

## **Compliance Program Effectiveness**

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### **The Presentation: Order of Topics**

- ◆ Seven Core Elements of a Compliance Program
- ◆ Compliance as Preventative Medicine
- ◆ “True Value” of a Compliance Program
- ◆ Two-Dimensional Approach to Measuring Compliance Program Effectiveness
- ◆ Measuring Effectiveness Among Six Compliance Program Indicators
- ◆ The Long-Term Care Industry and Compliance: Specific Issues
- ◆ Questions and Answer

## Compliance Sources

Evaluating and Improving A Compliance Program: A Reference Guide for Healthcare Board Members, Healthcare Executives and Compliance Officers, Health Care Compliance Association

Early Evidence of Compliance Program Effectiveness is Inconclusive, General Accounting Office, April 1999

The Compliance Effectiveness Study: A Study of the Relationships between the Sentencing Guidelines' Compliance Program Provisions and Effective Compliance, Lori S. Richardson Pelliccioni, Doctorial Dissertation, University of California, Los Angeles, 2002

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## Questions to Consider

- ◆ Is our compliance program working effectively?
- ◆ Is measuring compliance program effectiveness important to the long-term care organization?
- ◆ How do we measure effectiveness considering that few substantive benchmarks to measure effectiveness have been established?

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## The Seven Core Elements of a Compliance Program

- ◆ The seven core elements, required by the USSCG, include:
  - Standards and Procedures
  - Oversight - Compliance Officer or Compliance Committee
  - Delegation of Authority: Screening of Employees and Contractors, etc.
  - Training and Education
  - Auditing and Monitoring
  - Enforcement and Disciplinary
  - Corrective Action Procedures (Response and Prevention)

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## The Seven Core Elements of a Compliance Program

Office of Inspector General (OIG) and Department of Justice (DOJ) have suggested, "...compliance programs are the most important step a provider can take to minimize regulatory risks."

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## Compliance Effectiveness

Sentencing Guidelines – An effective compliance program can mitigate criminal penalties.

DHHS – An effective compliance program can mitigate civil penalties.

What is “effective”?

Containing the seven elements does not in itself equate to effectiveness.

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## Compliance Effectiveness

### Federal Sentencing Guidelines

A program that “prevents and detects violations of law....a program that has been reasonably designed, implemented and enforced so that it generally will be effective in preventing and detecting criminal conduct...The hallmark of an effective program to prevent and detect violations of law is that the organization exercised due diligence in seeking to prevent and detect criminal conduct.”

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## Compliance Effectiveness

U.S. Department of Health and Human Services:

Defines effective as a program that prevents improper payments.

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## Compliance as “Preventative Medicine”

Compliance programs provide “preventative medicine” for healthcare providers against the legal and regulatory risks they face in a complex and ever-changing healthcare environment.

An effective compliance program builds within an organization the structure and culture of best business practices; thus, facilitating the delivery of superior patient care.

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## Effectiveness Measures

Awareness ( Industry)

Proper Billing (GAO and HHS)

Interestingly, the Defense Industry does not measure effectiveness.

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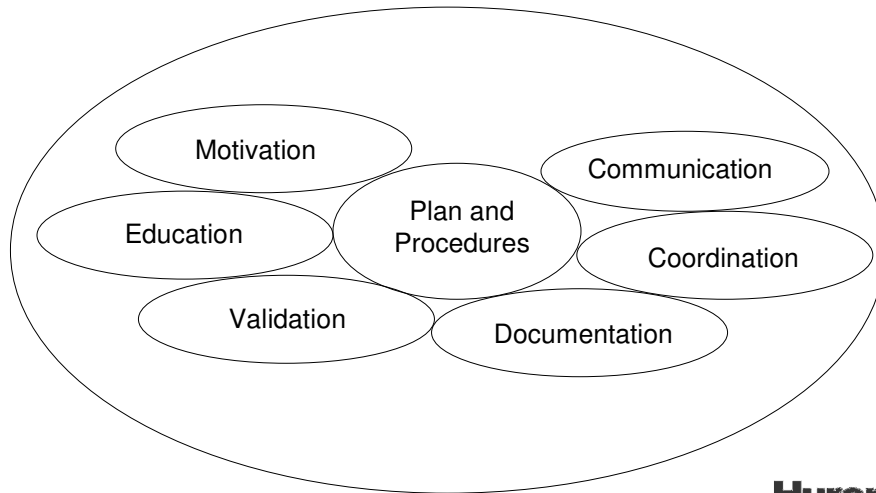
## The “True Value” of an Effective Compliance Program

The “true value” of an effective compliance program does not derive solely from program implementation and the programs ability to protect from those risks identified by the organization; instead, “true value” is derived from the organizations implementation of best practices, which attribute to improved organizational performance and patient care.

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## Compliance Dynamics



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## Effectiveness: A Two-Dimensional Evaluation

- ◆ Effectiveness is evaluated along two dimensions:
  - Effort
  - Outcome

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## Effort Defined

*“Effort is the time, money, resources and commitment that an organization puts into building and improving a compliance program.”*

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## Effort

In the first several years of a program, effort is one measure of effectiveness that an organization can use to assess its compliance program.

**Practice Tip:** Always document effort - Documentation is the key to demonstrating the effectiveness of the compliance program.

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## Effort: General Questions to Address

- ◆ *Best Practices*: How do the resources devoted to the program compare to similarly situated organizations (size and complexity)?
- ◆ *Risk*: Are we addressing the issues that create the greatest risk for similar organization engaged in similar activities?
- ◆ *Audit*: Are we conducting periodic audits and are we promptly refunding overpayments?
- ◆ *OIG Guidance*: Have we addressed the issues that the OIG has identified in its guidance documents?

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## Outcome Defined

*“Outcomes are the impact that our efforts have on our level of compliance.”*

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## Outcome

As the compliance program matures, the principal measure of effectiveness moves from effort to outcomes.

**Practice Tip:** Always document outcomes—documentation is the key to demonstrating the effectiveness of the compliance program.

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## Outcome Assessment General Examples

- ◆ If our education efforts are adequate, coding will improve over time.
- ◆ If our process efforts are adequate, we will have fewer instances where employees fail to receive required training.

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## Measuring Effectiveness Among Six Compliance Program Indicators

- ◆ Indicator # 1 – Policies and Procedures
- ◆ Indicator # 2 – Ongoing Education and Training
- ◆ Indicator # 3 – Open Lines of Communication
- ◆ Indicator # 4 – Ongoing Monitoring and Auditing
- ◆ Indicator # 5 – Enforcement and Discipline
- ◆ Indicator # 6 – Investigation, Response, Prevention

Indicators should be evaluated along the two dimensions of effort and outcome.

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## Policies & Procedures Rationale

- ◆ In order to effectively operate a compliance program, an organization must generally develop written standards, policies and procedures designed to address its principal risks.
- ◆ These written standards communicate:
  - Organizational values and expectations regarding employee behavior
  - The operation of the compliance program
  - Internal standards for compliance with laws and regulations
  - The consequences of noncompliance to both the organization and the individual

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## Policies & Procedures

### Relevant Issue

- ◆ Relevant Issue: What Policies and Procedures Should be Included in an Effective Compliance Program?
  - Building an effective compliance program does not require the development of hundreds or even dozens of policies and procedures.
- ◆ Most compliance programs include policies and procedures that fall into three broad categories:
  - A code of conduct
  - Policies relating to the operation of the compliance program
  - Policies addressing the organization's principal legal (substantive) risks

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## Policies & Procedures

### Code of Conduct Defined

*The code of conduct is typically a document that sets forth in general terms the organization's commitment to comply with the law.*

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## **Policies & Procedures**

### **Operational Policies Defined**

*Operational policies and procedures address the operation of the compliance program itself.*

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## **Policies & Procedures**

### **Substantive Policies Defined**

*Substantive policies address the principal legal risks of the organization.*

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## Policies & Procedures Two-Dimensional Evaluation

### ◆ Effort

- Do policies and procedures exist for relevant topics and areas?
- Has a risk assessment been completed to identify the relevant risk areas?
- Are the policies comprehensive?
- Are policies understandable and capable of being fully applied?
- Have the requirements of the policies and procedures been communicated to employees?
- Have any audits been conducted to monitor compliance with the policies and procedures?

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## Policies & Procedures Two-Dimensional Evaluation

### ◆ Outcome

- Have audits revealed fewer errors in the areas where policies have been implemented?
- Upon testing, are the internal controls established by policies working?
- When interviewing employees during an audit or review, do they understand what the policies require?

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## Ongoing Education & Training Rationale

- ◆ Why is ongoing education and training a measure of effectiveness?
  - The existence of an education and training program is an important component of compliance programs for a number of reasons, including the following:
    - Promotes understanding of and compliance with relevant federal, state and local laws and regulations.
    - Enables implementation of the compliance program's policies and procedures and ensure that employees understand their role in the compliance process.
    - Demonstrate the organization's commitment to compliance and ensure that commitment is carried out throughout the organization.
    - To communicate the effect that industry standards and governmental requirements have on an organization's business activities and to improve skills for identifying potential compliance issues.

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## Ongoing Education & Training Relevant Issues

- ◆ Education and training programs should typically include:
  - Information regarding how the organization's compliance program operates.
  - Information on specific laws and regulation (e.g., reimbursement, coding, prompt payment requirements, etc.) which impact the organization.
  - The consequences of noncompliance (e.g., recoupment, fines, penalties, exclusion) to both the organization and the individual.

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## Ongoing Education & Training Two-Dimensional Evaluation

### ◆ Effort

- Organizational policies require employees to receive periodic training and education regarding the organization's compliance program.
  - Measure the percentage of employees who received training regarding the organization's compliance program promptly following commencement of employment.
  - Measure the percentage of employees in higher risk roles who receive specific, job related education designed to reduce the incidence of noncompliance in the department or function at intervals established by the provider.

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## Ongoing Education & Training Two-Dimensional Evaluation

### ◆ Effort continued

- The organization evaluates the roles of its agents and provides education (or requires the agent to provide education) or such agents directly impact the organization's compliance.
- The organization can demonstrate it has evaluated the role of non-employee agents and contractors and assessed the need to ensure they are adequately trained.
- The organization has a plan to train those non-employee agents or contractors who are determined to need training.

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## Ongoing Education & Training Two Dimensional Evaluation

- ◆ Effort continued
  - The content of the education and training addresses the operation of the compliance program and the substantive legal issues that most directly impact the organization's risk and the employee's duties.
  - The organization has engaged in an assessment of its most significant risks through reliance by reviewing applicable OIG guidance, fraud alerts and work plans, through consultation with healthcare counsel or other experts, or by some other mechanism (consistent with the organization's size and resources) reasonably calculated to identify its principal risks.
  - The organization has a process to monitor changes in laws and regulations relating to its greatest risk areas and modifies education content as appropriate.

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## Ongoing Education & Training Two-Dimensional Evaluation

- ◆ Effort continued
  - The organization assesses the effective of its education efforts by utilizing tests, which evaluate employee comprehension, measuring impact on job processes, or some other mechanism designed to ensure the training is effective.
    - Failure to fulfill compliance education requirements is grounds for an employee's discipline up to and including termination.
    - The organization consistently ensures that employees complete required education and takes appropriate steps where employees do not.

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## Ongoing Education & Training Two-Dimensional Evaluation

### ◆ Outcome

- Organization has documentation that training and education of employees has occurred.
- The organization and its Compliance Officer have documentation that proves that policies and procedures and the Standards of Conduct have been distributed to all applicable employees.
  - Frequently, organizations will have a tear out sheet in the back of the Standards of Conduct and will request that individuals simply sign the form and send it to the Compliance Officer upon receipt of the Standards of Conduct.
- There is documentation in employee files showing discipline for employees who do not complete training or who do not return the receipt of the Standards of Conduct.

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## Open Lines of Communication Rationale

Compliance programs operate most effectively in organizations that encourage employees and business partners to report suspected wrongdoing so that it can be investigated and properly addressed.

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## Open Lines of Communication Relevant Issue

Creating and maintaining a mechanism to encourage and facilitate candid communication.

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## Open Lines of Communication Two-Dimensional Evaluation

- ◆ Effort
  - Do the necessary communication policies exist and have they been implemented and maintained?
  - Are reporting mechanisms appropriate to the size of the organization (i.e., suggestion boxes in smaller facilities vs. continuously available hotlines in larger, more geographically diverse, organizations)?
  - Is the reporting mechanism available to all levels of the organization and to those affiliated with the organization?
  - Are reporting mechanisms publicized throughout the organization?

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## Open Lines of Communication Two-Dimensional Evaluation

### ◆ Outcome

- Is analysis being conducted on reports to determine whether response is timely and thorough?
- Is there a trending of questions, issues raised or potential misconduct to direct where the organization should be focusing its efforts?
- Have employees been surveyed to evaluate their knowledge of the reporting mechanism?
- Does evidence show that there is a confidence in the reporting mechanism?

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## Ongoing Monitoring & Auditing Rationale

Effective compliance programs include proactive monitoring and auditing functions that are designed to test and confirm compliance with legal requirements and with the organization's written compliance standards.

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## Ongoing Monitoring & Auditing Two-Dimensional Evaluation

### ◆ Effort

- Is the organization conducting a regular auditing and monitoring program consistent with the size, complexity and scope of its business operations?
- To the extent possible, are audit staff responsible for conducting compliance audits independent from the areas of the organization that they are auditing?
- Does the organization have a written compliance auditing and monitoring plan that includes subject, method, and frequency of audits?

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## Ongoing Monitoring & Auditing Two- Dimensional Evaluation

### ◆ Effort continued

- If any major findings were made, was senior management an/or the Board notified as appropriate in a timely manner?
- When appropriate, have government agencies been notified of adverse finding in a timely manner?
- Have written corrective action plans been produced and followed when adverse findings were made?
- Are overpayments promptly refunded?
- Are audit plans build on organizational history?
- Have audit results been disseminated to the appropriate groups for corrective actions?

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## Ongoing Monitoring & Auditing Two-Dimensional Evaluation

### ◆ Outcome

- Do the results of audits indicate that the organization understands and is complying with internal and external laws, regulations, rules and policies?
- Does analysis of the results of repeat audits indicate an upward trend of improvement in the organization's understanding of and compliance with internal and external standards?

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## Enforcement & Discipline Rationale

When compliance failures occur, there must be a process for enforcing compliance standards and for disciplining responsible individuals when discipline is appropriate. Enforcing standards and disciplining the individuals who violate them underscores the organization's commitment to compliance.

Discipline is an OIG indirect measure.

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## Enforcement & Discipline Two-Dimensional Evaluation

### ◆ Effort

- Does the organization have policies and procedures addressing enforcement of compliance standards and discipline of individuals who violate them?
- Does the organization screen employees and business partners before initiating a relationship and periodically thereafter to assure that they have not been excluded by the OIG?
- Are enforcement and disciplinary standards communicated throughout the organization?
- Is compliance an element of performance reviews and incentive compensation decisions?

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## Enforcement & Discipline Two-Dimensional Evaluation

### ◆ Outcome

- Percentage of success in meeting the reporting requirements of Corporate Integrity Agreements (CIAs)?
- Percentage of success in meeting audit recommendations?
- Does a review of disciplinary actions taken as a result of compliance failures indicate that discipline is consistently and fairly administered?
- What is the percentage of employees who satisfy the compliance elements of their performance reviews and incentive compensation decisions?

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## Investigation, Response & Prevention Rationale

An effective compliance program will include a process by which the organization can respond to actual or potential violations of the program.

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## Investigation, Response & Prevention Two-Dimensional Evaluation

### ◆ Efforts

- Has the organization developed a process for investigating reports of suspected non-compliance?
- Has the organization developed a process for responding appropriately to discovered non-compliance?
- Are the findings, status and outcomes of internal investigations reported regularly to appropriate oversight and management bodies?
- Has the organization developed written policies or protocols for responding to government investigations?

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## Investigation, Response & Prevention Two-Dimensional Evaluation

### ◆ Outcomes

- Can the organization demonstrate that ongoing harm is halted promptly upon discovery of confirmed non-compliance?
- Does aging of closed and ongoing investigations demonstrate that the organization is promptly resolving reports of suspected non-compliance?
- Are the organizations corrective action responses to investigations consistent with legal requirements and with the recommendations of relevant regulatory agencies?
- Do the organizations monitoring efforts indicate that preventative measures taken in response to non-compliance are effective in eliminating future instances of similar non-compliance?

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## Compliance Effectiveness Important Points to Remember

- 1) Documentation
- 2) Awareness
- 3) Proper Billing
- 4) Proactive and Corrective Action
- 5) Quality of Care
- 6) Culture of Integrity

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## **Question & Answer Session**

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