Measuring the Effectiveness of a Compliance Program
Using the DOJ Guidance

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**This presentation does not constitute legal advice. You should contact your attorney to obtain advice with respect to any particular issue or problem.**

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A Little Humor Before We Begin

**I WAS TOLD THERE WOULD BE DOCUMENTATION**
Where are we going?

Part One
Introduction and Overview

Part Two
Discussion and Analysis of the three “Fundamental Questions”

Part Three
Application of the three “Fundamental Questions” to Seven Elements of an Effective Compliance Program

Part Four
Review and demonstration of tool

Part One
Introduction

Basics

Overview

Part Two
Discussion and Analysis of the three “Fundamental Questions”

Part Three
Application of the three “Fundamental Questions” to Seven Elements of an Effective Compliance Program

Part Four
Review and demonstration of tool
Introduction

1. Why are we here?
2. Why is it important?
3. What will I learn?

What is Healthcare Compliance

Healthcare Compliance – The ongoing process of meeting or exceeding the legal, ethical, and professional standards to a particular healthcare organization or provider. (Kusserow)

1. A culture of compliance promotes prevention, detection and resolution of instances of conduct that do not conform to government laws, public and private payor healthcare program requirements, and ethical and business policies.

2. The biggest challenge for healthcare organizations and their compliance officers is to keep track of all of the requirements and regulations, which are extremely numerous.
What is Healthcare Compliance

OIG Seven Elements of an Effective Compliance Program

1. Implementing written policies, procedures and standards of conduct.
2. Designating a compliance officer and compliance committee.
3. Conducting effective training and education.
4. Developing effective lines of communication.
5. Conducting internal monitoring and auditing.
7. Responding promptly to detected offenses and undertaking corrective action.

What does it meant to be compliant?

1. Avoiding or minimizing liabilities, including legal or regulatory penalties and potential civil litigation.
2. Following applicable federal and state laws and regulations.
3. Not presenting false claims for payment.
4. Developing effective processes, policies, and procedures to define appropriate conduct, training the organization’s staff, and monitoring adherence to the processes, policies, and procedures.
5. Having verifiable metrics.
6. Identifying gaps in the program and taking action to correct them.
Overview

1. What’s new?
2. Where to Focus
3. Data and Metrics

Part Two

Discussion and Analysis of the three “Fundamental Questions”

1. Is the corporation’s compliance program well designed?

2. Is the program being applied earnestly and in good faith? In other words, is the program being implemented effectively?

3. Does the corporation’s compliance program work in practice?
**Question One**

Is the corporation’s compliance program well designed?

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**Risk Assessment**

i. Risk Management Process
ii. Risk-Tailored Resource Allocation
iii. Ongoing Program Improvement

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**Polices and Procedures**

i. Design
ii. Comprehensiveness
iii. Accessibility
iv. Responsibility for Operational Integration
v. Ethical Leadership (Gatekeepers)
Question One
Is the corporation’s compliance program well designed?

Training and Communication

i. Risk-Based Education & Training
ii. Form/Content/Effectiveness of Education & Training
iii. Communication and Awareness about Misconduct
iv. Availability of Guidance

Confidential Reporting and Investigative Process

i. Effectiveness of Reporting Mechanism
ii. Properly Scoped Investigation by Qualified Personnel
iii. Investigation and Response
iv. Resources and Monitoring
Question One
Is the corporation’s compliance program well designed?

Third Party Management

i. Risk-Based and Integrated Process
ii. Appropriate Controls
iii. Management of Relationships
iv. Real Actions and Consequences

Question One
Is the corporation’s compliance program well designed?

Mergers and Acquisitions

i. Due Diligence Process
ii. Ethics and Compliance integration into the mergers and acquisition process
iii. Process connecting due diligence to Implementation
**Question Two**

Is the program being applied earnestly and in good faith? (In other words, is the program being implemented effectively?)

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**Commitment by Senior and Middle Management**

(Ethical Leadership)

i. Conduct at the Top  
ii. Shared Commitment (Solve Problems Together)  
iii. Oversight

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**Question Two**

Is the program being applied earnestly and in good faith? (In other words, is the program being implemented effectively?)

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**Autonomy and Resources**

(Organizational Structure and Accountability)

i. Organizational Structure  
ii. Seniority and Stature  
iii. Experience and Qualifications  
iv. Funding and Resources  
v. Autonomy (Accountability)  
vii. Outsourced Compliance Functions
**Question Two**
Is the program being applied earnestly and in good faith? (In other words, is the program being implemented effectively?)

**Incentives and Disciplinary Measures**

i. Human Resource Process (Transparency)
ii. Consistent Application
iii. Incentive System

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**Question Three**
Does the corporation’s compliance program work in practice?

**Continuous Improvement, Periodic Testing & Review**

i. Internal Audit
ii. Control Testing (Monitoring)
iii. Evolving Updates (Continuous Improvement)
iv. Culture of Compliance
Question Three
Does the corporation’s compliance program work in practice?

Investigation of Misconduct

i. Properly Scoped by Qualified Personnel
ii. Response to Investigations

Analysis and Remediation of Any Underlying Misconduct

i. Root Cause Analysis
ii. Prior Weakness
iii. Payment Systems
iv. Vendor Management
v. Prior Indications
vi. Remediation
vii. Accountability
Part Three

Application of DOJ Guidance to Other Compliance Guidance

1. Office of Inspector General Seven Element of an Effective Compliance Program


Element One

Implementing written policies, procedures and standards of conduct

A. Implementing written policies, procedures and standards of conduct

i. Design

ii. Comprehensiveness

iii. Accessibility

iv. Responsibility for Operational Integrity
Element One
Implementing written policies, procedures and standards of conduct

B. Communications

i. Communication and Awareness about Misconduct
ii. Availability of Guidance

Element Two
Designating a compliance officer and compliance committee

A. Autonomy and Resources

i. Organizational Structure
ii. Seniority and Stature
iii. Experience and Qualifications
iv. Funding and Resources
v. Autonomy (Accountability)
vi. Outsourced Compliance Functions
Element Three
Conducting effective training and education

A. Training

i. Risk-Based Education and Training

ii. Form/Content/Effectiveness of Education and Training

Element Four
Developing Effective Lines of Communication

A. Confidential Reporting and Investigative Process

i. Effectiveness of Reporting Mechanism

ii. Properly Scoped Investigation by Qualified Personnel

iii. Investigation and Response

iv. Resources and Monitoring
Element Five
Conducting internal monitoring and auditing

A. Continuous Improvement, Periodic Testing, and Review
   i. Internal Control
   ii. Control Testing (Monitoring)

Element Six
Enforcing standards through well-publicized disciplinary guidelines

A. Incentives and Disciplinary Measures
   i. Human Resources Process (Transparency)
   ii. Consistent Application
   iii. Incentive System
Element Seven
Responding promptly to detected offenses and undertaking corrective action

A. Investigation of Misconduct

i. Properly Scoped by Qualified Personnel
ii. Response to Investigations

Element Seven
Responding promptly to detected offenses and undertaking corrective action

B. Analysis and Remediation of Any Underlying Misconduct

i. Root Cause Analysis
ii. Prior Weaknesses
iii. Payment Systems
iv. Vendor Management
v. Prior Indications
vi. Remediation
vii. Accountability
A. How do they interact?

i. Common Elements

ii. Similar Questions

iii. Overlapping Requirements

B. Where is there overlap in items?

i. Risk Management/Risk Assessment

ii. Policies and Procedures

iii. Training and Communications

iv. Investigations and Discipline

v. Structure

C. What are key takeaways

i. “Paper” Compliance is not sufficient
ii. Metrics and Data Matter
iii. Need to demonstrate “effectiveness”
iv. A violation does not equate to an ineffective program and you can demonstrate change during investigation process

Part Four

Measuring the Effectiveness of Your Compliance Program using the DOJ Guidance

1. How to use the tool

2. What to do with the data you create
Questions???

Everyone has a hand in Compliance

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