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**Environmental
Scanning and Risk
Assessment**

**Health Care Compliance Association
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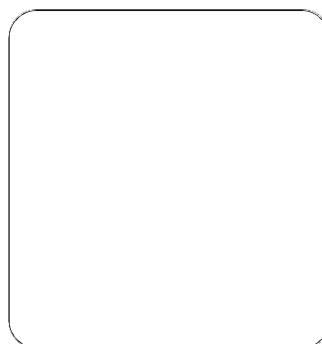
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AGENDA

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

OBJECTIVES

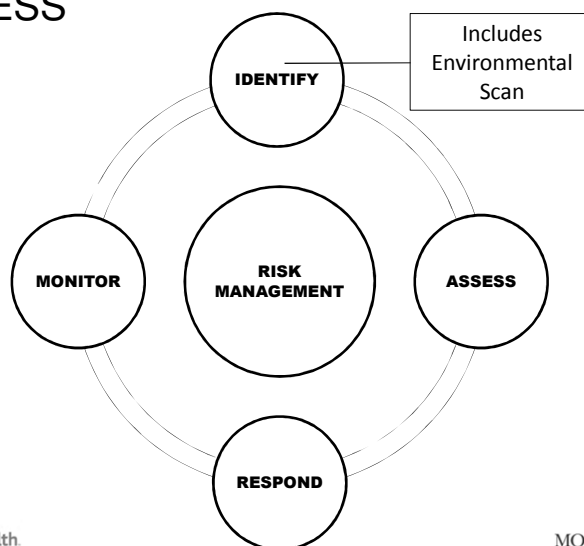
- Define the key steps in a robust risk management process
- Understand how environmental scanning could improve your organization's ability to envision and plan for future risks and opportunities
- Consider how to reduce your risk profile, using the tenets of environmental scanning



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)
- US Sentencing Guidelines (2004)/The 8th Element
- 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?

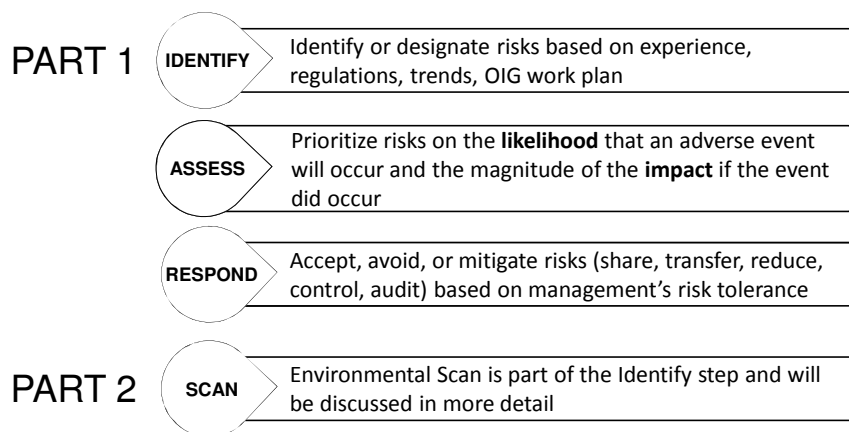
AUDITING COMPLIANCE IS AN OIG "PROFIT CENTER"

- 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 – 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)

IDENTIFY

- 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?

IDENTIFY

- 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)


 IDENTIFY

- 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


 ASSESS

Illustrative Likelihood Scale

Rating	Descriptor	Definition
3	Frequent	> 50% chance of occurrence
2	Possible	> 10% up to 50% chance of occurrence
1	Unlikely	< 10% chance of occurrence

Illustrative Likelihood Scale		
Rating	Descriptor	Definition
3	Major	<ul style="list-style-type: none"> Financial loss of > \$1 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 Expected levels of staff morale problems and turnover

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RISK MATRIX EXAMPLES

ASSESS

Risk	Reputation	Financial	Legal	Risk Impact	Likelihood	Detectability	Vulnerability	Controls	Risk Prioritization Score (RPS)	Comments
				0			0		0	
				0			0		0	
				0			0		0	
				0			0		0	
				0			0		0	

Risk Area Identified	Likelihood of Adverse Event	Magnitude of Adverse Event	Inherent Risk Score	Internal Controls Mitigation	Residual Risk	Comments

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RISK TOLERANCE

The word "ASSESS" is written inside a diamond-shaped icon with a circular border.

- 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

The word "RESPOND" is written inside a diamond-shaped icon with a circular border.

- 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

A circular icon with a diamond-shaped cutout on the left side, containing the word "RESPOND" in all caps.

- Define (SMART) goals and implement risk response tracking
 - **S**pecific
 - **M**easurable
 - **A**ttainable
 - **R**elevant
 - **T**ime-based

PART 2 – WHAT IS ENVIRONMENTAL SCANNING?

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- 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

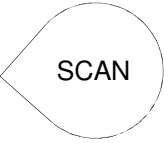
ENVIRONMENTAL SCANNING: OBJECTIVES



- 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



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ENVIRONMENTAL SCANNING: INTERNAL



- Involve cross-functional stakeholders and subject matter experts across the organization including:

Board Representative	Human Resources	Pharmacy
Business Office	Imaging	Privacy Officer
Compliance	IRB Representative	Registration
Emergency	Laboratory	Research
Enrollment	Legal	Risk Management
Executives	Medical Staff	Security Officer
HIM	Nursing	


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ENVIRONMENTAL SCANNING: EXTERNAL



SCAN

- 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



SCAN

- 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



SCAN

- 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

PART 3 – REDUCING RISK PROFILE

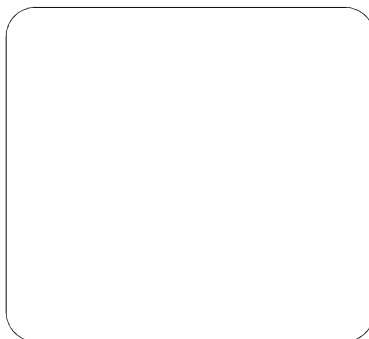
Based on the topics prioritized by participants, we will discuss as a group, as many topics as time allows:

- **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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