

Independent Review Organization: A Contract with the HHS Office of Inspector General



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Corporate Integrity Agreement (CIA)

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As part of the resolution of an investigation into a healthcare provider's alleged fraud, a provider may enter into a Corporate Integrity Agreement (CIA) through which the provider consents to various compliance obligations in exchange for the OIG's promise not to seek exclusion of that provider, pursuant to the OIG's authority under section 1128(b)(7) of the Social Security Act.



CIA Requirements generally include:

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- Compliance Officer and Committee
- Training and Education of Covered Persons
- Written Policies and Procedures
- Disclosure of Overpayments and Probable Violations of Civil, Criminal and/or Administrative Law
- Review Procedures
- Disclosure Program
- Ineligible Persons Screening
- Annual Reports



What is an Independent Review Organization (IRO)?

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- An accounting, auditing, or consulting firm which provides independent and objective reviews.
- The retention of an IRO is required by a CIA.
- The types of reviews to be conducted by an IRO:
 - Systems Review(s)
 - Transactions Review(s), e.g. claims review or arrangements review



CIA requirements regarding an IRO

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- Expertise in the relevant substantive matters
- Expertise in general requirements of the relevant Federal health care programs
- Appropriate credentials/certifications
- Knowledge of statistical sampling (if applicable)
- Sufficient staff and resources (in-house) to perform the work on a timely basis in accordance with CIA deadlines
- Must be independent and objective per *Government Auditing Standards* published by the GAO (the “Yellow Book”)



The role of an IRO

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- From the Government's perspective, the IRO serves as an extension of the Government's own auditing and monitoring functions.
- Though selected and paid by the entity, the IRO is accountable to the OIG



The OIG maintains the right to:

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- Approve the IRO
- Access the IRO's workpapers, correspondence between the IRO and provider, etc.
- Meet with the IRO
- Question and perform a Validation Review of the IRO's work
- Require replacement of the IRO



“One size does not fit all”

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- The IRO must have the requisite level of expertise and qualification in the specific area under review (inpatient, DME, laboratory, pharmaceutical, etc).
- The fact that an entity has served as an IRO for one type of entity does not mean it is qualified for all types of IRO engagements.



Standards for IRO Review

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- An IRO is required to conduct its reviews in accordance with Generally Accepted Audit Standards (“GAGAS”).
- GAGAS are established by the Government Accountability Office (GAO) and published in its “Yellow Book”
- GAO issued a fourth revision of the “Yellow Book” standards in July 2007.



Overview of the Yellow Book - GAGAS

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- Establish general standards for both governmental and nongovernmental audits and reviews
- Establish field work standards
- Establish reporting standards



GAGAS applies to:

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- Financial Audits
- Attestation Engagements
- Performance Audits



GAGAS provides a framework for conducting audits and attestation engagements with:

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- Independence
- Objectivity
- Integrity
- Competence



GAGAS contains the requirements and guidelines to address:

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- Ethics
- Independence
- Professional competence and judgment
- Quality control
- Performance of field work
- Reporting



IRO reviews are to be guided by the following **Ethical Principles:**

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- The public interest
- Integrity
- Objectivity
- Proper use of Government information, resources, and position
- Professional Behavior



Independence

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- In all matters relating to audit and review work, the audit organization and individual auditor must be free from:
 - personal impairments to independence
 - external impairments to independence
 - organizational impairments to independence



Overarching Independence Principles

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- The audit organization must not provide non-audit services that involve performing management functions or making management decisions
- The audit organization must not audit its own work or provide non-audit services in situations in which the non-audit services are significant or material to the subject matter of the audit.



Other GAGAS Standards Governing IRO reviews

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- Professional Judgment
- Competence
- Quality Control and Assurance



Selecting an IRO



Qualifications:

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- Can a proposed IRO perform the tasks outlined in the CIA?
- Can the proposed IRO effectively staff a five year engagement?
- Can the proposed IRO effectively manage competing stakeholder interests in a balanced and fair manner?
- Does the proposed IRO have the sophistication to handle a complex case in a timely and competent manner?
- Are the proposed IRO's costs and charges competitive?
- Does the proposed IRO have a good reputation and is it supported by references?



Issues relating to Independence, integrity, and objectivity of an IRO

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- New OIG Guidance in 2010: <http://oig.hhs.gov>.
- Is the proposed IRO independent and objective, and able to perform the required reviews consistent with GAGAS?



Issues relating to Independence, integrity, and objectivity of an IRO

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- What types of non-audit services performed by an organization **would** potentially impair its independence, integrity, and objectivity to serve as an IRO?



IRO Relationships that **are not** appropriate

- A provider uses a billing system or coding software that was developed or designed by the potential IRO and the entity being engaged to perform an IRO claims review.
- Personnel of the potential IRO furnish specific training that addresses the subject matter of the CIA review.
- The potential IRO participates in management decisions and has developed the provider's policies, procedures, or internal control systems.
- The potential IRO participates in decision making relating to CIA disclosure requirements, such as determining which allegations warrant further investigation or the appropriate corrective action to take in response to identified deficiencies/problems.
- The potential IRO performs an assessment of the strengths and weaknesses of the provider's internal controls associated with the specific risk areas that are addressed in the CIA.
- The potential IRO is engaged by the provider to design or implement new processes or internal controls that relate to the subject matter of the CIA review(s).
- The provider has outsourced its internal audit function to the potential IRO.
- The IRO is engaged in providing consulting services to the provider during the term of the CIA on a matter that is related to the subject matter of the CIA reviews.



Issues relating to Independence, integrity, and objectivity of an IRO

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- What types of non-audit services performed by an organization **would not** present an impairment to its independence, integrity, and objectivity to serve as an IRO?



Issues relating to Independence, integrity, and objectivity of an IRO

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- The organization furnishes general compliance training that addresses the requirements of a CIA and introduces employees to a provider's overall compliance program.
- The organization performs routine tasks relating to a provider's confidential disclosure program, such as answering its "hot line" or transcribing allegations received via the hot line or a suggestion box.
- The organization performs screening of provider employees and vendors to determine their eligibility to participate in Federal health care programs by checking various Governmental databases and reporting screening results to the provider.
- The organization conducts a compliance program review for a provider before the CIA is executed.
- The organization assists in the development and/or performance of work plans for a provider's internal audit department not related to the subject matter of the CIA.
- The organization provides services to a provider under an engagement that is completed prior to and not related to the CIA reviews, and the services do not involve the performance of management functions.
- The organization performs an assessment of a provider's internal controls, even if they are related to the subject matter of the CIA, as long as the IRO is not responsible for designing or implementing corrective action based on its internal controls assessment, or otherwise performing management functions.



Enhancing the value of IRO reviews: OIG Perspective

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- “Eyes” and “ears” of the OIG
- Maintains ongoing contact with OIG and provides feedback



Enhancing the value of IRO Reviews: Entity perspective

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- Concurrent review of compliance program
- Assessment of compliance program elements and effectiveness
- Report findings to senior management
- Report findings to Board of Directors



Resources

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- **OIG Open Letters**
 - <http://oig.hhs.gov/fraud/openletters.html>
- **Results of the Corporate Integrity Agreement Survey, August 2001**
 - <http://oig.hhs.gov/fraud/docs/complianceguidance/ciasurvey.pdf>
- **Building a Partnership for Effective Compliance The Third Government-Industry Roundtable-- A Report on the July 30, 2001 Roundtable Discussion on Corporate Integrity Agreements**
 - <http://oig.hhs.gov/fraud/docs/complianceguidance/Roundtable0901.pdf>
- **Frequently Asked Questions Related to OIG Corporate Integrity Agreements**
 - <http://oig.hhs.gov/fraud/cia/docs/ciafaq1.html>
- **Frequently Asked Questions Related to the Independence of an IRO**
 - <http://oig.hhs.gov/fraud/cia/docs/ciafaqiropdf>
- **Self-Disclosure of Provider Misconduct: Assessment of CIA Modifications**
 - <http://oig.hhs.gov/fraud/cia/docs/assessment.htm>
- **Independent Review Organizations Must Meet GAO “Yellow Book” Standards**
 - <http://www.compliance.com/articles/independent-review-organizations-must-meet-gao-yellow-book-standards/>
- **Independent Review Organizations: Where to Start in the Selection Process?**
 - <http://www.compliance.com/articles/independent-review-organizations-where-to-start-in-the-selection-process-journal-of-health-care-compliance-sep-oct-2010/>



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