New Frontiers In HIPAA & Privacy Enforcement:
State Courts, FTC, and OIG

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1. Dramatic Increase In Breaches
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Case Examples

Case Examples Organized by Covered Entity

- General Hospitals
- Health Care Providers
- Health Plans / HMOs
- Outpatient Facilities
- Pharmacies
Recently Reported Breach Incidents

- **The MetroHealth System** (May 15, 2015) – malware discovered on three Cardiac Cath Lab computers; a BA had disabled antivirus software on the computers during a software upgrade.

- **Hattiesberg Clinic** (April 2, 2015) – former employer (O.D. provider) accessed patient demographics to notify them of his new employer and practice location.

- **Aspire Indiana** (February 10, 2015) – several unencrypted laptops stolen, containing PHI and SSN, and identifying information; 45,000 patients and employees affected.
Major Care Insurers Affected

- Anthem (February 5, 2015) – 79 million subscribers affected.
- Premera Blue Cross (March 17, 2015) – 11 million customers.
- CareFirst (May 20, 2015) – 1.1 million customers.
- FBI investigating; health care organizations are “soft targets”
Also At Risk . . .

- Dozens of health care companies and corporate deal advisers (including law firms).
Breach By The Numbers

• Since 2009:
  • 1,100 health data breaches
  • 120 million individuals affected
    https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf
  • Ponemon Institute’s 2015 survey shows 91% of healthcare organizations and 59% of Business Associates have experienced a data breach
Staggering Costs:

• HITECH violation fines up to $1.5M
• Breach costs $5.6B in 2015
• Economic impact of medical identity theft $30.9B annually

2. States Are Stepping In
Connecticut – *Byrne v. Avery Ctr. For Ob & Gyn* (Nov. 11, 2014)

- HIPAA lacks a private right to action. But . . .
- HIPAA regulations may be used to set the Standard of Care for state negligence claims.
- Negligence and Emotional Distress Claims allowed.
- Predict: Increase suits against Covered Entities and Business Associates.
Indiana – *Walgreen Co. v. Hinchy* (Nov. 14, 2014)

- Landmark Decision: Walgreen liable under state negligence law for employee’s misconduct.
- $1.4 M verdict upheld.
Florida – *Murphy v. Dulay* (Oct. 10, 2014)

- Expansive presuit PHI disclosure (records and physician interviews) **not** preempted by HIPAA.
California

• New California statute regulating medical software companies and privacy
Ohio

*Gomcsak v. Dawson* 2002
*Hageman v. Southwest* 2008
*Turk v. Oiler* 2010

Med mal cases: Plaintiffs use HIPAA to resist discovery
Additional Agency Enforcement Actions


• Indiana AG enforced HIPAA for first time (Jan. 2015).
Manufacturers should develop cybersecurity controls to assure medical device security and maintain device functionality and safety.

- limit access to devices to authenticated users; strengthen password protection; physically lock devices (if appropriate).
- restrict software updates to authenticated code.
- ensure secure data transfer to/from device.
- include features that allow security threat to be detected, logged and acted upon.

FTC: Settlement With Health Billing Company (Dec. 2014)

• Billing company deceptively obtained consumer’s medical information when they signed up for billing portal to track health bills violated Section 5 of FTC Act.

• Sanction: Consent Order, forced to destroy all sensitive data, ban on misleading consumers.
3. Next Wave of PHI Protections
Strict Enforcement of Business Associates

- “Senior Health Partners (N.Y. health plan) blames BA for Breach.”
- Nurse’s laptop and unencrypted mobile phone stolen (Nov. 26, 2014).
  - OCR data: 25% - 64% of HIPAA breaches involve business associates.
  - Growing mistrust of BA’s ability to handle sensitive patient information.
Criminal Exposure Increasing

• Criminal attacks are number one cause of data breaches in healthcare.
• Individuals and Covered Entities can be prosecuted.

OIG Work Plan 2015

• NEW! Disaster Planning: Examine hospitals’ compliance with HIPAA requirement to create contingency plans to protect PHI in emergencies.

• Ongoing: Do hospitals have adequate safeguards to protect sensitive PHI on medical devices that integrate with EMRs?
4. Essential Action Steps

1. People
   - Employee training
   - Monitor employee compliance
   - Educate personnel on criminal penalties
   - Create a Zero Tolerance Culture
   - Address customer (patient, family, employee) concerns
Essential Action Steps

2. Processes

• Utilize in OCR’s Security Rule Risk Assessment Tool
• Stay up to date on Patches and Upgrades
• Review and Audit BA compliance with Security and Privacy Rules
• Disaster Preparedness: include safeguards for PHI
Essential Action Steps

3. **Product**
   - Tighten up privacy policies and ensure enforcement (CEs and BAs)
   - Follow best practices for drafting BAAs
   - Update Privacy/Security Breach Incident Response Programs
   - Ensure adequate insurance to cover emerging negligence and tort-based risks
   - Portable devices: trace, encrypt, secure medical devices: heighten awareness of manufacturer obligations for marketing secure devices
RESOURCES
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Statutes/Regulations

- HIPAA
  - Pub. L. 104-91; 42 USC 1320d-1320d-8
  - Privacy Rule: 45 CFR Part 160, Part 164 (Subparts A and E)
  - Security Rule: 45 CFR Part 160, Part 164 (Subparts A and C)
  - Enforcement Rule: 45 CFR Part 160 (Subparts C-E)
- HITECH Act of 2009

Cases

- *Byrne v Avery Center for Ob & Gyn PC*, Supreme Court of Conn., Case No. SC 18904 (Nov. 11, 2014)
RESOURCES

Guidance

• HHS, OIG Work Plan FY 2015 (p. 22)
• FDA, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (Oct. 2, 2014)

Data

• Experian, *2015 Second Annual Data Breach Industry Forecast*
Questions
Thank You!

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