# Lessons Learned From a Corporate Integrity Agreement


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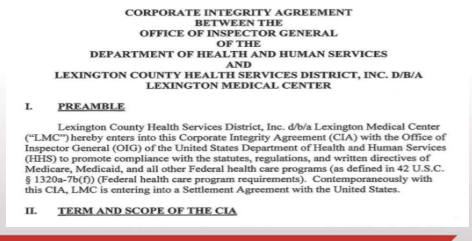
## Objectives

- Define Corporate Integrity Agreement
- Define an Independent Review Organization
- Explain Common Themes – Hospice CIAs
- Applying CIA best practices to your Compliance Program
- Discuss Actions of the Prudent Hospice

## What is a Corporate Integrity Agreement?



CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
LEXINGTON COUNTY HEALTH SERVICES DISTRICT, INC. D/B/A
LEXINGTON MEDICAL CENTER

I. PREAMBLE

Lexington County Health Services District, Inc. d/b/a Lexington Medical Center ("LMC") hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, LMC is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

## What is a Corporate Integrity Agreement?

- The Office of Inspector General ("OIG") negotiates Corporate Integrity Agreements ("CIA") with health care providers and other entities as part of the settlement of federal healthcare program investigations arising under various civil false claims statutes.
- Providers or entities agree to the obligations set forth in the CIA, and in exchange, the OIG agrees not to seek their exclusion from participation in Medicare, Medicaid, or other federal healthcare programs.

## When are Corporate Integrity Agreements used?

- A CIA is typically entered into in conjunction with a civil settlement between the U.S. government and a healthcare provider/entity arising under the False Claims Act ("FCA"), or when an organization has been found guilty of defrauding the Centers for Medicare and Medicaid Services ("CMS") or any other federal healthcare program.
- CIAs are an effective enforcement tool used to fight health care fraud, waste, and abuse.
- The purpose of a CIA is to promote compliance with health care regulations and can be used to address quality of care and program integrity issues.
- CIAs are not meant to be punitive but instead drive compliant behavior and set minimum standards for which a health care provider/entity should be held accountable.

## Corporate Integrity Agreement: General Information

- CIAs have common elements, but each one is tailored to address the case's specific facts and may incorporate elements of a preexisting compliance program.
  - Common Requirements:
    - hire a compliance officer/appoint a compliance committee;
    - develop written standards and policies;
    - implement a comprehensive employee training program;
    - retain an IRO to conduct annual reviews;
    - establish a confidential disclosure program;
    - restrict employment of ineligible persons;
    - report overpayments, Reportable Events, and ongoing investigations/legal proceedings; and
    - provide an implementation report and annual reports to OIG on the status of the entity's compliance activities.
- The duration of a CIA is typically five years.

## Corporate Integrity Agreement: General Information (Cont.)

- Successor Liability:
  - If the provider decides to sell any or all of its business that is subject to a CIA, the CIA shall be binding on the purchaser of the business unless the provider obtains a written determination from the OIG that the proposed purchaser and the business will not be subject to the requirements of the CIA following the closing of the transaction.
- Cause for Early Termination:
  - Typically, the OIG does not terminate a CIA before the end of the provider's CIA term based on its performance under the CIA. However, providers may request modifications to the terms of their CIA.
  - A provider's CIA may be terminated early if the provider ceases participating in federal healthcare programs or ceases its operations altogether due to a sale, bankruptcy, etc.

## Corporate Integrity Agreement: General Information (Cont.)

- Consequences for Failure to Comply with the Terms of a CIA:
  - The OIG may impose stipulated penalties for the failure to comply with certain obligations outlined in the CIA.
  - Example of Stipulated Penalty:
    - In 2019, North Broward Hospital District ("Broward Health") paid a stipulated penalty of $690,000 for failing to comply with certain CIA requirements, including the failure to:
      - (1) develop and implement written policies designed to promote compliance with the Antikickback Statute and the Stark Law;
      - (2) provide all employees with general compliance training;
      - (3) implement and comply with all of the arrangements and procedures requirements of the CIA; and
      - (4) comply with certain program disclosure requirements.

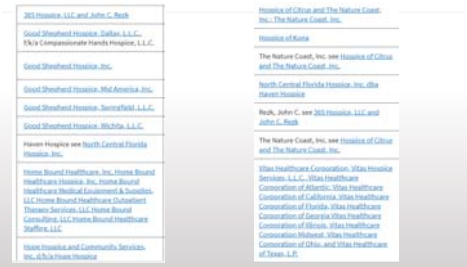
## What is an Independent Review Organization?

- Health care organizations are often required to select an Independent Review Organization ("IRO") as part of their compliance obligations under a CIA, which often require that a claims review be conducted by an IRO.
- An IRO acts as a third-party medical review resource that provides objective, unbiased medical determinations that support effective decision making, based only on medical evidence.
- The OIG does not maintain a list of recommended or approved IROs. However, the OIG can reject the providers' selection of the IRO within 30 days of the provider's notice.
  - Generally, within 60 to 90 days of the CIA's effective date, a provider is required to engage an IRO.
  - If a provider changes an IRO, notification of this change must be provided to the OIG within 30 days.

## What is an Independent Review Organization? (Cont.)

- The qualifications for an IRO are outlined in the CIA. In general, with respect to a claims review, the IRO must:
  - (1) assign individuals to perform the claims review who have expertise in the applicable Medicare and State Medicaid program requirements;
  - (2) assign individuals to design and select the claims review sample who are knowledgeable about appropriate statistical sampling techniques;
  - (3) for the coding portion of the claims review, assign individuals who have a nationally recognized coding certification, and, for CIAs that require a review of medical necessity;
  - (4) assign licensed nurses or physicians with relevant education, training, and specialized expertise to make the medical necessity determinations required by the claims review.
- CIAs typically require the IRO's findings in the claims review report to be provided to the OIG. The claims review report will include a description of the claims review methodology, statistical sampling documentation, and the claims review findings, including both narrative and quantitative results. The provider is required to repay any overpayments identified by the IRO.

## Search by "hospice" – Active CIAs




https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp

## Common Themes of Hospice CIAs

| Common Issues | Common Situations |
|---|---|
| • Improper billing<br>• Inflated levels of care<br>• Patient eligibility<br>• Inducements to beneficiaries<br>• Inappropriate referrals<br>• Delayed discharging<br>• Lack of compliance programs | • Submitting and receiving reimbursements for patients who weren't eligible for hospice benefits because the patients did not have a life expectancy prognosis of six months or less.<br>• Setting goals for the number of continuous home care days billed to Medicare and using aggressive marketing tactics and pressuring staff to increase the volume of continuous home care claims, without regard to whether the patients actually required this level of crisis care.<br>• Admitting ineligible patients in order to meet targets imposed by management.<br>• Adopting procedures to delay and discourage staff from discharging patients who were not appropriate for hospice services.<br>• Failing to implement an adequate compliance program. |

## Common Themes of Hospice CIAs (Cont.)

- Example of a Hospice CIA:
  - Hernando-Pasco Hospice, Inc. ("HPH Hospice") agreed to pay $1 million to resolve allegations that it violated the FCA by submitting false claims for hospice services to Medicare and Medicaid for patients who did not need end of life care.
  - The government alleged that HPH Hospice caused staff to admit ineligible patients to meet targets imposed by management, adopted procedures to delay and discourage staff from discharging patients who were not appropriate for hospice services, instructed staff to make false or misleading statements in patients' medical records to make them appear eligible when they were not, and failed to implement an adequate compliance program that might have corrected these problems. HPH Hospice also resolved allegations that it billed the government at higher reimbursement rates than it was entitled to receive, and provided illegal kickbacks when it provided free services to skilled nursing facilities in exchange for patient referrals.
  - As part of its settlement, HPH Hospice agreed to enter into a CIA with the OIG that provides for procedures and reviews to be put in place to avoid and promptly detect conduct similar to that which gave rise to the settlement.

## Implications of Medicare Sub-Regulatory Guidance

- Sub-regulatory guidance, also known as agency guidance, cannot be relied upon for determining whether a violation of a federal statute or regulation has occurred because such sub-regulatory guidance does not have the force of law.
- Criminal and Civil Enforcement Actions brought by the Department of Justice ("DOJ"):
  - Violations must be based on applicable legal requirements, not mere noncompliance with guidance documents issued by federal agencies, because guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation. Thus, the DOJ should not treat a party's noncompliance with a guidance document as itself a violation of applicable statutes or regulations.
  - On January 25, 2018, Associate Attorney General Rachel Brand issued a memorandum stating that the DOJ was prohibiting its attorneys from relying on agency guidance documents to create standards for which it will determine compliance with existing statutes or regulations. Specifically, the DOJ prohibited its civil litigators from using noncompliance with guidance documents as a basis for proving violations of applicable law in affirmative civil enforcement cases.

## Implications of Medicare Sub-Regulatory Guidance (Cont.)

- Hospice Agency Guidance
  - Information provided in agency guidance, for example, Interpretive Guidelines, is not binding. The Interpretive Guidelines are a component of Appendix M of the State Operations Manual and provide guidance to personnel conducting surveys of hospices.
  - Interpretive Guidelines do not establish requirements that must be met by hospices, do not replace or supersede the law or regulations, and may not be used alone as the sole basis for a citation. All mandatory requirements for hospices are outlined in relevant provisions of the Social Security Act and other regulations.
  - However, the Interpretive Guidelines do contain authoritative interpretations and clarification of statutory and regulatory requirements and are used to assist in making determinations about a hospice's compliance.

## Implications of Medicare Sub-Regulatory Guidance (Cont.)

- On December 7, 2020, the Department of Health and Human Services ("DHHS") published the Good Guidance Practices final rule, codified at 45 C.F.R. §§ 1.1 - 1.5 ("Rule"), regarding the use of sub-regulatory guidance by DHHS. Below are the takeaways from the Rule:
  - The Rule prohibits DHHS from (i) issuing any guidance document that establishes a legal obligation that is not reflected in a duly enacted statute or in a regulation lawfully promulgated under a statute, or (ii) using any guidance document for purposes of requiring a person or entity outside DHHS to take any action, or refrain from taking any action, beyond what is required by an applicable statute or regulation.
  - The Rule requires that each guidance document must identify itself as "guidance" and requires that unless the guidance is authorized by law to be binding, the guidance documents must include the following language: "The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law."

## Implications of Medicare Sub-Regulatory Guidance (Cont.)

- The Rule requires that any significant guidance document (that may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more) (i) be approved by the Secretary of DHHS, (ii) be submitted to the Office of Information and Regulatory Affairs for review, and (iii) be subject to public notice and comment.
- The Rule directs DHHS to maintain a guidance repository on its website www.hhs.gov/guidance., which shall contain all guidance documents that have been issued by any component of DHHS.
- The Rule establishes a petition process that allows any interested party to petition DHHS to withdraw or modify any particular guidance document because it imposes binding obligations on parties beyond what is required by the terms of applicable statutes and/or regulations, or because a component of DHHS is using a guidance document to create additional legal obligations beyond what is required by the terms of applicable statutes and/or regulations. This petition process does not create an administrative exhaustion requirement or affect the availability of other legal actions.

## Applying CIA best practices to your Compliance Program

*If it's good enough for the Feds, who are we to argue?*

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## CIA "Best Practices" – a proactive approach

- Board of Directors training
- Claims Review
- Annual Risk Assessment
- Arrangements Review
- Oh, wait: How often do you check the OIG's LEIE?
  - How is that documented?

## CIA "Best Practices" – Board of Directors Training

- The BOD, or a committee of the Board, shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA.
- The Board must include independent (i.e., non-executive) members.

## CIA "Best Practices" – Board of Directors Training

At a minimum, the Board shall be responsible for

- Meeting at least quarterly to review/oversee the compliance program, including performance of the Compliance Officer.
- Board training – at least 2 hours – on corporate governance responsibilities.
  - Unique responsibilities of health care Boards, risks, oversight areas
  - Discussion of the OIG's Guidance on Board Member Responsibilities.

## CIA "Best Practices" – Claims Review

- At least annual
  - Repayment, Education, QAPI
- Paid claims v. Prospective approach
- Eligibility
- Appropriate Level of Service
  - How are your doctors documenting a GIP LOC?
- Long Length of Stay
  - Uninterrupted services for 210 days or more

## CIA "Best Practices" – Annual Risk Assessment

- ..develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with participation in the Federal health care programs
- Claims or Arrangements Review offense
- Include Compliance, Legal, Department Leaders

## CIA "Best Practices" – Annual Risk Assessment

Purpose
- Identify and prioritize risks
- Develop internal audit work plans related to those risks
- Implement the internal audit work plans
- Develop corrective action plans in response to the results of any internal audits
- Track the implementation of the corrective action plans in order to assess the effectiveness of such plans.

## CIA "Best Practices" – Annual Risk Assessment

Gather
- OIG's Work Plan
- ADR categories
- Compliance hotline feedback
- Last year's risk assessment
- Results of internal audits/process reviews

Corrective action, education

Repeat…

## CIA "Best Practices" – Arrangements Review

- Do you have arrangements (signed contracts, handshake or a "wink and a nod") that could violate any federal regulations such as the Anti Kickback Statute.
  - Fair market value agreements with those who could refer federal health care program business to your hospice?
    - Rental of space owned by a referral source
    - Palliative care NP/LCSW placed in an oncology practice 1 day per week.
    - Medical Directorships with physicians who can/do refer patients
    - Incentive program for new admissions

## CIA "Best Practices" – Arrangements Review

- Documented business need or rationale for the relationship/arrangement
- Documented FMV process methodology, if applicable
- Executed BAA, if applicable, is on file
- Arrangement is committed to writing
- Compliance periodically monitors each arrangement to test if it conforms to terms, for example
  - Rationale to support the 10 Medical Directors/MD Board Members is documented (geographically, a neurologist due to # of Dementia patients, oncologists due to # of cancer patients, other?)
  - each contracted Medical Director is paid $150/hr for certain functions each month.
  - Validate payments equal the invoices submitted and invoices have sufficient detail to support number of hours submitted for payment and functions/services provided. All documented in compliance records

## Actions of the Prudent Hospice™

- Hospices should be aware of potential consequences when failing to comply with a CIA, including monetary penalties.
- Hospices should be aware of the benefits of entering into a CIA, which includes the potential for avoiding exclusion from participation in Medicare, Medicaid, or other federal healthcare programs.
- Hospices should be aware of the multiple requirements outlined in a CIA, including the IRO's involvement in continuous monitoring, claims review and reporting to the OIG.

## Actions of the Prudent Hospice™, cont'd

- Hospices should incorporate the OIG's Guidance on Board Member Responsibilities in Board of Directors training.
- The prudent hospice should consider implementing an annual risk assessment into its compliance program.
  - Consider incorporating risk areas identified in recent CIAs
- Hospices should conduct annual eligibility and level of care audits, take corrective action based on findings, and consider those findings at the next audit.

## Questions?

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The information enclosed was current at the time it was presented. This presentation is intended to serve as a tool to assist providers and is not intended to grant rights or impose obligations.

Although every reasonable effort has been made to assure the accuracy of the information within these pages, the ultimate responsibility for the correct submission of claims and response to any remittance advice lies with the provider of services.