

# Is Your Compliance Program Effective?

Debbie Troklus  
Ankura Consulting

Lea Fourkiller  
Ankura Consulting

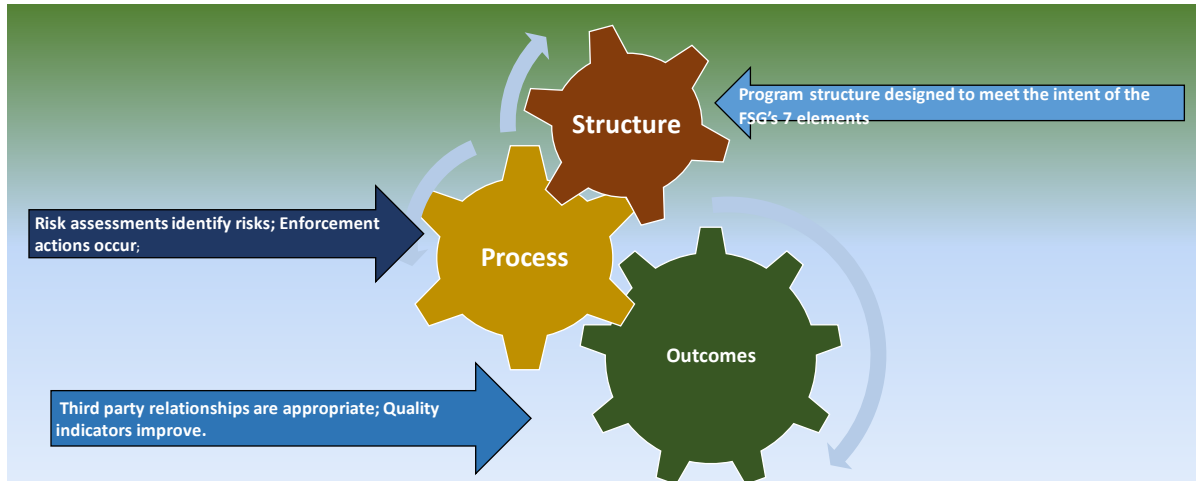
Sheryl Vacca  
SVP/Chief Risk Officer  
Providence St Joseph Health



## Topics for Discussion

- Why Evaluate Program Effectiveness
- What to Measure
- How to Measure
- Response, Reporting and Follow Up

## Core Elements of an Effective Program



## Structure, Process and Outcome Indicators

1. **Structure Indicators** – foundational elements, e.g., policies, procedures, committees, reporting structure, hotline
2. **Process Indicators** – achievement of individual objectives, e.g., survey completed, LEIE screening being done, education plan developed and implemented
3. **Outcome Indicators** – more *behavioral* - the **impact** that compliance efforts have on an organization's level of compliance

# What is the Government Focus?

Federal Sentencing Guidelines state...an organization shall:

1. Exercise due diligence to prevent and detect criminal conduct; and
2. Otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.
3. Effectiveness mentioned in both 2004 and 2010 FSG revisions.

OIG Guidance mentions “effectiveness” at least 24 times in their documents.

OIG and DOJ Settlement Letters

***Desired Effect:*** Promote adherence to applicable Federal and State law, and the program requirements of Federal, State and private health plans.”

## Why Evaluate Program Effectiveness?

### External expectations

- Customers, Business Partners, Shareholders
- Government and Regulatory Agencies

### Internal expectations

- People want to work for ethical companies
- Measurement is part of any good management program
- Management expects results
- Supports risk management
- Essential to improving Compliance Program

# What to Evaluate and Measure

- Design
  - Is the program well-designed?
- Implementation
  - Is the program effectively implemented?
- Effectiveness
  - Does the program actually work in practice?

## Tools to Help Measure Effectiveness

### U.S. Department of Justice (DOJ)

- February 2017 “**Evaluation of Corporate Compliance Program**” insight from the DOJ providing common questions, topics, and factors considered by the DOJ Fraud Section when investigating and evaluating the existence and *effectiveness* of a corporations’ E&C program, *to include an expectation organizations will periodically evaluate program effectiveness*. ([www.justice.gov](http://www.justice.gov))

### U.S. Dept of Health and Human Services, Office of Inspector General (HHS-OIG):

- March 2017 publication issued by HHS-OIG entitled, “**Measuring Compliance Program Effectiveness – A Resource Guide**”. This resource provides insights, examples, and suggested approaches to designing and implementing effective E&C programs, *to include an expectation organizations will periodically evaluate program effectiveness*. ([www.oig.hhs.gov](http://www.oig.hhs.gov))

## How to Measure – *Example Methods*

- ✓ Desk Audits
- ✓ Counting Inputs & Outputs
- ✓ Focus Groups
- ✓ Individual Interviews
- ✓ Statistical Analysis
- ✓ Testing
- ✓ Audits
- ✓ Surveys
- ✓ Exit Interviews
- ✓ Self-Assessments
- ✓ Mock Evaluations
- ✓ Deep Dives

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## Response to Findings

### *Practice Considerations:*

- ✓ When you evaluate, be prepared to act on and respond to what you find
- ✓ Develop and implement action plans as needed for effectiveness and continuous improvement
- ✓ Never believe: “*Everything is perfect*”
- ✓ No matter how good the assessment and findings are, don’t get complacent

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# Reporting – *Findings & Effectiveness*

## *Considerations:*

### **Audience**

- ✓ *Board, Leadership Team, CECO, Compliance Committee, Other*
- ✓ *Ensure governing body and leadership understand their role and oversight responsibility*

### **Assessment Findings and Program Effectiveness**

- ✓ *Share assessment results and level of program effectiveness with the Board and Leadership; provide periodic and on-going reporting and updates*
- ✓ *Metrics/findings shared should be focused, measurable, timely and relevant*
- ✓ *Include open action plans, target dates, status, trends, progress, etc.*

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# Reporting – *Findings & Effectiveness*

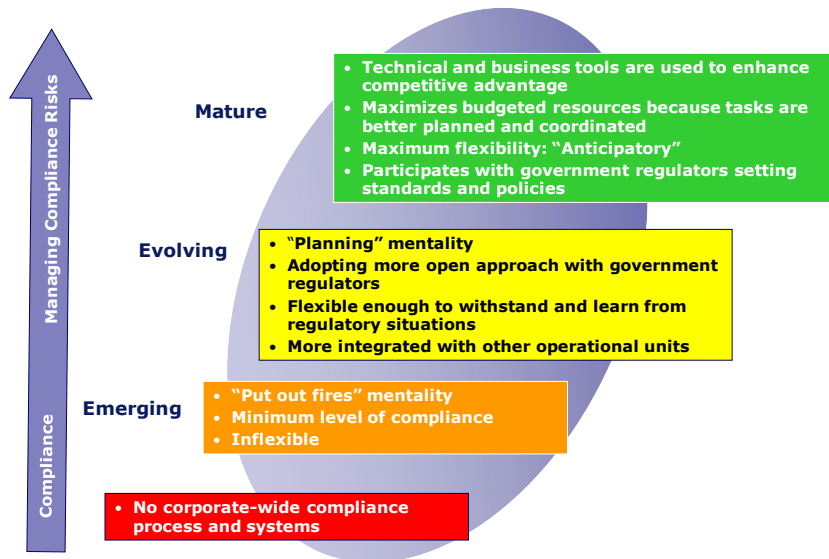
## *Considerations (Cont.):*

### **Documentation**

- ✓ *Keep written assessment materials upbeat where possible; find some positives!*
- ✓ *Follow established Records and Information Management guidelines and standards*
- ✓ *Consider format (paper or electronic, summary version or detail, etc.)*

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## Compliance Program Maturity Determination: Effectiveness Indicators



## Resources

- Measuring Compliance Program Effectiveness: A Resource Guide, HCCA-OIG Compliance Effectiveness Roundtable, January 17, 2017
- U.S. Department of Justice, Criminal Division, Fraud Section, Evaluation of Corporate Compliance Programs
- Practical Guidance for Health Care Governing Boards on Compliance Oversight, OIG, U.S. Department of HHS, AHIA, AHLA and HCCA

# APPENDIX

## Compliance Program Outcome Metrics

Identified Risks	Type of Compliance Risk	Outcome Measurement
<b>Standards of Conduct and Policies and Procedures</b>		
Stark/Anti-Kickback Violations	Regulatory Reputation Financial	1) Decrease in reports of potential violations 2) Decrease in attorney fees related to Stark issues 3) Decrease in fines paid for violations
Data privacy and security breaches	Regulatory Reputation Financial	1) Decrease in number of reportable breaches - Regulatory Fines - Notification and remediation costs 2) Decrease in costs for remediation of breach
<b>Oversight (Governing Body, Compliance Structure and Compliance Officer)</b>		
No Governing Body oversight and knowledge of compliance risks and mitigation activities	Regulatory Reputation	1) Governing Body Committee minutes reflect discussion of compliance risks and mitigation activities on a periodic basis
<b>Education and Training</b>		
Unresolved Conflicts of Interest (AMCs)	Regulatory Reputation Financial	1) Increase in conflict of interest reporting and resolution 2) Decrease in attorney fees related to resolution of conflict issues
Inaccurate Bills Submitted to Government Payors	Regulatory Reputation Financial	1) Decrease in denials and government reimbursement payback

# Compliance Program Outcome Metrics

Identified Compliance Risks	Type of Compliance Risk	Outcome Measurement
<b>Communication/Anonymous Reporting</b>		
Qui-tam report	Regulatory Reputation Financial	1) Increase in employee education related to Standards of Conduct and internal reporting
<b>Enforcement and Screening</b>		
Contracting without controls for appropriate pre-service screening	Regulatory Reputation Financial	1) Increase in percentage of new providers and vendors screening prior to initiating services who have been either debarred or sanctioned by the government. 2) Decrease in attorney/risk management fees for potential lawsuits related to poor quality or lack of appropriate credentialing
<b>Audit and Monitoring Activities</b>		
Insufficient resources to monitor and address high risk regulatory requirements	Regulatory Reputation Financial	1) Approved audit plan activities have been conducted by appropriately trained resources 2) Additional audits, as needed, have been conducted without constraint to overall audit plan
<b>Response and Prevention</b>		
Remediation does not occur and/or is not ongoing	Regulatory Reputation Financial	1) Subsequent audit(s) or external reviews of identified risk areas show remediation has occurred and is sustained

## How to Measure – *Example Methods*

### *Definitions and Examples*

#### Desk Audits

- Helps to assess design; review of mainly documents and records from a stationary location; may require risk subject-matter experts

#### Counting Inputs & Outputs

- Examples include regulatory actions/violations; specific program steps (e.g., employees trained, investigations closed, audits conducted and findings); Helpline calls (e.g., substantiated, asking for advice, etc.)

#### Focus Groups

- More in-depth than surveys; smaller groups; enables group interaction; start with conversational question; avoid including direct reports; consider two facilitators – one for questions and one for notes

# How to Measure – *Example Methods*

## *Definitions and Examples*

### Individual Interviews

- o Quiet, private location, no phones, no interruptions; more candor and depth than other methods; just ask and people will share; consider key people directly involved, observers, managers, stakeholders, etc.

### Audits

Systematic review of people, processes, technology, and records (including electronic); typically a checklist approach (e.g., include some open-ended questions); auditing activity may have a negative image generally so take steps to avoid this challenge

### Testing

- o Test controls and activities. Call the Hotline and provide a mock-issue for resolution; call the consumer complaint line; mystery shoppers. Be careful not to get carried away!

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# How to Measure – *Example Methods (Cont.)*

## *Definitions and Examples*

### Statistical Analysis

- o Screen; look for anomalies, red flags, etc. (e.g., one sales unit with margins out of line, market shares unusually stable in one market); method helps to detect discrimination; hotline stats help identify potential challenge areas and needs

### Surveys

- o Provides broad perspective of employee views; can also include customers, suppliers, etc.; shows reach of program; can benchmark data over time; surveys should be professionally designed (e.g., unprofessional questions and techniques hurt accuracy); avoid processes where a “boss” can directly or indirectly control employee input

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## How to Measure – *Example Methods (Cont.)*

### *Definitions and Examples*

#### Exit Interviews

- In person, phone, or email; can be part of existing processes; people may be more candid, but be aware of potential filtering; examine results for patterns. Example: “Anything you saw or heard while here that is a possible legal or Code violation?”

#### Self Assessments

- Self-review of compliance/ethics performance by managers; best to limit to process and not try to assess wrongdoing; provide a set of questions; more credible if you spot check results for potential filtering; more educational than a true measurement tool

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## How to Measure – *Example Methods (Cont.)*

### *Definitions and Examples*

#### Mock Evaluations

- Engage a colleague to serve as a “mock” prosecutor; conduct a mock evaluation and probe weaknesses (e.g., gaps); great method to identify areas for improvement; real world prosecutors tend to focus by risk area, talk with employees and review what is in writing; prosecutors will expect that you have done the same level of review

#### Deep Dives

- In depth, open-ended reviews; includes a combination of various methods and tools (e.g., audit, focus groups, interviews, etc.); look for risks and challenges not on your “list”; interview at all levels, walk the site, etc.; look for positives and best practices

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