

Measuring the Effectiveness of a Compliance Program Using the DOJ Guidance

HCCA Compliance Institute
Sunday March 29, 2020

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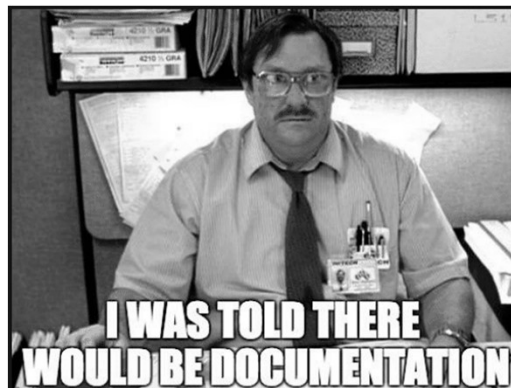
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A Little Humor Before We Begin



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Where are we going?

Part One

Introduction and Overview

Part Two

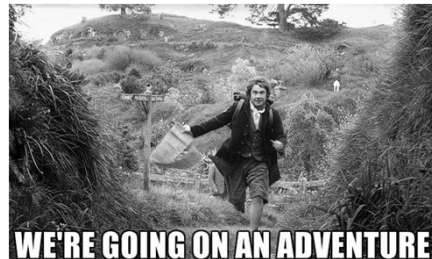
Discussion and Analysis of the three
“Fundamental Questions”

Part Three

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

Part Four

Review and demonstration of tool



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Part One

Introduction

Basics

Overview



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Introduction

Introduction

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



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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.

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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.
6. Enforcing standards through well-publicized disciplinary guidelines.
7. Responding promptly to detected offenses and undertaking corrective action.



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What is Healthcare Compliance

What does it mean 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.



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Overview

Overview

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



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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?



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Question One

Is the corporation's compliance program well designed?

Risk Assessment

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



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Question One

Is the corporation's compliance program well designed?

Polices and Procedures

- i. Design
- ii. Comprehensiveness
- iii. Accessibility
- iv. Responsibility for Operational Integration
- v. Ethical Leadership (Gatekeepers)



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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



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Question One

Is the corporation's compliance program well designed?

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



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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



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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



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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?)

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?)

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)
- vi. Outsourced Compliance Functions



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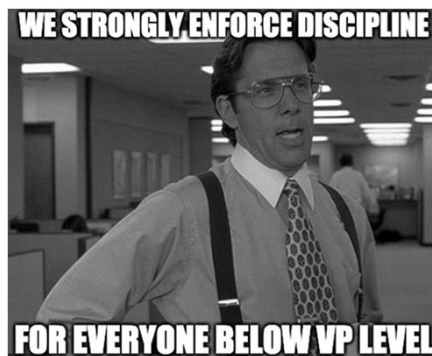
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Question Two

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

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



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Question Three

Does the corporation's compliance program work in practice?

Investigation of Misconduct

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



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Question Three

Does the corporation's compliance program work in practice?

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



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Part Three

Application of DOJ Guidance to Other Compliance Guidance

1. Office of Inspector General Seven Element of an Effective Compliance Program
2. “Measuring Compliance Program Effectiveness: A Resource Guide” – HCCA-OIG Compliance Effectiveness Roundtable

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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



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Element One

Implementing written policies, procedures and standards of conduct

B. Communications

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



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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



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Element Three
Conducting effective training and education

A. Training

- i. Risk-Based Education and Training
- ii. Form/Content/Effectiveness of Education and Training



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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



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Element Five
Conducting internal monitoring and auditing

A. Continuous Improvement, Periodic Testing, and Review

- i. Internal Control
- ii. Control Testing (Monitoring)



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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



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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



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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



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“Measuring Compliance Program Effectiveness: A Resource Guide” – HCCA-OIG Compliance Effectiveness Roundtable

A. How do they interact?

- i. Common Elements
- ii. Similar Questions
- iii. Overlapping Requirements



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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



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“Measuring Compliance Program Effectiveness: A Resource Guide” – HCCA-OIG Compliance Effectiveness Roundtable

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



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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



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Questions???



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Everyone has a hand in Compliance

