United States Department of Health & Human Services

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# Access Guidance and Enforcement Update

**Office for Civil Rights (OCR)**
**U.S. Department of Health and Human Services**

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## HIPAA Right of Access Guidance

- http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html
  - 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

## 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

## Access – Timeliness

Access must be provided within 30 days (one 30-day extension permitted) BUT expectation that entities can respond much sooner





## Calculating Costs for Access Fees: 3 Acceptable Methods

1. Actual costs
   - Actual labor for copying (at reasonable rates, including only the time to create and send a copy in the form, format, and manner requested), **postage**, and **supplies** (paper, USB drive, toner, CD)
2. Average costs
   - Cost schedule based on average labor costs for standard requests is okay
   - Per page fee acceptable only for paper records (copied or scanned)
   - Applicable supply and postage costs may be added to average labor costs
3. Flat fee for electronic copies of electronic PHI only ($6.50 cap).
   - An alternative to calculating actual or average costs for certain requests

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## Access – Right to Direct PHI to 3rd Party

- Individual has right to have entity transmit PHI to 3rd party of individual's choice (e.g., for research)
- Same requirements for providing access directly to the individual apply (e.g., fee limitations, form and format and timeliness requirements)

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## BREACH HIGHLIGHTS AND RECENT ENFORCEMENT ACTIVITY

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## 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





## September 2009 through July 31, 2016

- Approximately 1,630 reports involving a breach of PHI affecting 500 or more individuals
  - Theft and Loss are 45% of large breaches
  - Hacking/IT now account for 12% of incidents
  - Laptops and other portable storage devices account for 29% of large breaches
  - Paper records are 23% of large breaches
  - Individuals affected are approximately 159,445,990

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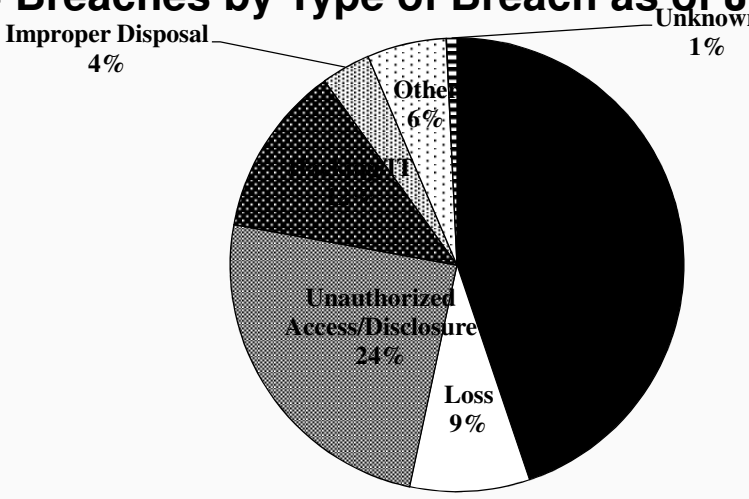
HIPAA Breach Highlights

## 500+ Breaches by Type of Breach as of July 31, 2016

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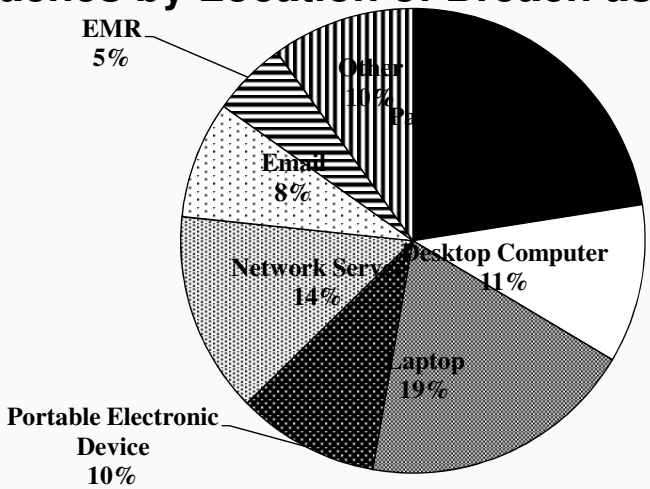
HIPAA Breach Highlights

## 500+ Breaches by Location of Breach as of July 31, 2016

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## What Happens When HHS/OCR Receives a Breach Report

- 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 a number of smaller breaches

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## General Enforcement Highlights

- Over 137,770 complaints received to date
- Approximately 885 compliance reviews initiated
- Over 24,331 cases resolved with corrective action and/or technical assistance
- Expect to receive 17,000 complaints this year

As of 3/31/2016

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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
  - 35 settlement agreements that include detailed corrective action plans and monetary settlement amounts
- 2 civil money penalties

**As of July 31, 2016**

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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 Action

## 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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