How to Prepare for an OCR Audit

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HCCA Compliance Institute

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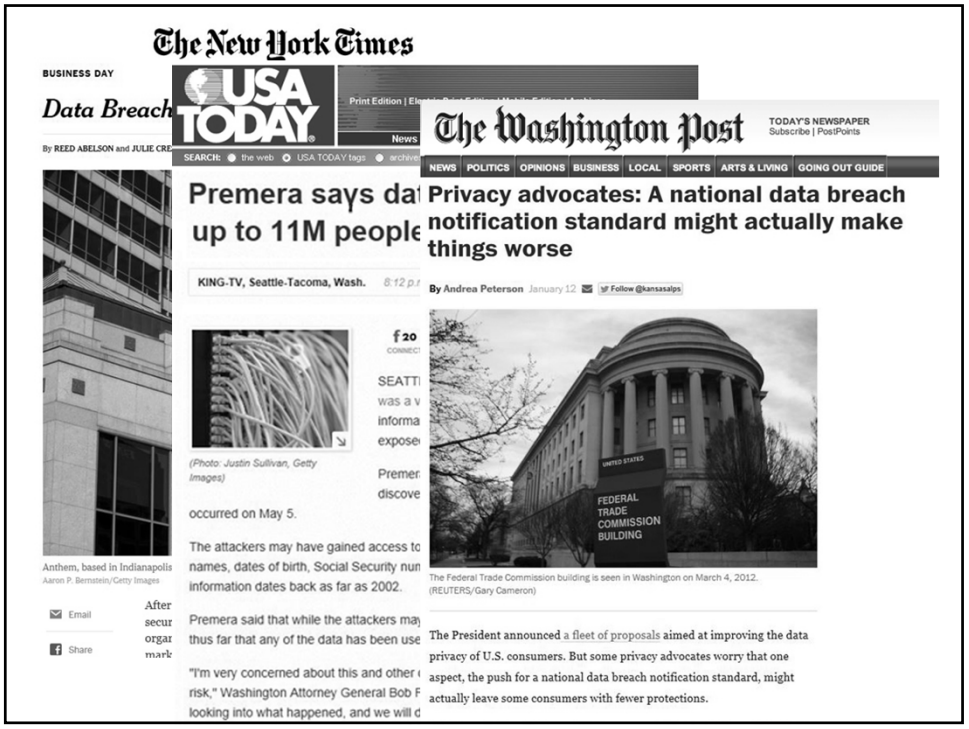
Headlines

- 2 recent cybersecurity breaches affecting 91 million plan members in total
- Proposed national data breach notification standard
- Executive orders on cybersecurity
- Medical devices
- FTC enforcement actions
- Health care going global
- Cost of data breaches



HIPAA Enforcement Actions

- As of early 2015, over $25M in OCR settlements and CMPs
  - 23 enforcement actions
  - $1M average settlement
  - OCR warns this is just the beginning
  - State enforcement

Recent OCR HIPAA Settlements

- AK community mental health agency $150,000 for malware exposure (Dec 2014)
- IN health system - $800,000 for medical records dumping (July 2014)
- NY hospital - $3.3M for PHI accessible over internet (May 2014)
- NY university - $1.5M for PHI accessible over internet (May 2014)
- MO PT Center - $1.7M for stolen laptop (April 2014)
- AR health Plan - $250,000 for stolen laptop (April 2014)
- WA county govt - $215,000 for ePHI on public server (March 2014)

Other Enforcement Actions & Regulatory Activity

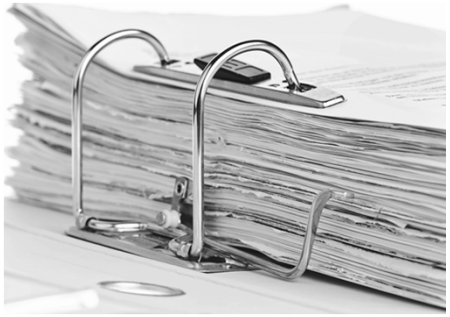
- DOJ
- FTC
- FCC
- State Attorneys General
- State licensing boards
- Joint Commission
- Meaningful use
- Individual and class-action lawsuits
- False Claims Act??

OCR Audit Program Phase 1

- HITECH requires HHS (OCR) to perform periodic audits of CE and BA compliance with HIPAA Privacy, Security, and Breach Notification Rules
- OCR established a pilot audit program to assess the controls and processes CEs implemented to comply
- In this program, OCR developed a protocol used to gauge efforts of 115 CEs in 2011-2013
- External auditors utilized
- Findings published

Scenario

- CE received audit notice from OCR and KPMG
- Request for documents and information
- Date for KPMG auditors to meet at the CE on-site
- 20 initial audits
- Field work 1/12 to 3/12



OCR Audit Program Phase 1

- Most common Privacy Rule deficiencies
  - Notice of privacy practices
  - Access of individuals
  - Minimum necessary
  - Authorizations
- Most common Security Rule deficiencies
  - Risk analysis
  - Media movement and disposal
  - Audit controls and monitoring

OCR Audit Program Phase 1

- Most common cause for deficiency
  - Entity unaware of the requirement
- Other causes
  - Lack of application of sufficient resources
  - Incomplete implementation
  - Complete disregard

OCR Audit Program Phase 2

- Audit Program Phase 2 (originally scheduled for 2014-15)
  - 1200 CEs in audit pool
  - 550-800 CEs to be selected for online “pre-survey”
  - 350 CEs to be audited in 2 rounds
  - 50 BAs to be audited
- What does the delay mean?

OCR Audit Program Phase 2

- Audits to be conducted primarily by OCR staff
- Targeted areas of compliance
- Desk audit approach
- 2 weeks to produce documentation
- Some on-site visits
- CEs to produce list of BAs

How to Conduct an Assessment

- Follow OCR Audit Protocol

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☑ All (169) ☑ Security (78) ☑ Privacy (81) ☑ Breach (10)

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Section	Established Performance Criteria	Key Activity	Audit Procedures	Implementation Specification	HIPAA Compliance Area
§164.308	§164.308(a)(1): **Security Management Process §164.308(a)(1)(ii)(a)** - Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity,...	Conduct Risk Assessment	Inquire of management as to whether formal or informal policies or practices exist to conduct an accurate assessment of potential risks and vulnerabilities to the confidentiality, integrity, and avail...	Required	Security

How to Conduct an Assessment

- Keep in mind published OCR Audit Protocol has not been updated for HITECH Final Rule
- Selection of subsidiaries and service lines
- Consider expanded review
  - Inventory documents
  - Physical walk-throughs, interviews
  - Employer-sponsored group health plan
  - Additional questions

How to Conduct an Assessment

- Consider internal self-review v. independent mock audit
- Consider attorney-client privilege
- Watch out for:
  - Insufficient or nonexistent Risk Analysis
  - Freshly minted, but unimplemented policies

Additional Questions to Ask

- Who's on the team?
- Hybrid entity, OHCA and ACE statuses
- Cyber liability coverage
- Use of OCR guidance and resources
- OCR complaint/closure letter – documentation of response
- Breach log match up with individual and OCR notices
- Documentation of BA issuing breach notices
- Inclusion of medical devices in risk assessment

Additional Questions to Ask

- Due diligence in transactions
- Vendor screening due diligence
- Off-shore data
- Return of PHI at termination of contracts
- Other - PCI DSS, FDCPA, TCPA, state law

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