Interactive Approach to Compliance Risk Assessment in Healthcare

HEALTHCARE COMPLIANCE 204:
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- Identifying risk
- Prioritizing risk
- Reporting and communicating risk
What Are Compliance Risks

Situations and processes that are currently in place at your company that may create exposure to legal penalties, financial forfeiture and material loss an organization faces when it fails to act in accordance with industry laws and regulations, internal policies or prescribed best practices.

A compliance risk assessment is the identification, measurement and prioritization of likely relevant events or risks that may have a material consequence on your company’s ability to achieve its’ objectives.

A compliance risk assessment involves gathering feedback and information from the many sources.
Compliance Risk Assessment

Sources:

- One-on-one meetings with client leaders and the business owners of complex or high-risk operating units.
- Data provided by the client’s operational leaders that will help us to evaluate the potential scope of risks in critical risk areas.
- Industry surveillance: – Reviewing the initiatives being undertaken by peers. – Studying recent enforcement actions that may be relevant from organizations similar to our client. – Trends and discussions that may be prominent at industry conferences and in current government presentations and literature.
- Enforcement agenda for the key oversight agencies that are focused on organizations ostensibly similar to our client’s.
- Results and observations gathered during the current year's audit plan and/or investigative activities that were led by the Compliance Program or Internal Audit, as applicable.
- Feedback from Compliance Committee meetings.
- Controls currently in place at the client to address identified risk areas.
- Trends from the organization's hotline log to evaluate whether they may suggest emerging risks.

Why Do A Risk Assessment?

- Increased government scrutiny
- Proactive versus reactive
- Identify and prioritize risk
- Allocate resources
- Implement corrective action plan
- Reduce compliance violations
- Decrease potential fines and expenses
- Meet Federal Sentencing Guidelines
- Meet the Governing Authorities Guidances
A Risk Assessment Review Will...

- Reduce the settlement if investigated
- Clarify necessary budgeting expenses for compliance
- Prioritize existing compliance resources
- Fulfill your Board’s compliance oversight responsibility
- Determine whether education has been adequate and whether staff understands policies and procedures
- Establish whether employees trust and use the anonymous reporting mechanism
- Ensure that reported incidences are resolved

Universal Business Risks

- Erroneous records and/or information
- Unacceptable accounting principles
- Government criticism
- Legal action
- High costs
- Unrealized or lost revenue

- Loss or destruction of assets
- Public dissatisfaction
- Fraud
- Conflicts of interest
- Inappropriate management policy and/or decision making process

Management responsibility

- Identifying risk
- Implementing controls
  - Avoid risk
  - Transfer risk
  - Accept risk
  - Reduce or mitigate risk

Things that affect risk

- Organizational ethics
- Financial demands
- Technology
- Competition
- Marketing
- Growth organization
  - Mergers/Jt Ventures/Acquisitions/Alliances
- Laws/Rules/Regulations
- Unknowns
Risk Assessment Process

1. Risk Identification
2. Risk Ranking
3. Risk Prioritization
4. Control Evaluation
5. Work & Mitigation Plans

Risk Impact

- Reputational
- Financial
- Legal & Compliance
Risk Areas

- Sample risks
  - Cultural issues
  - No controls in a business process
  - New regulations, systems, products or leadership
  - No policies, guidance or standards in a specific area
  - A need for education
  - A need for policy revision
  - Ineffective communications
  - Billing, documentation and/or coding issues
  - Third party relationships
  - Stark/Physician relationships

Risk Areas......

- US - CMS Fraud Areas
  - Sudden changes in billing
  - Increased beneficiary complaints
  - Geographic changes in billing
  - Identity theft (provider and beneficiary)

- Revenue Cycle Services
  - Complex codes
  - Complex billing procedures
  - Coders proficiency/skillset
  - State laws
  - Pain management

- Human Resources
  - Wage & Hour
  - Workplace Violence & Harassment
  - Hiring/Firing
  - Family Medical Leave Act (FMLA)
  - Drug Free Workplace
  - Equal Opportunity

- Privacy & Security
  - HIPAA Security
  - HIPAA Privacy
  - PCI Standards
  - State Regulations
  - Contractual Requirements
Risk Likelihood

- **Risk Likelihood**
  - Improbable 1
  - Remote 2
  - Occasional 3
  - Frequently 4
  - All the Time 5

- **Likelihood**
  - Occasional
  - All the Time

Risk Detectability and Controls

- **Risk Likelihood**
  - Improbable 1
  - Remote 2
  - Occasional 3
  - Frequently 4
  - All the Time 5

- **Detectability and Controls**
  - Occasional
  - All the Time

- **Likelihood**
  - Occasional
  - All the Time
### Risk Prioritization

<table>
<thead>
<tr>
<th>Topic</th>
<th>Reputation</th>
<th>Financial</th>
<th>Legal</th>
<th>Risk Impact</th>
<th>Likelihood</th>
<th>Detectability</th>
<th>Controls</th>
<th>Risk Likelihood</th>
<th>Comments</th>
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<td>Fraud</td>
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<td>Drugs</td>
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<td>2</td>
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<td>5</td>
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### Internal Controls

**Preventive Detective Directive**
Mitigating Compliance Risks

- Document responsible parties for existing compliance duties, even if some compliance duties are not formally labeled or known as “compliance”.

- Document a compliance risk assessment and catalog risks, including defining your company’s risk appetite.

- Review your compliance risk management approach and suggest changes based upon industry best practices.

- Document how your compliance risks are currently identified, prioritized, scored, and managed.

- Identify where medium or high-level risks may exist that have not been identified and document reasons why some compliance risks may have been previously undocumented.

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Compliance Role

- Management Develops Mitigation Plan for Identified Risks
  - CO facilitates the completion of the mitigation plans with management
  - CO monitors mitigation plans to help ensure risks are mitigated

- CO will use the Risk Assessment prioritization for the starting point for developing the compliance plan for auditing, monitoring and education plans.
- Discuss Risk Assessment with Executive Management to identify any unexplored issues or concerns prior to final report.
- Develop a complete, accurate and realistic report that addresses the needs of the organization.
- Risk Assessment will serve as the “bench mark” to which future risks can be compared.
Risk Assessment Tool

What is the risk?* Describe the identified risk How is risk currently managed?** Comments/Concerns

Example: Serving food
Preparing and serving food to 100 people during an event (food is not being prepared or served by vendor)

Students are required to wash their hands before handling food.
Onsite refrigerator for proper food storage.
Ensuring all equipment, dishware and utensils are clean and sanitary before use.

Some people attending event may have food allergies.
Want to ensure food is cooked adequately.

Fraud  Drugs  Employee Theft

Risk Scoring Tool

Risk Calculation

<table>
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<tr>
<th>Impact</th>
<th>Likelihood</th>
<th>Impact</th>
<th>Likelihood</th>
<th>Risk Score</th>
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<tr>
<td>Moderate</td>
<td>Low-Medium</td>
<td>2</td>
<td>5</td>
<td>10</td>
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<tr>
<td>High</td>
<td>Medium</td>
<td>4</td>
<td>4</td>
<td>16</td>
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<td>Catastrophic</td>
<td>High</td>
<td>6</td>
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<td>36</td>
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</table>

Do you need to do anything else to reduce or control the risk? Responsible Person/Job Title Target Completion Date

Print signage that warns of food allergens and place in front of food station.
Purchase thermometers to check the food temperature.

John Smith 12/30/2014

Risk Register

Purpose of Risk Assessment:  
Department/Unit Name:  
Administrative Structure:  
Completed By:  

Date:  

Date of Next Risk Assessment:  

Identified Risk  Action to take to reduce risk  Responsible Person/Job Title  Update/Status

Actual Completion Date  Current Assessment  Risk Score (Original)  Risk Score (New)

Impact | Likelihood | Risk Calculation Comparison

Catastrophic | Low-Medium | 25 | 10
Mild | Medium | 14.66666667 | 6
Moderate | Low | 8.33333333 | 3

# N/A  

# N/A  

# N/A  

# N/A  

# N/A  

# N/A
Institute a Pharmacy Self-Monitoring protocol

Revise automated drug dispensing software to provide daily reports of manual overrides

Training for staff

Use data analytics & daily reports to monitor activity

How is the risk currently managed?
Policy # __________ defines process for documenting the manual dispensing of controlled substances.

**Drug Diversion**

Staff is overriding the automated drug dispensing software system

How is the risk currently managed?
Policy # __________ defines process for documenting the manual dispensing of controlled substances.

**Solutions**

- Institute a Pharmacy Self-Monitoring protocol
- Revise automated drug dispensing software to provide daily reports of manual overrides
- Training for staff
- Use data analytics & daily reports to monitor activity