

A Practical Approach to Risk Assessment and How it Ties to Compliance Effectiveness

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Betsy Wade, MPH, CHC, CNA
Chief Compliance & Ethics Officer
Signature HealthCARE

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*"There are risks and costs to a program of action, but they
are far less than the long-range risks and costs of
comfortable inaction."*

~ John F. Kennedy

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Objectives

- Understand how Risk Assessment, Monitoring and Auditing, Compliance Work Plans and Reporting drive Compliance Effectiveness
- Learn how to quantify and track results to demonstrate Compliance Effectiveness to your Compliance Committee and Board
- Tools and Resources to help you assess your organization's Compliance Effectiveness and measure resultsTools and Resources
- References

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1. HOW MANY OF YOU REPRESENT?

- ACADEMIC HEALTH CARE
- NON-PROFITS
- FOR-PROFITS
- PUBLICLY TRADED FOR-PROFITS

2. HOW MANY OF YOU CONDUCT A RISK ASSESSMENT?

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What is Risk?

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What is Risk?

- **Originates from:**
 - the Italian *risco*, which means danger, and *rischiare*, which means runs into danger
- **Noun that means:**
 - a situation involving exposure to danger
 - a possibility of harm or damage against which something that is insured
 - the possibility of financial loss or injury
- **Verb that means:**
 - exposing someone or something valued to danger, harm or loss
 - to incur the risk or danger of
 - acting or failing to act in such a way as to bring about the possibility of an unpleasant or unwelcome event

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What affects Risk?

- **Cash flow and liquidity**
- **Competition**
- **Evolving Technology**
- Financial demands
- **Joint Ventures**
- Laws/Rules/Regulations
- **Mergers/Acquisitions/Alliances**
- Organizational Ethics
- Politics
- Type of industry
- **Unknown**

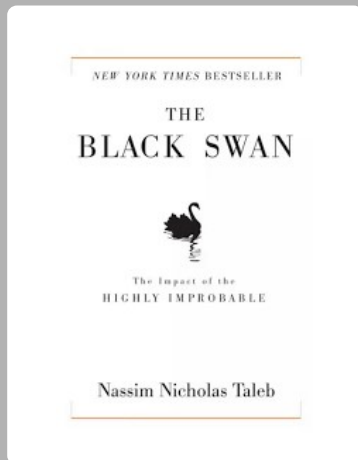
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What are common business risks?

- Cybersecurity
- Government investigations
- Litigation and other legal action
- Reductions in payment rates, unrealized or lost revenue
- Loss or destruction of assets
- Customer dissatisfaction
- Fraud and abuse
- Conflict of interest
- Unacceptable accounting prin

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What are uncommon business risks?

- **Black Swan Events:**
 - an event or occurrence that deviates beyond what is normally expected of a situation that would be extremely difficult to predict
 - an outlier that carries an extreme impact, usually catastrophic
 - the event is a surprise to the observer
- **Examples:**
 - 9/11
 - Black Monday (1987) (2015)
 - dot com bubble (2001)
 - Brexit

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WHAT WOULD BE A BLACK SWAN EVENT IN HEALTH CARE?

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Risk Assessment and Compliance

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Risk Assessment and Compliance

Risk Assessments are foundational to a Compliance Program:

- U.S. Sentencing Guidelines
- Corporate Integrity Agreements

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UNITED STATES SENTENCING COMMISSION
GUIDELINES MANUAL



[Incorporating guidelines amendments effective November 1, 2016, and earlier]

Risk Assessment and Compliance

U.S. Sentencing Guidelines mandate the Organization shall:

(A) **Assess periodically the risk that criminal conduct will occur**, including assessing the following:

- i. The nature and seriousness of such criminal conduct...
- ii. The likelihood that certain criminal conduct may occur because of the nature of the organization's business...
- iii. The prior history of the organization...

(USSG § 8B2.1(b)(5)(7) and (c); USAM 9-28.800 Comment; OECD Handbook, B, p. 10 *et seq.*)

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Risk Assessment and Compliance

Corporate Integrity Agreements include the following Risk Assessment requirement:

- The ***risk assessment*** and internal review process shall require compliance, legal, and department leaders, at least annually, to:
 - (1) identify and prioritize risks,
 - (2) develop internal audit work plans related to the identified risk areas,
 - (3) implement the internal audit work plans,
 - (4) develop corrective action plans in response to the results of any internal audits performed, and
 - (5) track the implementation of the corrective action plan in order to assess the effectiveness of such plans.

The Covered Entity shall maintain the risk assessment and internal review process for the term of the CIA.


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Effective ways to conduct a Compliance Risk Assessment

A Risk Assessment:

- Is a five-stage systematic process of evaluating those things, situations and processes that may cause harm to the organization resulting in non-compliance with regulatory requirements.
- Is conducted by a group of individuals representing different functions in an organization to identify, assess and prioritize compliance risk to reduce the probability of occurrence and/or impact unfortunate events.
- Analyzes what can go wrong, how likely it is to happen, what the potential consequences are, and help an organization determine risk mitigation steps and establish controls.
- Helps the organization judge “the tolerability of the risk on the basis of a risk analysis” while considering influencing factors.

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Effective ways to conduct a Compliance Risk Assessment

- **All healthcare providers that participate in federal healthcare programs, including but not limited to:**
 - Durable Medical Equipment companies
 - Emergency transport services
 - Hospitals and health systems
 - Home health agencies
 - Hospice
 - Pharmaceutical manufacturers
 - Physician practices
 - Skilled Nursing Facilities
 - Etc.

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Effective ways to conduct a Compliance Risk Assessment

- **Risk Assessments are a team effort:**
 - Compliance
 - Internal Audit
 - Legal
 - Risk Management
 - Operations

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WHO ELSE WOULD YOU
INCLUDE IN THE PROCESS?

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**Effective ways to
conduct a Compliance
Risk Assessment**

- **Risk Assessments can be performed anytime:**
 - Usually about the same time annually
 - Usually started during budget planning cycle
 - Typically done during the third and fourth quarters of the organization's fiscal year
 - Continuous process year after year



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Sample steps and timeline for Risk Assessment process

- Q2 – Planning and Risk Identification
- Q3 – Risk Ranking / Prioritization and Develop Work Plans
- Q4 – Compliance Committee and Board approval of Work Plans
- Q1 – Q4 Begin Monitoring and Auditing, analyze outcomes and develop action plans, and report results
- Repeat Cycle



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Effective ways to conduct a Compliance Risk Assessment

- **There is not one way to do a Risk Assessment.**
- **Develop the best method for your organization.**
- **Scale it to the organization's size and complexity.**
- **Points to decide:**
 - Compliance risks only vs. Enterprise Risk Management
 - Internal vs. external third-party
 - Manually vs. risk assessment software

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Risk Assessment Process

- **Adopt Risk Assessment Policy that details:**
 - *Who* is responsible for the Risk Assessment process
 - *What* process or framework is used to conduct the assessment (ie – compliance only, Enterprise Risk Assessment, COSO, RIMS)
 - *When* the annual assessment is conducted
 - *The scope* of the assessment (what entities or departments will be included)
 - *How* the results will be ranked and prioritized
 - *How* the results will be used to create the Internal Audit Plan and Compliance Monitoring Plan
 - *How* the Risk Assessment results, Internal Audit Plan and Compliance Monitoring Plan will be approved by the Compliance Committee and the Board

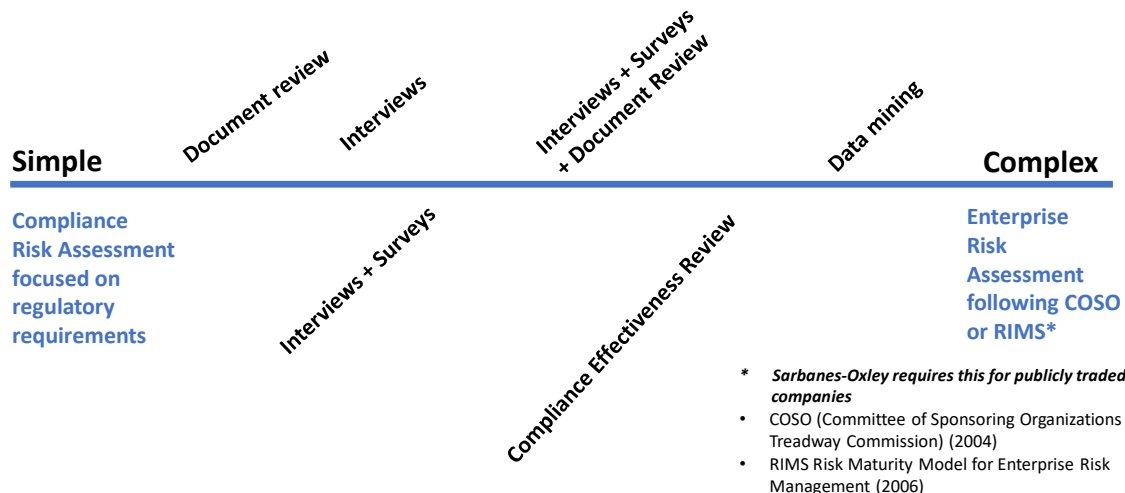
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Risk Identification

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Risk Identification



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Risk Identification

- **Review Documents**
 - Compliance Program Guidance
 - Corporate Integrity Agreements
 - Court documents
 - Government Agency Priorities
 - Industry Newsletters
 - Interviews
 - Laws
 - NCDs/LCDs
 - New Payment Models
- **Other Methods**
 - OIG Audits
 - OIG Work Plan and updates
 - OIG Fraud Alerts
 - PEPPER Reports
 - Previous Audits and Reviews
 - Regulations
 - Special Advisory Bulletins
 - State and federal survey results
 - Third Party Litigation

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Risk Identification



- **Conduct Interviews**

- Board members
- Senior management
- CEOs
- VPs
- Department leaders

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**WHAT OTHER AREAS
WOULD YOU INCLUDE?**

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Risk Identification

- **Conduct Data Mining**
 - PEPPER Reports
 - Denials data
 - CMS Open Payments Database
 - Excluded providers
 - Licensure
 - Star ratings
 - Survey data
 - Litigation data
 - Etc.



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Risk Identification

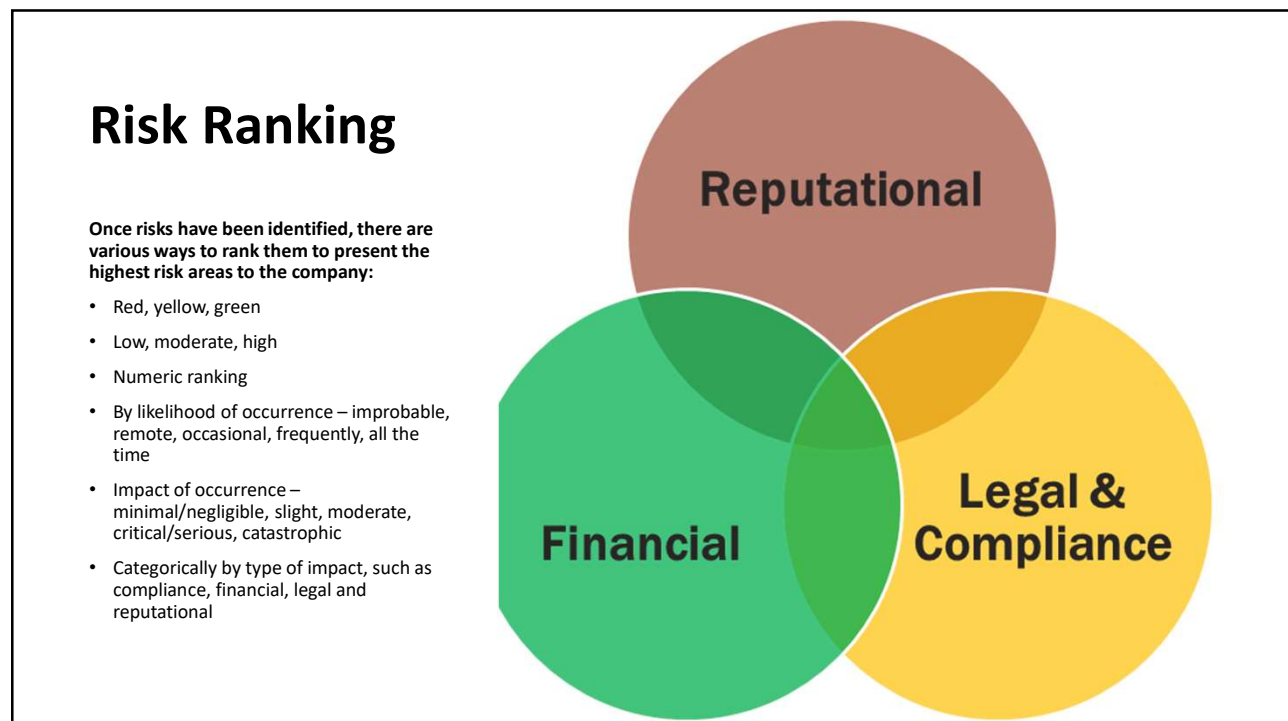
The types of risk varies based on type of entity and the departments within the entity. Here are some examples:

- Bad debt
- Billing and coding
- Clinical quality
- Clinical research
- Cost reports
- Credentialing
- Credit balances
- Documentation
- Emergency Preparedness
- Environmental
- Excluded providers
- Finance
- HIPAA Privacy and Security
- Information Technology
- Licensure
- Marketing
- Medical Necessity
- Mergers, Acquisitions and Divestitures
- Physician Transactions (Stark)
- Policies and Procedures
- Record retention
- Regulatory
- Reimbursement
- Staffing and Payroll Based Journal
- State and federal surveys

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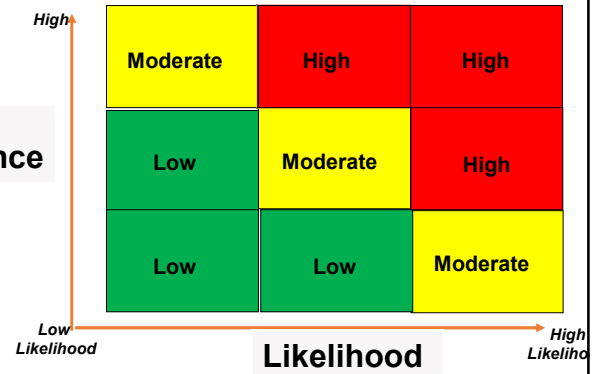


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Risk Ranking

RISK ASSESSMENT SCORECARD		
Risk Rating Scale		
#	Threat Category	RISK PRIORITY
1	Stark Laws & Kickback Statutes	125
2	Privacy and Security	100
3	Disaster Recovery	80
4	Antitrust/Competition Laws	60
5	Corporate Culture	50

Consequence

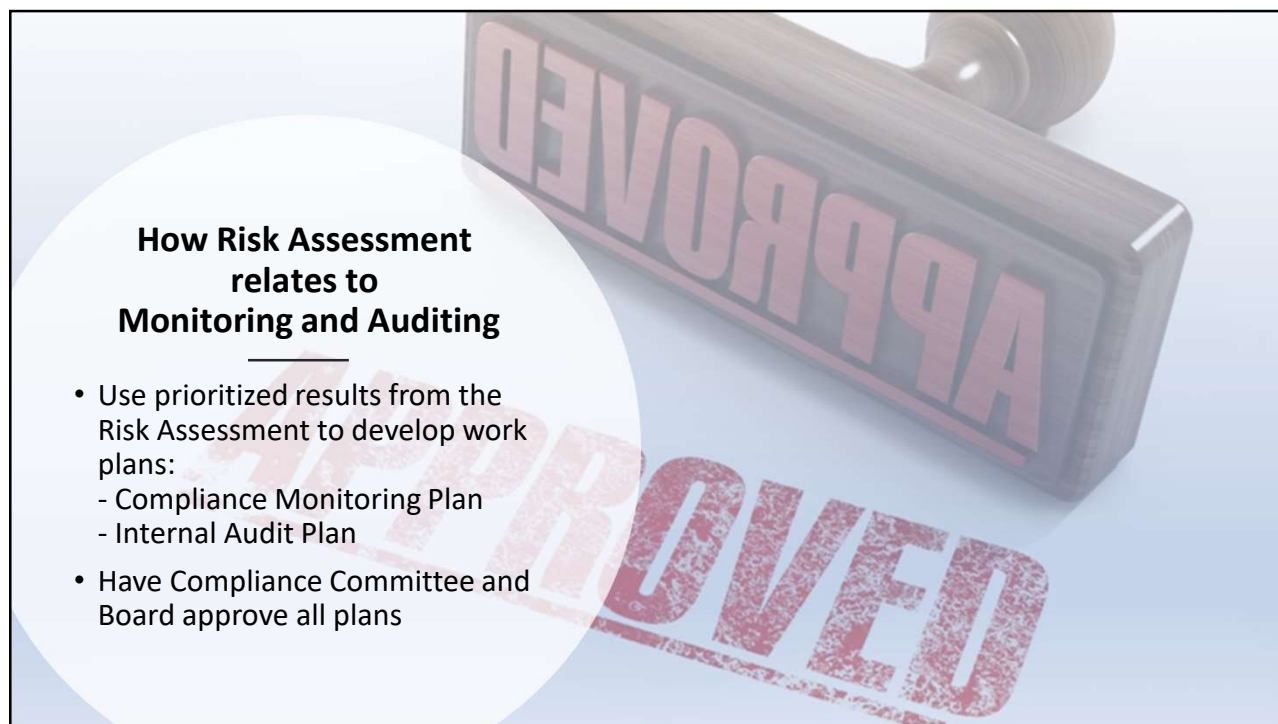


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How Risk Assessment relates to Monitoring and Auditing

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How Risk Assessment relates to Monitoring and Auditing

- Use prioritized results from the Risk Assessment to develop work plans:
 - Compliance Monitoring Plan
 - Internal Audit Plan
- Have Compliance Committee and Board approve all plans

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How Risk Assessment relates to Monitoring and Auditing

- **What should you include in monitoring and auditing?**
 - Education completion
 - Hotline call analysis (types of calls, number of calls, by entity/region/state)
 - Whether hotline calls were logged within 2 business days
 - Repayments within 60 days (government audits, internal audits, compliance monitoring, investigations)
 - Excluded providers
 - ETC....



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How Risk Assessment relates to Monitoring and Auditing

- Conduct auditing and monitoring and report out findings to management, the Compliance Committee and the Board
- Develop Corrective Action Plans with owner
- Conduct follow up to test effectiveness of Action Plans
- Document, document, document

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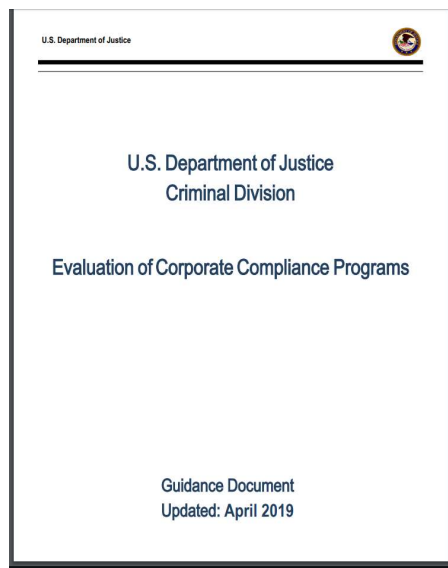


How Risk Assessment and Compliance Effectiveness Tie Together

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How Risk Assessment and Compliance Effectiveness Tie Together

1. Risk Assessment
2. Monitoring and Auditing
3. Compliance Work Plans
4. Measuring and Reporting



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How Risk Assessment and Compliance Effectiveness Tie Together

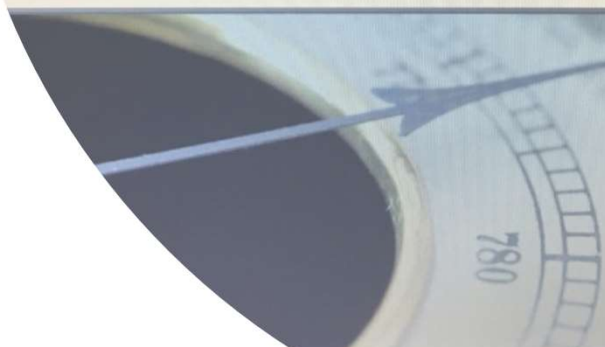
Risk Assessment is a key component of measuring Compliance Program effectiveness:

- *Evaluation of Corporate Compliance Programs* (U.S. Department of Justice Criminal Division, April 2019)
- *Measuring Compliance Program Effectiveness: A Resource Guide* (Health Care Compliance Association-Office of Inspector General Compliance Effectiveness Roundtable, March 2017)
- *Evaluation of Corporate Compliance Programs* (U.S. Department of Justice, February 2017)

Measuring Compliance Program Effectiveness: A Resource Guide

DATE: MARCH 27, 2017

CA-OIG Compliance Effectiveness Roundtable
Roundtable Meeting: January 17, 2017 | Washington, DC



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How Risk Assessment and Compliance Effectiveness Tie Together

Measuring Compliance Program Effectiveness: A Resource Guide

2.56	Compliance Resource knowledge and competence	Survey, focus groups and interviews
2.57	Compliance staff knowledge of current regulatory changes and laws	Document review and interviews. Review certificates of attendance at conferences/other educational events, tools used to keep compliance staff current, compliance budget (to support access to current regulatory changes and laws.
2.58	Monitoring of regulations that impact the organization	Document and process interviews (Refer to Guide for list of questions)
2.59	Risk Assessment Cycle	Audit adherence to risk assessment cycle and annual documented risk assessment has been communicated to oversight committee
2.6	Risk based work plan that covers compliance plan elements with board approval and regular reporting on those projects to board	Compliance Committee and board minutes review
2.61	Work plan development based on risk assessment	Process and document review
2.62	Prioritization of risk and consultation with applicable risk partners (legal, HR, IT, risk management)	Documentation and process review. Is there a risk based plan? How was it developed?
2.63	Exit interview	Compliance concerns that come up in exit interviews are addressed

p. 15, 2.56-2.63

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How Risk Assessment and Compliance Effectiveness Tie Together

• *Evaluation of Corporate Compliance Programs* (U.S. Department of Justice Criminal Division, April 2019, p. 2-3)

- **Risk Management Process** – What methodology has the company used to identify, analyze and address the particular risks it faced? What information or metrics has the company collected and used to help detect the type of misconduct in question? How have the information or metrics informed the company's compliance program?
- **Risk-tailored Resource Allocation** – Does the company devote a disproportionate amount of time to policing low-risk areas instead of high-risk areas...? Does the company give greater scrutiny as warranted to high-risk transactions ... than more modest and routine hospitality and entertainment?
- **Updates and Revisions** – Is the risk assessment current and subject to periodic review? Have there been any updates to policies and procedures in light of lessons learned? Do these updates account for risks discovered through misconduct or other problems with the compliance program?

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How Risk Assessment and Compliance Effectiveness Tie Together

"We recognize that each company's risk profile and solutions to reduce its risks warrant particularized evaluation. ... The starting point for a prosecutor's evaluation of whether a company has a well designed compliance program is to understand the company's business from a commercial perspective, how the company has identified, assessed, and defined its risk profile, and the degree to which the program devotes appropriate scrutiny and resources to the spectrum of risks."

*~ Evaluation of Corporate Compliance Programs
(U.S. DOJ Criminal Division, Updated April 2019)*

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IF YOU WEREN'T DOING
RISK ASSESSMENT BEFORE
WILL YOU NOW?

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Tools and Resources

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Sample Tools and Resources

- Risk Assessment policy
- Risk Assessment questions
- Internal Audit Plan
- Compliance Monitoring Plan
- Compliance Program Effectiveness Gap Analysis Tool
- Compliance Committee and Board Reporting Scorecard

**ALL OF LIFE IS THE
MANAGEMENT OF RISK,
NOT ITS ELIMINATION**

WALTER WRISTON

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Policy and Gap Analysis Tool

Draft Risk Assessment Policy and Process

In accordance with Office of Inspector General (OIG) Compliance Program Guidance, the U.S. Sentencing Guidelines and in support of the eighth element of an effective compliance program, Signature HealthCARE has developed and implemented a centralized risk assessment and internal review process to identify and address risks associated with Signature's participation in Federal health care programs, including but not limited to the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. Annually, Compliance, Internal Audit, Legal and Operations conducts a risk assessment and internal review process that:

- Identifies and prioritizes risks.
- Develop internal audit and compliance monitoring work plans related to the identified risk areas.
- Implements the Internal Audit and Compliance Monitoring work plans.
- Develop corrective action plans in response to the results of any internal audits or compliance monitoring performed, and
- Track the implementation of the corrective action plans in order to assess the effectiveness of such plans.

The risk assessment process is conducted during the fourth quarter of the fiscal year and includes:

- Reviewing the OIG Workplan and Workplan updates for audit areas that are applicable to Signature HealthCARE.
- Reviewing OIG Audit results, Corporate Integrity Agreements, Department of Justice settlement agreements, advisory opinions, fraud alerts and other government publications for risk areas that may be applicable to Signature HealthCARE.
- Reviewing PEPPER Reports, internal risk scorecards, prior audit results, government audit results, exit interviews, hotline call trends, investigation trends, risk management cases, QAPI, for potential areas to review or follow up.
- Reviewing regulatory changes and emerging legislation/regulations, such as changes in government payment models or implementation of new regulations, that could impact the organization.
- Presenting summary of government audit focus areas to Senior Leadership and Operations for consideration during development of the annual Internal Audit Plan and Compliance Monitoring Plan.
- Conducting a survey of Signature entities to identify gaps in compliance.
- Facilitating discussion with Senior Leadership and Operations to address gaps.

Sample Compliance Effectiveness GAP Analysis.xlsx - Protected View - Excel				
A	B	C	D	E
1.4	Root Cause Analysis	What is the company's root cause analysis of the misconduct at issue? What systemic issues were identified? Who in the company was involved in making the analysis?		
1.5	Prior Indications	Were there prior opportunities to detect the misconduct in question, such as audit reports identifying relevant control failures or allegations, complaints, or investigations involving similar issues? What is the company's analysis of why such opportunities were missed?		
1.6	Remediation	What specific changes has the company made to reduce the risk that the same or similar issues will not occur in the future? What specific remediation has addressed the issues identified in the root cause and related opportunity analysis?		
2.4	Conduct at the Top	How have senior leaders, through their words and actions, encouraged or discouraged the type of misconduct in question? What concrete actions have they taken to demonstrate leadership in the company's compliance and remediation efforts? How does the company measure its senior leadership's behavior? How has senior leadership modeled proper behavior to subordinates?		
2.5	Shared Commitment	What specific actions have senior leaders and other stakeholders (e.g., business and operational managers, Finance, Procurement, Legal, Human Resources) taken to demonstrate their commitment to compliance, including their remediation efforts? How is information shared among different components of the company?		
2.6	Oversight	What compliance expertise has been available on the board of directors? Have the board of directors and/or external auditors held executive or private sessions with the compliance and control functions? What types of information have the board of directors and senior management examined in their exercise of oversight in the areas in which the misconduct occurred?		
3.4	Compliance Role	Was compliance involved in testing and decisions relevant to the misconduct? Did the compliance or relevant control functions (e.g., Legal, Finance, or Audit) ever raise a concern in the area where the misconduct occurred?		
3.5	Integrity	How has the compliance function compared with other strategic functions in the company in terms of culture, compensation levels, rank/title, reporting line, resources, and access to key decision makers? What has been the business case for compliance and relevant control functions personnel? What role has compliance played in the company's strategic and operational decisions?		
3.6	Experience and Expertise	How has the compliance and control personnel had the appropriate experience and qualifications for their roles and		

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Auditing and Monitoring Plans

Distribution of Notice of Privacy Practices									
A	B	C	D	E	F	G	H	I	J
1	Sample Compliance Monitoring Plan for FY								
2	Description of Monitoring Activity	Risk	Frequency	Sample Size	Locations	Assigned To	Date	Results	
3	Annual Compliance Education	Compliance Education	Annually	100%	All				
4	Internal Compliance Call and Compliance Monitoring	Compliance Monitoring	Monthly	100%	All				
5	Internal Compliance Call and Compliance Monitoring	Compliance Monitoring	Quarterly	100%	All				
6	Non-Pharmaceutical Compliance	Non-Pharmaceutical Compliance	Annually	100%	All				
7	Non-Pharmaceutical Compliance	Non-Pharmaceutical Compliance	Annually	100%	All				
8	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
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82	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
83	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
84	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
85	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
86	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
87	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
88	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
89	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
90	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
91	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
92	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
93	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
94	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
95	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
96	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
97	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
98	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
99	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				
100	Compliance Officer/Compliance Officer/Compliance Officer	Compliance Officer/Compliance Officer/Compliance Officer	Monthly	100%	All				

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F3 PROTECTED View Be careful—files from the Internet can contain viruses. Unless you need to							
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Compliance Risk Assessment Take Aways

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Compliance Risk Assessment Take Aways

- Risk Assessment isn't a whether or not to do it, it's a must
- Risk Assessments are scalable to the complexity and size of the organization
- There is not one way to do a risk assessment and organizations should determine what works best for them
- Risk Assessment requires a collaborative team
- Risk Assessment is a continuous cycle that is completed annually
- Risk Assessment can help an organization identify potential risks and implement measures to prevent them from occurring
- Risk Assessment is an indication of an effective Compliance Program

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