

The Do's and Don'ts for Signing Information Technology Service Contract Agreements

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Seeing Into The Future

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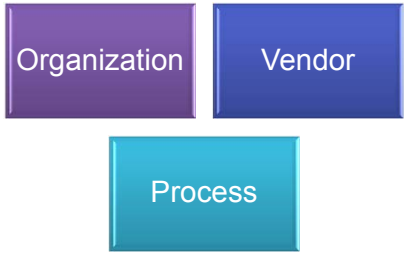
Outline

- I. Why have contracts?
- II. **Planning ahead**
- III. Key terms
 - General contract issues
 - Using the cloud?
 - Other considerations

Outline

- I. **Why have contracts?**
- II. **Planning ahead**
- III. **Key terms**
 - **General contract issues**
 - **Using the cloud?**
 - **Other considerations**

Preliminary Considerations



The diagram consists of three colored boxes: a purple box labeled 'Organization', a blue box labeled 'Vendor', and a light blue box labeled 'Process'. The 'Organization' and 'Vendor' boxes are positioned at the top, side-by-side, while the 'Process' box is centered below them.

Why Have Contracts?

- ❖ Psychological effect
 - Writing = serious
- ❖ Set the rules of the road
 - Define expectations
 - Establish a shared understanding
 - Budgetary constraints
- ❖ Put 'marketing speak' in writing
- ❖ Framework to follow when things go wrong

Preliminary Considerations

Build the IT Acquisition Team

- Executive Leadership
 - Chief Technology Officer
 - Chief Financial Officer
- Chief Privacy Officer
- Clinical Leadership
- Administrative Leadership
- Users/Stakeholders (e.g., maybe not direct users, but technology interfaces w/another department)
- Legal/Compliance
- Risk Management
- Team will likely vary with technology purchase

Organization

Preliminary Considerations

Develop a Work Plan

- Determine what the organization needs
- Is this a long-term purchase or a short-term investment?
- How do you see your organization growing in 5, 10, 15 years?
- What are the HIT objectives?
 - ***Make a list of the requirements***
- What are the legal requirements - federal, state, other contracts (e.g., some contracts require data to be stored in the US)

Organization

Preliminary Considerations

Vendor Selection

- Have multiple vendors
 - Request for proposal
- Check references
 - Visit with those already using technology
 - Verifiable history of meeting deadlines and pricing (i.e., avoiding "change orders" = increased costs)?
 - Verifiable history of producing products that **WORK**?
- What is the development roadmap?
 - Time constraints?
 - Budget constraints?

Vendor

Preliminary Considerations

Assess Existing Infrastructure

- Environment is generally a complex combination of IT applications
 - Clinical decision support system
 - Clinical data repository
 - Pharmacy
 - CPOE
 - EHR
 - Labs
 - Don't forget mobile apps, telehealth and remote monitoring devices, etc.
- How does your proposed IT purchase fit within your existing environment?

Organization

Preliminary Considerations

Vendor Selection

- Financial viability of vendor
 - Will this vendor be around in 10 years?
 - Can this vendor afford to live up to the indemnification promises?
 - Can this vendor afford insurance (self-insured)?
- Are you the vendor's target market?
- *Can you (vs. should you) move to the cloud?*
- *Can (vs. should) data be stored off-shore?*

Vendor

Preliminary Considerations

Consider the Users

- What is the current workflow?
- Will a change in process be necessary?
- What are ***their*** functional requirements?
- Interview the users
 - Are they open to new technology?
 - How will they be impacted?
 - Are the *users* part of the process?

Organization

Preliminary Considerations

HIT Solutions are Complex

- Existing environment is complex
- But, new solution may also be complex
 - Software
 - Hardware
 - Integration (e.g., EHR and lab, HIE, ACO, State reporting, federal quality reporting initiatives, etc.)
 - Implementation issues
 - SLAs
 - Connectivity

Vendor

Pre

Setback for Sutter after \$1B EHR crashes

"No access to medication orders, patient allergies and other information puts patients at serious risk"

SACRAMENTO, CA | August 28, 2013

This story was updated at 2:16 p.m. ET.

Healthcare IT News

The nearly \$1 billion electronic health record system at Sutter Health in Northern California failed early this week, leaving nurses and clinical staff unable to access any patient information for a full day.

On Aug. 26 at approximately 8 a.m., the Epic EHR system failed, at which time nurses, physicians and hospital staff had no access to patient information, including what medications patients were taking or required to take and all vital patient history data, according to reports from the California Nurses Association, part of National Nurses United, the largest nurses union in the U.S.

Days earlier, the EHR system was also down for eight hours due to a planned upgrade; nurses could still read medication orders and patient histories but had to record new data on paper to then be re-entered into the system later.

[See also: Nurses demand delay of EHR rollout.]

Vendor

Preliminary Considerations

Implementation

- Detailed implementation plan
 - Timeline
 - Milestones
 - Accountability
 - Build in slack time
 - Downstream impact?
- Measurement
- Monitoring
- Reporting
- Necessary resources?
 - Know the staff from vendor, but what about your staff?
 - What about third parties (e.g., interfaces)

Process

Preliminary Considerations

List of Necessary Functions

- Select vendor based on *your needs*
 - Match needs to included modules
- Resist temptation to rely solely on "vendor's documentation"
- Room for growth?
 - Where will you be in 5 years?
 - Can you lock in prices?
 - Is the solution scalable?
- What are the necessary support components?
 - Hardware, 3rd party licenses (who pays?), connectivity
- Reengineering, changes to process?

Vendor

Outline

- Why have contracts?
- Planning ahead
- Key terms**
 - General contract issues**
 - Using the cloud?**
 - Other considerations**

Preliminary Considerations

Process

- Mode of Selection
 - Interview vs. RFP
- Educating users/key stakeholders
 - Is technology creating more work for someone (e.g., EHRs and physician data entry)
- What are the desired outcomes?
- Who is responsible/accountable?
- What are the budgetary constraints?

Process

Key Terms

❖ Definitions	❖ Termination / ADR
❖ Functional Specifications	❖ Data Ownership
❖ License	❖ Confidentiality, Privacy and Security
❖ Payment Terms	❖ Indemnification and Limitation of Liability
❖ Testing and Acceptance	❖ Damages
❖ Warranties	❖ Disclaimers
❖ Future Regulations	
❖ Maintenance and Support	

Definitions

- ❖ Easy to ignore... but, they're important
 - Consider:
 - "Affiliate" means, with respect to any Person, another Person that, at the time of determination, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, the first Person, whether by contract, possession (directly or indirectly) of power to direct or cause the direction of the management or policies of such entity or the ownership (directly or indirectly) of securities or other interests in such Person.

Definitions

- ❖ Easy to ignore... but, they're important
 - Consider:
 - "Go Live" means, with respect to each item of the Software, the point in time at which there is **fully functioning** data exchange with respect to such software on the computer systems of Client.
 - Vs.
 - "First Productive Use: means Client's **first use of an item of the Software** to send or process patient, health plan or materials information for clinical, financial or operational use.
 - Vs.
 - "Licensee shall be afforded access to software maintenance and support services without charge up to the first of the month following the **system go live date (i.e., date of first productive use).**" ← *assuming go live date means that the system works?*

Definitions

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Subject to the terms and conditions contained herein, Licensor hereby grants to Licensee: . . .

(b) the nonexclusive, royalty-free right and license to grant sublicenses of the Licensed Software, either alone, or bundled with Licensee's, its **Affiliates'** or third-party software, for use by Licensee's and **its Affiliate Sublicensees'** (as defined below) customers within the Field of Use.

Definitions

- ❖ Consider reviewing definitions for
 - Affiliate
 - Documentation
 - Error / Chronic Error
 - First Productive Use or Go Live Date
 - Intellectual Property
 - Interface
 - Internal Business Purpose
 - License
 - Modification, Upgrade, Improvement
 - Software
 - System
 - Third Party Software
 - Use

Definitions

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Subject to the terms and conditions contained herein, Licensor hereby grants to Licensee:

Definition of "Affiliate" may impact:

- Price
- Who can use the software
- What happens in the event of a buy-out

Licensee's and **its Affiliate Sublicensees'** (as defined below) customers within the Field of Use.

Functional Specifications

- ❖ Should enumerate your own specs
 - Be careful with reliance on "Documentation" as the source of specifications
 - Consider:
 - **Documentation** means the product manuals accompanying the Software and/or Hardware. However, Documentation (a) may describe (i) some functionality for configurations that Client does not have and (ii) **modules or products not included**, and therefore are not applicable, and (b) may contain **certain sections that, from time to time, may be out of date** in a manner that will not have a material effect on Client or the value of the Software to Client.

Functional Specifications

- ❖ Consider why you're purchasing the software
 - Meet regulatory requirements
 - Quality improvement
 - Data analytics
- ❖ Serve as a list against which to measure performance
 - Include the list that was made during the planning stages
 - **Include the response to the RFP**

The screenshot shows a webpage from InformationWeek with the headline "Software Audits: Are You Ready?". The article text states: "Study reveals more than half of companies have faced software audits within the past two years. Microsoft, Oracle, SAP, and IBM top list of auditors." It also lists the top five vendors: Microsoft, Oracle, SAP, IBM, and Adobe. A sidebar on the left contains navigation links like "Home", "News & Commentary", "Authors", "Slideshows", "Video", "Reports", "White Papers", and "Events".

License

- ❖ Scope - Includes
 - **Who** – people that will need access to the software
 - Organic growth vs. growth by acquisition
 - Do non-employees need to access?
 - **What** – the functions that must be covered
 - Make it broad
 - ACO, HIE, PHR, Internet of Things . . .
 - **Where** – geographic reach of license rights as well as any physical restrictions on installation/use
 - Telemedicine?

Payment Terms

- ❖ When does the vendor get paid?
 - Milestones vs. dates
 - Revenue Recognition Rules
 - 25% due upon contract execution, 20% due upon installation, 30% due upon First Productive Use, etc.
 - What happens if the vendor misses a milestone?
- ❖ Is everything included in the price?

License

- ❖ License terms should be reviewed carefully
 - Restricted to number of CPUs?
 - If so, what happens when the machine is imaged? Does that qualify as a use under the license?
- ❖ Improper use opens organization up to claims of copyright infringement
 - Attachmate Corporation
 - Business Software Alliance audits

Payment Terms

- ❖ Request the Total Cost of Ownership (TCO)
 - Measures all the costs of identifying and acquiring software, installation, operation, and software retirement
 - Hardware replacement (e.g., in 3 years), staffing, consulting, training, additional software (e.g., underlying db license only supports X no. users), etc.
- ❖ When can prices be increased?
 - Consider including some limitations and discounts
- ❖ What happens upon a failure to pay?

Payment Terms

- ❖ Requirements
 - ❑ Failure to Pay. Failure to make **any payment due** to Vendor in accordance with this Agreement will result in forfeiture of Client's right to receive any or all services. Failure to (i) comply with the limitations set forth in Paragraph 3 (*Scope of License*), or ii) pay all the license fees and subscription fees for the Software in accordance with this Agreement will **result in termination of Client's Software license**, termination of this Agreement and will obligate Client to immediately return all Software and Documentation to Vendor.
- ❖ When
 - ❑ **But, what if there is a good reason not to pay?** (e.g., chronic down time, chronic errors for "fixed" issues, lack of support, etc.)

Warranties

- ❖ Cover
 - ❑ Scope and duration of the performance warranty
 - ❑ Remedies for nonconformance
- ❖ Standard
 - ❑ Comparison vs. "has the skill and experience necessary to fully perform the services required hereunder"
 - ❑ Comparison "shall perform and provide all required service and support diligently, in a workmanlike manner, and in accordance with the prevailing industry standards"
 - ❑ No comparison
 - ❑ Security
 - ❑ Skills **But, what standards?**

Testing and Acceptance

- ❖ Opportunity for testing and acceptance
 - ❑ Contract should allow for both pre-live and post-Go Live testing
- ❖ What happens if fails?
 - ❑ Give vendor time to remedy? How long? How many attempts?
 - ❑ If can't remedy, is a **full** refund appropriate?
 - License fees vs. All fees (i.e., professional service fees)
 - Will have pushback (Revenue Recognition Rules)

Warranties

- ❖ Sunset issues
 - ❑ Sunset vs. will continue to provide maintenance
- ❖ Everything needed is listed (otherwise vendor's responsibility)
- ❖ Vendor (or its affiliates or business partners) may not hold Customer's data hostage for any reason

Warranties

- ❖ Cover
 - ❑ Scope and duration of the performance warranty
 - ❑ Remedies for nonconformance
- ❖ Standard
 - ❑ Compliance with documentation/specifications
 - ❑ Consider incorporating response to RFP
 - ❑ Interfaces, third-party software, hardware, custom programming
 - ❑ No viruses, malware, backdoors, etc.
 - ❑ Security and privacy
 - ❑ Skills and expertise to do the work

Future Regulations

- ❖ Why is your company purchasing the software?
- ❖ Is there a need for the software to comply with future regulations? (e.g., ICD-10, ePrescribing, PQRI, HIEs, State Registries, etc.)
 - ❑ IF so, then this should be part of the warranty
- ❖ Consider regulations that are directed to vendor **vs.** regulations that impact YOUR use of the vendor's software
 - ❑ Who pays?

❖ Why software is the common enemy

❖ If we

Open Letter From a Small EMR Vendor To Our Customers and Our Friends in Washington

By HAYWARD K. ZWERLING, MD

I want to update you on ComChart EMR's "Meaningful Use Certification" status.

ComChart EMR will continue to be certified as a Complete EMR for Stage 1 Meaningful Use. Unfortunately, we will not be able to meet the Stage 2 (or greater) Meaningful Use certification requirements as these requirements are technically extremely difficult to implement.

In addition to the Meaningful Use mandates, there continues to be a never ending stream of new mandates such as ICD-10, etc.)

Data Ownership

- ❖ Data is power
 - Analytics, Benchmarking, Population-based research = \$\$\$
- ❖ Who owns the data?
 - You own it but...

As between the Parties, Provider will have ownership of Provider individual patient medical records and lab and clinical data (the "Data") entered into and maintained in the Software on behalf of Physician. **Notwithstanding the foregoing, Provider hereby grants Vendor and Vendor's Affiliates a perpetual exclusive license to use the Data for analysis and research, with a right to disclose and sublicense use of the Data and Data analysis to third parties including non-affiliated third parties, provided that any such Data will be in de-identified form prior to such use, analysis, disclosure or sublicense.**

Maintenance and Support

- ❖ Service Level Agreement vs. Support and Maintenance Agreement
 - SLAs may focus on uptime
 - Support and Maintenance may focus on upgrades, releases, new versions, etc.
- ❖ Support
 - Time and hours (check time zones)
 - Response time vs. Repair times
 - Onsite or remote diagnostics?
- ❖ Other issues
 - Customizations, interfaces, and hardware
 - Price increases?
 - Continuity of use issue
 - What are the rights if vendor ceasing supporting the product?
 - Limit vendor's termination rights

Data Ownership

- ❖ When evaluating ownership, use, and de-identification
 - Is the data transfer actually a "sale" under HIPAA (which requires approval by the patient)
 - Does HIPAA really permit a vendor to de-identify data for **vendor's use**?
 - Health care operations means any of the following activities of the CE to the extent that the activities are related to covered functions: . . . (v) Consistent with the applicable requirements of § 164.514, creating de-identified health information or a limited data set, and fundraising **for the benefit of the covered entity**. 45 CFR § 164.501
 - So the question becomes, what benefit is the CE receiving?
 - Data subject to re-identification; will vendor offer full indemnification?

Termination & ADR

- ❖ Continuity of use issue
 - When can the agreement be terminated? (e.g., immediately upon non-payment?)
 - Do you own the software or license the software? What about the customizations?
- ❖ Build in dispute resolution and escalation process
 - Each party should designate a person in charge
 - Then go to senior executive → higher levels as appropriate
 - Mediation (binding/non-binding?)
 - Arbitration vs. court?
- ❖ Transition period
 - Vendor to assist in transition? At what price?
- ❖ **Dispute should not stop performance of contract**

Confidentiality, Privacy and Security

- ❖ Confidentiality
 - Both parties may be disclosing proprietary information – is an NDA or confidentiality agreement needed?
 - Broad or narrow?
 - Rely solely on BAA?
- ❖ **Data breach remediation is expensive** (and costs are rising... buy insurance!)
- ❖ "Security incident" vs. "breach"
 - Who decides?
 - When is notification to CE required?
 - Who is responsible for notification to patients?
 - What are the remedies? Is there a carve-out? Indemnification subject to the cap?
 - Indemnification?

Confidentiality, Privacy and Security

- ❖ **BAA – no one size fits all**
 - Data ownership issues may be in both Master Agreement and the BAA – which agreement wins?
- ❖ **Security requirements**
 - “. . . develop, implement, and maintain **commercially reasonable** physical, technical and administrative safeguards”
 - “. . . has security protocols that meet or exceed compliance with any required laws, regulations and the **SSAE 16, SOC 1 and SOC 2 standards**, which shall be audited on an annual basis by a third-party auditor. Vendor shall provide to Provider a copy of such audit report upon written request.”

Indemnification and Limitation of Liability

- ❖ **Limitations of Liability**
 - MUTUAL
 - Is a cap appropriate? At what amount?
 - Carve out the vendor’s indemnification and confidentiality obligations from any limit on liability (including HIPAA)
 - Can have separate caps for different types of damages

Indemnification and Limitation of Liability

- ❖ **Indemnification**
 - Applies generally to third party claims against you, that arise due to your use of the software
 - Mutual or not?
 - Should you be indemnifying the vendor for “Vendor’s negligence”?
 - Cover
 - “acts, omissions, or negligence” **vs.** “gross negligence” **vs.** “willful misconduct”
 - property damage/personal injury (although unlikely)
 - property rights infringement claims (patent, trademark, copyright, etc.)
 - data breaches and security incidents that don’t involve a HIPAA related data breach

Damages Disclaimers

- ❖ Address types of damages that are available (not amount of damages)
- ❖ Vendor will typically disclaim incidental, consequential, and other “indirect” damages
 - Disclaimers are typical and should be MUTUAL
 - BUT, beware that they do not undercut otherwise available remedies

Indemnification and Limitation of Liability

- ❖ **Indemnification**
 - Review the disclaimers related to “practice of medicine”
 - Is the system a clinical decision support tool?
 - Can errors be reported?
 - Vendor should pay all costs (not just those awarded in a court action because what happens if settle?)
 - How much is 100% indemnification worth from a vendor that is judgment proof?
 - Be careful in assuming vendor’s liability
 - Insurance policies typically exclude coverage for “assumed contractual liability”
 - Require vendor to purchase insurance

Using the Cloud?

- ❖ **Due diligence**
 - **Organizational**
 - How old is the company? Will it be around for the term of your contract?
 - Can the vendor afford to pay for a data breach?
 - Ask for a copy of the disaster recovery plan
 - **Technical**
 - Audit rights
 - Risk analysis?
 - Encryption?
 - Marketing vs. what you’re getting

Using the Cloud?

❖ Due diligence

❑ Organizational

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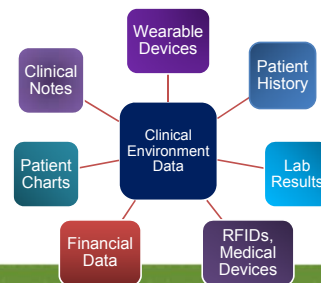
14. NO WARRANTY

COMPANY PROVIDES THE SERVICE "AS IS", "WITH ALL FAULTS" AND "AS AVAILABLE". TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, COMPANY MAKES NO (AND SPECIFICALLY DISCLAIMS ALL) REPRESENTATIONS OR WARRANTIES OF ANY KIND, WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY . . . THAT THE CONTENT WILL BE SECURE[.]

ToS for a company that markets a HIPAA compliant solution

Other Considerations

❖ Big data and analytics



Using the Cloud?

❖ Service levels and uptime

❖ Who is actually in charge of your data?

❑ Is your data safe?

❑ Contractors vs. employees

❑ Assignment of rights vs. responsibilities

❖ Data use, misuse, and de-identification

❖ Data access issues

❖ What remedies make sense? Is termination really an option?

❖ What is the pricing?

❑ Pass through for "regulatory" compliance? Taxes?

❑ Price increase limitations?

❖ Incorporation of url terms

Other Considerations

❖ Big data and analytics

❑ **Having and analyzing the data is the key to future success**

- To improve patient outcomes, data must be analyzed and shared across the providers, suppliers, etc. to enable improvement

❑ **Data science is not perfect – information will be missed**

- Predictive analytics? What algorithms? Have the differences been discussed? Do they matter for your purposes?
- If analytic methods are applied improperly, then mistakes will likely propagate
 - Damages caps?
 - Skills of the data analyst?
 - Requirement to repair algorithm?

Other Considerations

❖ Service levels and uptime

❖ What happens in the event of litigation?

❑ Accessing data for eDiscovery

○ Understand architecture

❑ Who pays to pull the data?

❑ Obligation to notify you in the event the FBI pulls a server?

❖ Access by individuals with disabilities

❖ Ability to terminate users

Disclaimer

This slide presentation is informational only and was prepared to provide a brief overview of potential IT contracting issues. It does not constitute legal or professional advice.

You are encouraged to consult with an attorney if you have specific questions relating to any of the topics covered in this presentation, and Melnik Legal PLLC would be pleased to assist you on these matters

Questions?

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