

Corporate Integrity Agreements: The Role of an Independent Review Organization (IRO)

Amanda Walker Copsey, Senior Counsel

Office of Counsel to the Inspector General
US Dept of Health and Human Services

Glen Moyers, Partner

Forensic Services, Healthcare Sector, KPMG, LLP

Steven W. Ortquist, Founder & Principal

Arete Compliance Solutions, LLC

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Agenda

- OIG Risk Spectrum and CIAs
- Different types of IRO Reviews
- Risk-based Reviews & Data Analytics
- Repayment and Extrapolation
- Independence, Objectivity, and Qualifications
- Findings and Recommendations
- Practical Tips

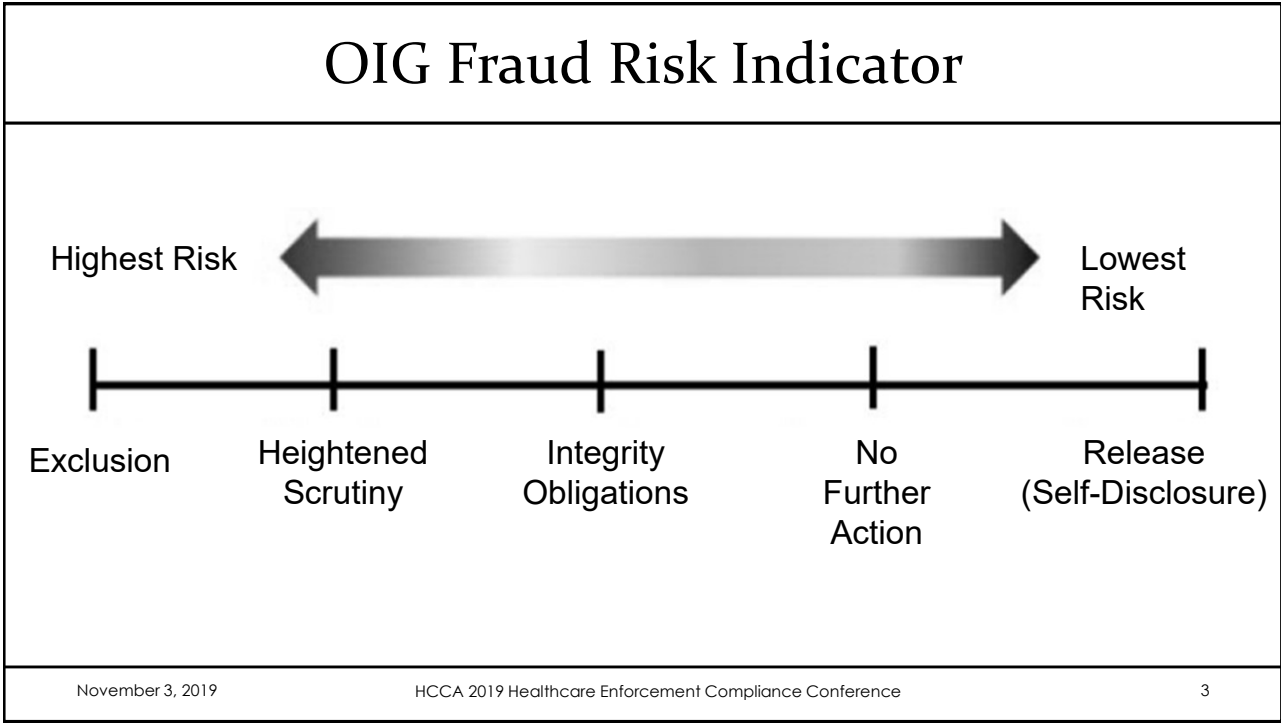


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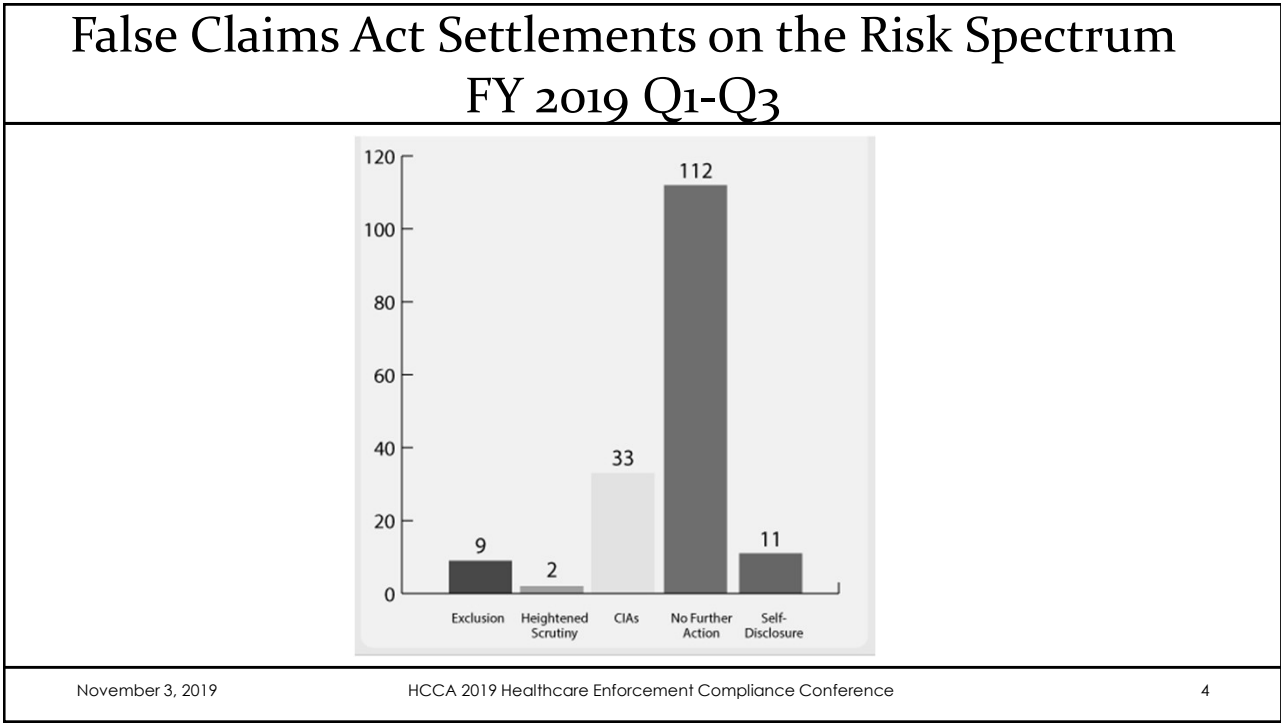
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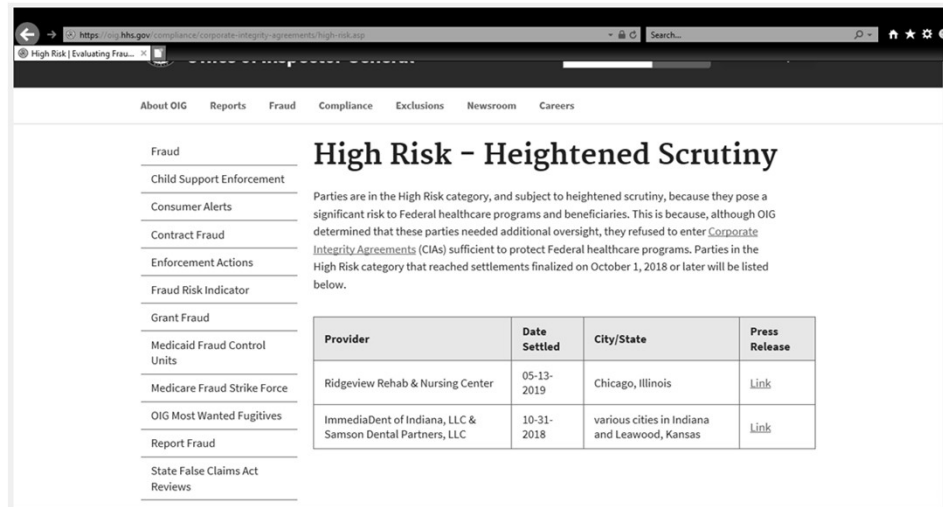


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High Risk



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Criteria for Implementing Section 1128(b)(7) Exclusion Authority

- OIG's expectations for providers to implement robust compliance programs, promptly respond to government investigations, and self-disclose fraud
- Presumption that exclusion should be imposed
- Compliance "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

**<http://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf>
(April 18, 2016)**

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Corporate Integrity Agreements and Integrity Agreements

Purpose: improve quality of care and promote compliance

- CIAs (typically last 5 years)
 - Require various compliance obligations including:
 - Compliance officer and committee; policies and procedures; training; disclosure program; ineligible person screening; reportable events; implementation and annual reports
 - Annual IRO Reviews
- IAs (typically last 3 years)
 - Quarterly IRO Reviews

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Independent Review Organization (IRO)

- Appendix A of the CIA
 - Outlines qualifications and responsibilities of IRO
- Accounting, auditing or consulting firm for claims reviews; law firm, lawyer, consulting firm for arrangements reviews
- Must be independent and objective
- Selected by provider, subject to OIG objection

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Different Types of CIAs

- Claims Reviews
- Arrangements Reviews
- Quality of Care Reviews
- Specialty Reviews



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Claims Reviews - Objective

- The IRO reviews a sample of claims submitted by the Obligated Entity and reimbursed by Medicare, to determine whether the items and services furnished were medically necessary and appropriately documented and whether the claims were correctly coded, submitted and reimbursed
- A determination is made based on the criteria above whether a sampled claim represents an Overpayment
- The results of the sample assessment may be extrapolated

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Claims Reviews - Populations

- Populations consist of claims submitted in a 12-month period
- In OIG's discretion, OIG may limit the Population to one or more subset(s) of Paid Claims to be reviewed
- OIG may also select the facilities that will be subject to the Claims Review in each Reporting Period
- Typically, the Obligated Entity may submit proposals identifying suggestions for the subset(s) of Paid Claims to be reviewed and the facilities to be reviewed

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Claims Reviews - Assessments

- Sampled claims are assessed based on supporting documentation from the Obligated Entity or under its control and applicable Medicare program requirements
- For each claim that results in an Overpayment, the IRO reviews the systems and processes that generated the claim and identifies problems or weaknesses that may have resulted in the Overpayments

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Claims Reviews - Reporting

- Descriptions of the populations, data sources, protocols used and any supplemental materials provided
- Narratives describing the billing and coding systems and controls at the Obligated Entity
- Explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.), including the results of the Claims Review sample
- Quantitative information regarding the claims assessed and findings

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Risk-Based Reviews



- CIA Appendix B: OIG may limit the Population to one or more subset(s) of Paid Claims to be reviewed
- Provider may submit proposals for subset(s) of Paid Claims
- OIG Division of Data Analytics

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Repayment

- Provider must repay its Medicare contractor (or other applicable payor) any overpayments identified as a result of an IRO claims review
- Documentation of amount refunded
- Consult CMS Overpayment Rule to determine whether extrapolation overpayment must be paid
 - 42 U.S.C. § 1320a-7k(d) and 42 C.F.R § 401.301-305



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Extrapolation

- Terms of the CIA Appendix B may vary
- Older CIAs trigger full sample review for error rate of 5% or greater
 - Systems review also required
- Recent CIAs do not include 5% threshold but require estimate of actual overpayment in the population at the mean point estimate

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Independence and Objectivity



- CIA Appendix A
- <https://oig.hhs.gov/fraud/cia/docs/iro-guidance-2016.pdf>
- <https://www.gao.gov/yellowbook/overview>

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Arrangements IRO Independence and Objectivity Changes

- OLD IRO Independence and Objectivity

“The IRO must perform the Arrangements Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office” (the “Yellow Book”)

- NEW IRO Relationship to [Obligated Organization]

“The IRO shall not (1) currently represent or be currently employed or engaged by [Obligated Organization] or (2) have a current or prior relationship to [Obligated Organization] or its owners, officers, or directors that would cause a reasonable person to question the IRO’s objectivity in performing the [Systems Review and Transactions Review]

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Arrangements IRO Qualifications Changes

- An ~~accounting firm, auditing firm~~, consulting firm, law firm or lawyer knowledgeable about the requirements of the AKS and Stark Law, regulations and guidance
- Possess expertise in fair market valuation issues or has the ability to associate a valuation firm to assist in conducting the transactions review
- Sufficient staff and resources to conduct the reviews required by the CIA on a timely basis

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Arrangements Systems Review

A review of the systems, processes, policies and procedures adopted by [Obligated Organization] related to the initiation, review, approval and tracking of Arrangements, specifically including:

- Focus Arrangements Tracking System
- Documenting the names and positions of individuals involved in the negotiation, review and approval of Focus Arrangements
- Tracking remuneration [to confirm that parties are complying with terms when making payment]
- FMV documentation, including FMV amount, range and corresponding time periods; date of the FMV opinion; who conducted the FMV evaluation; and Covered Person(s) who received the FMV report

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Arrangements Systems Reviews

- Tracking service and activity logs to confirm performance of services,
- Monitoring use of space, supplies, devices, equipment or other items and services to ensure use is consistent with the terms of the Arrangement,
- Initiating arrangements (authority) and specifying business need/rationale
- Review and approval process (legal, other internal, business need/rationale, FMV)
- Compliance Office's annual review
- Effective responses when problems are discovered

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Arrangements Systems Review Report

- A description of the documentation (including policies) reviewed and personnel interviewed
- A detailed description of systems, policies, processes and procedures relating to the [Focus Arrangements Procedures]
- Findings and supporting rationale regarding weaknesses in systems, policies, processes and procedures relating to the [Focus Arrangements Procedures]
- Recommendations to improve the systems, policies, processes or procedures relating to the [Focus Arrangements Procedures]

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Arrangements Transactions Review

- Verifying that Focus Arrangements are maintained in the FATS
- Randomly selected sample of Focus Arrangements
- Verifying that (for) each Focus Arrangements
 - Is in the FATS, including (i) identity of parties, (ii) names and positions of persons involved in negotiating, review and approval, (iii) relevant terms (items, services, equipment, space, effective date, term date, etc.), (iv) performance (i.e., service or activity logs, monitoring, etc.)
 - Was subject to the internal review and approval process (including legal and business review)
 - Was determined to be FMV, remuneration was properly tracked and has adhered to contract terms

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Arrangements Transactions Review

- Business need/rationale was specified
- Service & activity logs were completed and reviewed
- Use of space, supplies, equipment, etc was monitored
- Focus Arrangements requirements were met (in writing, code of conduct and policies distributed, contract certification inserted)

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Arrangements Transactions Review Report

Arrangements Transactions Review Report shall include:

- Review Protocol – description of the process used by the IRO to identify arrangements subject to the Review
- Sources of Data – full description of the documentation and other information relied upon by the IRO in performing the Review
- Supplemental Materials – identification of any supplemental materials, date accepted, relative weight given, process by which the supplemental materials were accepted and IRO's reasons for accepting.
- Review Findings – IRO findings re: whether the obligated organization complied with the Focus Arrangements Procedures and Requirements with regard to each Focus Arrangement in the sample
- Names and Credentials – of individuals who conducted the reviews

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Quality of Care – Independent Monitor Review

- Quality monitor selected by OIG in consultation with provider
 - Monitor is not an agent of OIG but may be removed by OIG at its sole discretion
- Assesses provider's quality control systems, responsiveness to quality of care issues, resident care, staffing, outcome measures, resident discharge potential, quality of care dashboard, facility and capital improvements
- Quarterly site visits and reports

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Specialty IRO Reviews

- Sales and marketing reviews
- Drug price reporting reviews
- Ambulance claims reviews
- EHR – software quality reviews



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Practical Tips – IRO Report

- IRO may submit a workplan to OIG prior to performing the review
- Report should be organized to track the requirements of the CIA and any appendices
- Quantitative results
- Clear narrative explanation of IRO findings
- IRO Recommendations
 - Provider's response and corrective action plans

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Practical Tips - Working Successfully with IRO

- Assemble a team and a plan well in advance
- Carefully assess timelines and milestones
- Perform “test runs” of data acquisition to avoid surprises and delays
- Define relevant and appropriate claims assessment steps and criteria well in advance
- Provide detailed review procedures to OIG in advance for comment

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Conclusion

QUESTIONS



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