How Comprehensive Risk Assessments and Work Plans Set the Foundation for Successful Compliance Programs

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Objectives

• Develop a deeper understanding of compliance risk assessments and work plans and their importance within the framework of the compliance program
• Explore various methods for conducting risk assessments and work plans, including a practical case study
• Discuss practical considerations and approaches
Trinity Health’s 22-state diversified system

$17.6B
In Revenue

1.3M
Attributed Lives

$1.1B
Community Benefit Ministry

131K
Colleagues

7.5K
Employed Physicians and Clinicians

25.6K
Affiliated Physicians

93
Hospitals*

22
Clinically Integrated Networks

13
PACE Center Programs

109
Continuing Care Locations

*Owned, managed or in JOAs or JVs.

Trinity Health - Integrity & Audit Services

CEO

SVP – Integrity & Audit Services, System Integrity & Compliance Officer

Vice President - Audit Services

Vice President - Integrity & Compliance

Trinity Health Integrity & Audit Committee

Hospital CEO/Executive

Hospital Integrity & Compliance Officer

Director - HIPAA Privacy & Privacy Official

(Dual accountability)
Nuts & bolts: what is a compliance risk?

• Many definitions
• Some attempts to distinguish compliance risks from other forms of risk
• Typically defined as any potential violation of laws, regulations, rules, Codes/Standards of Conduct, or professional ethics that threaten an organization’s ability to prosper – financially, reputationally or in terms of the quality of service delivered to customers/patients.

Nuts & bolts: what is a compliance risk assessment?

• Process that provides valuable insights into the compliance vulnerabilities of the organization and state of the risk mitigation environment
  • Strength of controls
  • Risk culture – awareness, importance and how managed
• Well known as an element of an effective compliance program
• Essential element of broader compliance program and directly informs the development of mitigation activities
Why conduct a compliance risk assessment and what makes it an essential element of an effective compliance program?

• Helps identify and mitigate compliance risks and make efficient use of resources
• Can’t address a risk unless you’re aware of it
• Helps identify gaps in risk mitigation efforts
• Ever changing and complex compliance risks (e.g. MACRA/APMs)
• Addition of new business lines and units
• Adds value to compliance function – growing need to understand broader range of risks and related business processes
• Helps compliance leadership understand and accurately report on risks to senior management and board

Why conduct a compliance risk assessment and what makes it an essential element of an effective compliance program? (continued)

• Provides a structured approach – not ad hoc or based on intuition of compliance staff
• Educates senior management and other business line leaders
• Provides support for requests for additional resources
• Enables senior management and board to more effectively meet their responsibilities to organization
• Develops a more risk sensitive culture
Compliance risk assessments versus other types of risk assessments

- Enterprise Risk Management (ERM) and Internal Audit risk assessments
- Need for a separate compliance risk assessment given stakes
- Scope of compliance, ERM and IA risks assessments are different
  - ERM – strategic goals of organization
  - IA – more focus on financial statements and operations
- There is some overlap in process and scope
- May be opportunities to coordinate with ERM and IA processes

Understanding risks helps add value

- Inherent vs. residual risks
  - Inherent – risks absent of controls and mitigation activities
  - Residual – risks evaluated relative to controls and mitigation activities
  - More efficient to focus on residual risks – risk mitigation activities and work plan should be developed around residual risks
  - But if inherent risks are high, important to ensure controls are working effectively
- A deeper understanding of key risks and related business processes adds value to compliance function and risk assessment process
  - When and how an adverse event may occur
  - Mapping risks to accountable stakeholders and controls
  - Prioritizing risks
  - Efficiently allocate resources to address risks
Risk assessment methodology – common approach

• Need for a systematic approach to the risk assessment
  • Definitions can be helpful
• A common approach includes:
  1. Identify business lines/units and key processes
  2. Identify regulators and enforcement agencies
  3. Identify risks and controls and map to accountable stakeholders
  4. Evaluate sufficiency of controls
  5. Rate residual risks
  6. Report

Trinity Health’s risk assessment methodology
Trinity Health – planning and data gathering

- Initial Risk Assessment and Surveys process
  - Electronic Surveys (see handouts)
  - Compliance risk assessment tool (see handouts)
- Risk Assessment and Planning Meetings (Who, When, Where)
- Topics to discuss
  - Strategic initiatives
  - Significant System Implementations
  - Regulatory Compliance Matters
  - Market Pressures and Competition
  - Other Priorities

Trinity Health – leveraging our understanding of organizational risk

Relevant Sources

- Regulatory Agencies/Enforcement
  - DHHS/OIG
  - CMS
  - DOJ
  - IRS Tax-Exempt Organization Division
  - HRSA Office of Pharmacy Affairs
  - Office of Civil Rights (HIPAA)
  - DEA
  - State Medicaid activity
  - State Attorney Generals
- New or changing laws and regulations
- Prior year audit findings
- Industry media reports
- Accounting Changes
- State insurance departments
- Trinity Health Enterprise Risk Management
Trinity Health - Top-Down/Bottom-Up Risk Assessment

- Finance
- Human Resources
- Risk
- Legal
- Operations
- Physician
- Population Health
- Revenue
- Supply Chain Management
- Treasury
- IT
- Clinical
- External Auditors

- Integrity & Compliance Officers
- Compliance Committees
- Management and Leadership

The risk assessment process is inherently subjective – not all stakeholders will necessarily agree on the identity and priority of risks.

Trinity Health - Top Risks and Planning Priorities

**Hospitals**
- Inpatient services
  - Coding of Complex DRGs
  - Proper Patient Placement (IP v. OP/Observation)
  - Discharges and Readmissions
  - Discharge/Transfers Coding
- Outpatient services
  - Bundled services
  - Billing modifiers
  - New OPPS regulations
- Provider-based clinics
- 340B drug discount program
- Sec. 501(r) requirements for tax-exempt hospitals

**Physicians**
- E&M documentation and coding
- Use of Advanced Practice Professionals
- Billing modifiers
- Highly-productive providers
- Use of Electronic Health Records
- Relationships with industry/ conflicts of interest

**General**
- Financial relationships with physicians and referral sources
- Clinical research compliance
- Conflicts of interest/physician relationships with industry
- New Acquisitions integration
- New Reimbursement Models
- Legislative reforms

**Alternative Payment Models (ACOs, BPCI)**
- Compliance programs
- Participation requirements
- Gainsharing distributions

**Continuing Care**
- Inpatient Rehabilitation
  - Coverage/medical necessity
  - IRF assessments and reporting
- Home Health
  - Face-to-Face visit requirements
  - OASIS assessments
  - Conditions of Participation
- Skilled Nursing Facilities
  - MDS assessments, RUG scoring
  - Utilization of therapy services
- PACE
  - HCC/risk adjusted coding

**HIPAA Privacy and Security**
- OCR Audits
- Breach Response
- Social Media
- External Communications
Trinity Health - re-thinking compliance risks in Alternative Payment Model (APM) programs

Compliance Risks in Fee for Service
- Overutilization of services
- Lack of medical necessity, appropriateness
- Coverage requirements
- Procedural coding
- Billing requirements
- Provider documentation

Compliance Risks in APMs
- Underutilization of services
- Withholding medically necessary services
- Avoidance of “At-Risk” beneficiaries
- Beneficiary freedom of choice
- Other APM program requirements
- Selection of network providers
- Risk adjusted coding (HCCs, diagnosis)

Risk assessment methodology – additional thoughts

- No single approach to an effective process
- Process should be tailored to your organization
- Common features of good and bad approaches
- Strive toward a proactive, dynamic process
  - Update on a regular basis to address changes to risks and controls

Risk Assessment Maturity Model

<table>
<thead>
<tr>
<th>Reactive</th>
<th>Fragmented</th>
<th>Optimized</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unstructured</td>
<td>Mechanical, periodic process</td>
<td>Structured</td>
</tr>
<tr>
<td>Key risks missing</td>
<td>Results don’t adequately inform work plan</td>
<td>All key risks identified</td>
</tr>
<tr>
<td>Lack of leadership involvement</td>
<td>Lack of support</td>
<td>Support of leadership</td>
</tr>
<tr>
<td>Not linked to work plan</td>
<td>Not regularly updated</td>
<td>Active participation</td>
</tr>
<tr>
<td>Not evaluating or considering controls</td>
<td></td>
<td>Ongoing process</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Coordinating with other risk assessments</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Common language used</td>
</tr>
</tbody>
</table>

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Developing the compliance work plan – the basics

- Purpose of the work plan is to address key risks identified in compliance risk assessment process through risk mitigation activities
- Consider available resources and risk appetite of organization
- Typical activities – audits, monitoring, education and training, policies and procedures, technology implementation, etc.
- Typical format
  - Description of risk
  - Controls present
  - Accountable stakeholder
  - Description of risk mitigation activity
  - Timeline for completion
  - Categorized by business unit and line
- Work plan should be reviewed and approved by board and senior management
- Work plan should be communicated to key stakeholders

Trinity Health’s work plan development process
Trinity Health - developing the compliance work plan

- Now what????
  - What do you do with all of this data and information
  - Need to balance resources and experience compared with the different risks identified
  - No right or wrong way (high level analysis, heat maps, matrixes, etc.)

- Example System office compliance work plan
  - Projects performed using System level resources to support local compliance program

- Example of hospital Compliance Officer internal work plan
  - Use of local resources to support the local compliance program

Trinity Health - discuss auditing in today’s environment
Trinity Health – identified risks addressed on the work plan

Audit and Consulting Projects
Monitoring Support
Education & Training
Input to Policy & Procedure Development
System/Process Improvement

Compliance Work Plan

Trinity Health - examples of work plan projects

<table>
<thead>
<tr>
<th>Project Description</th>
<th>Objective/Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home Care Services</td>
<td>Evaluate compliance with Medicare home health regulations, focusing on recent changes to OASIS assessments, physician face-to-face visit requirements, and the Medicare prospective payment system (PPS) for home care.</td>
</tr>
<tr>
<td>Hospital Services: Inpatient and Outpatient Review</td>
<td>Assess documentation quality, ICD-10-CM and ICD-10-PCS coding accuracy, query composition and overall compliance with Medicare/Medicaid and other third-party payer requirements for a sampling of inpatient and outpatient hospital claims.</td>
</tr>
<tr>
<td>Hospital Services: Proper Patient Placement (Two Midnight Rule)</td>
<td>Data analytics will be used to assess compliance with CMS Two Midnight Rule requirements and Company standards for the proper placement of patients in inpatient or outpatient level of care.</td>
</tr>
<tr>
<td>Inpatient Rehabilitation Services</td>
<td>Assess documentation, coding and billing for compliance with Medicare Conditions of Participation and payment requirements for inpatient rehabilitation facilities (IRF), with particular focus on recent changes in IRF assessments and reporting.</td>
</tr>
<tr>
<td>Professional Services: Compliance Benchmarking and Monitoring</td>
<td>Benchmarking employed providers claims data in comparison to CMS and industry data with focus on areas of compliance risk identified by CMS audit contractors and DHHS-OIG. Results of analyses are used to support continuous compliance monitoring by provider networks.</td>
</tr>
<tr>
<td>Professional Services: Physician Practice Review</td>
<td>Assess the adequacy, completeness and timeliness of medical record documentation, usage of provider documentation templates, coding systems, internal controls, charges, and coding in accordance with Medicare and Medicaid requirements for Trinity Health provider networks. Additionally, ICD-10 coding will be evaluated to identify appropriateness of assignment which is aligned with costs and risks associated with Hierarchical Condition Categories (HCC).</td>
</tr>
<tr>
<td>Professional Services: Education and Support</td>
<td>Education and training support provided to management and staff working in employed provider networks and clinics, including monthly and annual education programs.</td>
</tr>
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Trinity Health – developing the local compliance work plan

- Overview of process
- Example Local Compliance officer work plan
- See handout

Other considerations and tips

- Don’t reinvent the wheel - leverage existing materials when possible
- Communication is key – difference between compliance risk assessment and other similar processes, importance, timing, etc.
- Consider developing a work group to lead efforts
- Define scope, e.g. all business lines?
- Risk universe – don’t need to identify every conceivable risk out there
  - May be a point of diminishing returns
  - Focus on high risks and material risks
- Be sure to include SMEs in the process
Other considerations and tips (continued)

- Risk assessment should be dynamic and tailored to your organization (whether conducted internally or by a consulting firm)
  - Think of it as a living document
- Consider efficiency – the mitigation activities that will provide the most benefit
- Important to document your efforts and processes
- Multi-state health systems need to consider state law
  - Local and regional compliance personnel are essential in this process
- Know when to engage external experts
- Leverage data when possible to identify risks

Other considerations and tips (continued)

- Track changes to risk ratings over time – can provide useful insights
- Consider implementing new technologies – reputation monitoring tools, social media data, surveys, risk mapping tools, etc.
- Don’t let the process become just a routine exercise – a good process can add tremendous value to the compliance program and the organization
Questions

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