United States Department of Health & Human Services

Office for Civil Rights

Updates in Privacy, Security, and Breach Enforcement

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

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June 7, 2019

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Updates

- Breach Notification
- Enforcement
- Audit

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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
- Business associate must notify covered entity of a 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

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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
  - Receive over 350 breach reports affecting 500 individuals or more per year
- OCR opens investigations into breaches affecting 500+ individuals, and into a number of smaller breaches
- Investigations involve looking at:
  - Underlying cause of the breach
  - Actions taken to respond to the breach (breach notification) and prevent future incidents
  - Entity's compliance prior to breach

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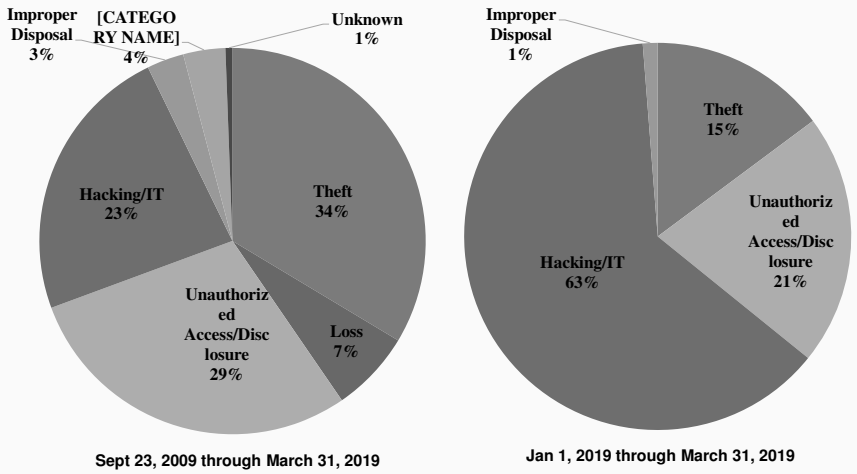
500+ Breaches by Type of Breach



Sept 23, 2009 through March 31, 2019

Jan 1, 2019 through March 31, 2019

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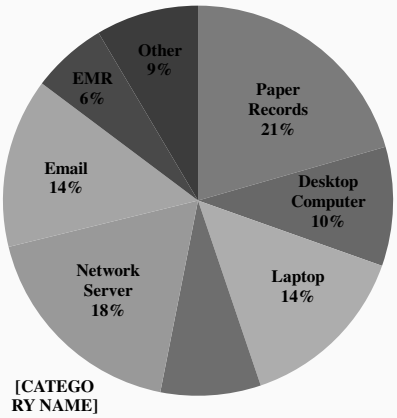
500+ Breaches by Location of Breach



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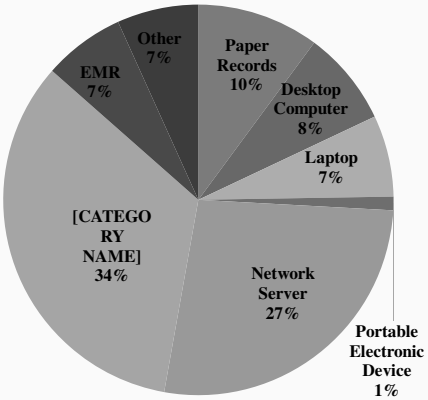

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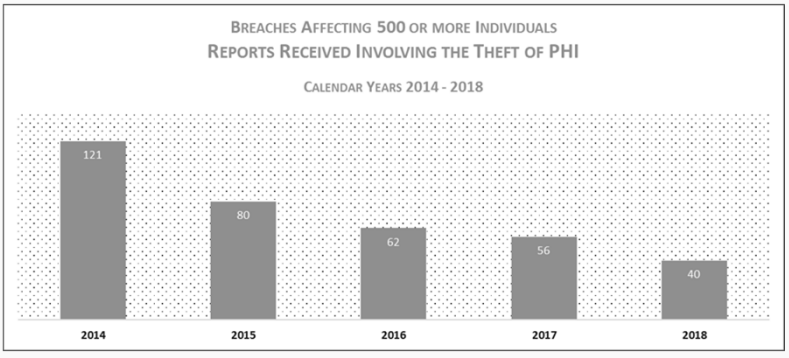

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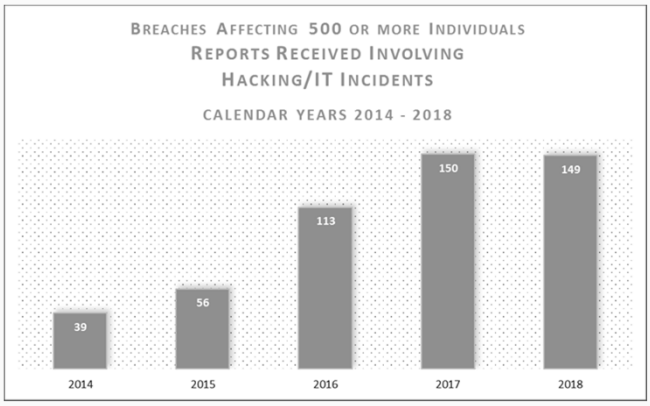

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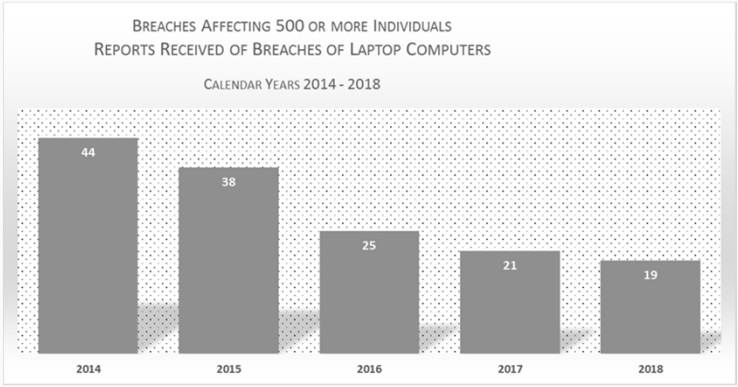

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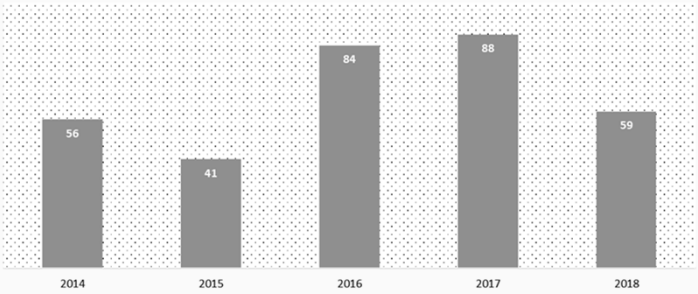
BREACHES AFFECTING 500 OR MORE INDIVIDUALS
REPORTS RECEIVED OF BREACHES OF NETWORK SERVERS
CALENDARS YEARS 2014 - 2018



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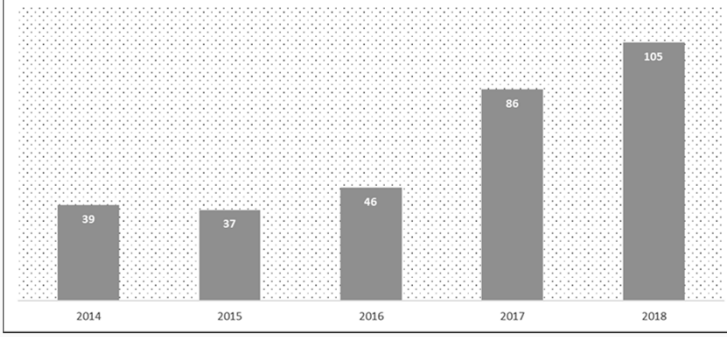
BREACHES AFFECTING 500 OR MORE INDIVIDUALS
REPORTS RECEIVED OF BREACHES INVOLVING EMAIL ACCOUNTS
CALENDAR YEARS 2014 - 2018



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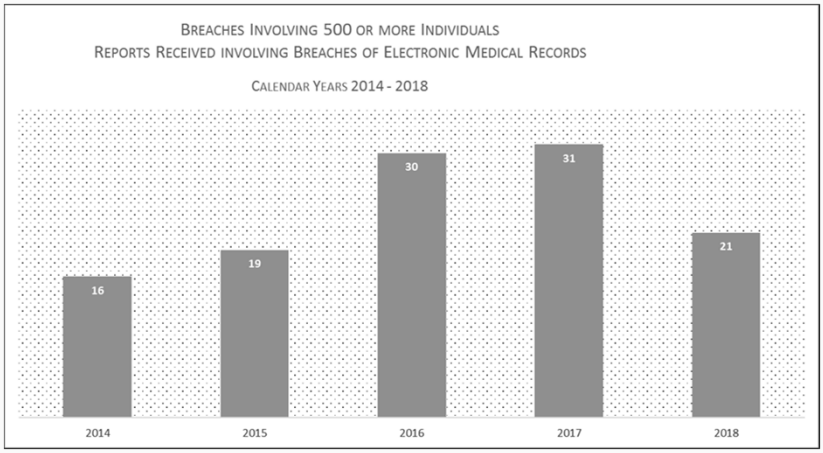

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General HIPAA Enforcement Highlights

- Expect to receive over 26,000 complaints this year
- In most cases, entities able to demonstrate satisfactory compliance through voluntary cooperation and corrective action
- In some cases, the nature or scope of indicated noncompliance warrants additional enforcement action
- Resolution Agreements/Corrective Action Plans
  - 60 settlement agreements that include detailed corrective action plans and monetary settlement amounts
- 4 civil money penalties

As of March 31, 2019

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2018 Enforcement Actions

2/2018	Fresenius Medical Care North America	$3,500,000
2/2018	Filefax	$100,000
6/2018	University of Texas MD Anderson Cancer Center (CMP)	$4,348,000
9/2018	Boston Medical Center	$100,000
9/2018	Brigham and Women's Hospital	$384,000
9/2018	Massachusetts General Hospital	$515,000
10/2018	Anthem	$16,000,000
11/2018	Allergy Associates of Hartford	$125,000
12/2018	Advanced Care Hospitalists	$500,000
12/2018	Pagosa Springs Medical Center	$111,400
12/2018	Cottage Health	$3,000,000

Total $28,683,400

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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
- Individual Right to Access

Issue: Incomplete or Inaccurate Risk Analysis

- Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the [organization]. See 45 C.F.R. § 164.308(a)(1)(ii)(A).

Case Example: Anthem, Inc.

- Largest U.S. PHI breach in history.
  - 78.8 million individuals affected
- Failure to conduct an enterprise-wide risk analysis
- Inadequate safeguards to prevent and address spear phishing attacks
- Settlement with RA/CAP, $16,000,000

Issue: Lack of Business Associate Agreements

- HIPAA generally requires that covered entities and business associates enter into agreements with their business associates (BAAs) to ensure that the business associates will appropriately safeguard protected health information.
- See 45 CFR §§ 164.502(e), 164.504(e), and 164.308(b).

Case Example: Advanced Care Hospitalists

- Filed a breach report confirming that patient information was viewable on a medical billing services' website
- Never had a BAA with the individual providing medical billing services
- No policy requiring business associate agreements until April 2014; in operation since 2005
- Settlement with RA/CAP, $500,000

Issue: Impermissible Disclosures

- A covered entity, including a health care provider, may not use or disclose protected health information (PHI), except either:

  (1) as the HIPAA Privacy Rule permits or requires; or

  (2) as the individual who is the subject of the information (or the individual's personal representative) authorizes in writing.

Case Example: Allergy Associates of Hartford, P.C.

- A patient contacted a local television station to speak about a dispute that had occurred between the patient and a doctor at Allergy Associates. The reporter subsequently contacted the doctor for comment and the doctor impermissibly disclosed the patient's protected health information to the reporter.
- OCR's investigation found that the doctor's discussion with the reporter demonstrated a reckless disregard for the patient's privacy rights.
  - The disclosure occurred after the doctor was instructed by Allergy Associates' Privacy Officer to either not respond to the media or respond with "no comment."
- Settlement with RA/CAP, $125,000

Corrective Actions May Include:

- Updating risk analysis and risk management plans
- Updating policies and procedures
- Training of workforce
- CAPs may include third party or outside monitoring

Some Best 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

Some Best Practices:

- 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

AUDIT

HITECH Audit Program

Purpose:

Identify best practices; uncover risks and vulnerabilities not identified through other enforcement tools; encourage consistent attention to compliance

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
- Evaluation of Pilot (2013) – issuance of formal evaluation report of pilot audit program
- Phase 2 (2016-2017) - desk audits of 207 covered entities and business associates

Phase 2 - Selected Desk Audit Provisions

- For Covered Entities:
  - Security Rule: risk analysis and risk management; and
  - 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 auditee protocol guidance for more details: http://www.hhs.gov/sites/default/files/2016HIPAADeskAuditAuditeeGuidance.pdf

Status

- 166 covered entity and 41 business associate desk audits were completed in December 2017
- Website updates with summary findings will be published in 2019

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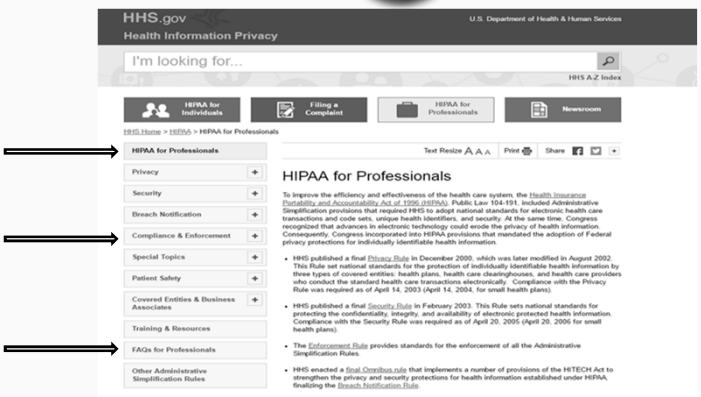
More Information



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