

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
- “Second Chance” to Participate in Federal Healthcare Programs
 - Exclusion release in exchange for commitment to implement and maintain CIA obligations

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



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DOJ Statistics – Settlements and Judgment



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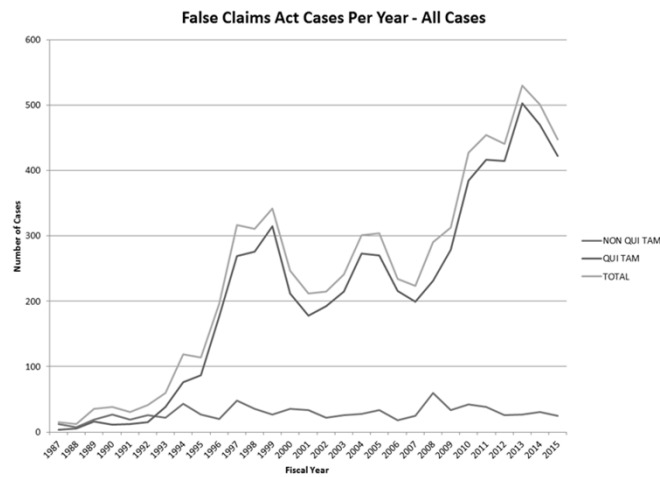
DOJ Statistics – *Qui Tam* Actions

- 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**



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DOJ Statistics – *Qui Tam* Actions



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Who Are *Qui – Tam* Litigants?

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

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CIAs

- OIG may require an entity to enter into a Corporate Integrity Agreement in exchange for an exclusion release (OIG’s promise not to exclude the provider for the underlying conduct in the FCA case)
- Operating under a CIA is not necessarily bad.
 - Culture change.
 - Mandated structure.
 - Formal reporting process.
 - Compliance Officer’s heightened standing.
 - Increased resources.
 - Organizational interest in corporate compliance.

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Key Elements of a CIA

- All CIAs contain the same basic terms.
- Specific provisions and obligations may be tailored to the underlying conduct in the FCA case, or to address other concerns by OIG.
 - Billing Fraud
 - Kickbacks
 - Failure of care/provision of worthless services or poor-quality services

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Key Elements of a CIA

- Key Definitions:
 - Covered Persons.
 - Arrangements.
 - Focus Arrangements.
 - Arrangements Covered Persons.
 - Professionally-recognized standards of care.
 - Reportable Event.
 - Overpayments / Substantial Overpayments

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Key Elements of a CIA

- Designation of:
 - Compliance Officer – the individual who bears responsibility for implementing and maintaining CIA obligations.
 - Compliance Committee

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Key Elements of a CIA

- Mandated Board Oversight:
 - Board is responsible for overseeing the implementation of the CIA.
 - Review and approval of Annual Report.
 - CIAs may include a requirement for an external Compliance Expert to the Board (i.e., Halifax Health).

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Key Elements of a CIA

- **Policies and Procedures**
 - Written standards to achieve organizational compliance.

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Key Elements of a CIA

- **Training and Education:**
 - Formation and execution of a Training Plan.
 - No Required Hours
 - Flexibility to Meet Changing Needs and Risks
 - Mandated Hours for Board on Oversight
 - Training Plan
 - Fraud and Abuse (Stark Law, Anti-Kickback Statute, False Claims Act and, Civil Monetary Penalties, Quality of Care).

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Key Elements of a CIA

- Implementation of changes to billing functions.
- Implementation of tracking of physician financial arrangements.
- Implementation of a quality assurance/quality review process.

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Key Elements of a CIA

- **Independent Review Organization (“IRO”)**
 - Selected by provider with approval of OIG.
 - Billing Oversight
 - Legal/Financial Arrangements Oversight
- **Independent Monitor**
 - Selected by the OIG, paid by entity
 - Performs Quality Reviews or other Specific Reviews
 - Broad, Independent Authority
 - May conduct independent investigations

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Key Elements of a CIA

- **Disclosure Program Requirements:**
 - Non-Retaliation Policy.
 - Reporting to Executive Leadership.
 - Reporting to Compliance Officer.
 - Anonymous toll-free compliance hotline.

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Key Elements of a CIA

- **Exclusion Screening**
 - Screening prospective and current employees against the LEIE to determine whether any Covered Person is an Excluded Person.

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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”.

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Key Elements of a CIA

- **Reportable Events to the OIG:**

- Substantial Overpayment (usually undefined).
- “Probable violation of criminal, civil, or administrative laws.”
- Failure to provide care in accordance with professionally-recognized standards of care.
- Employment or contracting with an ineligible person.
- Filing of bankruptcy.

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Key Elements of a CIA

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

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Key Elements of a CIA

- **Overpayments**
 - 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.

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Key Elements of a CIA

- **Certifications**

- Board Members.
- Executive Leadership
- Certifying Employees
- Defined, written process to guide individuals through certification process.
- Possible “roll-up” certifications from management to assist the Board and Executive Leadership to provide their Certifications.

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Key Elements of a CIA

CIAs permit the OIG to have inspection, audit, and review rights.

Many entities under CIAs have one or multiple onsite visits and inspections by the OIG (routine, nonroutine).

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Key Elements of a CIA

- **CIA**s have breach and default provisions.
- **Stipulated Penalties (Monetary Penalties):**
 - 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.

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Key Elements of a CIA

- **Exclusion for Material Breach:**
 - Repeated or Flagrant Violations of the CIA;
 - Failure to report a Reportable Event;
 - Failure to pay Stipulated Penalties;
 - Failure to comply with the Board Expert, IRO, and/or Independent Monitor provisions.

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Negotiable Terms

- Scope of IRO Review in Claims Reviews
- Required certifications “although certifications will be required, the source of the certifications may be negotiable”.
- CIA provisions may be negotiated to reflect the specific structure and/or operations of a company.
- CIAs are standardized and many provisions non-negotiable to “level the playing field” across entities operating under CIAs.

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Effective Compliance Programs

Analyzing and implementing key components of CIAs from similarly situated entities (same healthcare sector) can inform an entity’s compliance program and assist with the implementation of an **effective** compliance program.

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Questions

