AGENDA

- Part 1 – Key steps in risk management
- Part 2 – Environmental scan
- Part 3 – Interactive risk brainstorm
OBJECTIVES

- Define the key steps in a robust risk management process
- 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
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

COMPLIANCE RISK MANAGEMENT IS THE 8TH ELEMENT

- 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?

COMPLIANCE RISK MANAGEMENT IS THE 8TH ELEMENT (CONTINUED)

- 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?
AUDITING COMPLIANCE IS AN OIG “PROFIT CENTER”

- US Department of Health and Human Services OIG Fiscal Year 2016
- $5.00 returned for every $1.00 spent in enforcement for 2014-2016
- $2.5 billion in judgments and settlements
- Exclusion of 3,635 individuals and entities from federal healthcare participation
- 1,410 cases file charging more than 3,018 defendants; 2,041 defendants pleaded guilty and 275 others were convicted in jury trials

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
- Required by the CIA

RISK MANAGEMENT KEY COMPONENTS

PART 1

IDENTIFY
- Identify or designate risks based on experience, regulations, trends, OIG work plan

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

PART 2

SCAN
- Environmental Scan is part of the Identify step and will be discussed in more detail
PART 1 – RISK MANAGEMENT

- Identify
- Assess
- Respond

HOW TO IDENTIFY COMPLIANCE RISKS

- Start with your organization’s strategies and key initiatives
- Draw on your experience
- Consider regulations, policies, and procedures
- 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 (CONTINUED)

- Review auditing and monitoring results, prior risk assessments, and reports
- Evaluate how data mining, predictive analytics, and cross-jurisdictional intelligence might impact you
WHAT IS A RISK?

- Exposures now and in the next 3-5 years
- Key process or functions
- Key strategic initiatives
- Complex studies, processes, or functions with multiple stakeholders, hand-offs, control, and authority

WHAT IS A RISK? (CONTINUED)

- Open-ended surveys or interviews
  - Rely on the expertise of the individual being surveyed
  - Supports a wide range of potential risks
  - Can be difficult to adequately define and compare risks
  - One on one interviews allow for additional probing

ASSESS AND PRIORITIZE IDENTIFIED COMPLIANCE RISKS

### Illustrative Likelihood Scale

<table>
<thead>
<tr>
<th>Rating</th>
<th>Descriptor</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>
</tr>
</tbody>
</table>
**Illustrative Likelihood Scale**

<table>
<thead>
<tr>
<th>Rating</th>
<th>Descriptor</th>
<th>Definition</th>
</tr>
</thead>
</table>
| 3      | Major      | • Financial loss of > $5 million  
• Significant prosecution, fines, or litigation  
• Corporate integrity agreement or federal exclusion  
• Game-changing loss of market share or loss of major donor support  
• Loss of senior leadership |
| 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  
• Minor impact on market share or donor support  
• Expected levels of staff morale problems and turnover |

**RISK MATRIX EXAMPLES**

<table>
<thead>
<tr>
<th>Risk Area Identified</th>
<th>Likelihood of Adverse Events</th>
<th>Possible Financial Impact</th>
<th>Government Focus</th>
<th>Overall Risk Measurement</th>
<th>Priority Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improper Payment or Legal/Regulatory Violation</td>
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<tr>
<td>Adverse Publicity</td>
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</tr>
<tr>
<td>Financial Loss</td>
<td>Prosecution, fines, or litigation</td>
<td>Loss of Market Share or Donor Support</td>
<td>Impact to Leadership and Employees</td>
<td>Overall Risk Measurement</td>
<td>Priority Ranking</td>
</tr>
<tr>
<td>Low</td>
<td>1</td>
<td>1-2% of Gross Revenue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medium</td>
<td>3</td>
<td>&lt;2% of Gross Revenue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>5</td>
<td>&gt;7% of Gross Revenue</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
RISK MATRIX EXAMPLES

RISK TOLERANCE
• Continuum ranging from total avoidance of risk to total acceptance
• Tied to mission, organizational governance, and leadership
• Low probability that all identified risks can be addressed

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
• Identifying and prioritizing risks can create risk if nothing is done with the information
PLANNING EACH ELEMENT

• Define (SMART) goals and implement risk response tracking
  ◦ Specific
  ◦ Measurable
  ◦ Attainable
  ◦ Relevant
  ◦ Time-based

PART 2 – WHAT IS ENVIRONMENTAL SCANNING?

• The exploration phase of the strategic planning process
• The 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: INTERNAL

- Involve cross-functional stakeholders and subject matter experts across the organization including:
  - Board Representative
  - Business Office
  - Compliance
  - Emergency
  - Enrollment
  - Executives
  - HIM
  - Human Resources
  - Imaging
  - IRB Representative
  - Laboratory
  - Legal
  - Medical Staff
  - Nursing
  - Pharmacy
  - Privacy Officer
  - Registration
  - Research
  - Risk Management
  - Security Officer
  - Social Work
  - Strategic Planning
  - Technology
  - Training

ENVIRONMENTAL SCANNING: EXTERNAL

- Vendors
- Community physicians
- Payers
- Professional associations
- Regulatory and accreditation staff, publications, presentations
- Legal and risk management advisers
- External auditor and consultants
- Industry colleagues

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
IDENTIFY COMPLIANCE RISKS

• What is changing?
• What is new?
• What has gone wrong in the past?
• What can go wrong in the future?
• Where are you most vulnerable?
• Where is the greatest exposure?
• What industries and technologies are converging, creating new threats, or opportunities?
• What keeps you up at night?

PART 3 – 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

PART 3 – 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 – SAMPLE EVOLVING RISKS

- Ability to control genetics of humans, animals, and plants
- Bionic people
- Care across the continuum of care
- Change in health care delivery models
- Convergence of 3D digital design, medical imaging, and 3D printing
- Convergence of nanotechnology, biotechnology, information technology, and cognitive science
- Human trafficking
- Open health care information versus privacy
- Patient choice, patient power
- Rise in telemedicine
- Social determinates of health
- Wearable devices
- Human trafficking
- Open health care information versus privacy
- Patient choice, patient power
- Rise in telemedicine
- Social determinates of health
- Wearable devices

PART 3 – REDUCING RISK PROFILE

Based on the topics prioritized by participants, we will discuss as a group, as many topics as time allows:

- 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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