Environmental Scanning and Risk Assessment

Lori Laubach, CHC, Partner

Objectives

- Define the key steps in a risk management process – how do we improve it
- Understand how environmental scanning could improve your organization’s ability to envision and plan for future risks and opportunities
- Consider how to reduce your risk profile, using the tenets of environmental scanning
What is risk assessment?

**Risk:** Anything that will hinder or prevent your organization from achieving its goals or purpose.

**Risk Assessment:** Evaluating, measuring, and prioritizing likely relevant events or risks that may materially hinder or prevent your organization from achieving its goals or purpose.

Managing risk is a continuous process

Includes Environmental Scan
Why should you care?

- Office of Inspector General (OIG)
- Office for Human Research Protections (OHRP)/Food and Drug Administration (FDA)/Office of Research Integrity (ORI)
- Centers for Medicare and Medicaid Services
- Health Insurance Portability and Accountability Act (HIPAA)
- Stark/Anti-Kickback
- Organization/Board Responsibilities

In Guidance

- American Health Lawyers Association and OIG compliance guidance for Boards
  - Does the compliance program address the significant risks of the organization?
  - How were those risks determined, and how are new compliance risks identified and incorporated into the program?
  - How is the Board kept apprised of significant regulatory and industry developments affecting the organization’s risk?
  - How is the compliance program structured to address such risks?
Why conduct a risk assessment?

- Proactive versus reactive
- Supports enterprise risk management
- Cultural integration
- Raises awareness of program value
- Mitigation of penalties
- Continuous program improvement
- Basis for annual work plan
- Identifies needed resources
- OIG requires for organizations under a CIA

Risks

Compliance versus Internal Audit

**Compliance**

Threat from violations of laws, regulations, code of conduct or standards of practice

**Internal Audit**

Same but also consider financial statement risks and other operational risks
Risk management key components

- **Identify**
  - Identify or designate risks based on experience, regulations, trends, and regulatory agencies

- **Scan**
  - Environmental scan is part of the identify step and will be discussed in more detail

- **Assess**
  - Prioritize risks on the likelihood that an adverse event will occur and the magnitude of the impact if the event did occur

- **Respond**
  - Accept, avoid, or mitigate risks (share, transfer, reduce, control, audit) based on management’s risk tolerance

What is a risk?

- Exposures now and in the next 3-5 years
- Key process or functions which lack mitigation or could have impact on operations
- Complex studies, processes, or functions with multiple stakeholders, hand-offs, control, and authority
- Key strategic initiatives, mergers, etc
How to identify compliance risks

- Start with your organization’s strategies and key initiatives
- Consider regulations – what has changed
  - Updated or deleted policies, and procedures
  - Innovation
- Evaluate the OIG work plan, audits, and enforcement activity
- Consult requirements of other federal and state agencies OCR, OHRP, FDA, OSHA, OSHPD

How to identify compliance risks (cont.)

- Review auditing and monitoring results, prior risk assessments, and reports
- Evaluate how data mining, predictive analytics, and cross-jurisdictional intelligence might impact you
- Survey employees, key stakeholders, vendors
- Conduct individual interviews
- Convene focus groups and brainstorming sessions
- Convene content groups
Other Sources of Risks

- The OIG Work Plan is just a starting point – search for your specialty in other federal reports and keep current in your reading
  

- Keep in touch with your specialty societies that follow regulatory changes

- Search your Contractor website and newsletters for updates and changes in your contractor policy

Environmental scanning-What?

- Systematic process of collecting and analyzing information about an organization's internal and external environments for planning, forecasting, or choosing a preferred future

- Being integrated into leading edge risk management programs
Environmental scanning:
Objectives

- Detecting important economic, social, cultural, environmental, technological, and political trends, situations, and events
- Identifying potential opportunities and threats implied by trends, situations, and events
- Gaining an accurate understanding of the strengths and limitations of your organization
- Identifying and assessing risks as part of your risk management program

Environmental scanning:
Stakeholders

- Internal
  - Involve cross-functional stakeholders and subject matter experts across the organization
- External
  - Vendors, community physicians, legal and risk management advisers, external financial auditors
Environmental scanning: Techniques

- Review the literature broadly
- Consult your colleagues
- Benchmark with peers
- Survey employees, key stakeholders, vendors
- Conduct individual interviews
- Convene focus groups and brainstorming sessions
- Use delphi-type conferences and polling techniques

Sample evolving risks

- Ability to control genetics of humans, animals, and plants
- Bionic people
- Connectivity across the continuum of care
- Convergence of 3D digital design, medical imaging, and 3D printing
- Convergence of nanotechnology, biotechnology, information technology, and cognitive science
- Open health care information versus privacy
- Patient choice, patient power
- Rise in telemedicine
- Wearable devices
Assess and prioritize identified compliance risks

- Evaluate risks on the likelihood that an adverse event will occur
- Rank risks - High, Medium, Low

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Assess and prioritize identified compliance risks

- Quantify the magnitude of the impact on your organization if the event did occur

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| 3     | Major      | Financial loss of > $1 million
|       |            | Significant prosecution, fines or litigation
|       |            | Corporate integrity agreement, federal exclusion
|       |            | Game-changing loss of market share, loss of major donor support
|       |            | Multiple senior leaders leave |
| 2     | Moderate   | Financial loss > $500 thousand to $1 million
|       |            | Prosecution, fines or litigation
|       |            | Report to regulator with immediate correction to be implemented
|       |            | Loss of market share and donor support
|       |            | Major staff morale problems and increased turnover |
| 1     | Minor      | Financial loss of < $500 Thousand
|       |            | Fines or refunds required
|       |            | Reportable incident to regulator with no follow up required
|       |            | Little impact on market share or donor support
|       |            | General staff morale problems and turnover |
Incorporating the Risk Assessment

- Risks identified and prioritized
  - High risk is costly to the practice with a high likelihood of occurrence (Impact and vulnerability)

- Controls
  - Policies and procedures
  - Education and training
  - Audits
  - Quality assessment
  - Management approvals
  - Other

Risk matrix examples
Risk Response Work Plan

- Once risks have been identified and prioritized it is important to take action and address risks
  - Transfer
  - Avoid
  - Reduce
  - Accept
  - Monitor
  - Audit

- Identifying and prioritizing risks can create risk if nothing is done with the information
Reducing risk profile

- A risk profile is an evaluation of the threats to which an organization is exposed and the organization’s willingness to take risks
- Reduce your organization’s risk profile by increasing the creativity and efficacy of your organization’s risk identification process
- Improve your risk identification process with an effective environmental scanning process
- Take what you learn from environmental scanning and develop scenarios of possible futures

Reducing risk profile

- Involve a cross section of experts in evaluating threats and opportunities that could impact your organization
- Assess the current initiatives and controls already in place to address risks
- Determine the additional actions and investments needed to adequately address risks
Part 3 – Reducing risk profile

Case #1 – Convergence of 3D digital design, medical imaging, and 3D printing

• What compliance risks are introduced?

• What mitigation strategies should compliance be using?

• Can you suggest any best practices?

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Part 3 – Reducing risk profile

Case #2 – Rise in Telemedicine

• What compliance risks are introduced?

• What mitigation strategies should compliance be using?

• Can you suggest any best practices?
Wrap up

- We quickly ran through the key steps in a robust risk management process

- We defined and explained how environmental scanning can improve how you identify and address risks

- And together we shared our knowledge and experiences regarding a few emerging or evolving risk area

QUESTIONS?

Lori Laubach, CHC
Partner
Lori.Laubach@mossadams.com
(253) 284-5256
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