Risk Assessments and Work Plans - Key Spokes in the Circle of Compliance
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Laura Range, Vice President, Deputy Chief Compliance Officer
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Agenda

- Why risk assessments are essential
- Sample approach to conducting a meaningful risk assessment
- Compiling and reporting results
- Developing remediation activities and Work Plan items to address risk assessment findings
**Compliance Life Cycle**

**Risk Assessments and Work Plans—An Overview**

**Defined:** A Risk Assessment is the identification and evaluation of potential risk within your organization. It involves the analysis of systems and processes against a benchmark, standard, law or regulation along with the determination of the level risk (high, low, or medium) associated with the activity.

**Work Plan:** The purpose of a Work Plan is to address risk identified in the Risk Assessment process that created the greatest exposure to an organization. Components of the Work Plan include: clear description of the risk, identification of current controls and safeguards in place, assignment of accountability for remediation the risk, and due date for completion.

**Reporting:** An effective Work Plan must be communicated to all key stakeholders at the beginning of the process and with periodic updates on the status of the Work Plan. At a minimum it should include Senior Leadership and the Governing Body of the Organization. In addition the Work Plan is a useful tool in promoting compliance to others within the organization.
**Risk Assessment Preparation**

- **Legal/Enforcement**: Regulatory changes, legal actions, OIG audits and investigations, DOJ cases, etc.
- **Industry Trends**: New business/service lines, changes to current business model, or acquisitions, etc.
- **Auditing/Monitoring Results**: Compliance issues reported, trend data based on reported compliance issues, internal/external audit results, policy reviews, scorecard results, etc.
- **Financial Impact**: Negative impacts with regard to the organization's bottom line or future earnings.
- **Reputational Impact**: Damage to the organization's reputation— as a result of bad press or social media discussion, loss of customer trust, or decreased employee morale.
- **Risk Assessment Preparation**

**Risk Assessment Process: Sample Approach**

1. **Survey Development**: Determine type of risk assessment and expected return
2. **Conduct Risk Assessment**
3. **Collect Risk Information**
4. **Scoring and Prioritization**: Tabulate risk assessment results and categorize findings
5. **Remediation Planning, Reporting**: Compile results, review, and develop Work Plan. Report results for input/approval by key stakeholders
6. **Manage Work Plan completion**
7. **Remediation Tracking**: Ongoing

<table>
<thead>
<tr>
<th>Date</th>
<th>Start</th>
<th>End</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Conduct Risk Assessment</td>
<td>Date</td>
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<tr>
<td>Date</td>
<td>Collect Risk Information</td>
<td>Date</td>
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<tr>
<td>Date</td>
<td>Manage Work Plan completion</td>
<td>Date</td>
</tr>
<tr>
<td>Date</td>
<td>Remediation Tracking</td>
<td>Date</td>
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**Broad Based Risk Assessment Survey: Sample Approach**

**“Proactive” Risk Assessment**

Survey to Define Risk Universe
Potential Participants:
- Board
- Senior Leadership
- Department Directors
- Staff

**Questionnaire/Indicators**
SURVEY QUESTIONS: (personal interviews or written survey)
1. Identify 5 potential compliance risks you see for your areas of operation and explain why.
2. Identify the top 3 (in rank order, 1 being the top priority) compliance risks for the organization. Explain why you chose these risks.
3. For each risk, do you feel current compliance safeguards (policies and procedures, etc.) are adequate to control risk?

SUPPORTING DATA INDICATORS:
Provide responders useful background material for consideration
Performance Data

**Focused Risk Assessment: Sample Approach**

**“ Reactive” Risk Assessment**

Survey to Define Risk Universe
Potential Participants:
- Department Directors
- Staff

**Process/Deliverables**
SURVEY INSTRUCTIONS:
1. Process
   - Establish a work group made up of hospital staff that are involved in the charging, coding, or ordering of replacement medical devices for procedures performed on an O/P or I/P basis (i.e. Materials Management, Surgery staff: surgery supply managers and charge entry staff, coders). The goal of the work group is to review the current processes/controls in place at your hospital to ensure Medicare is billed correctly for Medical Device Replacements.
2. Deliverables:
   1) Flow chart of process/controls established for your hospital,
   2) Documentation of the steps taken, findings, a summary of the controls in place to ensure compliance and any recommendations,
   3) Plans for ongoing monitoring to ensure compliance, and
   4) No chart reviews are required, unless necessary to understand the process at your hospital.

SUPPORTING MATERIALS:
Provide useful background material for consideration by the group. Examples: Medicare charges to date, Medicare rules and regulations, OIG audits, current related policies and procedures.
Comparison of the Two Risk Assessment Approaches

Focused

- Reinforces staff on importance of adherence to controls and procedures in a specific area of operations
- Allows timely response to Gov't initiatives or recent findings
- 30 to 60 Day process

Broad Based

- Process and results provide a larger impact on the Culture of Compliance, accountability and individual ownership of compliance
- Opportunity to provide education to those involved in the process and to receive their unscripted feedback
- Results will often impact inter-disciplinary functions within the organization and drive the Annual Work Plan
- 12 months or greater to address prioritized risk

Allows the organization to proactively identify and address unknown risks, rather than only assessing the potential impact of known risks.

Sample Survey

SECTION 1: HOSPITAL RISK IDENTIFICATION

Directions

- Based on the Top Triad risks for your facility, for each risk select the three most significant contributing factors and identify the level of risk. You are also asked to provide an explanation (paragraph) outlining the reason for your selection, i.e., why did you select this risk. Please be specific.

Risk Area

Contributing Factor

Level of Risk

SECTION 2: ORGANIZATION RISK IDENTIFICATION

Explanation of Risk

Sample Response

Sample Response

Explanation

Sample Response
Summary of Key Data Points Resulting from the Survey

Data Points

- Risk Area or Category assists in analyzing the overall survey results.
- Primary Contributing Factors help to further understand the reason for the perceived risk.
- Sufficient Safeguards identify if current safeguards are adequate.
- Risk Level assessed as High or Elevated, Medium, Low or alternatively whether it Will Happen, Most Likely to Happen, Might Happen, Likely not to Happen.
- Free Text Comments will contain a wealth of information that may generate additional categories for use in evaluating and tabulating the data.

Categorizing Free Text Data: Examples

- Regulatory
  - Medical Necessity
  - Physician Management
  - Provider Based Entities

- Physician Management
  - Credentialing
  - Medical Staff Management
  - Employed Physicians

- Hospital Operations
  - Policy Management
  - New Service Lines
  - Loaning Equipment
Survey Results by Category: Examples

- Physician Management: 25%
- Regulatory: 19%
- EMTALA: 13%
- Hospital Operations: 6%
- HIPAA: 5%
- OIG Work Plan

Harnessing the Power of Excel Pivot Tables: An Example

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<tr>
<th>Category</th>
<th>Elevated</th>
<th>Medium</th>
<th>Low</th>
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<th>% of Total</th>
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<td>17</td>
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<td>24</td>
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Compliance Charter

Work Plan Design: Sample Approach

Regulatory

Core Focus Areas

Physician Relationships
Provider Based Entities
Medical Necessity
**Work Plan Design: Sample Approach**

### Regulatory
- Design training for leadership on how to have difficult conversations with physicians from a legal, compliance and regulatory perspective
- Evaluate the “Site Neutral Payment” Final Rules impact on provider based entities
- Review processes used to determine medical necessity for inpatient status and O/P procedures

### Core Focus Areas
New Service Lines
Joint Venture/Partnership Management
### Work Plan Design: Sample Approach

- Design and develop tools for use when exploring and implementing new service lines,
- Evaluate monitoring effectiveness of Joint Ventures/Partnerships

### Work Plan Design: Additional Risk Considerations

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<tr>
<th>Hospital Operations</th>
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<td>Hotline Call Trends</td>
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<td>Audit Findings (Internal and External)</td>
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## Work Plan Monitoring: Sample Approach

### Hospital Operations

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<tr>
<th>Focus Area</th>
<th>Description</th>
<th>Current Risk Mitigation</th>
<th>Action Items</th>
<th>Focus Area Leader(s)</th>
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### Questions?
We should add a slide for Questions?
Range, Laura, 2/14/2017