

# Compliance Program Effectiveness

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Ryan Meade, JD, CHRC, CHC-F  
Director, Regulatory Compliance Studies  
Loyola University Chicago School of Law  
rmeade@luc.edu

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## Goals

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- The basics of compliance programs
- DOJ effectiveness of compliance program document (Feb 2017)
- OIG measuring effectiveness document (March 2017)

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## Federal Sentencing Guidelines

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- Controls sentencing of organizations for most federal criminal violations
- Sentencing credit for "effective programs to prevent and detect violations of law"

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### Federal Sentencing Guidelines

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- “To have an effective compliance and ethics program...an organization shall...otherwise promote and organizational culture that encourages ethical conduct and a commitment to compliance with the law.”
- The Federal Sentencing Guidelines set out the 7 classic “elements” of a compliance program

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### 7 Elements of a Compliance Program

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1. Standards and Procedures
2. Oversight
3. Education and Training
4. Monitoring and Auditing
5. Reporting
6. Enforcement and Discipline
7. Response and Prevention
8. (Risk and Effectiveness Assessments)




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### Standards and Procedures

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- Code of Conduct
  - Keep It Simple
  - Tailored to the organization’s culture, business, and corporate identity
  - Attestation
- Policies and Procedures
- Continuous Evaluation
- Assign Responsibility

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Compliance Oversight  
(appropriate Authority and Adequate Resources) 7

- Board
- Compliance Officer
- Oversight Committee
- Other Committees
- Compliance Positions
- Subject Matter Experts
- Management

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Management Responsibilities 8

- Communication regarding:
  - Ethics and compliance as a part of each employee's job responsibilities
  - Specific department compliance risk areas
  - Specific regulatory requirements for each employee's job responsibilities, including quality of care
  - Following the rules as a condition of employment

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Management Responsibilities 9

- Create an environment (culture) which:
  - Encourages open discussion of errors and concerns raised by employees
  - Allows for prompt reporting of compliance concerns
- Design systems and processes that:
  - Ensure compliance
  - Contain adequate controls (compliance, quality, and safety)
  - Are supported by detailed policies and procedures

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**Accountability** 10

➤Directors and Managers are accountable for

- Failure to detect and report non-compliance issues
- Any retaliation or retribution against individuals who report compliance concerns
- Compliance as an element of their performance evaluations
- Corrective action plans to support correction of non-compliant activity

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**Accountability** 11

➤Specifically for

- Internal controls
- Rules and regulations specific to departmental functions and activities
- Identification and management of any potential risk areas

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**Education and Training** 12

- Communication Process
- Internal Vs. External
- Mandatory Vs. Voluntary
- Method for Training
- Proof and Documentation
- Sanctions



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### Auditing and Monitoring

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- Evaluate Program Effectiveness
- Audit Plan and Methodology
- Internal "Audits"
- Compliance "Reviews"
- Outline Audit Procedures
- Staff Training
- Results Reporting

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### Reporting and Investigation

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- Anonymous
- Triaging and handling investigations from concerns
- Hotline
  - Policies and Procedures
  - Internal vs. External
- No Retaliation for Reporting
  - Privacy and confidentiality



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### Enforcement and Discipline

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- Appropriate and Consistent Responses
- Disciplinary Measures
- Stand firm
- Background Checks
- Incentives

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### Response and Prevention

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- Internal Investigation
  - Is it really a problem?
  - How serious is it?
  - Are there enough facts to investigate?
  - What are the areas for concern?
- Contact Counsel
- Interview Process
- Create Policy

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### Benefits of an Effective Compliance Program

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- Demonstrates organization's commitment to good corporate conduct
- Identify and prevent criminal and unethical conduct
- Create a centralized source of information on industry regulations
- Develop a methodology that encourages employees to report potential problems

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### Benefits of an Effective Compliance Program

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- Procedures that allow the prompt, thorough investigation of alleged misconduct
- Initiate immediate and appropriate corrective action
- Reduce the organization's exposure to civil damages and penalties, criminal sanctions, and administrative remedies, such as program exclusions

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**Continuous Improvement**

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OIG Compliance Program Effectiveness Document

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**“Measuring Compliance Program Effectiveness: A Resource Guide”**

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- Background
- Utility and Limitations
- Format—Each of 7 elements are broken down into groups of question topics that include
  - 1. What to Measure
  - 2. How to Measure
    - Document Review
    - Audit
    - Interview
    - Observation of Work Environment
    - Employee Survey

• <https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf>

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Element 1: Standards, Policies, and Procedures	
What to Measure	How to Measure
<b>Access</b>	
1.1 Accessibility	<ul style="list-style-type: none"> <li>Review link to employee accessible website/intranet that includes the Code of Conduct</li> <li>Survey - Can you readily access or reference policies and procedures? (Yes/No/Don't know)</li> <li>Survey - How and where do employees actually access policies and procedures?</li> <li>Test key word search (searchable)</li> <li>Audit and interview staff to these policies</li> </ul>
1.2 Actual Access	Audit how many actual "hits" on policies and procedures
1.3 Accessible language for codes, standards and policies	Flexch Kincaid measuring standard - no more than 10th grade reading level
1.4 Compliance program awareness and communication	<ul style="list-style-type: none"> <li>Survey employees to determine the extent to which the code of conduct and other compliance communications are available to employees</li> <li>Review to ensure the standards, policies, and awareness material is updated and distributed within organization's guidelines</li> </ul>
1.5 Impaired or disabled accessibility	Review accessibility options. Look at methods and speak to individuals.
1.6 Policy communication	Communication strategy of policies
1.7 Availability of policy content	Conduct surveys and observation
<b>Accountability</b>	
1.8 Accountability	Policy Coordinator designated
1.9 Ownership and accountability of policies	Audit process of how policies get enforced by chain of command when compliance is not the final approval. Is management taking responsibility for implementing and following policies?
1.10 Rhetoric policies and procedures	Confirm that listed owner of each policy and procedure is the actual owner.

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### Measuring Compliance Program Effectiveness: A Resource Guide

- Standards, Policies, and Procedures
  - Access
  - Accountability
  - Review / Approval Process
  - Quality
  - Assessment
  - Code of Conduct
  - Updates
  - Understanding
  - Compliance Plan
  - Confidentiality Statements
  - Enforcement

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### Measuring Compliance Program Effectiveness: A Resource Guide

- Compliance Program Administration
  - Board of Directors
  - Compliance Budget
  - Compliance Committees
  - Accountability
  - Compliance Officer
  - Staffing
  - Compliance Plan
  - Culture
  - Incentives
  - Performance Evaluation
  - Risk Assessments
  - Compliance Work Plan
  - Legal Counsel's Role, Other

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### Measuring Compliance Program Effectiveness: A Resource Guide

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- Screening and Evaluation of Employees, Physicians, Vendors and other Agents
  - Accountability for Screening
  - Conflict of Interest
  - Employee Accountability
  - Employee Disclosure
  - Employee Screening
  - Exit Interviews
  - High-risk Screening
  - Licensure
  - Response to Exclusion
  - Response to Screening
  - Vendor
  - Vendor Screening

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### Measuring Compliance Program Effectiveness: A Resource Guide

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- Communication, Education, and Training on Compliance Issues
  - Training
  - Accountability
  - Awareness
  - Board
  - Communication
  - Competency
  - Culture
  - Incentives
  - Vendors and Volunteers

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### Measuring Compliance Program Effectiveness: A Resource Guide

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- Monitoring, Auditing, and Internal Reporting Systems
  - Reporting System
  - Risk Assessments
  - Monitoring and Auditing Work Plan
  - Audit Process
  - Corrective Action Plans
  - Auditors
  - Non-Retaliation

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### Measuring Compliance Program Effectiveness: A Resource Guide

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- Discipline for Non-Compliance
  - Consistency
  - Awareness
  - Documentation
  - Promotion Criteria

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### Measuring Compliance Program Effectiveness: A Resource Guide

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- Investigations and Remedial Measures
  - Guidelines for Conducting an Investigation
  - Content of Investigation Files:
  - Quality and Consistency of Investigations
  - Tracking and Trending Investigations
  - Escalation of Investigations
  - Communication of Investigation Outcomes
  - Training of Investigators
  - Professionalism and Competency of investigators
  - Independence of Investigator

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### Measuring Compliance Program Effectiveness: A Resource Guide

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- Investigations and Remedial Measures (continued)
  - Involvement of Legal Counsel
  - Timeliness of Response
  - Corrective Action Plans / Remedial Measures
  - Root Cause Analysis
  - Adherence to non-retaliation policy
  - Government Inquiries/Investigations
  - Monitoring Results
  - Awareness of Investigation Process
  - Contract Provisions regarding Investigations

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DOJ Evaluation of Compliance Programs Document 31

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February 2017 Release 32

- "Evaluation of Corporate Compliance Programs"
- Released by Criminal Division of the Department of Justice
- "There are, however, common questions that we may ask in making an individualized determination. This document provides some important topics and sample questions that the Fraud Section has frequently found relevant in evaluating a corporate compliance program. The topics and questions below form neither a checklist nor a formula."
- <https://www.justice.gov/criminal-fraud/page/file/937501/download>

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Factors DOJ will consider 33

1. Analysis and Remediation of Underlying Misconduct
2. Senior and Middle Management
  - Demonstrates commitment and oversight
3. Autonomy and Resources
4. Policies and procedures
5. Risk Assessment
6. Training and communication

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Factors DOJ will consider 34

- 7. Confidential Reporting and Investigation<sup>6</sup>
- 8. Incentives and Disciplinary Measures
- 9. Continuous Improvement, Periodic Testing and Review
- 10. Third Party Management
- 11. Mergers and Acquisitions (M&A)

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Questions? 35

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