

Risk Area #5 Enforcement Actions

- *United States v. Antoon*; 3:04-cr-037-P (N.D. Tex. May 2006) - Physician convicted of accepting illegal kickbacks to sign fraudulent certificates of medical necessity for durable medical equipment supplier
 - Co-conspirator taped the paying of the kickbacks
 - Jury found physician obstructed a criminal health care investigation, altered or falsified records in a federal investigation, and endeavored to influence a grand jury
 - Sentenced to 54-months imprisonment

Compliance and Physician Fraud

- Review OIG work plans for areas of regulatory or enforcement interest
- Civil settlements and criminal prosecutions are barometers of generally unacceptable conduct
- Ensure only medically reasonable and appropriate costs are submitted
- Consider negatives of all financial relationships before signing

Benefits of Compliance

- Helps ensure physicians and providers are properly paid
 - CMS Compliance Hospital Pilot Project
- Avenue for employee grievances and complaints
- Prevents and deters health care fraud and abuse
- Elimination or reduction of potential liability
- Avoids having to justify a CCA rather than an IA or CIA

Questions