Integrating a New Healthcare Entity into Your Compliance Program

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Speaker Introductions

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**Agenda**

- Due diligence
- Impact of due diligence results
- Integration considerations and planning
- Integration: Day 1 / Week 1 / Month 1

**First Impressions Are Everything**

The creation of the new relationship(s):

- Your culture and theirs (mission statement)
- Non-profit, for-profit
- Secular, non-secular
- Independent versus coming from / into a system
First Impressions Are Everything

Diligence and integration planning go hand in hand – the discovery and dialogue is ongoing (never enough)

- Face-to-face opportunities are golden
- Balance need for information and visits with understanding that patient care and business operations are still the first priority
- Be mindful of body language, facial expressions, tone, how you speak to them and each other – we/they are watching/listening
- Comfort level that colleagues are open and forthcoming about their risks
- Words matter

No Matter How Well You Plan and Execute, there will always be a curveball
Due Diligence Review

Due Diligence

- Multidisciplinary process that:
  - Identifies existing risks that may be assumed through the transaction in order to develop mitigation strategies;
  - Identifies post-closing gaps; and
  - Informs the integration plan

- Perform due diligence:
  - With the entity(ies) targeted to join your organization, and
  - Entities being transferred within your organization
**Due Diligence Team**

- Clinical Integration
- Continuing Care (Home Care, Assisted Living, SNF, Hospice)
- Physician Network Operations
- Operations
- Revenue Excellence
- Payer Strategies
- Finance
- IT
- Mission
- Governance and Office of the President
- Human Resources
- Community Benefit
- Advocacy
- Communications
- Tax / Treasury
- Insurance / Risk Management
- Legal
- Compliance

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**Compliance Program Effectiveness**

An effective compliance program is critical in order to understand risks and liabilities that may impact transactional purchase price, Day 1 readiness and transaction execution.

**Imperatives**

- Understand potential exposure from Target programs by completing thorough due diligence
- Understand compatibility of programs between Target and Buyer
- Establish controls and policies to support compliance
- Develop a “culture of compliance” through education/training
- Consistently monitor activities for regulation or contract adherence

**Compliance Focus Areas (Illustrative)**

- **Employee Compliance**
  - Evaluate whether the organization has a compliance program that knows about and has addressed its regulatory risks.
  - Uncover risks such as: coding inaccuracies, documentation gaps, improper billing, etc.

- **Payer Contract Provisions**
  - Evaluate whether the organization has a compliance program that knows about and has addressed its regulatory risks.
  - Stark and anti-kickback violations that have not been addressed can have significant financial impact.

- **Legislation/Regulatory Environment**
  - Uncover risks such as: coding inaccuracies, documentation gaps, improper billing, etc.

- **Representative Activities**
  - Evaluate compliance program effectiveness through management interviews and review of compliance program documents, including evaluation of auditing and monitoring activities, exclusion checks, to assess risk of non-compliance.
  - Gain an understanding around regulatory activities such as corporate integrity agreements, subpoenas, investigations and/or repayments.
  - Evaluate paid claims for compliance with documentation, medical necessity requirements.
  - Evaluate the controls that support compliant employment or contracting with physicians.
Compliance Program Review Toolkit

Leadership & Oversight
- Board Reporting
- Department Resources
- Interviews

Risk Assessment/Work-Plan
- Audit Reports (Internal/External)
- PEPPER, RAC Reports
- Coding/Billing Review

Code of Conduct
- Compliance Program Management System
- Hotline Usage
- Discipline and Remediation
- Exclusion checks

Education
- Training (Orientation, Annual)
- Compliance Awareness Week

Conflicts of Interest
- Disclosure Processes
- Privacy
- Non-retaliation

Policies / Procedures
- Agendas / Minutes
- Contracts (physician, vendor)

Government Investigations
- CIAs
- Non-Prosecution Agreements

Program Metrics
- Root Cause Analysis
- Corrective Action Plans

Compliance Program Effectiveness
Assessment / Gap Analysis

- Read compliance committee minutes and Board reports
  - Follow up with questioning on compliance issues being reported

- Are interviewees aware of any material violations or potential compliance issues with risk of:
  - Health System Entity becoming subject to a Corporate Integrity Agreement ("CIA") or Settlement Agreement with CIA provisions
  - Criminal prosecution of management
  - Exclusion from Medicare and/or Medicaid
  - The finding of a violation of law by a regulatory body
Compliance Program Effectiveness
Assessment / Gap Analysis

- Look for issues and reserves for repayments
  - RAC audits
  - Routine audits
  - Investigations, settlements, CIAs

- Review:
  - PEPPER and assess outliers (coding, care management, billing)
  - Risk assessment, compliance work plan and related compliance and coding audits
  - Provider based billing
  - 340B
  - Physician arrangements

- Department(s) or new service lines yet to be audited

Due Diligence Red Flags

- Turnover of compliance officer / compliance team
- Lack of or limited compliance work plan
- Lack of audit/monitoring, minimal or unclear documentation of audit findings
- Lack of exit interviews for departing employees and related documentation
- Interviewees describe compliant procedures, but the process is not documented (policies, procedures, auditing and monitoring)
- Lack of corrective action plans and or root cause analysis in order to develop effective corrective actions
- Lack of reports to the full Board, lack of Board training on compliance or attention to and support of compliance initiatives
- Lack of repayments over time
Due Diligence Red Flags

- "Read the public information (e.g., annual report, 10-K); it's all there"
  - Read the 10-K footnotes!

- What's in the CIA / Non-Prosecution Agreement?
  - Obligations / warranties from the Target with the OIG, DOJ

Due Diligence Red Flags
Assess findings

- Is a repayment or voluntary disclosure needed
  - Work with experienced legal counsel to assess

- Conversation with Target - Need facts and circumstance specifics
  - What is the amount of liability you want to take on?
  - Risk?
  - Potential of whistleblower?
  - Front page news?
How Nimble Are You?

- Due diligence process can sometimes move very quickly
  - be prepared to assess and react
- Can you assess that Stark issue in 30 days?

It’s OK to Slow / Stop Due Diligence

- Communication is key: Make sure diligence leadership is informed of any compliance concerns that arise during due diligence
- Report issues, observations and potential impacts or implications
- Implications can include regulatory actions, repayment obligations, need for corrective actions and/or financial reserves
- Work with your organization’s leadership to develop an action plan
- Obtain legal advice where needed
What Can You Live With vs. a Deal Breaker?

- Issues identified in due diligence that require renegotiation of the sale
- Is the buyer accepting the obligations?
  - Compliance issues
  - Overpayments
  - Stark issues
- Understand how the transaction is structured and the your organization’s responsibility for compliance issues / liabilities

Due Diligence Informs and Sets Expectations for Integration
Effective Due Diligence = Day 1 Readiness

- Creation of new relationships
- Supports development of implementation of integration plan
- Early expectation setting

Integration Concerns

- Managing a complex process while keeping focus on core business operations
- Realizing synergy targets
- Integrating systems/processes
- Building a strategic platform
- Customer (patient) retention
- Workforce retention
- Cultural alignment
- Business continuity
Challenges to Compliance

- Capital Constraints
- Organizational Competing Priorities
- (Lack of) Communication
- Buyer’s / Seller’s Remorse

Commonly Overlooked Aspects of Due Diligence

- Culture
- Impact on People
- Resources Needed to Succeed
Culture

- Are the organizations compatible?
- Will the culture undermine the ability to adapt and integrate?
- No two organizations function in exactly the same way, no matter what their apparent similarities may be
- Due diligence must include an effective assessment of the two cultures and an understanding of what it will take for the two organizations to integrate

"A breeze blowing against the tip of an iceberg...it’s not going to have much impact unless the currents beneath the surface are going the same way"

(http://blog.thinkwiseinc.com/how-do-you-view-culture)

The Iceberg Effect

Understanding the influence of ORGANIZATIONAL CULTURE

Organizations are a lot like icebergs. They are mainly "observed" by the effects of beliefs and habits that are "below the waterline" and not readily thought about.

Most organizational initiatives focus on the "above the waterline" aspects of the organization. So, just like a breeze blowing against the tip of an iceberg, it's not going to have much impact unless the currents beneath the surface are going the same way.

This is what culture does for the organization.

(http://blog.thinkwiseinc.com/how-do-you-view-culture)
Impact on People

➢ What’s the tipping point for your compliance team to take on the Target?
  • Compliance FTE resources
    o Span of control
    o Right sizing
  • Knowledge base / skill set of compliance team
  • Program management and audit tools
  • Scope / Depth of the annual Work Plan

Integration Planning
Integration Plan

- Sets expectations
  - Buyer’s core values, mission statement, authority matrix

- Touch base / Reference point
  - A documented, repeatable process
  - Eight elements of an effective compliance program

Use Due Diligence Summary for Development of the Integration Plan

- Due diligence summary is your starting point; drill down to further understand the compliance department, tools and activities
  - Depends on the veracity and work performed during due diligence

- Develop a Compliance Program Integration Plan; take into consideration:
  - Organization structure
  - Infrastructure
  - Interdependencies
  - Costs (and expected financial synergies)
  - Gaps noted during due diligence

- If staff turnover is expected near or at Day 1, plan for timely transition of investigations, meetings, work plans, corrective actions
Take the Time ....

To orient the Target entity about your entity and your compliance program
- Leadership and oversight
- Team members
- Code of Conduct
- Culture of compliance

Elements of Integration
Due diligence findings frame integration planning

- Expectation Management (Core Operating Practices)
- Executive Sponsorship & Leadership
- Integration Methodology
  - Baseline Plan
  - Interdependencies
  - Tools & Templates
  - Database for tracking & reporting progress
  - Dashboards
  - Checklists
Current State of the Target’s Compliance Program

Operating Model

- [Name] is the Chief Compliance officer
- Compliance committee members
- Board committee (or equivalent)
- (Number) individuals are responsible for compliance activities
- Compliance activities include:
  - Compliance training
  - Compliance audits (approximately [number] per year)
  - HIPAA (privacy and security)
  - Clinical research
  - Hospital and physician practice
  - Investigations
- Tools and costs
  - Governance, risk and compliance system
  - Hotline monitored by outside company
  - Exclusion checks
  - FMV – [internal + any outsourced [add cost]]
  - Physician contract database [add cost] per month
  - Conflicts of interest tracking [add cost]
  - Other publications and regulatory research tools [add cost]
- Contracts and costs
  - Consultants
  - Law firms

Highlights of A Compliance Integration Plan

Program Transition
- Code of Conduct
- Hotline number / compliance management system
- Policies, procedures

HR / Workforce
- Job Description updates
- Annual Review form updates

Education & Training
- Learning Management System courses
- New hire education
- Compliance Awareness Week

Board / Sr. Leader Orientation
- Authority matrix and Board reporting
- Compliance Work Plan
- Local authority and accountability

IT Integration
- Website / Intranet access
- Access to shared files, audit tools
- Access to Learning Management System
Integration Planning Considerations

Deal terms and conditions impacting compliance:
• Merger or acquisition?
• What’s the authority matrix?
• Will colleagues be leased, hired, or both?
  o Subject to full new hire process including exclusions screening, or run it separately 30 days before transaction date?
  o Consider you may need to repeat some processes if you have blended hire/lease arrangement

Hotline, compliance program management
• Transition service agreement (software)
• Archiving or transferring the data

What departments (other than compliance) perform compliance functions?
• Exclusions screening (new hire, monthly / annual)
• Conflicts of Interest

FTE resources:
• Compliance officer and / or staff departure
• New compliance program support hires
• Third-party contractor auditing support
Integration Planning Considerations

Compliance Interdependencies and Interactions
- Legal, Internal Audit
- Revenue Cycle, Quality, Safety, HIM, Care Management, Insurance / Risk Management, HR, IT

Appropriate Resources
- Integration Management Office support
- Dedicated compliance integration resources
- Workforce, skill sets / subject matter expertise
- Tools (publications, audit tools)

Speed to Value
- Timely execution
- Delays = Lost opportunities, lost savings
- Prioritize integration initiatives
- Focus on priority initiatives

Authority Matrix
- Board recommend v. approve responsibilities move to System / Corporate Office Board
  - C-suite compensation
  - Compliance audit plan
- Compliance officer reporting to CEO and System Office compliance officer
- Governance and management
  - Local, regional, and national responsibilities
  - Target management and governance
  - System management and governance
  - Sponsorship and governance
Integration: Pre-close, Day 1, and Forward

Day 1 Readiness

If identified to have:
- Ineffective or weak compliance program
- Areas of risk with potential for whistleblowers

Ensure Code of Conduct, policies and procedures, and compliance training move into place Day 1!
Day 1 Readiness

Carryover or Must Transfer Day 1?

- Vendor contracts review
  - BAA and service agreement carryover

- Research, IRB
  - Will the Seller continue oversight for six months after transaction date, or must it transfer on Day 1?
  - Transferring an IRB and research takes time
    o Review studies
    o Research compliance
    o Fit your mission statement? Core values?
    o Impact on GME/residency program; Magnet status

Day 1 Readiness

MUST DO: 30-45 Days Before “Go” Date

- Exclusions screening
  - Workforce (full time, temporary)
  - Board of Directors
  - Physicians (employed and medical staff)
  - Vendors
  - Volunteers
**Day 1 Compliance Program**

MUST DO: 30-45 Days Before “Go” Date

- Compliance officer on-site
  - Introductions / Walking around on units

- Introduction of Compliance Program
  - Flat screens
  - Table tents in cafeteria
  - Hotline number magnets
  - Code of Conduct on intranet

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**Week 1 / Month 1 / Quarter 1 Compliance Program**

- New hire education
- Board of Directors education
  (introduction to compliance program)
- “One off” Conflict of Interest survey
  of senior leadership and Board
- Code of Conduct rollout
- Policies/ Procedures implementation
- Monthly exclusions screening implementation
Incorporating Lessons Learned

- Ongoing Improvement of Baseline Plan
  - Incorporate regulatory changes
- Perform an Integration survey approximately nine months post Day 1
  - Incorporate lessons learned
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