NEGOTIATING HEALTHY EHR AND HEALTHCARE IT CONTRACTS: IT'S NOT JUST HIPAA

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KEY ISSUES FOR TODAY

• Key risks and issues in EHR and Healthcare IT contracts;
• Practical advice regarding internal and external diligence, vendor selection, negotiation, and implementation process; and
• Who do you need on your team to make it all work?
Recently, a risk assessment performed for healthcare clients of CHAN Healthcare reviewed over 4,000 risks in healthcare across more than 280 healthcare entities.

Those risks were grouped into 5 categories:
- Care Transformation
- Compliance
- Information Technology
- Healthcare Operations
- Revenue Cycle Management

Of the 20 Top Risk Areas in Healthcare for 2017, 9 are directly related to electronic health records and IT systems:

- HIPAA Compliance
- Cybersecurity
- System Implementation
- Access Management
- Controls
- Vendor Management
- Clinical Documentation
- Case Management
- Patient Access

*Source: 20 of the Top Risk Areas in Healthcare, April 18, 2017, Sarah Cole, CPA, Crowe Horwath, available at [www.crowehorwath.com](http://www.crowehorwath.com)*
"Healthcare has the unenviable task of balancing protection of large amounts of personal and medical data with the need for quick access to practitioners. Internal actors are well represented with employees accessing patient data out of curiosity, or to commit identity fraud."


Top 3 Threat Actors in Healthcare:
- 32% External Threats
- 6% Partner Breaches
- 68% Internal Risks

KEY ISSUES – DATA BREACH INCIDENT ERRORS

Data Breach Incidents

- Misdelivery
- Disposal Error
- Loss
- Publishing Error
- Misconfiguration
KEY ISSUES IN EHR AGREEMENTS – CONTRACT ISSUES

• Indemnification and hold harmless clauses
• Confidentiality and nondisclosure agreements
• Warranties and disclaimers
• Limits on liability
• Dispute resolution
• Termination, transition, and wind down provisions
• Intellectual property ownership, licenses and disputes
KEY ISSUES - MINDING THE GAPS

• Implementation
  – Timing
  – Roles and Responsibilities
  – Milestones
  – Payment Structure

• Acceptance Testing
  – Criteria
  – Scope
  – Components vs. Solution
  – Sample vs. Production
KEY ISSUES - MINDING THE GAPS

• Performance Standards
  – Types
    • Availability
    • Integrity
    • Response and Remediation Time
    • Customer/User Satisfaction
  – Measurement
  – Reporting
  – Consequences/Credits
    • SLAs
    • Termination Rights
KEY ISSUES - MINDING THE GAPS

• Compliance with Laws
  – Applicable to Whom?
  – Changes in Law?
  – Compliance requirements?

• Compliance with Standards
  – Client Standards
  – Provider Standards
  – Bridging the gap

• Data Backup and Disaster Recovery

• Service Suspension or Blockage
KEY ISSUES - MINDING THE GAPS

• Governance and Project Management
  – Problem and issue reporting, management and remediation
  – Contract management

• Subcontractors and Subservice Organizations
  – Cloud and hosting providers
  – Impact on Solution

• Other Vendors and Service Providers
CONDUCT VENDOR DUE DILIGENCE

Vendor Due Diligence:

• What is it?

• Why do it?

• How to do it?
  – Pre-contract
  – During contract negotiations
  – Post-contract
WHAT IS VENDOR DUE DILIGENCE?

“You keep using that word. I do not think it means what you think it means.”
- Inigo Montoya, The Princess Bride

Traditional View:

• Investigation of Vendor and Vendor Capabilities
  – Can they do what they say?
  – References?
  – Financial viability?

• Business Think - effort level *often* based on contract cost/value, not on RISK
Does it add up?

- Request for new contract with backup tape storage provider. Contract value = $250-$1000 per month;
- Liability is limited to $5.00 per box;
- My mail arrives . . .

“Dear Sir or Madam,

We are writing to let you know that computer tapes containing some of your personal information were lost while being transported to an off-site storage facility by our archive services vendor.”

Diligence effort should instead be tied to RISK contract exposes you to, which includes:

– Harm to customers, employees, consumers;
– Harm to reputation;
– Business and distraction value;
– Breach investigation, notification, remediation;
– Criminal and/or civil lawsuits;
– Regulatory action, fines, penalties;
Key Point #1:

Business is typically focused on cost savings, run rate, cap-ex, op-ex and other perceived advantages of using a vendor. The challenge is to understand and match the solution to the risk. This may mean retaining some key data or functions in house to reduce risk. The standard is “reasonable”, not “commercially reasonable.”
WHY VENDOR DUE DILIGENCE?

- 97% of breaches featuring the use of stolen credentials leveraged legitimate partner/vendor access.
  - Verizon 2016 Data Breach Investigations Report

- Overall, 63% of all data breaches can be attributed to a third party vendor
  - Soha Systems Survey on Third Party Risk Management

- Examples:
  - Equifax-Hackers were able to use employee’s default PIN codes to log into W-2Express, an Equifax service. The default PIN codes used a common system—the employee’s Social Security number, and date of birth to access W-2 data. Hackers stole tax and salary data from a large number of W-2 Express users. Affected, Kroger, Stanford University and Northwestern University.
  - ADP-hackers registered accounts in the names of employees at over a dozen customers, including U.S. Bancorp in order to steal W-2 data from an ADP portal.
WHY VENDOR DUE DILIGENCE?

For each contract it is your obligation to:

- Understand and align current and evolving business needs with vendor product or service offering;
- Analyze risks & benefits of technological trends & developments:
  - outsourcing & off-shoring
  - ASP > SaaS > Cloud Services
  - dedicated environment > shared environment > utility computing > virtual/cloud computing environment
- Risk identification & mitigation – What happens if __________?
- Compliance with legal and industry obligations;
HOW TO CONDUCT VENDOR DUE DILIGENCE?

- **Pre-Contract**
  - Internal Diligence
  - External Diligence

- **Contract Negotiations**

- **Post-Contract**
PRE-CONTRACT – INTERNAL DILIGENCE

Perform an *Internal* Due Diligence – Know:

- YOUR Needs;
- YOUR Data;
- YOUR Environment, Network, Systems, Policies;
- YOUR People;
- YOUR current vendors, suppliers and service providers;
- YOUR locations, facilities, sites;
SCOPE THE PROJECT IN ADVANCE

• Establish clear, understandable and, above all, realistic Project objectives
• Describe in detail the functions the vendor will be asked to perform
• Specify who is responsible for completion of Project tasks - vendor or customer
• In addition to describing Project objectives, describe what the customer is seeking to avoid and what the customer does not want the vendor to do
SCOPE THE PROJECT IN ADVANCE

Establish a Financial Baseline:

- Prioritize Project objectives as necessary
- Specify key Service Level objectives
- Be sure that Project objectives have clear support from senior management - such support may be critical to overcoming institutional resistance to change
- Keep the focus on company objectives – not individual objectives
SCOPE THE PROJECT IN ADVANCE

• Estimate the costs of performing the outsourced functions internally over the anticipated period of the contract
• Apply a reasonable discount for anticipated savings through consolidation and use of a single vendor
• Use the result as a reference point for comparison with vendor proposals
Key Point #2:

Know and completely understand what data you are going to transfer to the vendor, what they will have access to, and what you are asking the vendor to perform or provide. Make sure their offering matches your needs.

“You see, what we're actually trying to do here is, we're trying to get a feel for how people spend their day at work... so, if you would, would you walk us through a typical day, for you?”  
-Bob Slydell, Office Space
INTERNAL DILIGENCE – YOUR DATA

Conduct internal due diligence on your own systems, facilities, data, operations, procedures and data privacy. Some of the question to ask are:

• What data do you have?

• Where is the data collected and how?

• What are you doing with it?

• Where do you have it?
INTERNAL DILIGENCE – YOUR DATA

- Who can access it?
- Who has access internally?
- What third parties have access and for what purpose?
- How long is it retained?
- When and how is it destroyed?
How do you answer those questions?

Include representation from all key organizational components:

– IT
– Subject matter experts
– Financial
– Tax
– HR
– Risk management
– Legal
– Outside consultants and advisors
CONSULTANTS AND EXPERTS

If you can dodge a wrench you can dodge a dodge ball.
BUILD THE RIGHT TEAM

• Select and retain consultants, experts and advisors early but at appropriate points in the process in order to gain the most benefit from their guidance and expertise.

• Choose a Team Leader who is respected within the organization, has the support of senior management, and has a genuine belief in the value of the Project.
BUILD THE RIGHT TEAM

• Ensure that the roles and responsibilities of each of the Team members are clearly identified and understood within the Team

• Encourage regular and open communications among Team members

• Enforce organizational discipline with the vendor/service provider from the top of the organization on down
WHAT IS THE IMPACT OF TIME?
External-Vendor Due Diligence Goal:

• They know you
• You know them

Important Questions:

• How long have they been providing this solution?
• What does their organization, resource level, work flow look like?
• What is the experience level of the vendor and vendor personnel?
• What is their reputation in the industry?
EXTERNAL-VENDOR DUE DILIGENCE

• What is their response to a problem?

• How will your data / intellectual property be protected?
  – Security and data protection policies and compliance?
  – Timely and repeated employee awareness and training?
  – Adequate system, physical and network security?
  – Business continuity / disaster recovery plan
  – Tested breach process?
  – Process for complaint handling?
  – Audit capabilities?
  – Who else are they accountable to (ONC Health Certification, PCI, SOC, TRUSTe, ISO/IEC, Privacy Shield)?
DUE DILIGENCE TOOLS:

- Put Nondisclosure Agreements in place
- Establish criteria for vendor selection, including relevant scoring categories, evaluation criteria and weighting of categories
- Develop an RFP designed to produce bids that can be compared quickly and easily
- Require specific responses from vendors – they must either accept or list specific objections or changes. Hold the vendor’s feet to the fire - require clarifications and supplements as necessary
DUE DILIGENCE TOOLS:

- Establish a primary point of vendor contact within the Team with exceptions only as agreed
- Hold bidder conferences and require vendors to present their proposals
- Visit reference accounts, particularly those within the industry and with comparable structures and organizations. Try to identify and visit a failed account
VENDOR SELECTION

Apply rational selection criteria (see also “Respect the Process”)

– Expertise in outsourced functions
– Relevant experience within the industry
– Relationships and alliances with key application and service providers
– Available resources
– Trust
– Cost
RATIONAL VENDOR SELECTION CRITERIA

– General reputation and results of reference account visits
– Compatible corporate cultures
– Conflicts of interest (services to competitors)
– Financial security and long term prospects
– Merger or acquisition prospects
HOW - VENDOR DUE DILIGENCE

• Pre-Contract
• Contract Negotiations
• Post-Contract
“There are negotiations being made that are going to answer all of your questions and solve all of your problems.”

-Michael Corleone, The Godfather

• Diligence doesn’t stop here, it goes deeper;

• Challenge vendor assertions, non-answers and any changes from RFP process, sales talk, etc.;

• Understand and put guardrails around risks identified during earlier diligence;
CONTRACT NEGOTIATIONS:

• Identify the primary negotiating team and the roles and responsibilities of the members
• Set realistic timelines for completion
• Consider use of a Term Sheet to identify and reach agreement on key business terms
• Assign responsibilities for specific documents
CONTRACT NEGOTIATIONS:

• Identify and complete remaining “Due Diligence” items sooner rather than later
• Provide the Team Leader with authority to make key decisions
• Make sure the vendor’s negotiating team also has the authority, in the room, to make key decisions
CONTRACT NEGOTIATIONS:

- Obtain a commitment from senior management that the vendor will not be permitted to “end run” the Team
- Know accepted industry practices
- Identify and address tough issues early in the process
CONTRACT NEGOTIATIONS

• Leave open the option to move to another vendor or abandon the Project
• Make sure the vendor knows that other vendors remain in play
• Avoid all public announcements until the deal is signed
• Avoid letter agreements that permit the vendor to “get started” before the deal has been finalized. Such arrangement shift significant leverage in the vendor’s favor
CONTRACT NEGOTIATION:

• Understand the impact to this contract of changes in:
  – Law;
  – Technology;
  – Locations;
  – Tax;
  – Personnel;
  – YOUR business and operations;
HOW – VENDOR DUE DILIGENCE

• Pre-Contract
• Contract Negotiations
• Post-Contract
POST-CONTRACT:

Key Point #3: Your job doesn’t end when the contract is signed. Monitoring and enforcing compliance is a key part of due diligence.
MONITORING AND ENFORCING COMPLIANCE:

• Your leverage disappears upon signature;
• Use the levers you have in the contract, they do you no good if you do not exercise them;
• Monitoring and enforcement applies both internally and externally – make sure your people are following the rules too!
Ask for and get:

– Periodic performance reporting;
– Periodic verification that compliance certifications are up to date
– Periodic financial, security and control audits, both internal and external;
– Ability to conduct your own audits, inspections and testing;
– Review of response and remediation plans;
– Plus, the ability to follow up, ask questions and get documentation to validate all of the above.
• Educate your people on processes, procedures, workflows, responsibilities, etc.
• Engage in on-going communication and training of the stakeholders;
• Re-visit policies and procedures to keep them consistent with the evolution of the business and changes in law, technology, etc.
KEY POINTS

1. Focus on RISK not just cost
2. Match THEIR offering with YOUR needs
3. CONTINUE to be diligent
QUESTIONS AND ANSWERS:

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