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

- Identify
- Assess
- Manage
- Respond

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

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 or designate risks based on experience, regulations, trends, and regulatory agencies
- Environmental scan is part of the identify step and will be discussed in more detail
- Prioritize risks on the likelihood that an adverse event will occur and the magnitude of the impact if the event did occur
- 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
  http://oig.hhs.gov/newsroom/whats-new/
• 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

**ILLUSTRATIVE LIKELIHOOD SCALE**

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Frequent</td>
<td>&gt; 50% chance of occurrence</td>
</tr>
<tr>
<td>2</td>
<td>Possible</td>
<td>&gt; 10% up to 50% chance of occurrence</td>
</tr>
<tr>
<td>1</td>
<td>Unlikely</td>
<td>&lt; 10% chance of occurrence</td>
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</table>

Assess and prioritize identified compliance risks

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

**ILLUSTRATIVE IMPACT SCALE**

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>3</td>
<td>Major</td>
<td>Financial loss of &gt; $1 million</td>
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<tr>
<td></td>
<td></td>
<td>Significant production, flow, or litigation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Corporate (agency agreement, federal inclusion)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Termination loss of market share, loss of major donor support</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Multiple senior leader losses</td>
</tr>
<tr>
<td>2</td>
<td>Moderate</td>
<td>Financial loss of $100K to $1 million</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prescription, flow or litigation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Report to regulator with immediate correction to be implemented</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Loss of market share or donor support</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Major staff morale problems and increased turnover</td>
</tr>
<tr>
<td>1</td>
<td>Minor</td>
<td>Financial loss of &lt; $100K Thousand</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Flow or network minimized</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minor disruption with no follow up required</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Little impact on market share or donor support</td>
</tr>
<tr>
<td></td>
<td></td>
<td>General staff morale problem and turnover</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Risk Area Identified</th>
<th>Improper Payment or Legal/Regulatory Violation</th>
<th>Adverse Publicity</th>
<th>Possible Financial Impact</th>
<th>Government Focus</th>
<th>Overall Risk Measurement</th>
<th>Priority Ranking</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Risk Area Identified</th>
<th>Financial Loss</th>
<th>Prosecution, Fines, or Litigation</th>
<th>Loss of Market Share or Donor Support</th>
<th>Impact to Leadership and Employees</th>
<th>Overall Risk Measurement</th>
<th>Priority Ranking</th>
</tr>
</thead>
</table>

Ranking Scale

- Low 1 ≤1% of Gross Revenue
- Medium 3 3-5% of Gross Revenue
- High 5 >7% of Gross Revenue

RISKS Categor

Risk 1
Risk 2
Risk 3
Risk 4

IMPACT

- Financial
- Reputation
- Legal/Regulatory
- Stakeholders
- Operational
- Strategic

Impact Score

- 5
- 4
- 3
- 2
- 1

VULNERABILITY

Likelihood/History

- Complexity
- Rate of Change
- % Uncontrolled

Total Vulnerability

Risk Priority Score

- 180.0
- 37.5
- 199.5
- 123.5

PRIORITIZATION

Comments

- Assess Risk Assessment Heat Map

1-Physician Contracts/Payments
2- MD Documentation, Billing, Coding, Charge Capture OPPS
4-Allscripts Electronic Medical Record (EMR)
5-Revenue Cycle Vendor Transition
3-Construction/Bond
7-Denials Management
8-ICD-10 Implementation (International Classification of Disease)
9-IT Systems Investment and Security
11-IT Stimulus Funding
12-Manufacturer Credit for Replaced Medical Device Not Reported
6-Government/RAC Audits
10-Changing Healthcare Competitive Environment
13-Infusions Charge Capture (Special Procedures - SPA)
14-OCR HIPAA Privacy and Breach Notification Rules
15-Allscripts/CPOE/Patient Keeper systems integration with ancillary systems
16-Bad Debt and Miscellaneous Adjustments to Patient Accounts Receivable
17-Revenue - Laboratory
18-New Medical Staff/Residency Program
19-Patient Credit Balances
20-Privacy and Security of Credit Card Payment Processing
181/425-Compliance with Medicare’s Transfer Policy
22-CCC Documentation, Billing, Coding, Charge Capture
23-Medical Supplies Inventory, Purchasing
24-Group Purchasing Organization (GPO) Contract Pricing
25-Vendor Credit Memos and Returns Management
26-Readmissions and Pre-Admit Services
27-Information Systems (IS) Security and Disaster Recovery
28-Physician Recruitment and Arrangements
29-Grossman Imaging Center
30-Human Resources Management
31-Emergency Room Compliance and Charge Capture
32-Chargemaster (CDM) Follow-Up
33-Physician Leadership, Buy-In to Quality of Care and Other Major Initiatives
34-Payments for Cancelled Surgical Procedures
35-Employee Meals and Payroll Deductions
36-HR Benefits - Increasing Costs
37-Pharmacy Management
38-Payroll Compliance
39-Executive/Employee Expense Reimbursement
40-Advanced Beneficiary Notice (ABN) Follow-Up
41-Medicare as Secondary Payer (MSP) Follow-Up
42-Sanction Checking for Employees and Vendors
43-Pharma-Compounding Issues
44-Pharma-Off Label Drug Usage
45-Master Patient Index (MPI) - Initiate
46-Payments for Discharges to Swing Beds in Other Hospitals

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?
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 areas

QUESTIONS?

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