

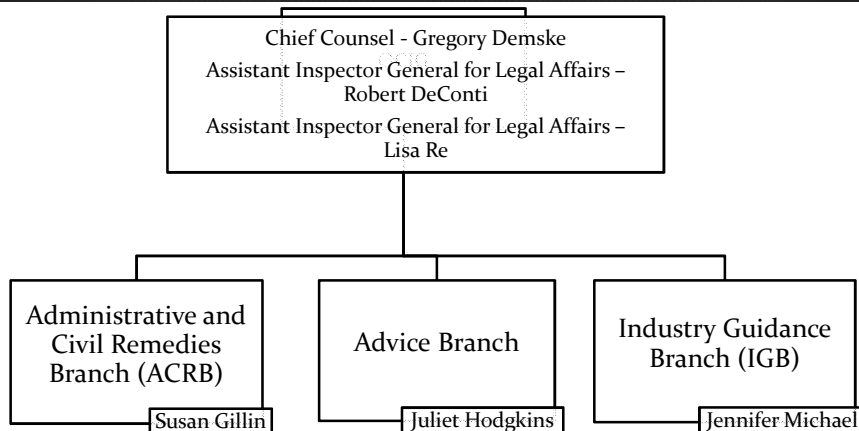


Corporate Integrity Agreement Developments Understanding the Government's Expectations

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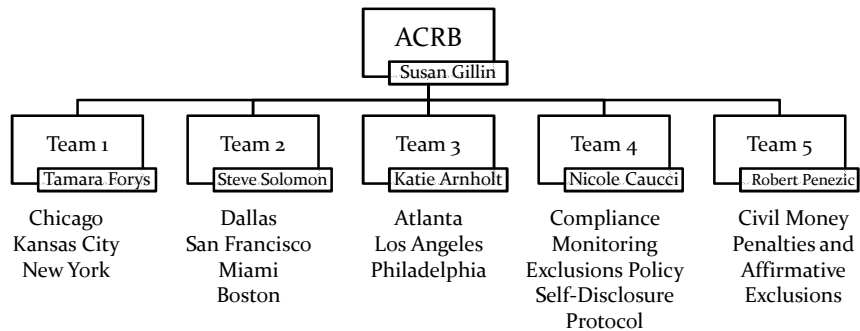


OCIG Structure





ACRB Structure



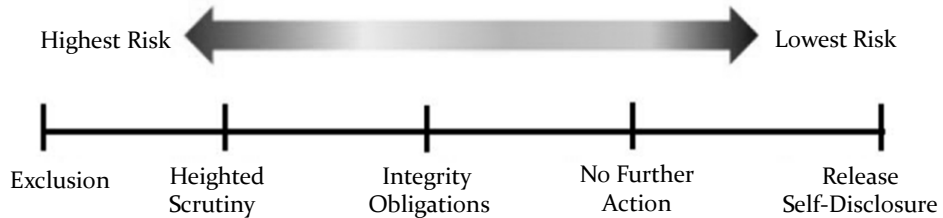
Background on CIAs

- **OIG enters into CIAs in connection with the settlement of health care fraud cases**
 - False Claims Act (FCA)
 - Civil Monetary Penalties Law (CMPL)
- **CIA in exchange for OIG's release of its permissive exclusion authority**
 - 1128(b)(7) (Fraud, kickbacks and other prohibited activities)





Risk Spectrum



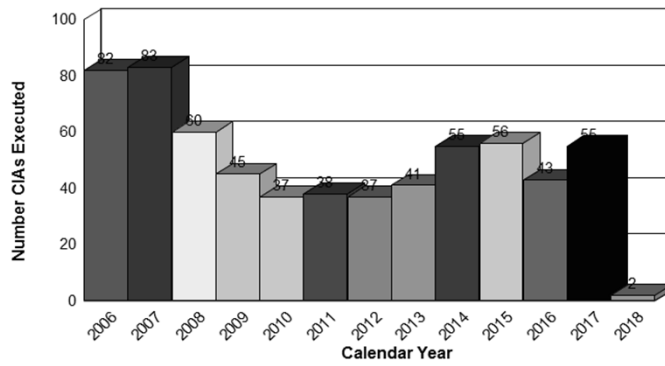
Section 1128(b)(7) Criteria

- Criteria for Implementing Section 1128(b)(7) Exclusion Authority, issued April 18, 2016
- Resolution of exclusion authority is based on assessment of future risk to the FHCPs.
- “Risk spectrum” from low to high risk based on: (1) nature and circumstances of conduct; (2) conduct during government investigation; (3) significant ameliorative efforts; and (4) history of compliance
- Highest risk will result in exclusion; below highest risk, OIG may require integrity obligations or take no further action

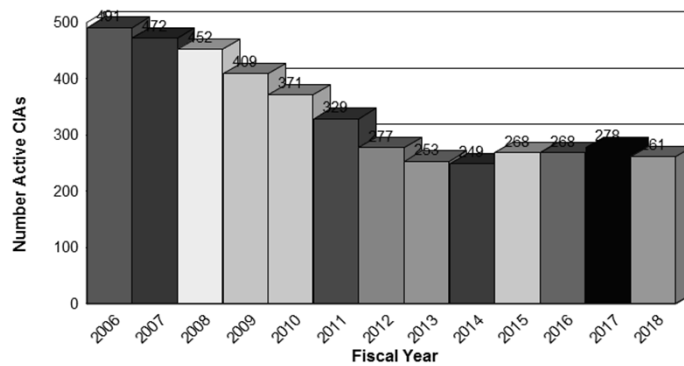




Number of New CIAs

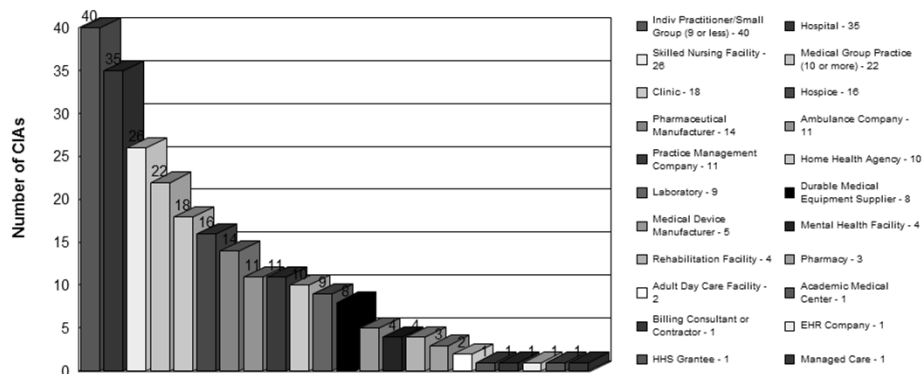


Number of Active CIAs





CIA by Subject Type



CIA Term

- CIAs have a 5 year term
- IAs have a 3 year term
- Term may be extended





CIA Requirements

- Compliance Officer
- Compliance Committee
- Management and Board Obligations
- Written Standards
- Training and Education



CIA Requirements

- Review Procedures
 - Claims Review
 - Arrangements Review
- Risk Assessment
- Disclosure Program
- Ineligible Persons





CIA Requirements

- Notification of Government Investigations
- Overpayments
- Reportable Events
- Implementation Report/Annual Reports
- Breach and Default
 - Stipulated Penalties
 - Material Breach



Recent Developments

- Board Compliance Obligations
 - Review and Oversight
 - Submit Description of Materials Reviewed
 - Resolution
 - Training
 - Compliance Expert





Board Resolution

- “The Board of Directors has made a reasonable inquiry into the operations of [Provider]’s Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, [Provider] has implemented an effective Compliance Program to meet Federal health care program requirements and the requirements of this CIA.”



Recent Developments

- **Management Certifications**

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and [Provider] policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of [Provider] is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”





Recent Developments

- **CEO Certification**

- a. to the best of his or her knowledge, except as otherwise described in the report, [Provider] has implemented and is in compliance with all of the requirements of this CIA;
- b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and
- c. he or she understands that the certification is being provided to and relied upon by the United States.



Recent Developments

- **Risk Assessment and Internal Review Process**

- Identify and prioritize risks
- Develop work plans related to identified risks
- Implement work plans
- Develop corrective action plans in response to audits
- Track implementation of corrective action plans





Recent Developments

- Claims Reviews
 - Eliminated discovery sample/full sample and error rate threshold
 - Review sample of paid claims for medical necessity, appropriate documentation, coding, and billing
 - For any paid claim that results in an overpayment, IRO to review systems and processes and identify problems and weaknesses



Recent Developments

- Claims Reviews
 - Repayment of identified overpayments
 - Evaluate claims review results under CMS overpayment rule to determine if repayment of extrapolated overpayment is required
 - Claims review report must provide an estimate of the actual overpayment in the population at the midpoint





Recent Developments

- IRO Requirements (Appendix A)
 - Must assign licensed nurses or physicians with relevant education, training, and specialized expertise to make the medical necessity determinations
 - Provider must ensure that IRO has access to all records and personnel necessary to complete the required reviews



Recent Developments

- Risk-Based Claims Review
 - OIG may limit the population to one or more subsets of paid claims
 - Provider or IRO may submit proposals for the subsets of paid claims to be reviewed
 - OIG also may select facilities that will be subject to the claims review





Recent Developments

- Provider-Specific Claims Reviews
 - Hospice
 - MDS Review
- Quarterly Claims Reviews in IAs
 - 30 paid claims per quarter
 - Repay identified overpayments and evaluate sample results under 60 day rule
 - IRO must identify actual overpayment in the population at the midpoint



CIA Enforcement

- CIA enforcement actions posted on
OIG's website
 - Stipulated Penalties
 - Material Breach

<https://oig.hhs.gov/fraud/enforcement/ciae/index.asp>





CIA Enforcement

- CMPL settlements of Reportable Event disclosures
 - Employment of excluded individuals
 - Kickbacks and self-referral violations
 - Improper billing

<https://oig.hhs.gov/fraud/enforcement/cmp/reportable-events.asp>

