

The OIG's New Corporate Integrity Agreement Form: How Your Organization Could Benefit

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Session Objectives

- ▶ Highlight key and new CIA provisions
- ▶ Discuss reasons for changes/amendments to the CIA form: What does the OIG hope to achieve?
- ▶ Discuss how substance of CIA requirements is part of effectiveness reviews for providers not under CIA
- ▶ Discuss how key and new CIA provisions might be beneficial to providers not under a CIA

Corporate Compliance Officer

- ▶ Corporate Compliance Officer
 - ▶ A member of senior management
 - ▶ Reporting relationships
 - ▶ To the CEO or Board
 - ▶ Not to the GC or CFO (and no responsibility to act as GC or supervise GC staff)
 - ▶ Compliance Officer duties are enumerated
 - ▶ Developing/implementing policies, procedures and practices to promote compliance
 - ▶ Reporting to the Board of Directors
 - ▶ Monitoring day-to-day compliance activities (and CIA reporting obligations)
 - ▶ Non-compliance job duties limited and do not interfere with compliance officer role

Compliance Committee

- ▶ Chaired by the Compliance Officer
- ▶ Includes members of senior management necessary to meet CIA requirements (e.g., billing, clinical, human resources, audit and operations)
- ▶ Meets at least quarterly
- ▶ Minutes of the Compliance Committee meetings made available to the OIG upon request (NEW)

Management Certifications - Certifying Employees

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

Certifying Employee Process

- ▶ What policies & procedures, legal requirements, CIA requirements, etc., are core to the certification?
- ▶ Will sub-certifications be required?
- ▶ What reports and other evidence or documents that reflect the state of compliance must be reviewed?

Board (or Committee) Resolution

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

Board Oversight & Board Resolution

- ▶ Board or Board Committee Members must be independent (i.e., non-executive)
- ▶ Required to meet quarterly to review and oversee the compliance program, including (not limited to) the performance of the Compliance Officer and the Compliance Committee
- ▶ Must submit to the OIG a description of the documents and other materials reviewed, and additional steps taken, in support of the CIA required board resolution
- ▶ Retention of a Compliance Expert (some CIAs)
- ▶ Must, for each reporting period, adopt the following resolution (signed by each member of the board or board committee) . . .
 - ▶ If unable to provide the resolution, must include a written explanation of the reasons why it is unable to conclude that the compliance program is effective, and the steps it is taking to implement an effective compliance program

Compliance Training Plan (NEW)

- ▶ Training Plan Requirement -
 - ▶ At least annual training for all Covered Persons
 - ▶ CIA, Compliance Program, Federal health care program requirements (including AKS and Stark)
 - ▶ Board Member Training
 - ▶ Training Records

Risk Assessment & Internal Review Process (NEW)

- ▶ Risk Assessment Process
 - ▶ A process for identifying and prioritizing potential risks;
 - ▶ An assessment plan to evaluate and respond to potential risks, including internal auditing and monitoring of potential risk areas;
 - ▶ Corrective action plans to remediate actual non-compliance; and
 - ▶ Tracking results to assess effectiveness of corrective action.
- ▶ Connection to the IRO processes in the CIA
 - ▶ May inform scope of claims review

Addition of Medical Necessity to IRO Reviews

- ▶ Claims are reviewed by the IRO to determine whether the items and services were *medically necessary and appropriately documented* and whether the claim was correctly coded, submitted, and reimbursed
- ▶ IRO qualification requirements updated

Overpayments Provisions (NEW)

- ▶ CIAs adopt the definition of “Overpayments” from the CMS rule (but CIA overpayment provisions are applicable to overpayments from all Federal health care programs)
- ▶ CIA requires development of policies to ensure compliance with requirements of the CMS Overpayment rule
- ▶ Overpayment obligations connected to Reportable Events requirements (“Substantial Overpayments”)

IRO Claims Review Provisions (NEW)

- ▶ Claims review may be risk based
- ▶ Overpayment obligations connected to IRO/claims review provisions
 - ▶ additional sampling/extrapolation no longer required as a result of error rates above a certain threshold
 - ▶ instead provider should evaluate its sample results in light of the CMS Overpayment Rule to determine what additional steps are required to demonstrate the exercise of due diligence (e.g., additional sampling, audits in other areas, extrapolation, etc.)

Annual Report Requirement: Summary of Audits by Medicare/Medicaid Program Contractors

- ▶ Must also report [ORGANIZATION's] response/corrective action plans
- ▶ Potential source of risk identification for future IRO reviews

Compliance Officer AND CEO Certification

- ▶ “To the best of [his/her] knowledge, except as otherwise described in the [implementation or annual] report, [ORGANIZATION] has implemented and is in compliance with all of the requirements of the CIA; and
- ▶ “[he/she] has reviewed the [implementation or annual] report and has made reasonable inquiry regarding its contents and believes that the information in the report is accurate and truthful.”

IAs for Practitioners and Small Entities

- ▶ Three year term
- ▶ Scaled down compliance program requirements
- ▶ More frequent audit requirements (quarterly claims review rather than annual claims review)
 - ▶ If resources are limited, focus of compliance resources should be on auditing/risk assessment

