



Corporate Integrity Agreements: Living Under a CIA or Using CIAs to Shape Legal/Compliance Programs

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REASONS FOR A CIA

- Government Investigation
- *Qui Tam* Case/Settlement



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DOJ Statistics – *Qui Tam* Actions

- Refresher: *Qui tam* lawsuits are brought by whistleblowers under the False Claims Act and they provide a reward if recovery is received by the government



- From January 2009 to the end of fiscal year 2015, the government recovered \$19.4 billion in settlements and judgments related to *qui tam* suits and paid whistleblower awards of \$3 billion during the same period

DOJ Statistics – Settlements and Judgment

Settlement and Judgment Recovery Dollars by FY - HHS Cases



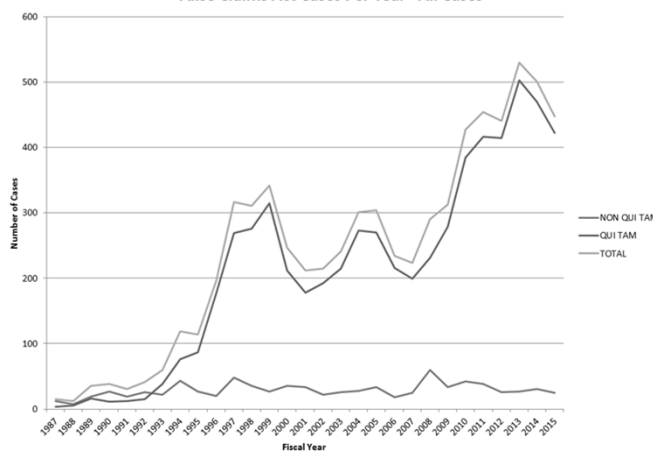
DOJ Statistics – *Qui Tam* Actions

- Of the **\$3.5 billion** the government recovered in fiscal year 2015, more than **\$2.8 billion** related to lawsuits filed under the ***qui tam*** provisions of the False Claims Act
- Whistleblowers filed 638 ***qui tam*** suits in fiscal year 2015 and the DOJ recovered \$2.8 billion
- Whistleblower awards during the same period totaled **\$597 million**



DOJ Statistics – *Qui Tam* Actions

False Claims Act Cases Per Year - All Cases



Who Are *Qui – Tam* Litigants?

- Disgruntled/Former Employees
- “Concerned” Employees
- Physicians
- Hospital/Health System Executives
- Consultants
- Compliance Staff Members

Effective Compliance Program

It is possible that documenting an effective compliance program could eliminate the need for a CIA.

CIAs

- Operating under a CIA is not necessarily bad.
 - Culture change.
 - Mandated structure.
 - Formal reporting process.

Key Elements of a CIA

Terms of CIA differ depending upon whether the cause of the CIA was for i) billing issues versus ii) physician financial arrangements.

Key Elements of a CIA

- Key Definitions:
 - Covered Persons.
 - Arrangements.
 - Focus Arrangements.
 - Arrangements Covered Persons.

Key Elements of a CIA

- Designation of:
 - Compliance Officer.
 - Compliance Committee.

Key Elements of a CIA

- Mandated Board Oversight:
 - Board is responsible for the implementation of the CIA.
 - Review and approval of Annual Report.
 - Sometimes requiring an external Compliance Expert to the Board (i.e., Halifax Health).

Key Elements of a CIA

- Policies and Procedures

Key Elements of a CIA

- Training and Education:
 - CIA requirements.
 - Compliance Program.
 - Fraud and Abuse (Stark Law, Anti-Kickback Statute, False Claims Act and, Civil Monetary Penalties).

Key Elements of a CIA

- Training and Education:
 - Mandated Hours for Board on Oversight
 - Training Plan
 - No Required Hours
 - Flexibility to Meet Changing Needs and Risks

Key Elements of a CIA

Implementation of tracking of physician financial arrangements.

Key Elements of a CIA

- Unallowable Costs on Cost Report:
 - Legal fees.
 - CIA implementation.
 - CIA oversight.

Key Elements of a CIA

- Independent Review Organization (“IRO”):
 - Billing oversight.
 - Legal/Financial Arrangements oversight.

Key Elements of a CIA

- Required Implementation of Reporting Requirements:
 - Non-Retaliation Policy.
 - Reporting to Executive Leadership.
 - Reporting to Compliance Officer.
 - Anonymous toll-free compliance hotline.

Key Elements of a CIA

Implementation of Process in order to determine whether any employee or medical staff member is an “Ineligible Person”.

Key Elements of a CIA

Mandated requirement of notifying the OIG of any governmental investigation or legal proceedings related to an alleged violation of fraud and abuse laws.

Key Elements of a CIA

Mandated repayment requirements of any overpayments, including requirements to notify the OIG and repay any identified overpayments “within 60 days of identification”, and implementing of remedial steps within 90 days after identification.

Key Elements of a CIA

- Reportable Events to the OIG:
 - Substantial Overpayment (usually undefined).
 - “Probable violation of criminal, civil, or administrative laws.”
 - Employment or contracting with an ineligible person.
 - Filing of bankruptcy.

Key Elements of a CIA

- Mandated Reports:
 - Implementation Report usually “within 120 days of the effective date of the CIA”.
 - Annual Reports usually “60 days after the effective date”.

Key Elements of a CIA

- Certifications:
 - Board Members.
 - Executive Leadership.
 - Possible “roll-up” certifications from management to assist the Board and Executive Leadership to provide their Certifications.

Key Elements of a CIA

CIA's permit the OIG to have inspection, audit, and review rights.

Some entities under a CIA have onsite visits and inspections by the OIG.

Key Elements of a CIA

- CIA's have breach and default provisions:
 - Failure to use an IRO.
 - Failure to submit Implementation Report or Annual Reports.
 - Failure to identify Unallowable Costs.
 - Failure to grant the OIG access for investigation.
 - False Certification.
 - Failure to adhere to the terms of the applicable CIA.

Negotiable Terms

- Scope of IRO Review in Claims Reviews
- IRO v. Legal IRO in Arrangements Reviews
- Required certifications “although certifications will be required, the source of the certifications may be negotiable”.

Effective Compliance Programs

Analyzing and implementing key components of CIAs from the same health care sector can assist in implementing an **effective** compliance program.



Questions



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