

SURVIVING A CIA

Health Care Compliance Association

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THE FUNDAMENTAL ASPECTS OF A CORPORATE INTEGRITY AGREEMENT (“CIA”)

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 an exclusion of that provider.

THE FUNDAMENTAL ASPECTS OF A CORPORATE INTEGRITY AGREEMENT (“CIA”)

These agreements give providers a chance to regain the government’s trust so that they may continue participating in the Federal Health Care Programs.

THE FUNDAMENTAL ASPECTS OF A CORPORATE INTEGRITY AGREEMENT (“CIA”)

Most parties to CIAs uphold this trust and honor the terms of the agreement. Other providers fail to comply with CIA obligations which may lead to enforcement action by the OIG.

TYPICAL CIAS REQUIRE THE ENTITY TO MEET THE FOLLOWING TYPES OF OBLIGATIONS:

Designate a Compliance Officer and a compliance committee

Develop policies and procedures

Educate board, staff and other specified parties (e.g., contractors)

Engage an Independent Review Organization (IRO) to perform annual audits and reviews

TYPICAL CIAS REQUIRE THE ENTITY TO MEET THE FOLLOWING TYPES OF OBLIGATIONS:

Implement a confidential disclosure program

Screen for excluded individuals

Report to the OIG certain information at specified intervals

Perform risk assessments

Refund identified overpayments within required timeframes and report to the OIG the occurrence of “reportable events”

File management certifications and Board resolutions

EMERGING CIA TRENDS

Use of Independent Monitors

Compliance Experts

Management Certifications and Increased Stipulated Penalties for False Certifications

Risk Assessment and Mitigation

Heightened IRO Qualifications

PROVIDERS MUST UNDERSTAND AND COMPLY WITH ALL OF THE TERMS OF THE CIA

CIAs include stipulated penalties for failure to comply with the terms; moreover, failure to comply may be considered a material breach of the settlement agreement, leading to exclusion from participation in Federal Health Care Programs.

Stipulated Penalties are monetary penalties, which may accrue daily.

HOW CAN A PROVIDER/SUPPLIER UNDER A CIA MAXIMIZE ITS CHANCES OF WORKING WELL WITH THE OIG?

Board of Directors

- Demonstrate meaningful and active engagement in the CIA implementation process
- Develop a regular schedule of receiving reports from the Compliance Officer regarding the status of CIA compliance
- Ensure that organization has strong processes for complying with internal risk assessment provisions of CIA
- Continually assess performance of Compliance Officer
- Meet with OIG monitor

HOW CAN A PROVIDER/SUPPLIER UNDER A CIA MAXIMIZE ITS CHANCES OF WORKING WELL WITH THE OIG?

Compliance Officer

- Accomplished at obtaining “buy in” from leadership and governing body
- Serves as the face of company and voice of compliance
- Views CIA as a platform, not a burden
- Genuine interest in building a positive working relationship with OIG
- Responsive to OIG’s questions, concerns, and requests for information
- Demonstrates transparency; proactively brings OIG’s attention to issues and problems

HOW CAN A PROVIDER/SUPPLIER UNDER A CIA MAXIMIZE ITS CHANCES OF WORKING WELL WITH THE OIG?

Compliance Committee

- Serve as an active resource to the organization on compliance matters
- Composed of individuals who can bring value to compliance processes and discussions, and have the standing to effectuate change within the organization
- Full involvement in internal risk assessment processes and corrective action implementation

Independent Review Organization (IRO)

- Prepare in advance for IRO reviews
- View IRO as a valuable resource— not simply “the auditor.”
- Leverage IRO’s expertise

TIPS ON HOW BEST TO SUCCEED UNDER A CIA

Read and understand the CIA thoroughly

Ask your OIG monitor questions and timely advise him/her of problems

Be able to “see the forest through the trees”

Do not rely on “off-the-shelf” compliance programs, policies, training materials. Customize your program.

Do not certify to 100% compliance unless you truly are 100% compliant

Do not coach employees prior to a site visit

TIPS ON HOW TO SUCCEED UNDER A CIA

Do not do all of your communication with OIG through outside counsel

Do not report matters that are not expressly reportable under the CIA

Do not try to influence your IRO

Do not lie

COMMON INQUIRIES MADE BY OIG WHEN MONITORING CIAS

- Assessing “placement” of compliance within the organizational structure
- Validating Compliance Officer’s standing and authority within organization
- Evaluating communication between Compliance Officer and Board
- Evaluating resources dedicated to compliance program
- Reviewing Compliance Committee Meeting Minutes
- Reviewing disclosure log and underlying investigation and reports
- Evaluating of development and implementation of corrective action plans

LEVERAGING THE CIA IN ANTICIPATION OF THE CIA RELEASE

Assess your program and its maturity level

Start strategizing with the Board Audit & Compliance committee of what the program should look like post CIA

Incorporate elements of next level compliance program such as Ethics, Integrity, Culture of Compliance

NOTABLE CASES OF EXCLUSION FOR MATERIAL BREACH OF A CIA

Church Street Health Management, a/k/a Small
Smiles Dental Centers

South Beach Community Hospital

LaFuente Ocular Prosthetics, LLC

RELEVANCE OF CIAS FOR PROVIDERS WHO ARE NOT BOUND BY ONE

OIG uses CIAs to communicate prudent approaches to compliance program design and compliance-related initiatives

Emerging trends in CIAs reflect OIG's escalating compliance expectations for entities participating in federal healthcare programs

Providers should monitor and address emerging compliance trends:

- Fortify compliance infrastructure
- A company's proactive efforts to monitor and address such emerging compliance trends often benefits the company when evaluated by Government enforcement agencies

QUESTIONS?