

# HCCA Virtual Compliance Institute

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## Corporate Integrity Agreements: A Closer Look at How OIG and Providers Work with Independent Review Organizations

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## Agenda

- The purposes of CIAs and IROs
- Independence, objectivity, and qualifications
- Keys to a successful IRO engagement
- Nuts and bolts of IRO reviews; provider/IRO risk-based review proposals
- Takeaways beyond the CIA – how different types of CIAs and IRO reviews provide a path forward



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## HHS OIG – Our Mission

- **Protect the integrity of HHS programs**
  - Biggest civilian federal oversight agency
  - Oversee every HHS program, including CDC, NIH, FDA, and CMS
  - 78% Medicare and Medicaid oversight; 22% Public Health and Human Services Oversight
- **Protect the health and welfare of the people these programs are meant to serve**

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## OIG's Multidisciplinary Approach

- Office of Audit Services (OAS)
- Office of Evaluation and Inspections (OEI)
- Office of Investigations (OI)
- Office of Counsel to the Inspector General (OCIG)
- Office of Management & Policy (OMP)



**Be sure to check out the OIG Work Plan!**

<https://oig.hhs.gov/reports-and-publications/workplan/>

– Updated monthly

**And now on to CIAs . . .**

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## Corporate Integrity Agreements

- Purposes:
  - Promote Compliance
  - Strengthen Compliance Program
  - Assess Entity/Individual Performance
- Means:
  - Section III. General Requirements
    - Compliance officer and committee; policies and procedures; training; disclosure program; ineligible person screening; reportable events; implementation and annual reports
  - Appendix B. IRO Reviews

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## Independent Review Organizations

- Private sector - must be independent, objective, qualified
- Selected by provider, subject to OIG objection
  - Claims: accounting, auditing or consulting firm
  - Arrangements: law firm, lawyer, consulting firm
- Selected by OIG, in consultation with provider
  - Quality of Care: independent monitors with clinical expertise paired with OIG monitor
- Appendix A of the CIA outlines qualifications and responsibilities

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## Different Type of IRO Reviews

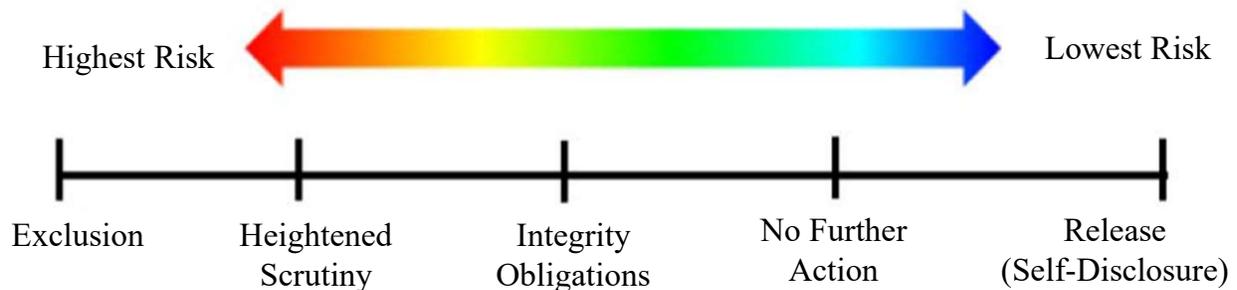
- Claims
  - Provider-specific (e.g., Ambulance, Hospital, Hospice, Skilled Nursing Facility)
- Arrangements
  - Transactions and Legal Reviews
- Quality of Care
- Pharmaceutical and Device Manufacturers

**More on this to come . . .**

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## OIG Fraud Risk Indicator



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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# High Risk

About OIG Reports Fraud Compliance Exclusions Newsroom Careers COVID-19 Portal

Fraud  
Child Support Enforcement  
Consumer Alerts  
Contract Fraud  
Enforcement Actions  
Fraud Risk Indicator  
Fugitives  
Grant Fraud  
Medicaid Fraud Control Units  
Medicare Fraud Strike Force  
Operation CARE  
Report Fraud  
State False Claims Act

## High Risk - Heightened Scrutiny

Parties are in the High Risk category, and subject to heightened scrutiny, because they pose a significant risk to Federal healthcare programs and beneficiaries. This is because, although OIG determined that these parties needed additional oversight, they refused to enter [Corporate Integrity Agreements \(CIAs\)](#) sufficient to protect Federal healthcare programs. Parties in the High Risk category that reached settlements finalized on October 1, 2018 or later will be listed below.

Provider	Date Settled	City/State	Press Release
MJHS Hospice and Palliative Care, Inc.	08-07-2020	New York, New York	<a href="#">Link</a>
Ridgeview Rehab & Nursing Center	05-13-2019	Chicago, Illinois	<a href="#">Link</a>
ImmediaDent of Indiana, LLC & Samson Dental Partners, LLC	10-31-2018	various cities in Indiana and Leawood, Kansas	<a href="#">Link</a>

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# Negotiating a CIA

- How much room for negotiation?
- Does the lawyer/law firm negotiating your settlement understand CIAs and IRO requirements?
- If you negotiate terms or requirements: Help OIG understand your organization and why you believe standard CIA approach may not be the best way to achieve OIG's CIA objectives
  - Discuss alternate approaches that are already working effectively
- Compliance Officer (and others charged with implementing the CIA) should be involved in the negotiation process
- Ask questions and clarify any ambiguous language



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## Preparing for CIA Implementation and Successful IRO Engagement

- Take corrective action for problems identified in the settlement
- Read the CIA literally and holistically; don't think about individual requirements in a vacuum
- Start implementing as soon as you know a CIA will be required (don't wait for the final agreement!)
- Understand IRO review, implementation report and annual report requirements, before you start to implement



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## Preparing for CIA Implementation and Successful IRO Engagement

- Begin your search for an IRO and/or board expert in advance of the CIA effective date
- Think about what the IRO will be auditing and have someone with expertise help you take an advanced look (mock IRO review)
- Work with your IRO to develop an engagement workplan in advance of the close of your first reporting/review period
- Assure you have adequate staff/resources to timely respond to IRO requests



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## Arrangements IRO Qualifications

The IRO shall:

- Assign individuals to conduct the Arrangements Review who are knowledgeable about the requirements of the AKS and Stark Law, regulations, and guidance
  - Legal IRO reviews may require the IRO to be a law firm or an individual with a law degree (e.g., Envision, William Beaumont, Prisma Tuomey)
- Possess expertise in fair market valuation issues or has the ability to associate a valuation firm to assist in conducting the transactions review
- Have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis

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## Claims Review IRO Qualifications

- Expertise in the Medicare and state Medicaid program requirements applicable to claims being reviewed
  - (SAMPLE SELECTION) personnel knowledgeable about the appropriate statistical sampling techniques
  - (CODING REVIEW) personnel who have and maintain (e.g., completed CE requirements) nationally recognized coding certification;
  - (MEDICAL NECESSITY DETERMINATIONS) licensed nurses or physicians with relevant education, training and specialized expertise
- Sufficient staff and resources to conduct the reviews required by the IA/CIA on a timely basis.

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# Independence and Objectivity

- Current claims review and old arrangements review language:
  - The IRO must perform the 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”).
- Current arrangements review language:
  - 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 reviews required by Appendix B to this CIA.

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## 2018 - GAO Yellowbook on Independence

- **Independence of Mind** – a state of mind that permits the conduct of an engagement without being affected by influences that compromise professional judgment, thereby allowing an individual to act with integrity and exercise objectivity and professional skepticism.
- **Independence of Appearance** – the absence of circumstances that would cause a reasonable and informed third party to reasonably conclude that the integrity, objectivity, or professional skepticism of an audit organization or member of the engagement team had been compromised.

### GAGAS Conceptual Framework (30 pages)

- Identify threats to independence
  - Evaluate significance of the threats identified, both individually and in the aggregate, and
  - Apply safeguards as necessary to eliminate or reduce threats to an acceptable level.
- Self-interest threat:** (auditors financial or other self-interests influence judgment)
  - Self-review threat:** (non-objective evaluation of auditor’s own non-audit work product.)
  - Bias threat:** (political, ideological, social or other convictions impact auditor objectivity)
  - Familiarity threat:** (auditor’s relationship with management or personnel of an audited entity, such as a close or long relationship, or an immediate/close family member)
  - Undue influence threat:** (influences or pressures external to the audit organization)
  - Management participation threat:** (threat created by dual role of management and auditor)
  - Structural threat:** (auditor placement and complex structure of the audited entity will impact auditor’s ability to perform work and report results)
    - Examples of threats, application guidance, etc.
    - <http://www.gao.gov/yellowbook>



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# Independence and Objectivity Problems?



- The IRO evaluates the provider's existing compliance program before the provider's CIA is executed, presents its conclusions regarding the strengths and weaknesses of the provider's existing compliance program, and makes recommendations regarding areas for improvement
- The IRO previously performed an assessment of the strengths and weaknesses of the provider's internal controls related to the CIA and made recommendations for improving internal controls
- The IRO developed the provider's policies, procedures or internal control systems
- The IRO performs an assessment of the strengths and weaknesses of the provider's internal controls associated with the specific risks that are the subject matter of the CIA and is engaged to design and implement internal controls to address identified weaknesses

<https://www.oig.hhs.gov/fraud/cia/docs/iro-guidance-2016.pdf>

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# CIA begins . . . now what?



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# Preparing for a Successful IRO Engagement

## Before Close of the First Review/Reporting Period

- Assure a common understanding of documents and information that will be required for the review(s)
- Establish access to IT systems (e.g., contract management system, EHR) as needed
- Establish a schedule for the review
- Assure appropriate staffing, access to information, etc. to adhere to the schedule
- Establish review procedures. Assure a common understanding of claims or arrangements populations and other key review elements. Clarify any question. (NOTE: provide review procedures to OIG Monitor in advance of first review for comment)

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## Claims Reviews - Objective

- IRO obtains paid claims population from the entity
  - Medicare, Medicaid, TRICARE
  - Insures that it is complete
  - Selects a random sample
    - Rat-Stats
    - Other method (EXCEL)
- Determines:
  - Whether items and services furnished were medically necessary
  - Were appropriately documented, correctly coded, submitted and reimbursed

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## Claims Reviews - Populations

- Population consists of claims submitted and paid in a 12-month period
- At OIG's discretion, may limit the population to one or more subset(s) of paid claims
- OIG may also select the facilities that will be subject to the claims review in each reporting period
- In some CIAs, e.g., hospitals, the entity may submit proposals identifying suggestions for the subset(s) of paid claims and facilities to be reviewed

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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 and/or the IRO may submit proposals for subset(s) of Paid Claims
- Utilize internal risk assessments and IRO feedback
- OIG Division of Data Analytics

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## Claims Reviews - Assessments

- Sampled claims assessed based on applicable program requirements
- Supporting documentation must exist and use of supplemental information must be explained
- Claims classified as:
  - Appropriately supported or
  - An error resulting in an overpayment

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## Claims Reviews - Overpayments

- For claims resulting in an overpayment:
  - Repaid within 60 days
  - Root cause analysis performed
  - Extrapolated at the mean point estimate
    - Consult CMS Overpayment Rule to determine whether extrapolated overpayment must be paid: 42 U.S.C. § 1320a-7k(d) and 42 C.F.R § 401.301-305
- Note 5% error rate language no longer used; appears in older CIAs

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## Claims Reviews - Reporting

- Within > 60 days
- Describes the population, data sources, protocols used and any supplemental materials provided
- Description of the billing and coding systems and controls
- IRO's findings and supporting rationale including the results of the claims review sample
- Quantitative information regarding the claims assessed and findings
- IRO's recommendations for improvements

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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 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 Review

- 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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## Hypothetical: Reading the CIA literally and holistically

III.D.1. “[Focus Arrangements] Procedures shall include the following:

a. *creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements and the information specified in Sections III.D.1.b-f below . . .*

b. *documenting the names and positions of Arrangements Covered Person(s) involved in the negotiation, review and approval of all Focus Arrangements,*

.....

d. *documenting all fair market value determination(s) for any Focus Arrangement, including the fair market value amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the fair market value amount or range, and the names and positions of Covered Person(s) who received and/or were otherwise involved with the fair market value determination(s) . . .*

Appendix B, Section C [Transactions Review]

*The IRO shall assess whether [the Obligated Entity] has complied with the Focus Arrangements Procedures and Focus Arrangements Requirements described in Sections III.D.1 and III.D.2. of the CIA [in the selected sample of Focus Arrangements].*

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## Practical Tips – IRO Reports

- 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
- Executive Summary
- Quantitative results
- Clear narrative explanation of IRO findings
- IRO Recommendations
  - Provider’s response and corrective action plans

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## Lessons Learned from CIAs

- Section III: General Compliance Requirements
- Appendix B: Different Types of IRO Reviews
  - Claims Reviews
  - Arrangements Reviews
  - Quality of Care
- CIA Reportable Event Settlements



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## Claims Review CIAs - False Claims

- Compliance Officer reports directly to CEO; not subordinate to GC or CFO
- Compliance Committee; Board compliance obligations; Management certifications; written standards; training and education; disclosure programs; ineligible persons screening
- Importance of internal audits, risk assessments to prioritize and target claims reviews to identify overpayments and maximize meaningful results
- Review IRO review requirements in Appendix B for entities in your industry sector; e.g., ambulance, hospitals, hospice, SNFs, inpatient medical necessity
- Respond to identified issues
  - quantify and repay Overpayments when appropriate; self-disclosure and potential Civil Monetary Penalties Law settlement with OIG

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## Arrangements CIAs - AKS/Stark

*The focus is on arrangements . . .*

**Arrangements** - every arrangement that involves, directly or indirectly:

- the offer, payment, solicitation, or receipt of anything of value; and is between an entity and any ***actual or potential*** source of health care business or referrals to that entity or any ***actual or potential*** recipient of health care business or referrals from that entity

**Focus arrangements**

- between any ***actual*** source or recipient of health care business or referrals and involves, directly or indirectly, the offer, payment, or provision of anything of value

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## Arrangements CIAs – AKS/Stark

- Centralized tracking system
- FMV determination
- Contract review and approval process
  - legal review, business need, FMV documentation (amount/range, time period, those involved in determination)
- Internal review
  - Compliance Officer review at least annually; reports findings to Compliance Committee
- External review
  - Engage independent review of systems and transactions
- Respond to identified issues
  - quantify and repay Overpayments when appropriate; self-disclosure and potential Civil Monetary Penalties Law settlement with OIG

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## Pharma/Device Reviews – AKS/Stark

- Focus on promotional activities, speaker programs, consulting arrangements, research-related activities, publication activities, medical education grant and charitable contributions
- Field Force Monitoring Program (FFMP) to evaluate and monitor sales personnel's interactions with Health Care Professionals (HCPs) and Health Care Institutions (HCIs); internal compliance personnel conduct full day ride-alongs
- IRO Systems Review – review of detailed list of required policies and procedures
- IRO Transactions Review – targeted groups of samples, e.g., call plans for selected HCPs and HCIs; consulting activities arrangements; grants and charitable contributions; Open Payments Database
- **Special Fraud Alert: Speaker Programs**  
<https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlertSpeakerPrograms.pdf>

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# Quality of Care CIAs - Patient Care and Medical Necessity

- Compliance Committee – Compliance officer and senior management (e.g. clinical operations and quality of care, human resources, operations)
  - Meet monthly; assess staffing; quality of care review program/root cause analysis/; quality of care dashboard
- Independent Monitor
  - Assess internal quality control systems
  - Baseline and periodic system improvement assessments based on site visit observations and interviews as well as review of relevant documents, survey findings, and other materials and records

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# CIA Reportable Event Settlements

**Enforcement Actions**

- About Enforcement Actions
- Civil Monetary Penalty Authorities
- Types of Civil Monetary Penalties and Affirmative Exclusions

## About Enforcement Actions

Details about HHS-OIG's enforcement actions and how we categorize them.

**On this page**

- [Criminal and Civil](#)
- [Corporate Integrity Agreement Enforcement](#)
- [Civil Monetary Penalties and Affirmative Exclusions](#)
- [Self-Disclosures](#)

## Corporate Integrity Agreement Enforcement Reportable Events

Providers under a Corporate Integrity Agreements (CIA) or Integrity Agreements (IA) with the OIG are required to disclose certain "Reportable Events" which include: a substantial overpayment, a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; and the employment of or contracting with an excluded individual. Matters disclosed to the OIG as a Reportable Event may implicate OIG's Civil Monetary Penalty authorities.

[View Reportable Events](#)

### SMHA Healthcare Agreed to Pay \$910,000 for Allegedly Violating the Civil Monetary Penalties Law by Providing Remuneration in the Form of Space and Free Services

After it disclosed conduct to OIG pursuant to its CIA, SMHA Healthcare, Inc. (f/k/a Memorial Health, Inc. (Memorial), SMHA Healthcare Center, Inc. (f/k/a Memorial Health University Medical Center, Inc. (MHUMC), SMHA Health Services Group, Inc. (f/k/a Provident Health Services, Inc., and SMHA Ventures, Inc. (f/k/a MPPG, Inc. (MPPG) (collectively, "Memorial Health"), enter into a \$910,450 settlement agreement with OIG. The settlement agreement resolves allegations that Memorial Health paid improper remuneration to physician entities in the following arrangements: (1) Memorial's hospital-affiliated physician practice group, MPPG, leased space for more than fair market value; (2) Memorial subsidiaries MHUMC and MPPG leased space for more than fair market value, and (3) Memorial subsidiary MHUMC provided free anesthetic agent and free IT services to an ambulatory surgery center that is a joint venture between MHUMC and another physician practice.

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## Practical Tips – CIA Takeaways

- Use CIAs and IRO reviews as a baseline of requirements for building an effective compliance program
- Goal is to improve and evolve
- Consult different types of CIAs to address different types of fraud and compliance risks
  - Billing/False Claims = Claims Reviews
  - AKS/Stark = Arrangements Reviews; Pharma/Device Reviews
  - Patient Care/Medical Necessity = Quality of Care Reviews
- Be proactive, not reactive; respond quickly to overpayments and issues identified through compliance strategies and implementation

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# Questions?

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