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Update on Administration and Enforcement of the HIPAA Privacy, Security, and Breach Notification Rules

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Updates

- Policy Development
- Breach Notification
- Enforcement
- Audit

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POLICY DEVELOPMENT

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Access Guidance

HIPAA Right of Access Guidance

- Issued in two phases in early 2016
 - Comprehensive Fact Sheet
 - Series of FAQs
 - Scope
 - Form and Format and Manner of Access
 - Timeliness
 - Fees
 - Directing Copy to a Third Party, and Certain Other Topics

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Access Guidance

Access – Scope

- Designated record set broadly includes medical, payment, and other records used to make decisions about the individual
 - Doesn't matter how old the PHI is, where it is kept, or where it originated
 - Includes clinical laboratory test reports and underlying information (including genomic information)

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Access – Scope (cont.)

- Very limited exclusions and grounds for denial
 - E.g., psychotherapy notes, information compiled for litigation, records not used to make decisions about individuals (e.g., certain business records) BUT underlying information remains accessible
 - Covered entity may not require individual to provide rationale for request or deny based on rationale offered
 - No denial for failure to pay for health care services
 - Concerns that individual may not understand or be upset by the PHI not sufficient to deny access

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Access – Requests for Access

- Covered entity may require written request
- Can be electronic
- Reasonable steps to verify identity
- BUT cannot create barrier to or unreasonably delay access
 - E.g., cannot require individual to make separate trip to office to request access

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Access – Form and Format and Manner of Access

- Individual has right to copy in form and format requested if “readily producible”
 - If PHI maintained electronically, at least one type of electronic format must be accessible by individual
 - Depends on capabilities, not willingness
 - Includes requested mode of transmission/transfer of copy
 - Right to copy by e-mail (or mail), including unsecure e-mail if requested by individual (plus light warning about security risks)
 - Other modes if within capabilities of entity and mode would not present unacceptable security risks to PHI on entity’s systems

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Access – Timeliness and Fees

- Access must be provided within 30 days (one 30-day extension permitted) BUT expectation that entities can respond much sooner
- Limited fees may be charged for copy
 - Reasonable, cost-based fee for labor for copying (and creating summary or explanation, if applicable); costs for supplies and postage
 - No search and retrieval or other costs, even if authorized by State law
 - Entities strongly encouraged to provide free copies
 - Must inform individual in advance of approximate fee

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Third Party Access to an Individual's PHI

- Individual's right of access includes directing a covered entity to transmit PHI directly to another person, in writing, signed, designating the person and where to send a copy (45 CFR 164.524)
- Individual may also authorize disclosures to third parties, whereby third parties initiate a request for the PHI on their own behalf if certain conditions are met (45 CFR 164.508)

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HIT Developer Portal

- OCR launched platform for mobile health developers in October 2015; purpose is to understand concerns of developers new to health care industry and HIPAA standards
- Users can submit questions, comment on other submissions, vote on relevancy of topic
- OCR will consider comments as we develop our priorities for additional guidance and technical assistance
- Guidance issued in February 2016 about how HIPAA might apply to a range of health app use scenarios
- FTC/ONC/OCR/FDA Mobile Health Apps Interactive Tool on Which Laws Apply issued in April 2016

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Platform for users to influence guidance
HIPAA/Genetic Information

Health app developers, what are your questions about HIPAA?

Welcome Learn More Questions Helpful Links Contact

HIPAA Health Information Privacy, Security and Breach Notification Rules
About HIPAA

Engage with OCR on issues & concerns related to protecting health information privacy in mHealth design and development
Submit & View Questions

October 2015

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Cloud Computing

Cloud Computing Guidance

- OCR released guidance clarifying that a CSP is a business associate – and therefore required to comply with applicable HIPAA regulations – when the CSP creates, receives, maintains or transmits identifiable health information (referred to in HIPAA as electronic protected health information or ePHI) on behalf of a covered entity or business associate.
- When a CSP stores and/or processes ePHI for a covered entity or business associate, that CSP is a business associate under HIPAA, even if the CSP stores the ePHI in encrypted form and does not have the key.
- CSPs are not likely to be considered “conduits,” because their services typically involve storage of ePHI on more than a temporary basis.
- <http://www.hhs.gov/hipaa/for-professionals/special-topics/cloud-computing/index.html>
- <http://www.hhs.gov/hipaa/for-professionals/faq/2014/may-a-business-associate-of-a-hipaa-covered-entity-block-or-terminate-access/index.html>

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Cyber Security Guidance Material

- HHS OCR has launched a Cyber Security Guidance Material webpage, including a Cyber Security Checklist and Infographic, which explain the steps for a HIPAA covered entity or its business associate to take in response to a cyber-related security incident.
 - Cyber Security Checklist - PDF
 - Cyber Security Infographic [GIF 802 KB]

<https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity/index.html>

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Cybersecurity Newsletters

- 15 issues in total
- 2017 Newsletters
 - January 2017 (Understanding the Importance of Audit Controls)
 - February 2017 (Reporting and Monitoring Cyber Threats)
 - April 2017 (Man-in-the-Middle Attacks and “HTTPS Inspection Products”)
 - May 2017 (Plan, Respond, and Report!)
- <http://www.hhs.gov/hipaa/forprofessionals/security/guidance/index.html>

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Ransomware Guidance

- OCR recently released guidance on ransomware. The new guidance reinforces activities required by HIPAA that can help organizations prevent, detect, contain, and respond to threats.
- <http://www.hhs.gov/hipaa/forprofessionals/security/guidance/index.html>

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BREACH HIGHLIGHTS AND RECENT ENFORCEMENT ACTIVITY

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Breach Notification

Breach Notification Requirements

- Covered entity must notify affected individuals, HHS, and in some cases, the media, of breach
- Business associate must notify covered entity of breach
- Notification to be provided without unreasonable delay (but no later than 60 calendar days) after discovery of breach
 - Annual reporting to HHS of smaller breaches (affecting less than 500 individuals) permitted
- OCR posts breaches affecting 500+ individuals on OCR website

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HIPAA Breach Highlights

September 2009 through July 31, 2017

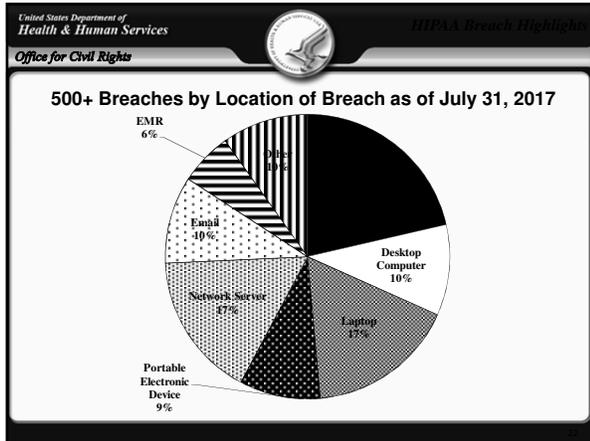
- Approximately 2,017 reports involving a breach of PHI affecting 500 or more individuals
 - Theft and Loss are 48% of large breaches
 - Hacking/IT now account for 17% of incidents
 - Laptops and other portable storage devices account for 26% of large breaches
 - Paper records are 21% of large breaches
 - Individuals affected are approximately 174,974,489
- Approximately 293,288 reports of breaches of PHI affecting fewer than 500 individuals

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HIPAA Breach Highlights

500+ Breaches by Type of Breach as of July 31, 2017

Type of Breach	Percentage
Unauthorized Access/Disclosure	27%
Loss	8%
Other	5%
Improper Disposal	3%
Unknown	1%



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HIPAA Breach Highlights
- OCR posts breaches affecting 500+ individuals on OCR website (after verification of report)
 - Public can search and sort posted breaches
 - OCR opens investigations into breaches affecting 500+ individuals, and into number of smaller breaches
 - Investigations involve looking at:
 - Underlying cause of the breach
 - Actions taken to respond to the breach (including compliance with breach notification requirements) and prevent future incidents
 - Entity's compliance prior to breach

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General Enforcement Highlights
- Over 158,293 complaints received to date
 - Over 25,312 cases resolved with corrective action and/or technical assistance
 - Expect to receive 17,000 complaints this year
- As of 7/31/2017

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General Enforcement Highlights



- In most cases, entities able to demonstrate satisfactory compliance through voluntary cooperation and corrective action
- In some cases though, nature or scope of indicated noncompliance warrants additional enforcement action
- Resolution Agreements/Corrective Action Plans
 - 49 settlement agreements that include detailed corrective action plans and monetary settlement amounts
- 3 civil money penalties

As of July 31, 2017

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Recent Enforcement Actions



2017 Enforcement Actions

- St. Luke's-Roosevelt Hospital Center
- Memorial Hermann Health System
- CardioNet
- Center for Children's Digestive Health
- Metro Community Provider Network
- Memorial Healthcare System
- Children's Medical Center of Dallas

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Recurring Compliance Issues



Recurring Compliance Issues

- Business Associate Agreements
- Risk Analysis
- Failure to Manage Identified Risk, e.g. Encrypt
- Lack of Transmission Security
- Lack of Appropriate Auditing
- No Patching of Software
- Insider Threat
- Improper Disposal
- Insufficient Data Backup and Contingency Planning

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Corrective Actions

Corrective Actions May Include:

- Updating risk analysis and risk management plans
- Updating policies and procedures
- Training of workforce
- Implementing specific technical or other safeguards
- Mitigation
- CAPs may include monitoring

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Good Practices

Some Good Practices:

- Review all vendor and contractor relationships to ensure BAAs are in place as appropriate and address breach/security incident obligations
- Risk analysis and risk management should be integrated into business processes; conducted regularly and when new technologies and business operations are planned
- Dispose of PHI on media and paper that has been identified for disposal in a timely manner
- Incorporate lessons learned from incidents into the overall security management process
- Provide training specific to organization and job responsibilities and on regular basis; reinforce workforce members' critical role in protecting privacy and security

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Audit Programs

AUDIT

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HITECH Audit Program

- Purpose: Identify best practices; uncover risks and vulnerabilities not identified through other enforcement tools; encourage consistent attention to compliance
 - Intended to be non-punitive, but OCR can open up compliance review (for example, if significant concerns are raised during an audit)
 - Also hope to learn from this next phase in structuring permanent audit program

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History

- HITECH legislation: HHS (OCR) shall provide for periodic audits to ensure that covered entities and business associates comply with HIPAA regulations. (Section 13411)
- Pilot phase (2011-2012) – comprehensive, on-site audits of 115 covered entities.
- 2013 – issuance of formal evaluation report
- 2016 – Phase 2 (ongoing) – between 200-250 onsite and “desk” audits of covered entities and business

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Selected Desk Audit Provisions

- For Covered Entities:
 - Security Rule: risk analysis and risk management;
 - Breach Notification Rule: content and timeliness of notifications; **or**
 - Privacy Rule: NPP and individual access right
- For Business Associates:
 - Security Rule: risk analysis and risk management **and**
 - Breach Notification Rule: reporting to covered entity
- See protocol on-line for details:
<http://www.hhs.gov/sites/default/files/2016HIPAADeskAuditAuditeeGuidance.pdf>

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Status

- 167 Covered entity desk audits underway; desk audits of business associates began in November.
- On-site audits will begin in 2017.
 - On-site audits will evaluate auditees against comprehensive selection of controls in the audit protocol:
<http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/protocol/>

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<http://www.hhs.gov/hipaa>
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