



# Insights from the DOJ: Management Accountability for an Effective Compliance Program

SUMMER CPE SYMPOSIUM – SESSION #2

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# Introductions

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# Overview



- **DOJ Playbook:** The U.S. Department of Justice (DOJ) released a playbook that its healthcare fraud prosecutors use to evaluate a company's compliance program (originated in February 2017, revised recently in March 2023).
- **Evaluation of Company Conduct by Prosecutors:** Management should be well versed in the factors that prosecutors will use to evaluate the effectiveness of a company's compliance program, which, in turn, influence the severity and materiality of any decisions to prosecute the company.
- **Best Practices:** We will discuss best practices that management teams can implement to demonstrate an effective compliance program.

# Healthcare Arrangements and Services



## Common Healthcare Activities

- Medical Director contract
- Lease MOB from Hospital to Physician Practice
- Hospital recruited physician to community
- Claims for Medical Services

## Common Violations of Law

- Hospital paid physician above FMV
- Hospital did not charge for closet, reducing rent below FMV
- Hospital gave physician free furniture (not in contract)
- Hospital submitted incorrect code receiving higher reimbursement

# Penalties for a False Claim from U.S. Supreme Court case



## Case:

Psychiatrist treats rural, elderly and poor population (Medicare, Medicaid)

Services include therapy, a 45 to 55 minute session (claim Code A)

Over 7-year period, documentation did not support Code A and should have billed for Code B, a shorter therapy session.

## Government claimed FCA financial penalties are \$80,750,000

1. Pay all claims monies received = 8,002 claims x payment received  
(entire claim to be repaid, not the difference)

2. Treble damages = all claims money received x 3

3. Civil Monetary Penalty per claim = 8,002 x \$10,000 (*CMP is from 1997*)  
(*current CMP is \$13,946 to \$27,894*)

# The Regulation of Healthcare



Enforced through laws: criminal laws, civil laws with financial penalties and exclusion from healthcare programs

Most claims involve healthcare and brought by whistleblowers (qui tam)

**Total Non-Qui Tam and Qui Tam FCA Recoveries by US Government (thousands \$)**



# 2023 Government “Recoveries” from False Claims



- Government FCA recoveries restore funds to federal healthcare programs such as Medicare, Medicaid, and TRICARE
- United States fiscal year ending September 30, 2023
- **\$2.68 billion recovered in False Claims Act settlements/judgments (543)**
- **\$267 million paid to relators (qui tam/whistleblowers)**
- “The False Claims Act remains one of our most important tools for rooting out fraud, ensuring that public funds are spent properly, and safeguarding critical government programs.”
- Note: Medicare expenditures exceed \$1 trillion, 8.4% increase in 2023

<https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023>

<https://www.healthaffairs.org/doi/10.1377/hlthaff.2024.00469>

# “Principles of Federal Prosecution of Business Organizations” in the U.S. Justice Manual

<https://www.justice.gov/jm/jm-9-28000-principles-federal-prosecution-business-organizations>



# Prosecutor's Evaluation of Company's Conduct



## Prosecutor determinations:

- Should charges be brought?
  - Civil
  - Criminal
- Should a plea (settlement) be offered?
  - Financial penalties?
  - Does conduct warrant monitoring or reporting to ensure compliance going forward?
- Should the company be allowed to continue to submit claims to government healthcare program or be excluded?

1) <https://oig.hhs.gov/fags/compliance-considerations/> (exclusion criteria)

# Conduct of the Healthcare Company



- CONDUCT – the seriousness and pervasiveness of conduct (the harm)
- RESPONSE TO CONDUCT
- CONFESSION
- PRIORS
- COOPERATE – under guidance of legal counsel
- GOOD FAITH – an effective compliance program demonstrates a good faith effort to comply with the laws
- CORRECTIVE ACTION – company plan to prevent conduct from recurring, and to remedy the harm from this conduct.

U.S. Sentencing Commission Chapter 8 – Sentencing of Organizations  
<https://www.ussc.gov/guidelines/2018-guidelines-manual/2018-chapter-8>

# U.S. Sentencing Guidelines, Section 8B2.1



## §8B2.1. Effective Compliance and Ethics Program

(a) To have an effective compliance and ethics program, for purposes of subsection (f) of §8C2.5 (Culpability Score) and subsection (b)(1) of §8D1.4 (Recommended Conditions of Probation - Organizations), an organization shall—

- (1) exercise due diligence to prevent and detect criminal conduct;
- (2) otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.

Such compliance and ethics program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct. ....

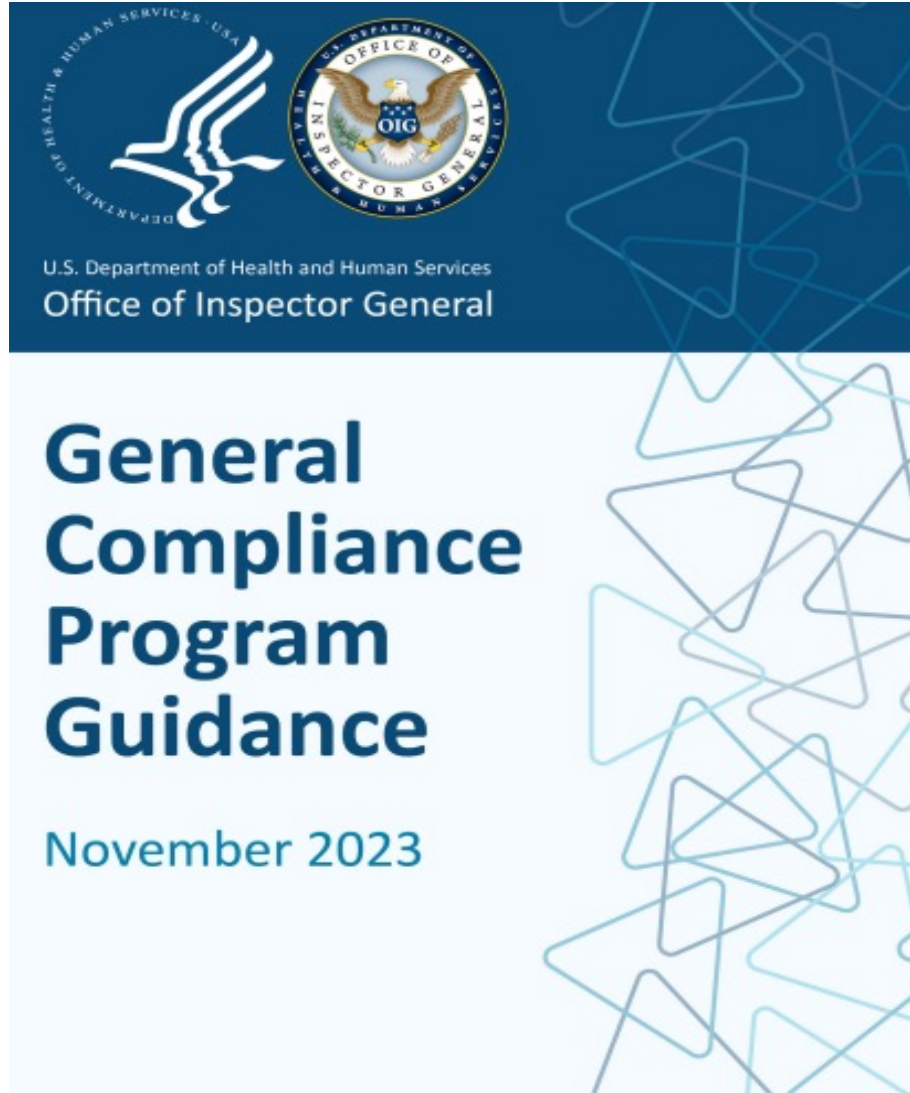
# Evaluate the Compliance Program



- Does company have a compliance program, and is it effective?
- Are the laws requirements defined in written policies? Policy training?
- Did company make significant investments into corporate compliance program and internal controls systems? (staffing, systems)
- Did testing of the program and controls demonstrate they would prevent/detect similar misconduct in the future?
- Did corporate leadership/board members demonstrate the following:
  - Oversight of compliance program
  - Knowledge of applicable laws
  - Engagement

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# Overview of the US Department of Justice Criminal Division's Evaluation of Corporate Compliance Programs



# General Compliance Program Guidance (GCPG)



<https://oig.hhs.gov/compliance/general-compliance-program-guidance/>

- One stop shopping – all compliance guidance for healthcare industry in one place, for both companies and individuals.
- Includes major updates to the GCPG – add patient safety and quality!
- Compliance with the GCPG is voluntary, non-binding, but mitigates liability.
- Guidance website is 91 pages of general compliance guidance, tools and references addressed to all varieties of federal health care program providers and suppliers, and includes:
  - ❖ Discussions/analysis of the key laws in health care fraud enforcement
  - ❖ Helpful references (with links) to resources for compliance professionals.
  - ❖ Recaps from prior guidance, CIAs, and various other OIG issuances.

# 2024 Industry Specific Compliance Program Guidance

<https://oig.hhs.gov/compliance/general-compliance-program-guidance/>

- In 2024, OIG will publish industry segment-specific compliance program guidance (ICPG) for different types of providers, suppliers and other participants
  - Tailored to fraud and abuse risks for each industry subsector
  - Includes compliance measures that can be taken to reduce risk
  - Replaces existing compliance guidance issued
  
- The four anticipated industry specific compliance guidance for 2024 are:

Medicare Advantage	Clinical Laboratories
Nursing Facilities	Hospitals (replaces 1998 guidance)



# The Seven Elements



The GCPG continues to emphasize the seven elements of compliance identified in the U.S. Sentencing Guidelines as the framework for its compliance program recommendations.

<https://www.ussc.gov/guidelines/2023-guidelines-manual/annotated-2023-chapter-8#8b21>

An infographic titled '7 Elements of a Successful Compliance Program'. It features a large blue number '7' in a hexagon. To the right of the number is the title. Below the title is a list of seven elements. To the left of the list is a yellow vertical bar. The background of the infographic is light blue with a white border.

## 7 Elements of a Successful Compliance Program

1. Written Policies and Procedures
2. Compliance Leadership and Oversight
3. Training and Education
4. Effective Lines of Communication with the Compliance Officer and Disclosure Program
5. Enforcing Standards: Consequences and Incentives
6. Risk Assessment, Auditing, and Monitoring
7. Responding to Detected Offenses and Developing Corrective Action Initiatives

In this section, we discuss the seven elements of an effective compliance program. Acknowledging the broad spectrum of entities playing a role in health care delivery today, our discussion below provides guidance generally applicable across the entire spectrum. **We discuss modifications small entities may use to implement these sections in [section IV.A](#).**

Our guidance in this section reflects our prior guidance; more than 25 years of experience monitoring Corporate Integrity Agreements (CIAs); feedback received in various forms from industry stakeholders; lessons learned from enforcement actions and investigations; and the ongoing evolution of the health care delivery system and technology used to support that delivery system.

OIG's longstanding belief is that an entity's leadership should commit to implementing all seven elements to achieve a successful compliance program. The guidance in this section is intended to help entities fulfill that commitment in a robust and meaningful way.

# “Themes” of the General Compliance Program Guidance

- Focus on operational effectiveness of the compliance program, not just the structure.
- Focus on the fluidity of compliance risks – compliance challenges change and so should the issues reviewed as part of the risk assessment.
- Focus on the compliance committee’s accountability – e.g., risk assessments managed by the Committee rather than Compliance Officer, attendance included in performance evaluations of Committee members. The Committee’s engagement reflects commitment of the organization.
- Focus on high level accountability from Committee, Board and Owners (e.g., Private Equity).

# Key Insights Noted in the GCPG – Regulatory

## Specific to the AntiKickback Statute

- Nature of the relationship between the parties
- Manner in which participants were selected
- Manner in which remuneration is determined
- Value of remuneration
  - FMV in an arm's-length transaction for legitimate, reasonable, and necessary services that are actually rendered
  - Is the determination of fair market value based upon a reasonable methodology that is uniformly applied and properly documented?
- Nature of items or services provided
  - Actually, needed and rendered, commercially reasonable and necessary to achieve a legitimate business purpose

# Key Insights Noted in the GCPG – Regulatory (cont.)



## Specific to the AntiKickback Statute (cont.)

- Federal program impact
- Clinical decision making
- Steering
- Potential conflicts of interest
- Manner in which the arrangement is documented

# Ongoing monitoring of Financial Arrangements with Referral Sources (see: IRO work plans).

## D. Financial Arrangements Tracking

Entities involved in Federal health care program business may manage a significant volume of financial arrangements and transactional agreements, including those between referral sources and referral recipients, which can implicate the Federal anti-kickback statute and the PSL, among other Federal fraud and abuse laws. While legal counsel may be involved in the initial structuring and drafting of these agreements, ongoing monitoring of compliance with the terms and conditions set forth in the agreements remains equally important from a fraud and abuse perspective. Entities should consider what type of centralized arrangements tracking system to establish, depending on the size of their organization, to ensure that proper supporting documentation is maintained, regular legal reviews are conducted, and fair market value assessments are performed and updated routinely as appropriate. As applicable, tracking systems should also account for service and activity logs and use of lease space and equipment to ensure consistency with contract terms. The business need or rationale for arrangements should also be documented. An effective and robust arrangements tracking system—that is audited regularly—is a compliance measure that can be taken to prevent violations and mitigate potential liability under the Federal fraud and abuse laws.



## CPCG – More on financials

- “Follow the Money” – Private equity and other private investors – governing bodies should carefully scrutinize the operations and incentive structures, especially investors who provide management services.
- Payment Incentives - Obtain a clear understanding of the various payment incentives within your entities. Fee for service (overutilization), capitation (stinting on care) and quality of care (gaming of data).
- Financial Arrangements - – Ongoing monitoring of financial arrangements with referral sources (IRO work plans).
- Regular reviews to keep billing and coding practices up-to-date
- Regular internal billing and coding audits

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# Government's expectations for demonstrating an effective compliance program and Best Practices

# Risk Assessment

- Company must assess its own risks
  - Identify new risks (new laws or enforcement actions)
  - Remove risks that are mitigated
  - Rank the risks (use criteria like impact, likelihood)





## GCPG emphasized a company's Annual Risk Assessment

Responsibility of the Compliance Committee with coordination with audit, quality and risk management functions.

- References the COSO Enterprise Risk Management Framework
- Use of data analytics and metrics.
- GCPG notes some common compliance risk areas (p. 34):  
Billing; Coding; Sales; Marketing; Quality of care; Patient incentives; Arrangements with physicians, other health care providers, vendors, and other potential sources or recipients of health care business
- <https://oig.hhs.gov/reports-and-publications/>

# Mitigate Risk and Measure Results



## Compliance Work Plan (Annual)

### “How” we will comply with laws

- Patient safety: patients receive proper and safe medical care. (Policy)
- Patient privacy: patient information is not shared with anyone who is not supposed to see the information.(Training)
- Billing of services: hospitals do not overcharge patients for medical services.

## Audit Plan (Annual)

### “Does our Plan work?” - measure results, analyze and revise plan if needed

- Review medical records for documentation of safety precautions in patient care and policies updated
- HIPAA training – how was universe of workforce identified, documentation of training provided.
- Billing/coding audits
- OIG Toolkits: Measuring Compliance Program Effectiveness  
<https://oig.hhs.gov/documents/toolkits/928/HCCA-OIG-Resource-Guide.pdf>

# Reporting



## **REPORT TO COMPLIANCE**

To promote organizational culture of ethical conduct, develop a system to prevent/detect criminal conduct

System to report compliance issues

Publicize the system

Provide options for reporting – anonymous, confidential

Report without fear of retaliation

## **COMPLIANCE OFFICER REPORT TO BOARD/COMMITTEE**

Track/Trend issues reported

Report trends to Committee/Board

Consider adding to compliance workplan

Report violations of law/criminal conduct identified

# OIG Action Items from Health Care Compliance Association April 2024



## COMPLIANCE OFFICER

### Roles & Responsibilities

- No financial, legal, operations, clinical roles
- No risk management
- Should advise leaders of compliance risks
- Same authority of a senior leader

### Reporting

- Do – report to CEO, Board
- Don't – report to Legal or Financial

## KEY RISKS

Quality and Patient Safety are part of compliance program

HIPAA Privacy Compliance is a risk to be addressed (breach patient information)

New entrants into Healthcare must be knowledgeable about laws– private equity companies, digital health companies

Follow the money – financial incentives, evaluate ownership and investment

Financial Arrangements Tracking

# Compliance Insights Noted in the GCPG

- Quality – Intersection with compliance noted throughout.
- Reporting Relationship– CCO should not be GC nor report to the GC.
- Compliance Committee – member attendance and participation included in each member’s performance and compensation evaluation.
- Board - should meet with the CCO no less than quarterly and reserve time each meeting for executive session, absent management.
- Board – evaluate the Compliance Committee’s risk assessment process.
- Board – receive annual reports on the entity’s effectiveness in addressing and resolving compliance committee identified risks.
- Training – ensure a mechanism for participants to ask questions about the content.
- Training – participation a condition of continued employment or engagement.

# OIG Action Items (more) from Health Care Compliance Association April 2024



## **COMPLIANCE COMMITTEE**

### Duties

Attendance

Active Participation

Performance Evaluations – include requirement to fulfill duties as committee member (compensation to be impacted)

Add Patient Safety and Quality into Compliance Program, Compliance Work Plan and Audit Plan

## **BOARD MEMBERS**

### Duties

Read “Practical Guidance for Health Care Boards on Compliance Oversight”

Knowledge of applicable laws, federal health care program requirements and compliance risks for U.S. healthcare

Allocate sufficient resources to CO maintain/monitor the company’s compliance program

Schedule executive meetings regularly for CO to advise board about the risks and compliance operations (do not meet “only” when a problem arises)

# US Sentencing Guidelines – Effective Compliance Program



8B2.1 ...minimally require the following:

The organization's governing authority **shall be knowledgeable** about the content and operation of the compliance and ethics program and shall **exercise reasonable oversight** with respect to the implementation and effectiveness of the compliance and ethics program.

High-level personnel of the organization **shall ensure that the organization has an effective compliance and ethics program**, as described in this guideline.

Thank you for your time today!







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