



HARRIS SLIWOSKI



# New Healthcare Compliance Guidance from the OIG

An Introductory Overview by Two Industry Experts





# Agenda

- Fraud and Abuse Laws
- Compliance Plans and “Mitigation”
- 7 Elements of a Compliance Plan
- Changes with New Guidance
- Department Impact
- Industry Specific Guidelines
- Considerations
- Questions
- Biographies



# Fraud and Abuse Laws

- The Big Four Federal Law:
  - Anti-Kickback Statute (criminal) – “thou shall not pay for referrals”
  - Stark Law (civil) – “thou shall not refer to certain entities”
  - False Claims (civil) – “thou shall not submit false claims”
  - Civil Monetary Penalties – “thou shall pay a lot of money for violations”
- What about State law?
  - It depends on the state
  - Some states have corollaries to the Big Four Federal Laws
- Compliance Plans
  - Tailored to risk areas for the Federal and State laws

# Compliance Plans and “Mitigation”

- The guidance discusses mitigation of risks in general
- But there is also special **legal** meaning
- One quote in the entire guidance document – “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.***”
- What does this mean from a legal perspective?



# Compliance Plans and “Mitigation” (cont’d)

- United States Sentencing Commission and Guidelines
- Used to determine appropriate criminal penalties
- Four factors that increase punishment are:
  - (i) the involvement in or ***tolerance of criminal activity***;
  - (ii) the ***prior history*** of the organization;
  - (iii) the violation of an order; and
  - (iv) the obstruction of justice.

# Compliance Plans and “Mitigation” (cont’d)

- Two factors that **mitigate** the ultimate punishment of an organization are:
  - (i) the ***existence of an effective compliance and ethics program***; and
  - (ii) self-reporting, cooperation, or acceptance of responsibility.
- What’s an effective compliance program?
  - That’s why we are here today



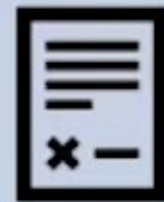


## 7 Elements of a Compliance Plan

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



# Common Policies Within the 7 Elements



Element 1

- Code of Conduct
- Compliance Plan
- Conflict of Interest
- Policy on gifts and gratuities
- Record Retention
- Exclusion & Licensure Screening
- HIPAA Privacy and Security (includes Breach Notification)
- Regulatory & Fraud Enforcement



Element 2

- Compliance Leadership Oversight



Element 3

- Training & Education



Element 4

- Open Lines of Communication
- Policy Maintenance



Element 5

- Compliance Standards, Sanctions, and Disciplinary Action Policy



Element 6

- Auditing & Monitoring Policy



Element 7

- Detected Offenses, Investigations, and Reporting to the Government
- Voluntary Self-Disclosure (can include in Detected Offenses)

# Element 1 – Written Policies & Procedures

Written policies and procedures are intended to guide your organization's relevant individuals to understand requirements and expectations, including:

- Organization's mission, vision, values
- Federal & State laws & regulations
- Organizational oversight & controls
- Internal duties & workflows
- Ethical behavior & risk assessment
- Internal & external communications



# Element 1 – Written Policies & Procedures

- Accessible to all relevant individuals
- Organizational policies vs. department/role specific policies
- Tracked and documented when reviewed
- Test for understanding
- Compliance Officer/Committee available to answer questions
- Reviewed, updated, maintained, and distributed

# Element 1 – Common Policies & Procedures

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- Compliance Plan
- Conflict of Interest
- Policy on Gifts & Gratuities
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## Element 2 – Leadership Oversight

- Sets the tone and commitment from the top indicating importance of compliance
- Active Compliance Committee
- Adequate resources and budget
- Compliance Committee and Board enhanced responsibilities



## Element 3 – Training & Education

- Based on organization's compliance risks and lessons learned
- Describes applicable Federal and State requirements
- Targeted training based on position and role
- Culturally accessible, varied formats





## Element 4 – Effective Communication

- Open lines of communication
- Confidentiality and non-retaliation policy
- Ability to report violations to Federal, State agencies
- Anonymous reporting



## Element 6 – Auditing & Monitoring

- Reporting System
- Risk Assessment
- Develop Auditing & Monitoring Workplan
- Audit Process
- Corrective Action Plans (CAPs)





# Element 7 – Responding to Offenses

- Detected offenses
- Investigations
- Coordination with Legal Counsel
- Reporting to the Government
  - Voluntary self-disclosure



# Changes with New Guidance

- New Entrants in the Healthcare Industry
  - Technology
  - Private Equity
  - New Service Lines for established organizations
- Compliance Programs for Small & Large Entities
- OIG Resources & Processes
- Quality and Patient Safety





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# Department Impact

- Quality

## Changes with New Guidance

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- Compliance Programs for Small & Large Entities

- OIG Resources & Processes

- Quality and Patient Safety





# Department Impact

- Quality
  - Quality of Care & Patient Safety
  - Acute, post-acute facilities (LTACH, AIR, SNF), and residential care
  - Guidance, “triggers” of harm
    - <https://oig.hhs.gov/oei/reports/ae-toolkits.asp>
- Grievances
  - Clinical Categories: Medication, Patient Care, Procedure/Surgery, Infection
  - Harm Event Type: NCC MERP, Preventability
  - Clinical review, up to and including Physicians
    - Peer Review → Contracting/Credentialing

# Department Impact Cont.

- Billing, Coding, & Risk Adjustment
  - FWA
  - Billing & Coding
  - RADV audits
- Contracting
  - Arrangement and agreement remuneration
  - Offshore
  - Third parties
- Credentialing
  - OIG/GSA/State sanction checks
- Prior Authorization & Utilization Management
  - DO NOT 'steer' to a service, entity, equipment, etc.
  - Monitor over/under utilization





# Considerations

- Policies, standards, workflows
- Conduct Risk assessments by department at least annually
- Maximize the effective use of AI and automation for audits
  - Canned reports
  - Uni or Bidirectional interfaces
- Monitor through Compliance or Quality
  - Mock audits
  - Data Analysis
  - Committee Review



## Considerations Cont.

- Policies, procedures, and corrective action
- Conduct Phase immediately
- Monitor and evaluate
  - Cause and effect analysis
  - Remediate
- Monitor and review, prevent reoccurrence
  - Track effectiveness
  - Self-disclose, where necessary



# Considerations Cont.

- Root cause and corrective action
  - Cease immediately
  - Investigate
  - Impact analysis
  - Remediate
  - Audit, and review, prevent reoccurrence
  - Track effectiveness
  - Self-identify, where necessary self-disclose



# Industry Specific Guidance – Current & New

- General Compliance Program Guidance (Nov. 2023):

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

- All other Industry Specific Guidance (1998 – 2008):

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

- Hospitals
- Home Health
- Clinical Laboratories
- 3<sup>rd</sup> – Party Medical Billing
- Durable Medical Equipment
- Hospices
- Medicare+Choice (Medicare Advantage)
- Nursing Facilities
- Small Group Physician Practices
- Ambulance Suppliers
- Pharmaceutical Manufacturers





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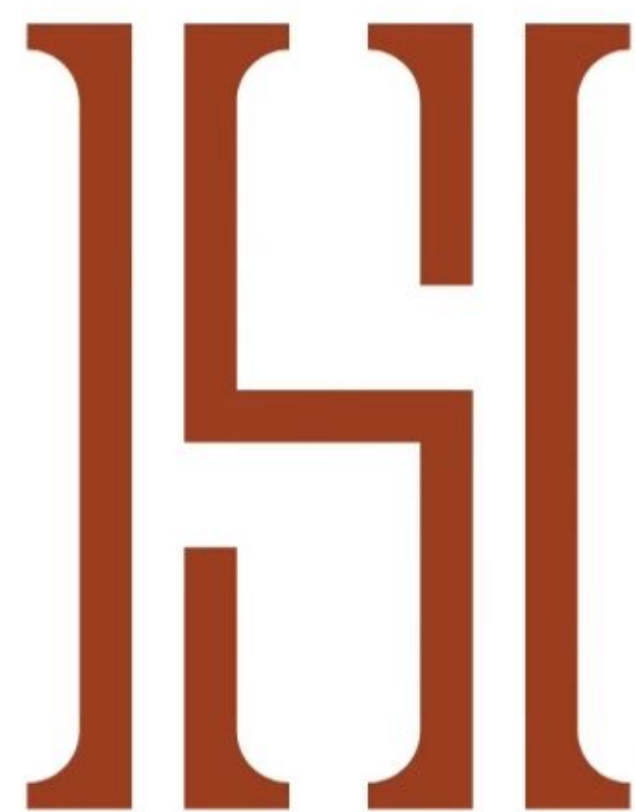
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# Questions







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SUBSCRIBED

