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New False Claims Act Exposures and Government Investigation Tips for Health Plans

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Roadmap

- False Claims Act ("FCA") Basics
- Recent Amendments to the FCA
- Heightened Enforcement
- New Risks For Health Plans
- Compliance Tips and Best Practices

FCA BASICS

FCA – Origin and History

- **Federal Civil False Claims Act ("FCA")**
  31 U.S.C. §3729 *et seq*.
  - Enacted in 1863 to punish contractors who defrauded the Union Army
  - Major amendments in 1986, 2009 and 2010
  - Since 1986, has become Government's primary enforcement weapon for combating fraud, waste, and abuse
  - Superlative recoveries in just past two years

FCA - Common Theories of Liability

1. **False Claim – *knowing submission*** of or causing another to submit a false claim to the Government or a recipient of Government funds.
2. **False Record or Statement –*knowingly making or using*** a false record or statement material to a false claim.
3. **Reverse False Claim** –***knowingly making*** a false record or statement material to an obligation to pay money to the Government, or ***knowingly and improperly avoiding*** an obligation to pay money to the Government.
4. **Conspiracy** – when a contractor ***conspires to do*** *any of the above.*

FCA – *Qui Tam* Provisions

- FCA actions may be initiated by individuals under the FCA's qui tam provisions
  - "Relators" (a/k/a "whistleblowers")
- Procedure:
  - Relator must file a complaint under seal
  - Relator must also serve written disclosures on DoJ describing "substantially all material evidence and information the person possesses"
  - DoJ has 60 days to investigate and make intervention decision (extensions are common)

FCA – *Qui Tam* Provisions

- Government Action (following investigation)
  - Intervene in the case and assume primary responsibility for the litigation
  - Decline intervention, allowing relator to proceed
  - Move to dismiss the case (even if relator objects)
  - Seek settlement
- Bars to *Qui Tam* Actions
  - Public Disclosure
  - First-To-File Rule
  - Previous Government Action

FCA – Damages & Penalties

- **Measure of FCA damages:** Difference between what the government actually paid and what it should have paid absent the alleged FCA violation – ***TREBLED!***
- FCA provides for penalties of $5,500 to $11,000 ***per claim*** and may be applied even in the absence of actual damages
- Most courts view the penalty provisions to be mandatory once liability is established, although some courts have exercised discretion.

FCA – Damages & Penalties

- In *qui tam* cases, qui tam relators ("whistleblowers") are entitled to:
  - "Relator's Share" of up to 25% of recovery in intervened cases and up to 30% of recovery in non-intervened cases;
  - Attorneys' fees and costs; and
  - Where retaliation claim is involved:
    - Reinstatement;
    - Double back pay + interest

FCA – Collateral Consequences

- Corporate "Death Penalty"
  - Suspension & Debarment (Gov't Contractors)
  - Exclusion (Health Care) from federal health programs (*e.g.*, Medicaid and Medicare)
- Criminal Conviction & Fines
  - If parallel proceedings under the "Criminal" Federal False Claims Act, 18 U.S.C. § 287

RECENT AMENDMENTS TO THE FCA

"Recent" Amendments

- Since May 2009, the FCA has been amended by three federal laws:
  - Fraud Enforcement and Recovery Act of 2009 ("FERA");
  - Patient Protection and Affordable Care Act of 2010 ("ACA"); and
  - Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 ("Dodd-Frank")

2009: FERA

- FERA significantly amended the FCA for the first time since 1986:
  - "Clarifies" that the FCA was "intended" to extend to **<u>any</u>** false or fraudulent claim for Government money or property, ***regardless of whether***:
    - A claim is actually "presented" directly to the Government;
    - The Government has physical custody of the money; or
    - The defendant specifically intended to defraud the government

FERA Changes To The FCA

- No need for "Presentment"
- Broader Definition of "Claim"
  - Liability attaches to a "claim" for federal funds if:
    - Government has provided any portion of the money used to pay the claim; and
    - The money is spent "on the Government's behalf" or "to advance a Government program or interest"

FERA Changes To The FCA

- Expands Conspiracy Liability
  - FERA expanded FCA conspiracy provision to cover agreements to violate any FCA liability provision
- Establishes "Materiality" Element
  - Now "natural tendency to influence" or "capable of influencing" test
- Increases Whistleblower Protections
  - Now extend to subcontractors and agents

FERA's Change To The FCA's "Whistleblower" Retaliation Provision

- Section 3730(h) provides remedies for persons wrongfully discharged or otherwise discriminated against because of "lawful acts done in furtherance of" an FCA action.
- FERA amended this the cause of action, which provides.

  Any ***employee, contractor, or agent*** shall be entitled to all relief necessary to make that ***employee, contractor, or agent*** whole, if that ***employee, contractor, or agent*** is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, or agent on behalf of the ***employee, contractor, or agent or associated others in furtherance of other efforts to stop 1 or more violations*** of this subchapter.

FERA's Change To The FCA's "Reverse False Claim" Liability Provision

- FERA greatly expanded liability relating to overpayments ("reverse false claims") primarily applicable to the health care industry

(~~7~~G) knowingly makes, uses, or causes to be made or used, a false record or statement material to ~~conceal, avoid, or decrease~~ an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

FERA's Change To The FCA's "Reverse False Claim" Liability Provision

- Key, ***but ambiguous*** terms (*i.e.*, lawyer fuel):
  - "knowingly" …
  - "improperly" …
  - "avoids" …
  - "obligation" …
  - "to the Government."

FCA – "Knowledge" Element

- Under the FCA, "**knowingly**" is "actual knowledge" of a falsity, but also includes "***deliberate ignorance***" or "***reckless disregard***" of the "truth or falsity" of a claim or statement.
  - What responsibility is placed on the potential "possessor" of an overpayment to identify the existence of that overpayment?
  - Compliance program requirements?

What Is an "Obligation"?

(3) the term "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and

- "Obligation" is confusingly defined as "an established duty, whether or not fixed" that arises from "a contractual, grantee, licensure or fee based relationship, from a statute or regulation, or from the retention of any overpayment."

Medicare/Medicaid "Obligations"?

"There can be no doubt but that the statutes and provisions … involving the financing of Medicare and Medicaid, are ***among the most completely impenetrable texts within human experience***. Indeed, one approaches them … with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of the matters addressed merely a passing phase."

Rehabilitation Assoc. of Va. v. Kozlowski, 42 F.3d 1444, 1450 (4th Cir. 1994).

ACA's Changes to the FCA

- Establishes that a violation of the Anti-Kickback Statute ("AKS") can be the basis for a false and fraudulent claim for purposes of the FCA
- Changes the intent-and-knowledge requirements under the AKS. Now, a "person need not have actual knowledge or specific intent to commit a violation of this section"
- Affects the Hanlester defense, which interpreted the AKS to require proof the defendant (1) had specific knowledge of the law, and (2) had specific intent to disobey the law. Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995)

ACA's Changes to the FCA

- Creates *Per Se* FCA Violation for Failure to Report and Return Overpayments:
  - Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of section 3729 of such title.
- Does not add a new liability provision to the FCA, but stipulates with only limited detail the procedural steps and time period to report and return an identified overpayment obligation in order to avoid potential FCA liability.

ACA's Changes to the FCA

- ACA provides a 60-day deadline for **reporting and returning** overpayments.
- The deadline is the later of:
  - (A) the date which is 60 days after the date on which the overpayment was identified; or
  - (B) the date any corresponding cost report is due, if applicable.
- Effective for overpayments "identified" as of the March 23, 2010 PPACA enactment date

Proposed CMS Rule on Reporting/Refunding Overpayments

- Proposed rule contains 60-day report and return requirement with a 10-year "lookback"
- Strong industry opposition to proposed rule, including:
  - Lack of clarity as to what triggers 60-day period
  - 10-year lookback longer than the 6-year HIPAA record retention provision
- Comment period closed April 16, 2012; issuance of final rule is pending

Public Disclosure Bar Evolution

- In 1943, Congress amended the FCA to jurisdictionally bar "parasitic relators" by prohibiting suits based on information in the Government's possession.
- In 1986, Congress revised the jurisdictional bar to encourage *qui tam* suits by removing the Government possession concept. Nevertheless, it sought to balance encouraging true whistleblowers with preventing parasites, so it added the "Public Disclosure Bar."
- March 23, 2010, ACA sought to make it easier for DOJ & relators to avoid the operation of the Public Disclosure Bar.

ACA Changes — “Public Disclosure”

- **No longer stated in terms of a jurisdictional bar.**
  - More vigilance required early; must be in an answer or dispositive motion or may be waived.
- **The court is not required to dismiss a relator’s action if the Government opposes a defendant’s motion to dismiss.**
- **Revision of the definition of “publicly disclosed”:**
  - Information only from “Federal” proceedings “in which the Government or its agent is a party”;
  - Information only from a “Federal report, hearing, audit or investigation”;
  - “News media” remains the same.
    - No definition of “news media”
    - Consider press release regarding overpayment refunds and self-disclosures

§ 10104(j), Effective March 23, 2010

Redline of Changes to Public Disclosure Bar

(A) ~~No~~The court shall ~~have jurisdiction over~~dismiss an action or claim under this section ~~based upon~~, unless opposed by the ~~public disclosure of~~Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed--

`(i) in a Federal criminal, civil, or administrative hearing~~,~~ in which the Government or its agent is a party;

`(ii) in a congressional, ~~administrative, or Government Accounting~~Government Accountability Office, or other Federal report, hearing, audit, or investigation~~,~~; or

`(iii) from the news media,

unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

§ 10104(j), Effective March 23, 2010

Redline of Changes to Public Disclosure Bar

(B) For purposes of this paragraph, "original source" means an individual who ~~has direct and independent knowledge of~~ either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which ~~the~~ allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section ~~which is based on the information~~.

§ 10104(j), Effective March 23, 2010

PPACA Changes — “Original Source”

- **PPACA modifies the original source requirement:**
  - Only requires a relator to have “knowledge that is independent of and materially adds to the publicly disclosed allegations,” which omits the prior requirement that the knowledge be “direct and independent of . . . the information on which the allegations are based.”
  - “Independent knowledge” and “materially adds” are undefined.

§ 10104(j), Effective March 23, 2010

HEIGHTENED FCA & QUI TAM ENFORCEMENT

Statistics & Trends

Heightened FCA Enforcement

- Creation of Health Care Fraud Prevention and Enforcement Action Team (“HEAT”)
- New laws and new tools for the Government to fight fraud, waste, and abuse
- FY 2011 DoJ Statistics
  - More than $4.1 Billion was recovered
  - $2.35 Billion from civil enforcement efforts
  - DoJ opened over 1,000 new criminal health care fraud and over 900 civil enforcement matters

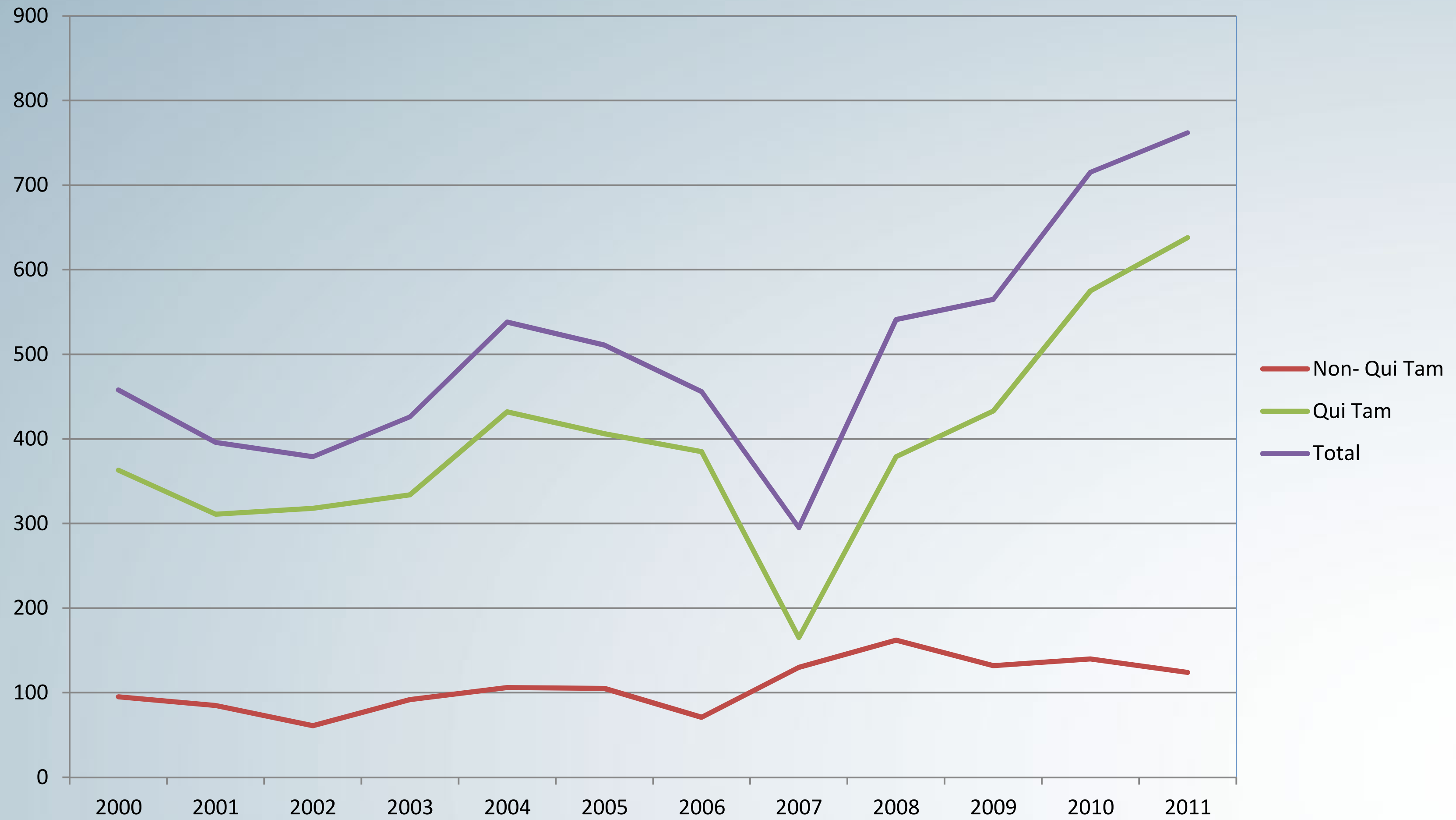
Heightened FCA Enforcement

- *Qui Tam* Enforcement
  - Government has huge backlog of *qui tam* cases under investigation – Over 1,300 pending under investigation this year
    - 885 (66%) cases allege a health care fraud violation
    - 867 (98%) of these 885 cases involve Medicare and/or Medicaid
  - Imperative to increase fraud enforcement, but little increased funding
  - Recent FCA amendments allow for *qui tam* relator "deputies"
  - Recent FCA amendments:
    - Allow Government to "veto" dismissal of "parasitic" qui tam suits based on public disclosure
    - Allow government to share fruits of investigation obtained through CIDs
    - Expand liability, exposure, and potential "bounties"
  - Result is sharp increase in relators able to pursue *qui tam* cases in non-intervened cases = Government "lottery tickets"

FCA Statistics - FY 2011

	FY 2011	Total (Since 1986)
New matters	762	12,132
Qui tam	638	7,843
Recoveries	$3,029,249,933	$30,315,593,792
Relator share	$532,193,735	$3,418,672,503

FCA - New Matters 2000-2011



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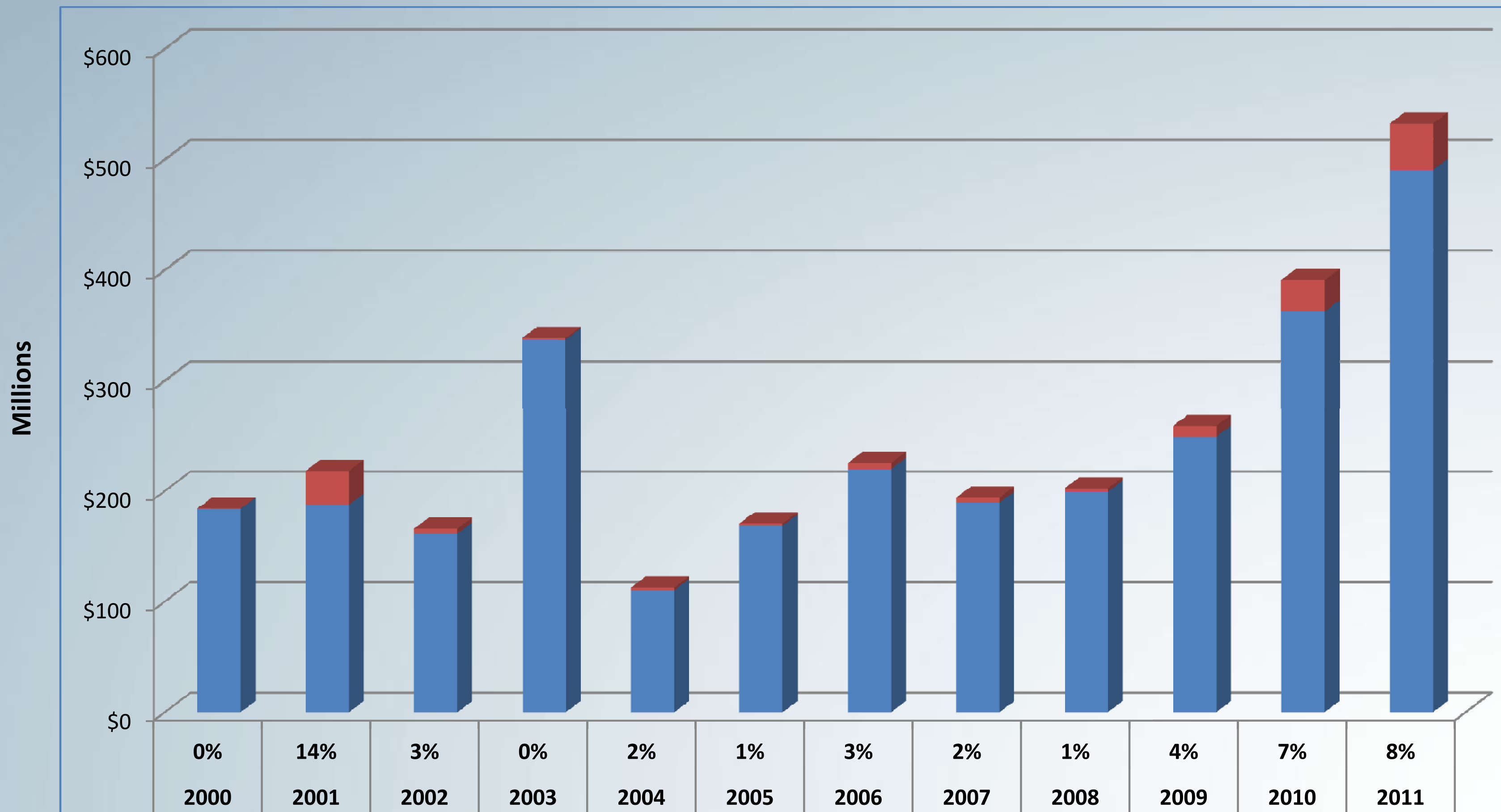
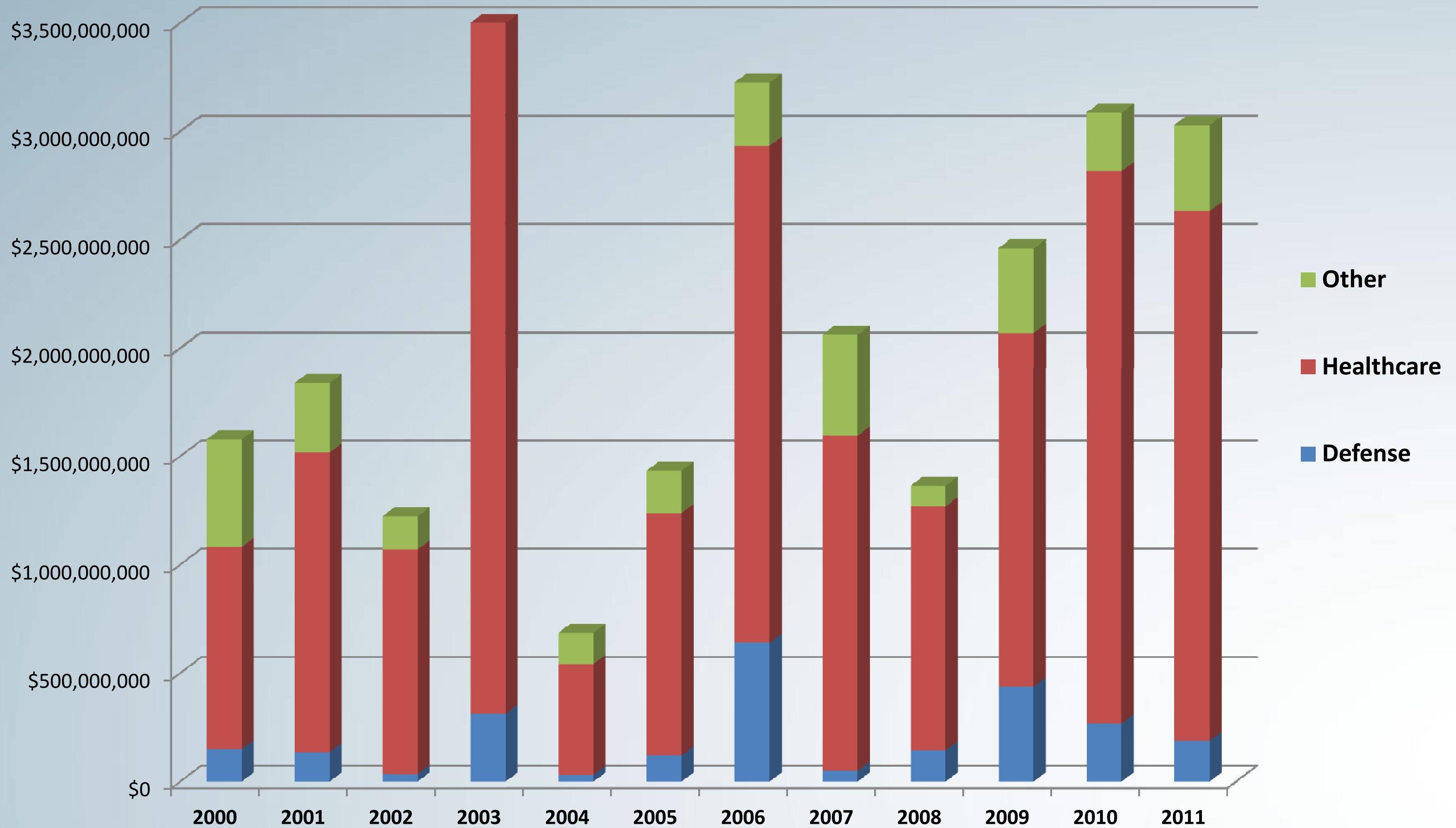
Importance of Intervention

- The **Government intervenes in roughly <u>30%</u>** of qui tam cases filed.
  - Rate has stayed roughly consistent since 1986
- In **intervened cases**, there is a **"success" rate** (settlement or verdict) of roughly **<u>90%</u>**
- In ***non-intervened cases***, the "success" rate is inversed or roughly **<u>10%</u>**

Relator's Share of Awards 2000-2011



Awards by Industry 2000-2011



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NEW RISKS FOR HEALTH PLANS

Provider Risk Areas

- Providers have been the traditional targets for FCA and *qui tam* actions based on such things as:
  - Overpayments
  - Price Inflation
  - Kickbacks
  - Off-label Promotion
  - Unnecessary / Ineligible Claims
  - Upcoding
  - Stark Act
  - Quality of Care

Payors, Plans, MCO Risk Areas

- Recent amendments to the FCA bring health plans into the Government's FCA "cross-hairs"
- Any false claim, record, or statement resulting in the receipt of federal funds can expose a health plan to FCA liability. Such risk areas include the following:
  - **Federal Employees Health Benefits Program** (*e.g.*, certification of community rate);
  - **Medicare Advantage** (*e.g.*, plan rate bid certs);
  - **Contractor Performance** (*e.g.*, timeliness of claims payments, notices of claim denials, reconsiderations, and appeals, marketing, enrollment/disenrollment, under utilization, accessibility of services);

Payors, Plans, MCO Risk Areas

- **Falsification of Reports/Certifications** (*e.g.*, regarding encounter data, quality-of-care review, enrollee health status reports, or data required to be submitted to the government);
- **"Red-Lining"** (*e.g.*, insurance companies that provide supplemental Medicare insurance coverage and paid on a per patient basis, improperly discourage enrollment by persons they deem to be sicker or at higher risk for serious illness, to decrease risk and enhance revenue); and,
- **Medicare Part D Fraud**
- **Intermediary Services** (*e.g.*, failure to provide appropriate level of services and/or to ferret out issues and fraud)

COMPLIANCE TIPS AND BEST PRACTICES

What Does the Future Hold? Mandatory Compliance Programs

- Mandatory Compliance Programs Mandated by the ACA
  - Section 6102 of the ACA makes compliance programs mandatory for nursing homes and skilled nursing facilities
  - Section 6401(a) of the ACA makes establishment of a compliance program with certain “core elements” developed by HHS a condition of participation in Medicare, Medicaid, and CHIP
  - CMS solicited comments in a proposed rule on compliance program requirements from industry stakeholders (e.g., us of seven elements of effective compliance programs from U.S. Federal Sentencing Guidelines)
  - In the final rule, CMS “punted” on the promulgation of compliance program requirements, indicating that the agency would issue a new notice of proposed rule making in the future

US Dept of HHS Press Release, January 24, 2011

Risk Mitigation Strategies

- Overall Compliance
  - Effective Corporate Compliance
  - FCA-Focused Compliance
  - Employee “Whistleblower” Risk Mitigation
    - Mandatory Arbitration Provisions
    - Employee Releases

Compliance Tips

- Identify Potential Sources of "Obligations" to Repay the Government
  - Claims Submissions
  - Enrollment Forms
  - Contracts
  - Certifications
- Receivables Monitoring, Auditing, Disclosure
  - The heightened risk for overpayment-based FCA liability mandates a robust analysis of a health care providers' receivables monitoring, auditing, policies and procedures, including disclosure strategies

Compliance Tips

- Remember that providers are not the only potential targets – health plans are now very much at risk
  - Failure to repay an overpayment
  - False certifying data in rate proposals, loss ratios, etc.
- Evaluate current compliance policies and programs
  - New risks mean new measures
  - Train, train, and train again

Compliance Tips

- Listen and investigate when an employee, contractor, agent, or anyone tells you that there is a "problem"
  - Remediate the identified problem promptly
  - Consider obligations, self-disclosure, and repayment strategies
  - Even if it appears that there may be no merit to the identified "problem," treating the individual report thoughtfully and with respect can prevent further action

Compliance Tips

- Finally, because FCA liability hinges in most respects on “knowledge,” which includes “***deliberate ignorance***” or “***reckless disregard***” of the “truth or falsity” of a claim or statement, a failure to have a robust compliance program can be construed to constitute knowledge.
- Conversely, the establishment, review, and audit of a compliance program, including the use of outside counsel, can help support a lack of knowledge to impose FCA liability.

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