

Environmental Scanning and Risk Assessment

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Margaret Hambleton
CHC-F, CHRC
Vice President and Corporate Compliance Officer
Dignity Health

Shirley Komoto
CHC, CIA, PMP
Director, Moss Adams, LLP

MOSS-ADAMS^{LLP}
Certified Public Accountants | Business Consultants

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AGENDA

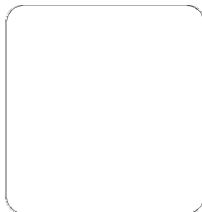
- Part 1 – Key steps in risk management
- Part 2 – Environmental scan
- Part 3 – Interactive risk brainstorm

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OBJECTIVES

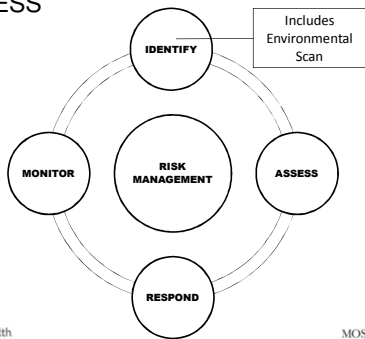
- Define the key steps in a robust risk management process
- Understand how environmental scanning could improve your organization's ability to envision and plan for future risks and opportunities
- Consider how to reduce your risk profile, using the tenets of environmental scanning



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



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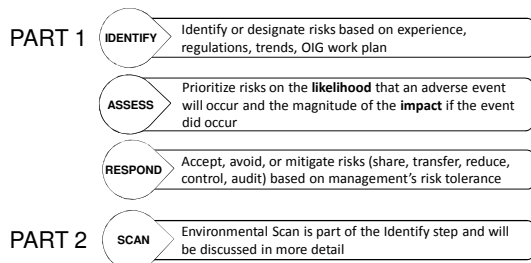
WHY CONDUCT A RISK ASSESSMENT?

- 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



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RISK MANAGEMENT KEY COMPONENTS




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PART 1 – RISK MANAGEMENT


- Identify
- Assess
- Respond

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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


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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



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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

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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

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ASSESS AND PRIORITIZE IDENTIFIED COMPLIANCE RISKS



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

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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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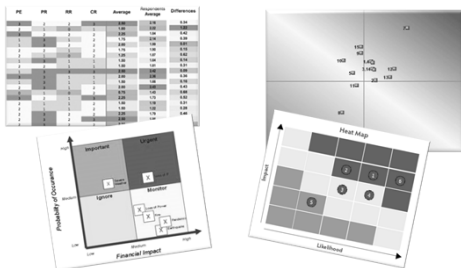
RISK MATRIX EXAMPLES

Risk Area Identified	Improper Payment or Legal/Regulatory Violation	Adverse Publicity	Possible Financial Impact	Government Focus	Overall Risk Measurement	Priority Ranking
Risk Area Identified	Financial Loss	Prosecution, Fines, or Litigation	Loss of Market Share or Donor Support	Impact to Leadership and Employees	Overall Risk Measurement	Priority Ranking

Ranking Scale	Low	1	<=1% of Gross Revenue
		2	1-3% of Gross Revenue
	Medium	3	3-5% of Gross Revenue
		4	5-7% of Gross Revenue
	High	5	>7% of Gross Revenue

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RISK MATRIX EXAMPLES



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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

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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


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PLANNING EACH ELEMENT 


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

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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


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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**




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

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**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

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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?

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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

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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

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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

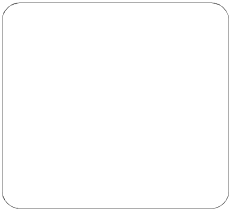
Based on the topics prioritized by participants, we will discuss as a group, as many topics as time allows:

- **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?



Shirley Komoto shirley.komoto@mossadams.com (562) 618-7993
Margaret Hambleton margaret.hambleton@dignityhealth.org (714) 347-7853

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