Risk Assessment Overview

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DHHS OFFICE OF INSPECTOR GENERAL (OIG)

*"Implementing an **effective compliance program** requires a substantial commitment of time, energy, and resources by senior management and [a company's] governing body . . ."*

"While it may require significant additional resources or reallocation of existing resources to implement an effective compliance program, the OIG believes that the long term benefits of implementing the program outweigh the costs."

http://oig.hhs.gov/authorities/docs/cpghome.pdf

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NEW U.S. DEPARTMENT OF JUSTICE (DOJ) GUIDANCE – JUNE 2020

- **Effective compliance programs** play a critical role in preventing misconduct, facilitating investigations, and informing fair resolutions.
- Guidance is intended to help promote corporate behaviors that benefit the American public and ensure that prosecutors evaluate the effectiveness of compliance in a rigorous and transparent manner.
- Intended to provide information on DOJ's multi-factor analysis of a company's compliance program.

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THREE "FUNDAMENTAL QUESTIONS"

1. Is a corporation's compliance program well designed?
2. Is the compliance program being applied "earnestly and in good faith?"
3. Does the corporation's compliance program work?

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IS THE COMPLIANCE PROGRAM WELL DESIGNED AND IMPLEMENTED?

Factors to evaluate in determining whether a corporate compliance program is properly designed for maximum effectiveness:

- **Risk Assessment – monitoring and auditing of high-risk areas**
- Policies and Procedures
- Training
- Communications
- Confidential Reporting Structure
- Investigation Process
- Third Party Relationships
- Mergers and Acquisitions (i.e. due diligence)

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Risk Assessment Process

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Slide 6

TH1 Thomas Herrmann, 9/11/2019

HOW ARE COMPLIANCE RISKS IDENTIFIED?

Is the compliance program designed to detect the types of misconduct most likely to occur in a particular line of business operating in a complex legal and regulatory environment?

- What methodology does a company use to identify, analyze, and address high risk areas?
- Does the company devote resources and scrutiny to high risk areas?
- Does a company's risk assessment undergo regular and periodic review, and is it updated as necessary?

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WHY ASSESS COMPLIANCE RISKS?

- Increased focus on compliance issues by regulators
- Recent high profile enforcement actions
- Ability to use results as a tool to drive strategic changes
- Insight into key issues/risks facing the business
- Expansion to new areas with other regulatory environments
- Pressure from stakeholders (e.g. customers)
- Greater transparency, sustainability, corporate governance

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RISK ASSESSMENT PROCESS

A **Risk Assessment** is a systematic process for identifying, evaluating, and prioritizing potential events that could negatively impact the organization.

A **Compliance Risk Assessment** is a risk assessment process that focuses on the **legal and regulatory risks.**

Enterprise Risk Assessment an assessment of all risks faced by an organization.

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RANKING OF RISKS

- **Likelihood**: What is the likelihood that a risk might occur within the next 12 months (in the context of not having adequate controls in place)?
- **Impact**: What is the impact to the company if the risk occurs?
  - Potential loss
  - Mission/Reputation
  - Financial
  - Legal
- **Assessment of Controls**: Measures the extent to which internal controls have been implemented to minimize a risk occurring.
- **Likelihood x Impact – Controls = Current Net Risk**

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RISK ASSESSMENT BENEFITS

- Identifies and prioritizes risks
- Drives efficient use of compliance resources
- Engages leadership in identifying and prioritizing Compliance risks
- Recommended “best practice” for a Compliance Program
- Process required and defined by OIG in Corporate Integrity Agreements (CIAs)

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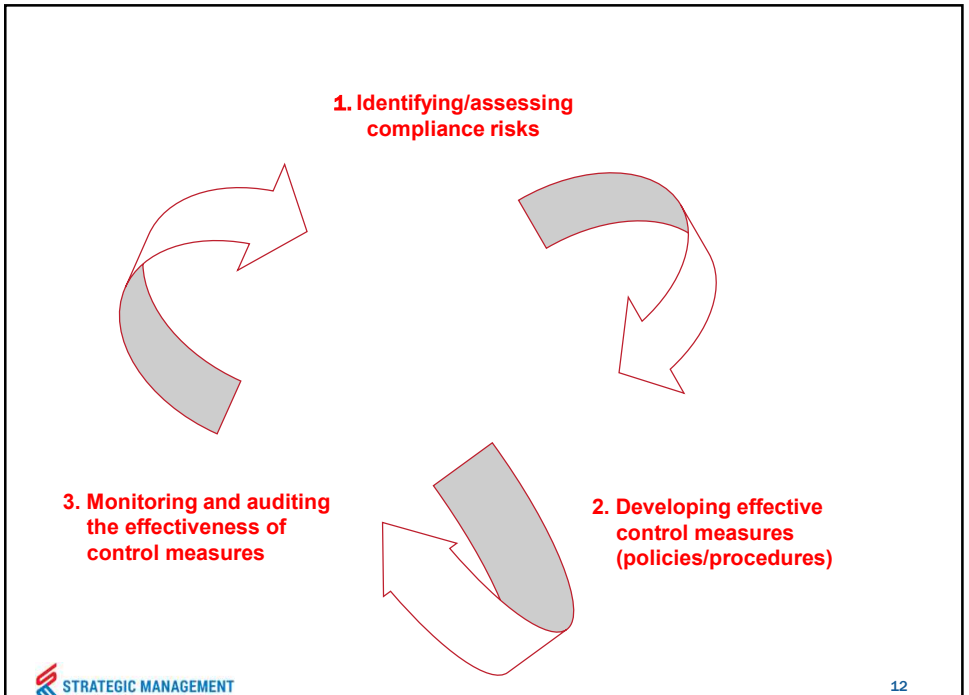

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COMPLIANCE RISK ASSESSMENT PROCESS

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RISK ASSESSMENT PLANNING

Points to consider when planning a risk assessment:

- Logistics
  - Capture of survey results
  - Interviews
  - Setting deadlines
  - Support resources necessary
- Documentation and Reporting
  - Evidencing process and results
  - Development of Controls/Corrective actions
  - Reporting to Executive Leadership and Board of Managers

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IDENTIFYING THE EXTERNAL RISK UNIVERSE

- CMS and OIG reports related to compliance;
- HIPAA related issuances and enforcement actions
- Other government and industry guidance;
- Internal Compliance audits and investigations;
- Results from ongoing monitoring efforts;
- Relevant external audits, evaluations, and reviews;
- Reports to the Compliance Office and Hotline;
- Breach reports; and
- Relevant operational and business events, such as the implementation of new IT systems, mergers and acquisitions, and new business units or facilities.

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IDENTIFYING INTERNAL COMPLIANCE RISKS

- Risk management questionnaires
- Exception reporting
- 'Independent' file reviews
- Positive confirmation of compliance
- Voluntary reporting
- Claims and complaints monitoring
- Financial measurement and reporting
- Oversight and supervision

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RISK SURVEY

Survey key personnel and Program Managers to gather information regarding the controls currently in place to mitigate each compliance risk identified. Questions to consider:

1. Is this Compliance Risk Area applicable to the organization?
2. Provide a ranking for this Compliance Risk Area (Low, Medium, or High).
3. How is this Compliance Risk Area managed? What are recommendations for improvement?

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RISK INTERVIEWS

- Conduct interviews to further discuss the Compliance Risk Areas and controls identified in the Survey responses.
- Interviews to consider:
  - CEO
  - COO
  - CFO
  - CMO
  - CIO
  - Legal
  - Privacy Officer
  - Security Officer
  - Revenue Cycle Managers

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FACILITATED SESSION TO EVALUATE/RATE RISKS

- Are we achieving desired outcome?
- If not, where are the gaps?
- Why are we not achieving this outcome?
- What is needed to do to achieve this outcome?
- What could be the consequences/impact?
- How should compliance efforts be prioritized to fill gaps?

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RISK PRIORITIZATION/RANKING

Conduct a likelihood and impact assessment, resulting in a risk ranking (High, Medium, or Low). This considers potential federal penalties, monetary fines, and financial damage or loss; the likelihood an adverse event would be identified and enforced; a measure of the organization's "risk tolerance"; and consideration of existing controls and risk strategies already in place.

Likelihood x Impact – Controls = Net Risk

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RISK PRIORITIZATION: LIKELIHOOD

What is the **LIKELIHOOD** or probability of an adverse event in this risk area to occur? What type of regulatory scrutiny exists for this risk area? Regulatory scrutiny is based on factors such as potential for audits by regulatory agencies, risk of Corporate Integrity Agreements, or serious negative public relations if sanctions occur.

Likelihood Definition	Score	Definition Range
Very unlikely	1	0-5%
More likely it would not occur but still cause for concern	2	5-20%
Fair chance	3	20-50%
Much more likely than not	4	50-80%
Extremely likely	5	Greater than 80%

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RISK PRIORITIZATION: IMPACT

Points to consider when measuring the risk impact:

- Magnitude of the potential loss
- Effect on the organization's mission and reputation
- Financial loss to the organization, including cost of potential fines and penalties
- Legal implications

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EXAMPLE OF RISK ASSESSMENT RANKING

#	Risk Area	Likelihood Score	Impact Score	Controls Score	Net Risk	Risk Ranking
1	Risk Description	5	5	3	22	High
2	Risk Description	4	5	4	16	High
3	Risk Description	3	5	2	13	Medium
4	Risk Description	3	5	3	12	Medium
5	Risk Description	3	5	3	12	Medium
6	Risk Description	4	3	2	10	Medium
8	Risk Description	4	3	3	9	Medium
9	Risk Description	3	3	3	6	Low
10	Risk Description	4	3	7	5	Low

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DEVELOP WORK PLAN

Step 1
Develop Controls to Mitigate High Risks

Step 2
Develop Compliance Audit Work Plan for Top Risks

Step 3
Implement Compliance Audit Work Plan

Step 4
Develop Corrective Action Plans in Response to Audit Results

Step 5
Track Implementation of Corrective Action Plans

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DEVELOP AUDIT WORK PLAN

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DISCUSSION AND QUESTIONS

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