Overview of Risk Assessments and Workplans

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Regulatory Requirements

• The U.S. Sentencing Commission Guidelines Manual (USSG) states:
  • “In implementing [a compliance program], the organization shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each requirement set forth...to reduce the risk of criminal conduct identified through this process.”¹

• Requirement in Corporate Integrity Agreements

¹ U.S. Sentencing Guidelines Manual § 8B2.1(c)
Risk Assessment Process

• Enterprise Risk Management or Compliance Risks?
  • Enterprise Risk Management
    • Addresses all forms of risk
      • Regulatory/Legal
      • Finance
      • Operational
      • Reputational
  • Compliance Risk
    • Limited to those areas under the umbrella of compliance (legal/regulatory)

Why Perform a Risk Assessment?

Be PROACTIVE, not reactive!
Risk Assessment Process

Risk Identification

<table>
<thead>
<tr>
<th>How</th>
<th>Who</th>
<th>When</th>
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</thead>
<tbody>
<tr>
<td>Interviews</td>
<td>Compliance</td>
<td>Annually, but a continuous process</td>
</tr>
<tr>
<td>Surveys</td>
<td>Internal Audit</td>
<td></td>
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<td>Document review</td>
<td>Legal</td>
<td></td>
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<tr>
<td>Audit results</td>
<td>Risk Management</td>
<td></td>
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<tr>
<td>Industry concerns</td>
<td>Stakeholders</td>
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</table>
Risk Rankings

Depends on:

- Likelihood of the risk occurring
- Severity of the impact to the organization
- Level of risk tolerance

Dealing with risk:

- Avoid
- Mitigate
- Transfer
- Assume

Risk Ranking
Workplans and Actions Plans

**Workplans**
- Reasonable
- Responsible parties
- Reportable

**Action Plans**
- Measurable
- Planned follow-up
- Future risk assessment

Trinity Health’s Risk Assessment Methodology
Trinity Health’s 22-state diversified system today

$19.3B In Revenue

1.5M Attributed Lives $1.1B Community Benefit Ministry

125K Colleagues 7.5K Employed Physicians & Clinicians 27.5K Affiliated Physicians

92 Hospitals* in 22 states 18 Clinically Integrated Networks 13 PACE Center Locations 106 Continuing Care Locations

*Owned, managed or in JOAs or JVs.

Integrity & Audit Services Leaders

President & CEO

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

Vice President - Audit Services

Vice President - Integrity & Compliance

Director - HIPAA Privacy & Privacy Official

Integrity & Compliance
- Integrity & Compliance Program Operations
- hotline
- education and communications
- exclusions screening
- support to RHM/MCOs
- support to regulatory investigations
- due diligence
- clinical research support
- internal audits
- coding and billing
- clinical
- regulatory

Audit Services
- Internal Audits
  - Financial
  - Operational
  - Information Systems
  - Regulatory (non-clinical/coding)
- Support to external financial statement audit
- Fraud investigations
- Continuous auditing and monitoring

Privacy
- Trinity Health Privacy Program leadership
- Support to RHM Privacy Officers
- Privacy incidents/breach response
- Research support

CPA, CIA, CISA, CFE

CHPC

Ministry CEO/Executive

Ministry ICOs

(Dual accountability)
Our risk assessment considers audit and enforcement priorities of health care industry regulators

Department of Justice
• Active in Medicare Strike Force regions
• Qui Tam/whistleblower investigations
• Opioid crisis current top priority

HHS Office of Inspector General
• 360+ active projects as of 4/30/19
• OIG Work Plan updated quarterly

Centers for Medicare and Medicaid Services
• CMS contractors perform regular audits of Medicare claims
• CMS also conducts program audits of Alternative Payment Models (ACOs, bundled payments)
• National Medicare FFS payment error rate in 2018 = 8.12%

Health Resources & Services Administration
• 340B program audits of hospitals and pharmacies

Internal Revenue Service
• Tax-exemption requirements for hospitals again being discussed in Congress

HHS Office of Civil Rights
• Investigation of HIPAA privacy and security breaches

State Medicaid Audits
• Some states have established Inspector General roles
• All states have established Medicaid Fraud Units
• Resources and extent of auditing varies by state

Trinity Health – planning and data gathering

• Initial Risk Assessment and Surveys process
  • Electronic Surveys
  • Compliance risk assessment tool

• 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
Top Survey Questions

* Please rank what you consider to be the top 3 risks, 1 being the highest risk, out of the risks listed below. On the next page, you will be asked to provide comments explaining why you have chosen these risks.

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Rank 1</th>
<th>Rank 2</th>
<th>Rank 3</th>
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</thead>
<tbody>
<tr>
<td>Cyber Security</td>
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<td>System Implementations</td>
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<td>IT Application Security</td>
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<td>Physician Financial Relationships</td>
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<tr>
<td>Mergers and Acquisitions</td>
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<tr>
<td>Physician Network Finance/Operations</td>
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<td>Significant Accounting Estimates</td>
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<tr>
<td>Regulatory Compliance</td>
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<tr>
<td>Pharmacy Controlled Substances</td>
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<tr>
<td>Risk Contracting Models</td>
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<tr>
<td>Health Plan Finances/Operations</td>
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<tr>
<td>Clinical Informatics Quality Measures and Reporting</td>
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<td>Wage and Hour/Labor Relations</td>
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<td>Other (1)</td>
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<td>Other (2)</td>
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<tr>
<td>Other (3)</td>
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Do you have any compliance risks with specific operating areas or process in your RHM?

☐ No
☐ Yes (please explain)

Over the past 12 months, have there been key management or significant staff turnover in key departments critical to compliance/operational/finance activities (e.g. PFS, HIM, Patient Access, Case Management, Clinical Documentation, Finance)?

☐ No
☐ Yes (please explain)

Are there significant new programs, service lines changes, or Ministry initiatives planned for the coming year?

☐ No
☐ Yes (please explain)

Are there any recent or anticipated changes in regulatory requirements at the local, state, or national level that you expect will have a significant impact on your Ministry?

☐ No
☐ Yes (please explain)
Top Survey Questions

During the past 12 months, have any regulatory agencies such as CMS (e.g., MAC, RAC, ZPIC), DHHS-OIG, Medicaid, state attorneys general, IRS or HRSA conducted audits / investigations / reviews resulting in significant findings?

- No
- Yes (please explain)

With the increased focus on payment for quality and performance outcomes, are there specific compliance / operational / financial risks you think your Ministry / Trinity Health should focus on in the next 12 months?

- No
- Yes (please explain)

Are there specific areas or processes you would like Integrity & Audit Services to review in FY18?

- No
- Yes (please explain)

* If applicable, please select the primary clinical / operational role that applies to you. Selecting one or more of these roles will direct you to detailed operational and compliance questions for the area.

- Home Care / DME
- Hospital (Operations / HIM / Billing / Revenue)
- Inpatient Rehabilitation Facility
- Physician Network
- Skilled Nursing Facility
- N/A
Risk Assessment Tool

**Accountable Care Organizations (ACO)**
- Medicare Durable Medical Equipment and Supplies Risk Areas (DMEPOS)

**Hospital Inpatient Services**
- Program for All-Inclusive Care for the Elderly (PACE)

**Compliance Program Risk Areas**
- Part C Medicare Advantage Plans
- Part D Prescription Drug Program

**Hospital Outpatient Services & Ambulatory Surgical Centers**
- Skilled Nursing Facility Risk Areas
- Research

**Other Hospital Compliance Risk Areas**
- Inpatient Rehabilitation Facility Risk Areas
- Home Health / Community-Based Care Risk Areas

**Ambulance/Transportation Areas**
- Physician and Other Professional Service Providers Risk Areas

**Hospice Risk Areas**
- Long-Term Care Hospitals (LTCH aka LTAC)

<table>
<thead>
<tr>
<th>Risk Assessment = The probability (or the likelihood of an occurrence) and the impact (or the effect of an occurrence). Probability + Impact = Risk Assessment:</th>
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<tbody>
<tr>
<td>High + High = High Risk</td>
</tr>
<tr>
<td>Moderate + High = High Risk</td>
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<tr>
<td>Low + High = Moderate Risk</td>
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<td>High + Low = Moderate Risk</td>
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<tr>
<td>Moderate + Low = Moderate Risk</td>
</tr>
<tr>
<td>Low + Low = Low Risk</td>
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</table>

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

- Price transparency
- 1 Day / 3 Day bundling rules
- 2 Midnight Rule
- EHR documentation practices
- Injections/infusions
- ICD-10 coding
- 340B drug discount programs
- Financial relationships with physicians and other referral sources
- Medical necessity NCD conformance
- Radiation oncology
- Financial Stewardship (PSAs)
- Readmissions
- Lab PAMA data collection
- Sepsis
- On/off campus provider-based clinics
- Radiation oncology
- Research—IRB, research operations and billing

Top Compliance Risks – Medical Groups and Provider Services

- Diagnosis coding/HCCs/risk adjustment
- Provider based “Creative Care” clinics
- Highly productive providers
- Prescribing practices for controlled substances
- Advance Practice Providers
- E/M services-documentation, coding
- EHR documentation practices
- Financial relationships with physicians and other referral sources
- Telehealth/Telemedicine
- Annual Wellness Visits
- Transitional Care Management
- Chronic Care Management
- Financial relationships with physicians and other referral sources
Top Compliance Risks – Continuing Care Services

**Home Care**
- Standard Audit Program (Coding, documentation F2F, monitoring, OASIS completion)
- New PPS effective 1/1/20; Audit Program will be amended to reflect changes and will be used April 2020 and forward
- Care coordination initiative

**Hospice**
- Standard Audit Program
- Palliative Care versus Hospice Placement
- Appropriate Certifications and Recertifications

**Skilled Nursing Facilities**
- Standard Audit Program (Coding, documentation, MDS, medical necessity)
- New PPS effective 10/1/19; Audit Program will be amended to reflect changes and will be used January 2020 and forward
- Care coordination initiative

**IP Rehab**
- Standard Audit Program (IRF PAI, coding, documentation)
- New PPS effective 10/1/19; Audit Program will be amended to reflect changes and will be used January 2020 and forward
- Care coordination initiative

**PACE**
- Baseline Standard Audit Program reviews

Flexibility in Risk Assessment Process
Flexibility in Risk Assessment and Work Plan

- Trinity Health fiscal year is from July 1 – June 30, risk planning starts in January prior to fiscal year (6 months before new fiscal year)
- Work plan is developed for the whole year
- Work plan audits and activities are evaluated on a continuous basis
  - Ask the question, does this project still makes sense today
  - Make adjustments based on new information
- OIG updates work plan on a monthly basis to capture emerging risks
- Targeted Probe & Education (TPE)
- OIG/MAC/State audits
- Monthly Integrity & Compliance officers meeting
- Current auditing results

Trinity Health’s work plan development process – ongoing auditing and monitoring based off of Risk Assessment
Trinity Health – Auditing and Monitoring

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.)

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

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

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 - 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 records 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>
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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
- Use of data
Other considerations and tips (continued)

• Risk assessment should be dynamic and tailored to your organization
  • 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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