

# The Eighth Element of an Effective Compliance Program

Presented by  
Kenneth L. Blickenstaff, BlickenWolf LLC  
and  
Kevin Bennett, StoneTurn Group LLP  
Scottsdale, Arizona  
Health Care Compliance Association  
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## Only the Beginning

- Global settlement in 1996 (“wave therapy”)
- First Integrity Agreement experience – 1996
- Medicaid Fraud Integrity Agreement – 1998
- The new millennium experience 1999 – OIG comments
- Corporate Integrity Agreements today
  - Industry Standards
  - Compliance expectations
- We have come a long way!

## **HCCA PERSPECTIVE**

### **Compliance Effectiveness Measurement**

- The Health Care Compliance Association (“HCCA”) has surveyed hospitals and systems nation-wide regarding a whole series of compliance related issues since 1998.
- Starting in 2007 (an indication as to when this was becoming a “hotter” issue), HCCA asked members to respond to “Do you measure the effectiveness of your compliance program?” In that survey, the respondents answered “yes” 60% of the time.
- In 2008, the result was 58%, thereby indicating that this process is becoming integrated within the majority of healthcare providers.

## **OIG GUIDANCE**

- The Office of Inspector General (OIG) originally provided hospitals with “compliance guidance” on February 23<sup>rd</sup>, 1998 with the publication of its Compliance Program Guidance for Hospitals.
- The OIG later published its Supplemental Compliance Program Guidance for Hospitals, which also includes a certain amount of clarification around compliance program expectations.
- The OIG considers this document to be “...a benchmark or comparison against which to measure ongoing efforts and as a roadmap for updating or refining their compliance plans.”

**7 Elements of the OIG's Hospital Compliance Guidance (1998) and 8<sup>th</sup> Element added in OIG's Supplemental Guidance (2005)**

1. Designation of a Compliance Officer and Compliance Committee
2. Development of Compliance Policies and Procedures, including Standards of Conduct
3. Developing Open Lines of Communication
4. Appropriate Training and Education
5. Internal Monitoring and Auditing
6. Responding to Detected Deficiencies
7. Enforcement of Disciplinary Standards
8. **Define Roles and Responsibilities, Assign Oversight for Compliance, and Conduct an Assessment of the Program's Effectiveness**

**RISK ASSESSMENT REQUIRED  
Federal Sentencing Guidelines - 2004**

- "Risk Assessment" has been added as the eighth element of those that comprise an effective compliance program, especially with the amendments to the FSGs in 2004.
- The Advisory Group to the Federal Sentencing Commission stated, "A detailed risk assessment is required to appropriately tailor a compliance program to a company's business circumstances."
- There are two aspects to risk assessment. First, risk assessment should be ongoing. Second, results of risk assessments should influence the design and implementation of the compliance program in order for it to be effective in preventing and detecting violations of law.

## **FEDERAL SENTENCING GUIDELINES**

- Although declared unconstitutional on January 12<sup>th</sup>, 2005, the United States Supreme Court held that the Guidelines will and should be used in at least an advisory capacity.

## **FEDERAL SENTENCING GUIDELINES AMENDMENTS (2004) – REFLECTING BEST PRACTICES**

### New Requirements:

- ✓ Management of program:
  - “High-level overall responsibility”
  - “Day-to-day operational responsibility”
- ✓ Board must provide reasonable oversight of “implementation and effectiveness” of program
  - Receive reports from individual with “day-to-day” responsibility
  - Ensure program has sufficient resources
- ✓ Ongoing ethics/compliance risk assessments

## **FEDERAL SENTENCING GUIDELINES AMENDMENTS**

### New Requirements:

- ✓ Company-wide, all-hands training (includes Board)
  - Training should be aligned with roles and risks
- ✓ Channels for internal reporting and advice
- ✓ Discipline and incentives must support program goals
- ✓ “Culture” of ethics and compliance
- ✓ **Evaluation of program effectiveness**

## **SIMILAR THEMES SARBANES-OXLEY**

Compliance information should flow up to management and the Board:

- ✓ §301(4) – Audit Committee must have mechanisms to receive reports on financial integrity
- ✓ §406 – Company must have a code of conduct that promotes internal reporting to a designated person

## **SIMILAR THEMES SARBANES-OXLEY**

Compliance information should flow up to management and the Board:

- ✓ §307 – “Up-the-Ladder” reporting for lawyers
- ✓ Whistleblower protection provisions – civil and criminal liability for retaliation

## **SIX MAJOR AREAS OF CHANGE**

- Culture and Responsibility of Organizational Leadership
- Effective Communication of Standards and Training
- Monitoring, Auditing, and Evaluation
- Reporting Systems
- Accountability & Remediation
- Ongoing Risk Assessment

## **CULTURE & RESPONSIBILITY OF ORGANIZATIONAL LEADERSHIP**

### Change

- Must actively promote culture of compliance with all laws
- Organizational leadership must be knowledgeable about content and operation of compliance program
- Directors must be knowledgeable about content and operation of compliance program and exercise reasonable oversight with respect to implementation and effectiveness of program

## **CULTURE & RESPONSIBILITY OF ORGANIZATIONAL LEADERSHIP**

### Change

- Compliance officer must be given adequate resources with which to implement and operate compliance program
- Compliance officer must periodically report directly to the Board of Directors (or a Board committee)
- Board must also hear directly from person(s) having day-to-day responsibility for compliance

## **CULTURE & RESPONSIBILITY OF ORGANIZATIONAL LEADERSHIP**

### Application Considerations

- Is compliance identified as a priority by top management?
- Are employees aware of compliance program and their responsibility for compliance?
- Are Board members familiar with compliance program and its implementation and effectiveness?
- Does the compliance officer enjoy a high level of authority within the organization?
- Does the compliance officer have access to senior management?

## **CULTURE & RESPONSIBILITY OF ORGANIZATIONAL LEADERSHIP**

### Application Considerations

- Does the compliance officer directly report to Board of Directors (or Board Committee)?
- How often does compliance officer report to the Board regarding implementation and effectiveness of compliance efforts?
- Are the resources dedicated to compliance efforts commensurate with size and complexity of operations?



## EFFECTIVE COMMUNICATION OF STANDARDS & TRAINING

### Change

- Conduct effective training vs. required participation in training programs
- Components of *Effective Training* - must educate all & motivate employees to comply

## EFFECTIVE COMMUNICATION OF STANDARDS & TRAINING

### Application Considerations

- Has training been done on the compliance program annually? Has it been updated?
- Assess the type of training conducted based on size/culture of your organization
- Is there documentation to show that every employee has been trained? Including Board Members? (test it)
- Has there been specific training on risk areas pertinent to your organization?
- Has your training been effective? (e.g. increased compliance questions)

## MONITORING, AUDITING & EVALUATION

### Change

- Monitoring is not optional - it is required
- Must monitor and audit areas of risk as defined by industry standards and specific areas of each provider
- Scrutinize adherence to program requirements
- Periodic regular evaluation of effectiveness
- Independence

## MONITORING, AUDITING & EVALUATION

### Application Considerations

- Do you have a written monitoring plan? (subject, method, frequency, periodically updated)
- Do you need or have you had an independent review of your program?
- Do you have written corrective action plans?
- What are your effectiveness measures?
- Is senior management made aware of findings?

## REPORTING SYSTEMS

### Change

- Must implement and publicize reporting mechanisms that encourage reporting of violations without fear of retaliation
- Must have an anonymous reporting mechanism
- Consider issue of confidentiality for reporters

## REPORTING SYSTEMS

### Application Considerations

- Are “whistleblower” protections documented and publicized?
- Are employees aware of how to report compliance violations?
- Does the organizational culture encourage reporting and support persons making reports?
- Is there an anonymous mechanism to report violations?

## **ACCOUNTABILITY AND REMEDATION**

### Change

- Organization must take action in response to detected violations
- Response needs to include appropriate disciplinary actions, steps to prevent similar future violations and implementation of appropriate modifications to program to improve detection and prevention

## **ACCOUNTABILITY AND REMEDATION**

### Application Considerations

- Are compliance violations dealt with consistently? Are individuals held accountable? Are disciplinary actions taken at all levels?
- Do you have a policy/procedure in place to address handling of violations? What is the involvement of senior management and the Board in the process?
- Does the procedure include evaluation and modification of compliance plan? Are remedial efforts documented?

## ONGOING RISK ASSESSMENT

### Change

- NEW Guideline at 8B2.1(c) - independence is implicit
- Tailor compliance program to company's business circumstances
- Determination of scope & nature of risks should be ongoing
- Results of risk assessments should influence design & implementation of an effective program

## ONGOING RISK ASSESSMENT

### Application Considerations

- How do you evaluate potential areas of risk? (who is involved, is the evaluation documented)
- How do you monitor changes in laws and regulations?
- Have your policies and procedures been reviewed & updated to reflect industry changes?

## **PFIZER AGREEMENT**

- Best practices may have never been better defined.
- III.A.3.a. – Audit Committee Compliance Obligation – at least quarterly review of Compliance Program, including evaluating its effectiveness.
- III.A.3.b. – see handout

## **WHAT CONSTITUTES EFFECTIVENESS**

Effectiveness of the  
Compliance Program?

YES

Effectiveness of  
Compliance Risk  
Assessments?

YES

## WHAT IT MEANS TO YOU

- An examination of the authorities above indicates that compliance risk assessments and internal departmental risk assessments must be performed and should be performed by an independent source.
- If there should be an investigation of your institution, a history of effective risk assessment may be a factor related to the imposition of a corporate integrity agreement by OIG.

## HOW DO YOU DO IT?

- **Risk of inaction**
- **Independence**
- **Program must be:**
  - **Effective**
  - **Comprehensive**
  - **Current**
  - **Proactive**
  - **Supportive**
  - **Ingrained in the culture in a positive way**

## **Where Do We Go from Here?**

- **No one knows for sure but we are better prepared to meet any contingencies**
- **We are ahead of the game – for now**
- **Your continued involvement and interaction is key**
- **Best practices search goes on!**
- **Thanks for all you are doing!**