HIPAA Basics: The Privacy Manual, Litigation Risks and Business Associates

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Hypothetical for Analysis

- University of Washington facts
  - 4,000 complete records hacked
  - Hacker: I did it just to show you how bad your security is - a warning
- Suppose another hacker attacks you and posts 1,000 records to the Internet
  - What's the liability?
  - How could you have limited exposure?
  - How do you defend?
  - How do you mitigate?

Hypothetical for Analysis

- University of Montana facts
  - No hospital at University of Montana
  - Grad student in psychology does research at children's hospital in St. Paul, Minnesota
  - 400 pages of PHI (psych records of 62 children) is sent back and posted on University's intranet (password protection)
  - Search engine leads directly to the URL
- Suppose your researchers do this?
  - What's the liability?
  - How could you have limited exposure?
  - How do you defend/ mitigate?

Hypothetical for Analysis

- University of Minnesota facts
  - 410 deceased organ donor identities revealed to recipients
  - Second breach in 90 days
- Suppose your facility made 2 errors within a short period of time?
  - How do you defend the second incident?
  - How do you make improvements?

Hypothetical for Analysis

- Eli Lilly
  - Releases e-mail addresses of 669 Prozac patients
  - Patients receive e-mail reminding them to take their medication, but in notice to them all addresses disclosed
- FTC Investigation and Settlement
  - Lilly must establish better safeguards
  - Subject to future fines for noncompliance
- Lesson for covered entities?

Potential Civil Liability - Ratcheting Duty of Care

Tort - Negligence

Tort - Invasion of Privacy

Publication of Private Facts

False Light (akin to Defamation)

Unauthorized Commercial Use

Tort - Breach of Confidence (Physician-Patient)

Tort - Defamation

Tort- Fraud

Statutory - Consumer Fraud

Contract - Breach of Confidentiality Clauses/Policies

Contract - Breach of Express or Implied Warranty

Contract - Suits by Business Associates

Contract - Suits by Vendors/ Customers (& vice versa)

Employment -related suits (HIPAA sanctions issues)

What Does the Law "Know" About HIPAA?

- Statutes and administrative regulations (*e.g.*, transaction sets, privacy, security rules) are laws
  - Epidemic of complexity
  - Ambiguities abound
  - Initial interpretation of complexity and ambiguity in laws requires legal reasoning
- What guidance for the lawyers?
  - No litigation yet, so no decided cases
  - Supreme Court in *Mead*: can't rely on informal administrative guidance

HIPAA - Statutory Standard

"Each [covered entity] … who maintains or transmits health information shall maintain reasonable and appropriate administrative, technical, and physical safeguards --

(A) to *ensure* the *integrity and confidentiality* of the information; and

(B) to protect against *any* reasonably anticipated

(i) threats or hazards to the *security or integrity* of the information; and

(ii) unauthorized uses or disclosures of the information; and

(C) *otherwise to ensure* compliance with this part by the officers and employees of such person."

(42 USC §1320d-2(d)(2); in effect now - does not require final security or privacy rules to become effective)

The Ratcheting Legal Standard

The T.J. Hooper case

- New Jersey coast (1928) - storm comes up, tug loses barge and cargo of coal
- Plaintiff barge owner: captain was negligent because he had no weather radio
- Learned Hand, J.: Barge owner wins
  - Rationale: to avoid negligence, keep up with technological innovations - they set the standard of care in the industry

What is the standard of care?

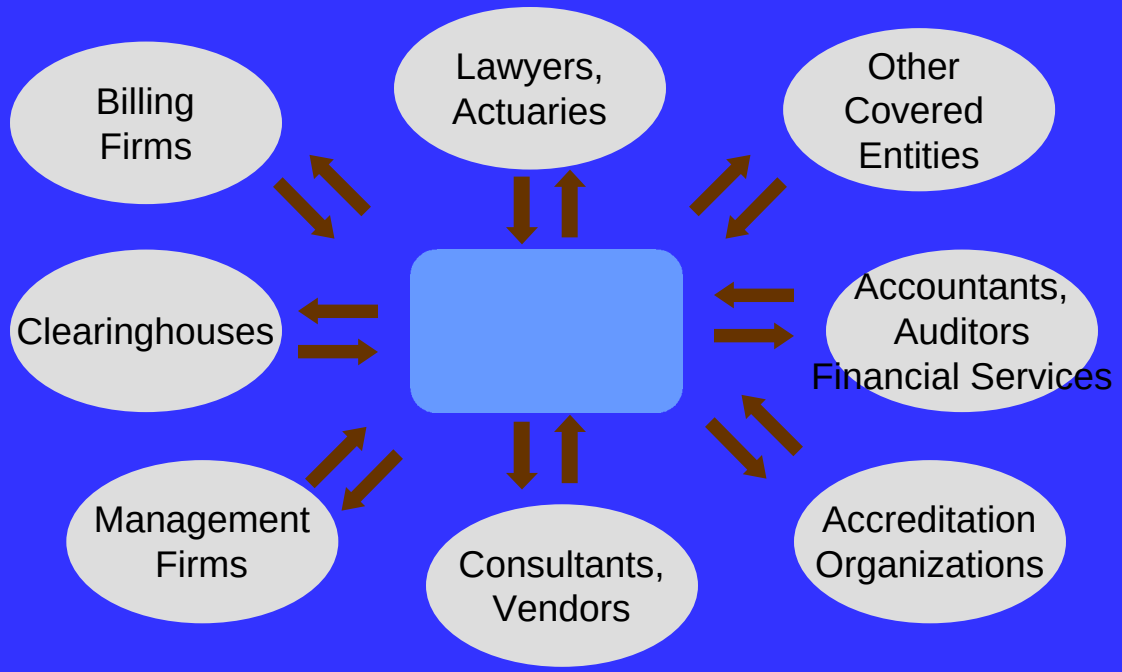
- The HIPAA security rules were abstracted from the defense establishment. The abstraction is now being imposed on health care.
- So the industry frame of referenced is the military-industrial complex, where NSA sets the rules.
- The financial industry also offers a frame of reference.
- These industries have been working for a long time on security, and have notably different structures and missions from health care.

Risk Management Analysis

- ✓ Does meeting the [proposed] regulation satisfy the HIPAA statute (reasonable and appropriate safeguards to ensure/ protect against any reasonably anticipated threat, hazard, or unauthorized use)?
- ✓ Does meeting the [proposed] regulation satisfy state tort law duties of prudent care?
- ✓ Examples: internal email; internal storage; remote use policies

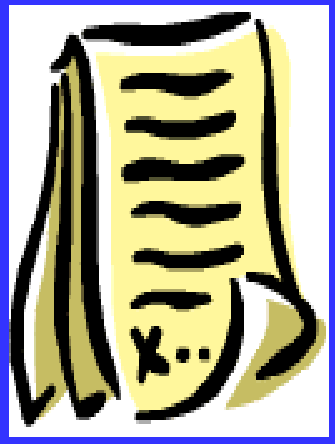
Use and Disclosure — Who Is a Business Associate?

- ✓ A person who receives individually identifiable health information and
- ✓ On behalf of a covered entity performs or assists with a function or activity involving use or disclosure of information or otherwise covered by HIPAA or provides certain identified services to a covered entity
- ✓ May be a covered entity



Use and Disclosure — Business Associate Contracts

- ✓ A covered entity may disclose protected health information to business associates if:
  - ✓ Obtains "satisfactory assurance" that business associates will appropriately safeguard the information
- ✓ Business associate contract required



Business Associate Agreements

BAA between covered entity and BA - BA must:

- ✓ Use appropriate security safeguards
- ✓ Report any improper use or disclosure *of which it becomes aware* to the covered entity
- ✓ "Ensure" its agents (including subcontractors) agree to same restrictions as in the BAA
- ✓ How much must you -- should you -- know about the security systems of your business associates?
  - ✓ If you deliberately don't ask for all details, what legal promises and assurances should you ask for?

Business Associates Liability Issues

- ✓ Privacy Rule, 45 CFR § 164.504(e)
  - ✓ "[W]e have eliminated the requirement that a covered entity actively monitor and ensure protection by its business associates." 65 *Fed. Reg.* 82641.
  - ✓ However: "Covered entities cannot avoid responsibility by intentionally ignoring problems with their contractors."
- ✓ The big question: What about duties under state tort law?
  - ✓ Prudent behavior standard
  - ✓ Enhanced by the HIPAA statutory standard?

Covered Entity - Vendor/ Business Associate Contract Negotiations - Litigation Risk Management

- A new set of risks for both sides
- No vendor is "HIPAA compliant," because the security is in the implementation. Only covered entities (and business associates) can be HIPAA compliant.
  - Some systems are just easier to engineer into a secure implementation -- and some can't be engineered that way as a practical matter.
  - Business process + technology = security
- Health care IT system vendors will ask for indemnification from covered entities against weak implementation.
- Will the provider community resist or cave in?

Enterprise Compliance Plan for Information Security

Achieving a reasonable level of security is a multifaceted task

+ Initial and on-going threat assessment (outside experts) >> enterprise security process
  + Computer security
  + Communications security
  + Physical security: access to premises, equipment, people, data
  + Personnel security
  + Procedural (business process) security
  + A pervasive security culture

"Effective program to prevent and detect violations of law"

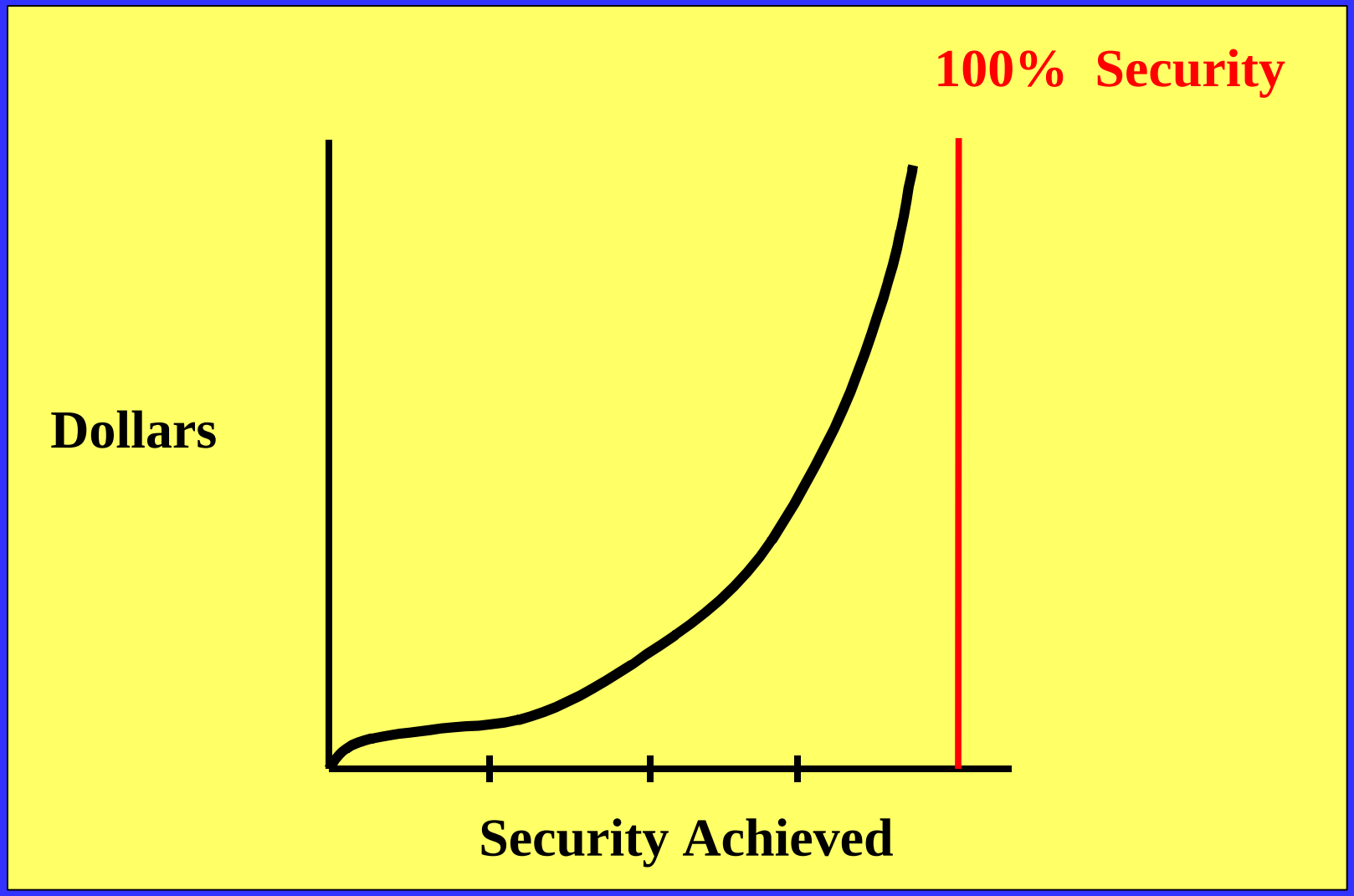
- ✓ Establish compliance standards
- ✓ High-level personnel must have been assigned overall responsibility
- ✓ Due care not to delegate substantial discretionary authority to those with propensity for illegal activity
- ✓ Effective communication of standards
- ✓ Reasonable steps to achieve compliance with standards
- ✓ Standards consistently enforced through appropriate disciplinary mechanisms
- ✓ All reasonable steps to respond once an offense is detected (including preventing further similar offenses)
- ⌗ Same principles as Business Judgment Rule (insulating corporate officers and directors from personal liability)

Expense v. Security Achieved

Expenditure compared to security achieved is not a linear relationship; it becomes geometric, then exponential, and is always asymptotic.

- **E.g.:**
  - **60% security = $ 1 million**
  - **80% security = another $ 2 million**
  - **95% security = another $ 4 million**
  - **etc.**
- **Budget issues are a major element of litigation risk management - you are dealing with the art of the practical**

Expense v. Security Achieved



Finally

- Security is a goal, a process, and a state of mind, not a steady state or a product.
- Technology is but a small part of security - and it must be implemented securely within the institution's business and clinical processes.
- Transaction & Code Set and Privacy rules are implemented within the framework of Security.
- The statute and rules are loaded with ambiguities.
  - Interpretation of the ambiguities and examination of options can't be done without legal analysis.
  - What other "law" bears on the issue?
  - Litigation risk analysis informs the risk-taking inherent in HIPAA-related business decisions.