Corporate Integrity Agreement Developments
Understanding the Government’s Expectations

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OCIG Structure
ACRB Structure

![ACRB Structure Diagram]

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

Highest Risk → Lowest Risk

Exclusion | Heighted Scrutiny | Integrity Obligations | No Further Action | Release Self-Disclosure

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
CIAs by Subject Type

- 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

• 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