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Leading the Way to Health Intelligence



A Primer on Moving to the Cloud
HIPAA, Encryption, eDiscovery, Oh My!

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Objectives

- Describe the differences between public clouds, private clouds, and hybrid clouds.
- Articulate how the choice of cloud impacts HIPAA/HITECH compliance.
- Explain the benefits and limitations of encryption.
- Differentiate between encryption in-transit, at-rest as well as between applications, hardware, and databases.
- Evaluate the benefits and costs of encryption in applications, hardware, and databases.
- Explain the impact of cloud environments on contract terms.
- Identify cloud specific eDiscovery issues and mitigation strategies.



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Agenda

- Public, private, and hybrid clouds.
- Security and compliance concerns.
- Encryption options, limitations and considerations.
- Impact of cloud on contract terms.
- Cloud eDiscovery issues and mitigation strategies.



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Public clouds

- Examples
 - Amazon, Azure, OpenStack, Google
- Use cases
 - Prototyping, analytics, high-elasticity
- Implementation considerations
 - Need strong DevOps resources
 - Must address availability in the application (aka watch that SLA)



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Public clouds

- Compliance & security considerations
 - Tricky BAA negotiations
 - Who owns the data?
 - Where is the data?
 - How is the data stored (e.g., siloes)?
 - Are there issues with “sharing” space?

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Public clouds



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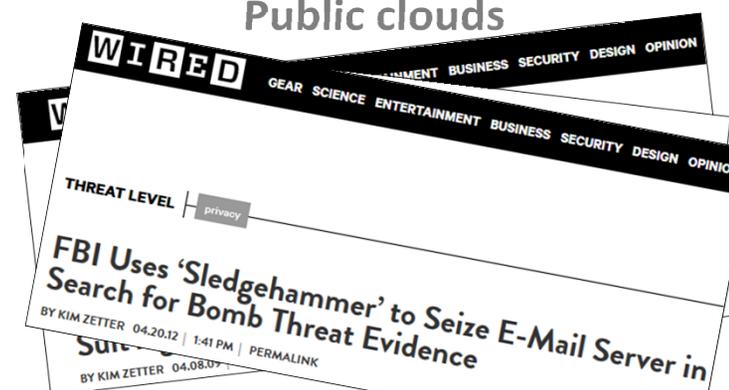
Public clouds



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Public clouds



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Anecdote

- Amazon crashes
 - April 2011 - Headline: “Amazon's Cloud Crash Disaster Permanently Destroyed Many Customers' Data”
 - October 2012 – Headline: “Amazon cloud goes down, taking Reddit, Airbnb and Foursquare with it”

Private clouds

- Examples
 - In-house infrastructure, some outsourced options
- Uses
 - Production applications, analytics, website/app hosting, interoperability
- Implementation
 - Virtualization expertise if in-house (expensive)
 - Trusted cloud Business Associate (if you can find one)

Private clouds

- Compliance & security considerations
 - In-house:
 - Do you have the people, processes, and technologies to protect PHI?
 - Outsource:
 - Is the cloud provider a suitable Business Associate? Have you done a walk-through? Asked the “right” questions? Will they help or hinder you sleeping at night?

Anecdote

- Some Federal government agencies are moving to private clouds
 - US Army, Air Force, DOJ, Department of Ed
- IDC Government Insights
 - “Federal **Public Cloud** spending will rise from \$110.4 million in FY2012 to over \$118.3 million in FY2014. . . . Federal **Private Cloud** spending will rise from \$1.5 billion in FY2012 to over \$1.7 billion FY2014.”
 - “IDC Government Insights expects to see [the Federal private cloud] market . . . reach \$7.7 billion by FY2017.”

Hybrid clouds

- Examples
 - Combining public and private servers
 - Combining physical and virtual servers
- Uses
 - High-transaction applications (analytics), image archival, interoperability
- Implementation
 - Virtualization expertise if in-house (expensive)
 - Business Associate who is trusted and maintains all desired environments (if you can find one)

Hybrid clouds

- Compliance & security considerations
 - Greater complexity can add more risk
 - Does it mean managing multiple cloud vendors?

Anecdote



- Department of Energy and National Nuclear Security Administration
 - “the DOE and NNSA are combining a private cloud and commercial cloud services to create a secure, hybrid cloud that will be available to other DOE departments, and potentially to other federal agencies”

Encryption

- Provides one or more layers in what should be a defense-in-depth approach to cloud security
- In-transit, at-rest ... what about backup?
- It's “free” != It's easy

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Encryption

- In the software
- In the database
- On the disk
- With an appliance

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Anecdote

- What technology are you using?
- Does the encryption technology meet HIPAA requirements?

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Anecdote

- What technology are you using?
- Does the encryption technology meet HIPAA requirements?



TRUE CRYPT
FREE OPEN-SOURCE
ON-THE-FLY
ENCRYPTION

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Anecdote

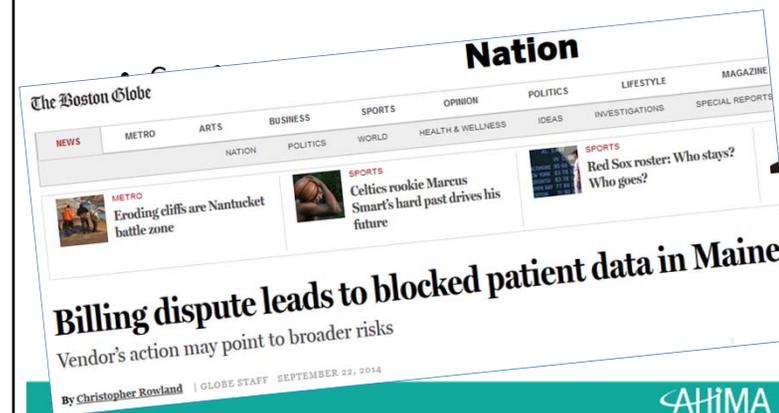


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Contract Terms

- Careful review needed of all terms (including data center use policies if incorporated)
 - “sole” **vs.** “reasonable discretion”
 - Data center’s “transition services limited to providing client access to retrieve data” **vs.** “provide reasonable transition services at its current rates, not to exceed \$250 per hour”
 - Termination for “failure to pay invoices” **vs.** “failure to pay *undisputed* amounts”

Contract Terms



Contract Terms

- Representation and warranties
 - “has the skill and experience necessary to fully perform the services required hereunder”
 - “shall perform and provide all required service and support diligently, in a workmanlike manner, and in accordance with the prevailing industry standards”
 - But, what industry standards? Consider
 - “has security protocols that meet or exceed compliance with any required laws, regulations or the SSAE 16, SOC 1 and SOC 2 standards”

Contract Terms

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

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Contract Terms

- Data ownership issues

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.

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Health Entrepreneur Debates Going To Data's Dark Side

Forbes

Yale Zhang, a medical device entrepreneur based in Atlanta, is debating whether to go to what he calls the 'dark side' of data. Specifically, he and his team are discussing whether they should store customer medical data and whether they should sell it to outside companies and data brokers.

Zhang's company [Safe Heart](#) makes a small device called an [iOximeter](#) that clasps onto your index finger and sends data to a smart phone headphone jack. It measures a person's blood oxygen saturation, heart rate, and perfusion index, information that can be useful in medicine, sports and aviation.

Like many businesses in today's data rich world, company founder Zhang realizes that he can make more money by selling user information to other companies. Unlike many business, he is willing to share some of the internal debate his company is having over the issue.

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Contract Terms

- Indemnification
 - "acts, omissions, or negligence" vs. "gross negligence" vs. "willful misconduct"
 - Mutual? Should all language be mutual?
- Liability caps
 - Few technology vendors will agree to unlimited liability; select a reasonable amount
- Consider
 - How do these terms relate to the BAA?
- Insurance?

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amednews.com

AMERICAN MEDICAL NEWS

Doctors strike back at EHR vendor with class-action suit

Physicians say Allscripts misled them about a software program's functionality and quality. The case could encourage more litigation as doctors become dissatisfied with systems.

By ALICIA GALLEGOS — Posted May 6, 2013

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Anesthesiologist Robert Joseph, MD, interviewed several electronic health record vendors when researching which EHR system would work best for his small Florida clinic. He finally chose a software program called MyWay, sold by a subsidiary of Allscripts Healthcare Solutions, because it was designed to fit small and solo practices.

But \$40,000 and dozens of training hours later, the program has created headaches for Dr. Joseph's practice, he said. He claims that the system never

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eDiscovery & Mitigation

- What happens during litigation?
- Does the contract include terms requiring the data center to cooperate? To provide access?
 - At what cost?
- Prohibition on deleting data subject to a litigation hold?
- Notification in the event of litigation?

eDiscovery & Mitigation

- Spoliation of evidence
 - Occurs when an individual or entity violates its duty to preserve relevant evidence
 - Such a finding may result in
 - imposition of sanctions
 - Instructions/disclosure to jury

Anecdote

- *Christou v. Beatport, LLC* (D. Colo. Jan. 23, 2013)
 - Sanctioned for failing to preserve text messages

Anecdote

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– “Accordingly, the Court grants the motion but orders as a sanction that **plaintiffs will be permitted to introduce evidence at trial, if they wish, of the litigation hold letter and defendants failure to preserve Mr. Roulier’s text messages. Plaintiffs may argue whatever inference they hope the jury will draw.** Defendants may present evidence in explanation, assuming of course that the evidence is otherwise admissible, and argue that no adverse inference should be drawn.”

Disclaimer

This slide presentation is informational only and was prepared to provide a brief overview of some cloud computing concerns. 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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