HIPAA Updates

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

Updated through October 31, 2019

Updates

- Policy
- Breach Notification
- Enforcement

Policy

Apps, APIs and the HIPAA Right of Access FAQs

- In April 2019, OCR issued new FAQs addressing the applicability of HIPAA to the use of software applications (apps) by individuals to receive health information from their providers.
- Provides guidance for covered entities, EHR developers and app developers.
- Reiterates the importance of HIPAA's right to access for individuals.

https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access-right-health-apps-apis/index.html

- **Notification of Enforcement Discretion Regarding HIPAA Civil Money Penalties Announced April 26, 2019**

Enforcement Notice			
Culpability	Low/violation*	High/violation*	Annual limit*
No Knowledge	$100	$50,000	**$25,000**
Reasonable Cause	$1,000	$50,000	**$100,000**
Willful – Corrected	$10,000	$50,000	**$250,000**
Willful – Not corrected	$50,000	$50,000	$1,500,000

https://www.federalregister.gov/documents/2019/04/30/2019-08530/enforcement-discretion-regarding-hipaa-civil-money-penalties

*The Department of Health and Human Services may make annual adjustments to the CMP amounts pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvement Act of 2015. The annual inflation amounts are found at 45 CFR § 102.3.

Direct Liability of Business Associates

Business associates are directly liable for HIPAA violations as follows:

- Failure to provide the Secretary with records and compliance reports; cooperate with complaint investigations and compliance reviews; and permit access by the Secretary to information, including protected health information (PHI), pertinent to determining compliance.
- Taking any retaliatory action against any individual or other person for filing a HIPAA complaint, participating in an investigation or other enforcement process, or opposing an act or practice that is unlawful under the HIPAA Rules.
- Failure to comply with the requirements of the Security Rule.
- Failure to provide breach notification to a covered entity or another business associate.
- Impermissible uses and disclosures of PHI.

Direct Liability of Business Associates

- Failure to disclose a copy of electronic PHI (ePHI) to either the covered entity, the individual, or the individual's designee (whichever is specified in the business associate agreement) to satisfy a covered entity's obligations regarding the form and format, and the time and manner of access under 45 C.F.R. §§ 164.524(c)(2)(ii) and 3(ii), respectively.
- Failure to make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.
- Failure, in certain circumstances, to provide an accounting of disclosures.
- Failure to enter into business associate agreements with subcontractors that create or receive PHI on their behalf, and failure to comply with the implementation specifications for such agreements.
- Failure to take reasonable steps to address a material breach or violation of the subcontractor's business associate agreement.

https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/factsheet/index.html

Direct Liability of Business Associates

Notably, OCR lacks the authority to enforce the "reasonable, cost-based fee" limitation in 45 C.F.R. § 164.524(c)(4) against business associates because the HITECH Act does not apply the fee limitation provision to business associates. A covered entity that engages the services of a business associate to fulfill an individual's request for access to their PHI is responsible for ensuring that, where applicable, no more than the reasonable, cost-based fee permitted under HIPAA is charged. If the fee charged is in excess of the fee limitation, OCR can take enforcement action against only the covered entity.

- https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/factsheet/index.html

BREACH HIGHLIGHTS AND RECENT ENFORCEMENT ACTIVITY

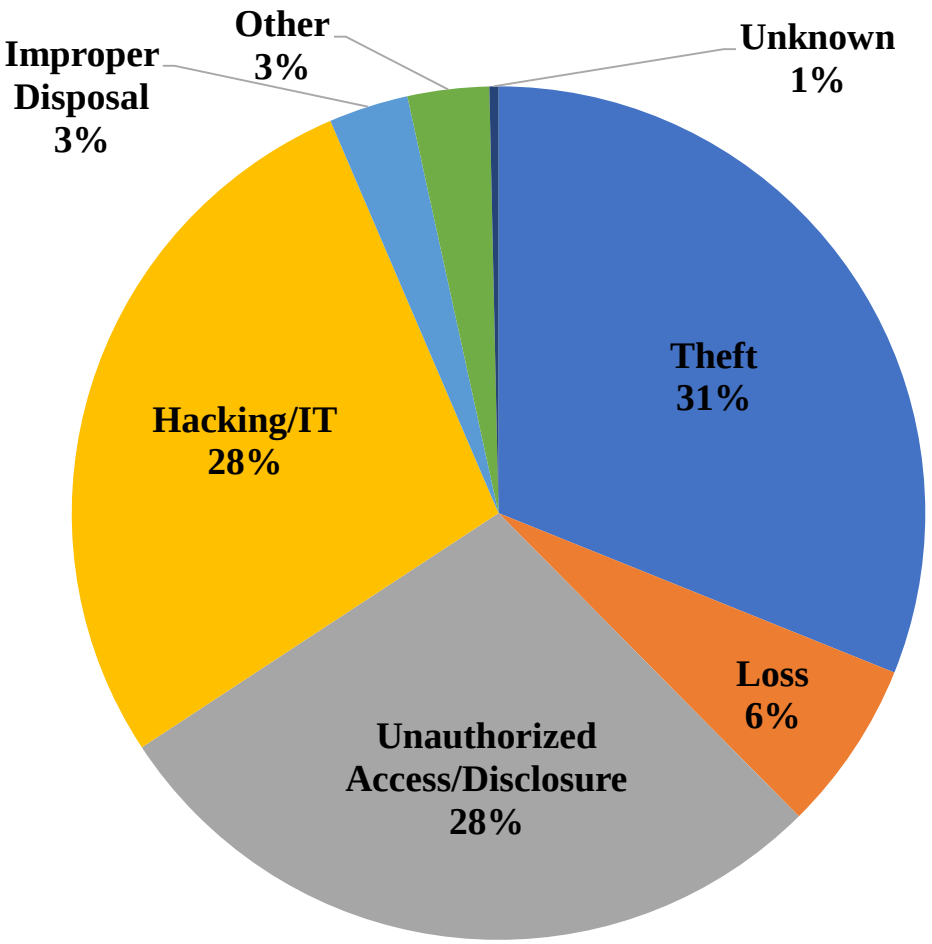
Breach Notification Requirements

- 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

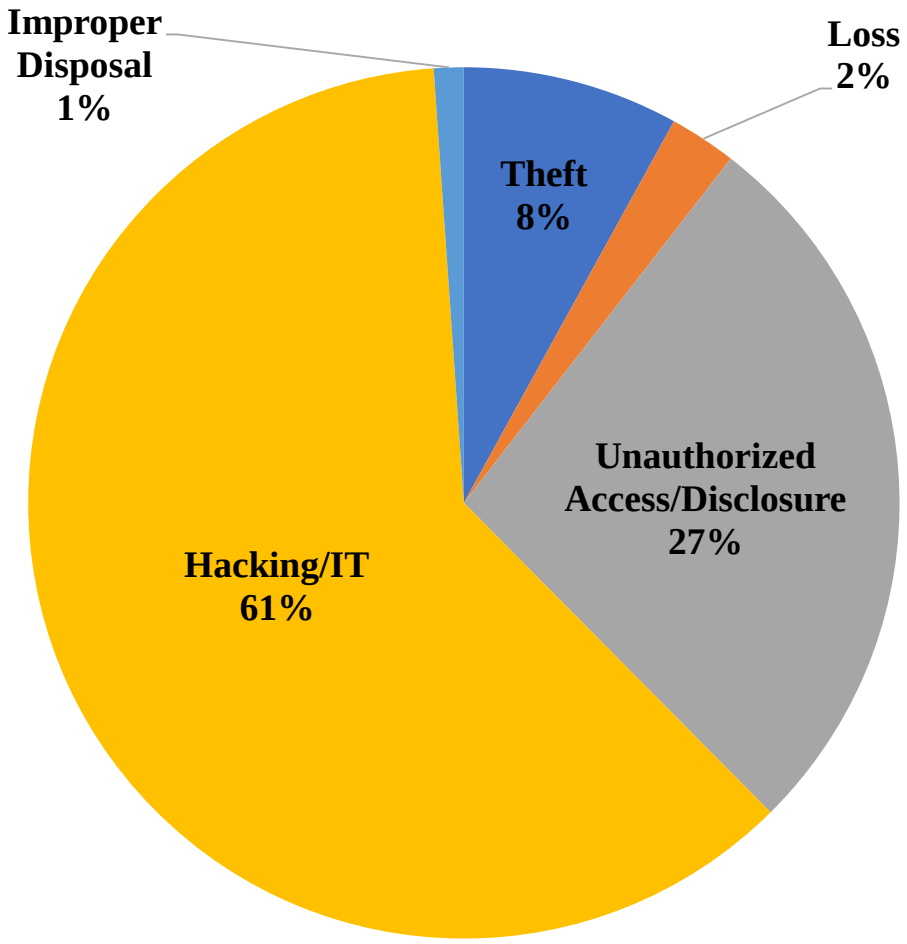
What Happens When HHS/OCR Receives a Breach Report

- 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

500+ Breaches by Type of Breach

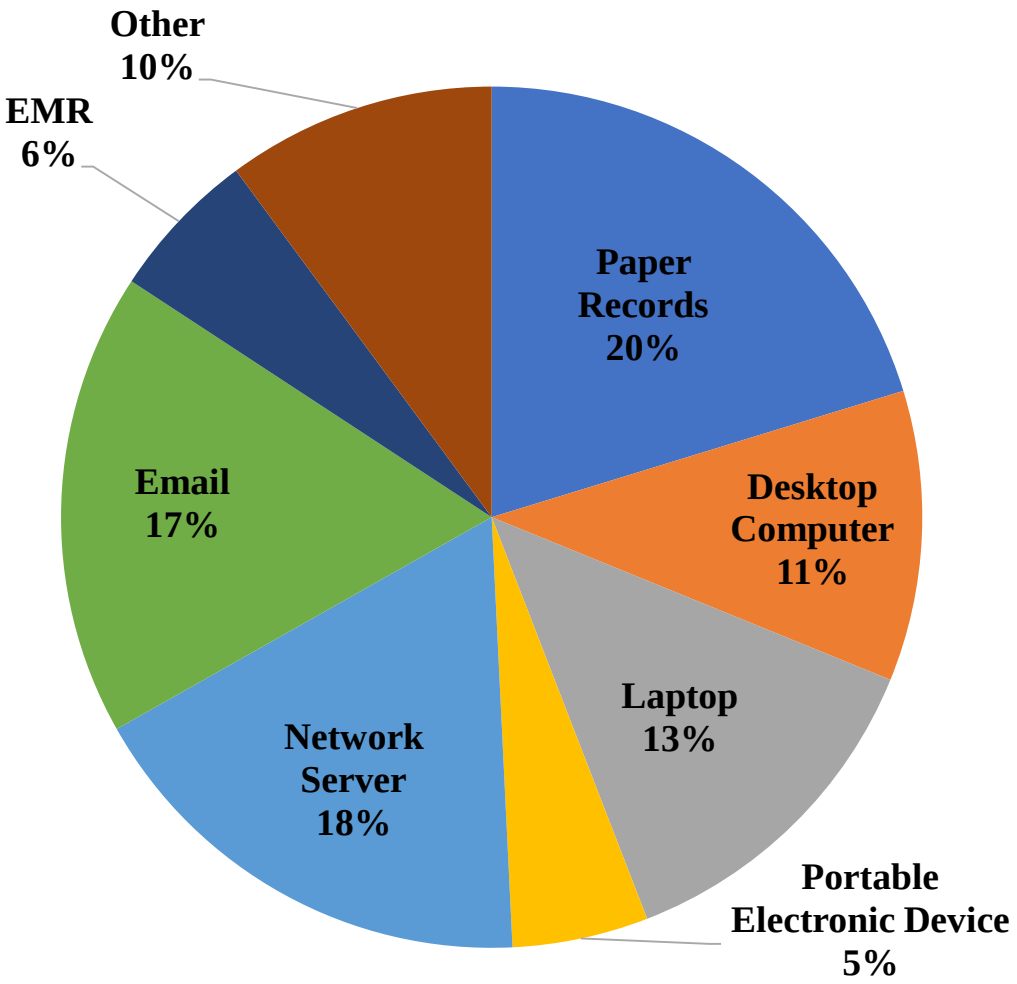


Sept 23, 2009 through September 30, 2019



Jan 1, 2019 through September 30, 2019

500+ Breaches by Location of Breach



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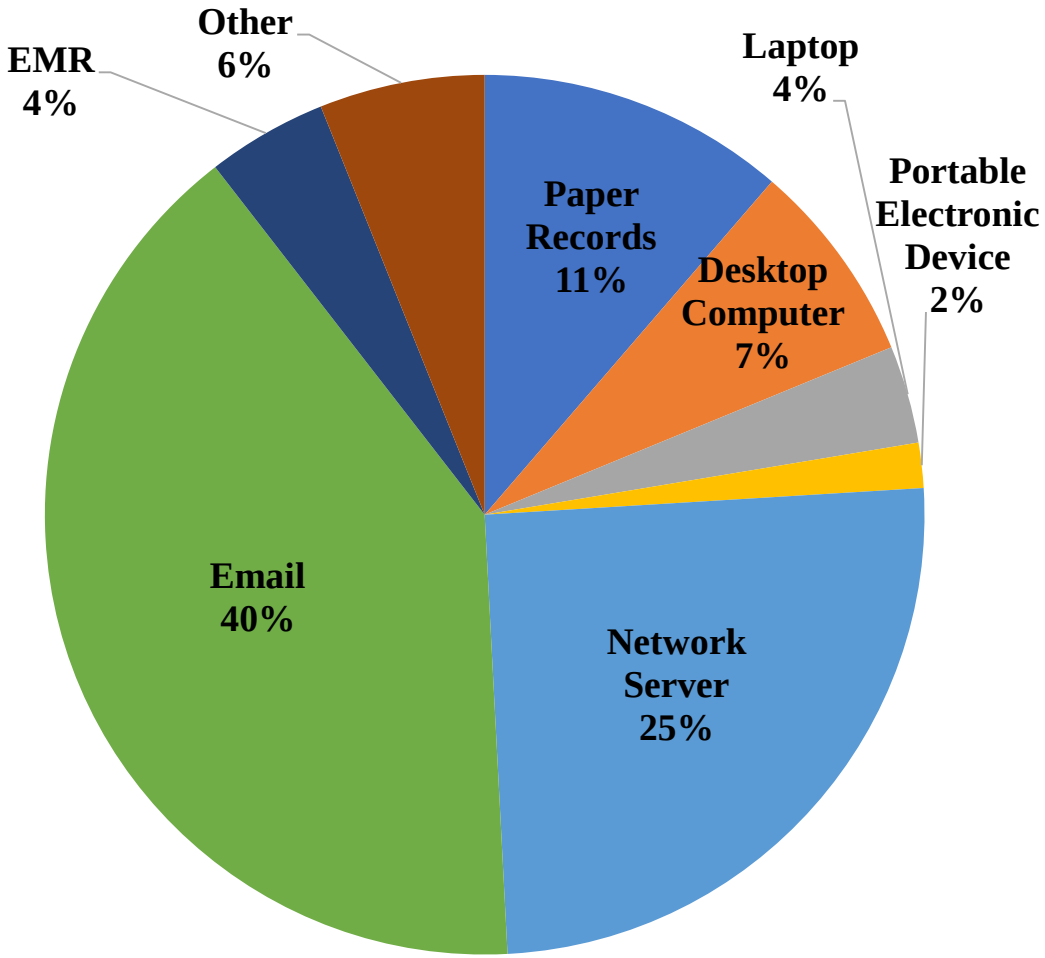
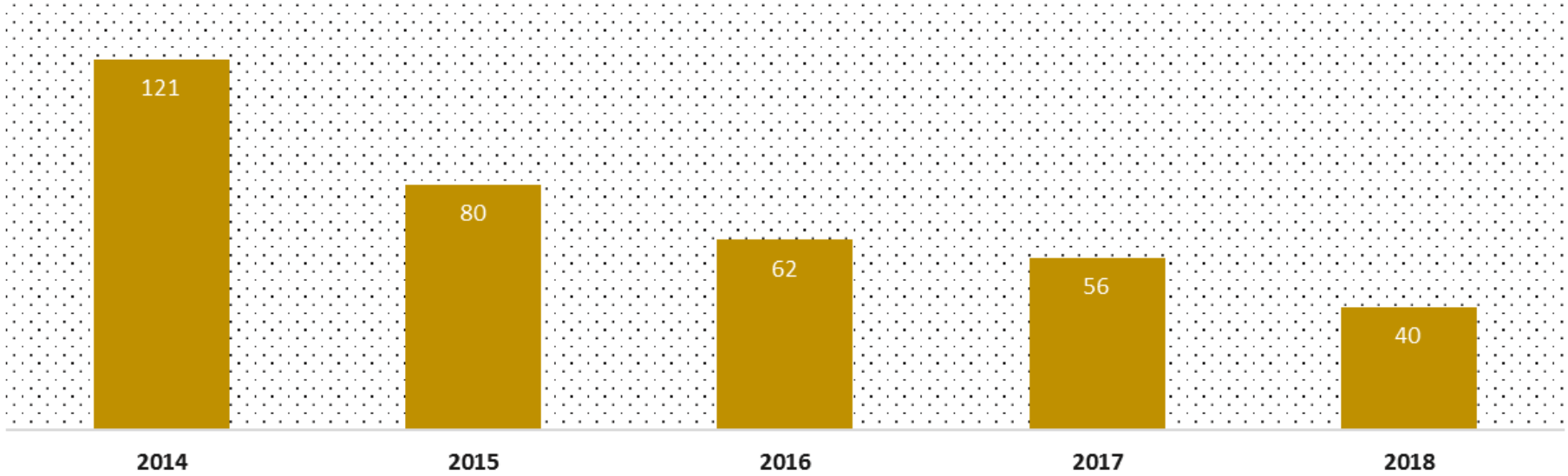


Jan 1, 2019 through September 30, 2019

Breaches Affecting 500 or more Individuals

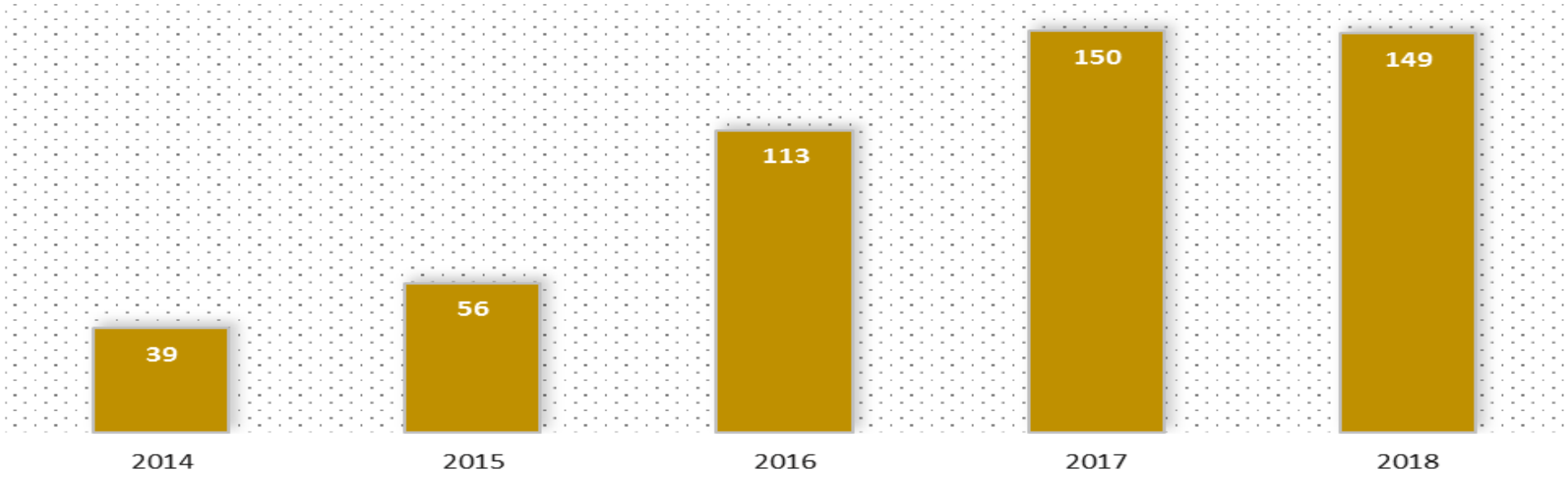
Reports Received Involving the Theft of PHI

Calendar Years 2014 - 2018



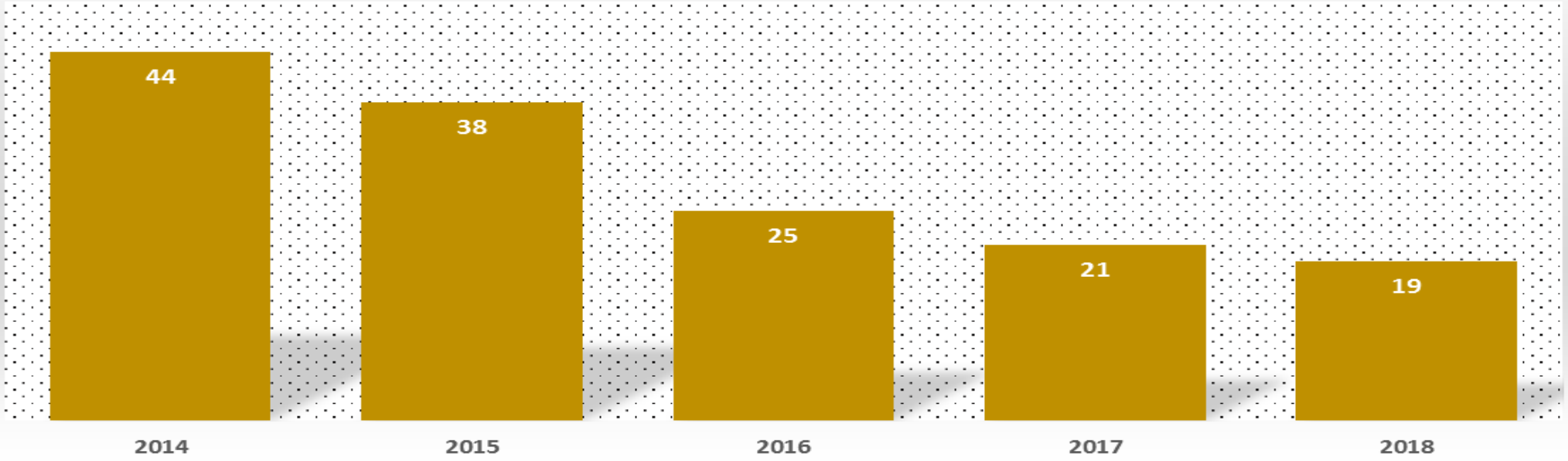
Breaches Affecting 500 or more Individuals
Reports Received Involving Hacking/IT Incidents

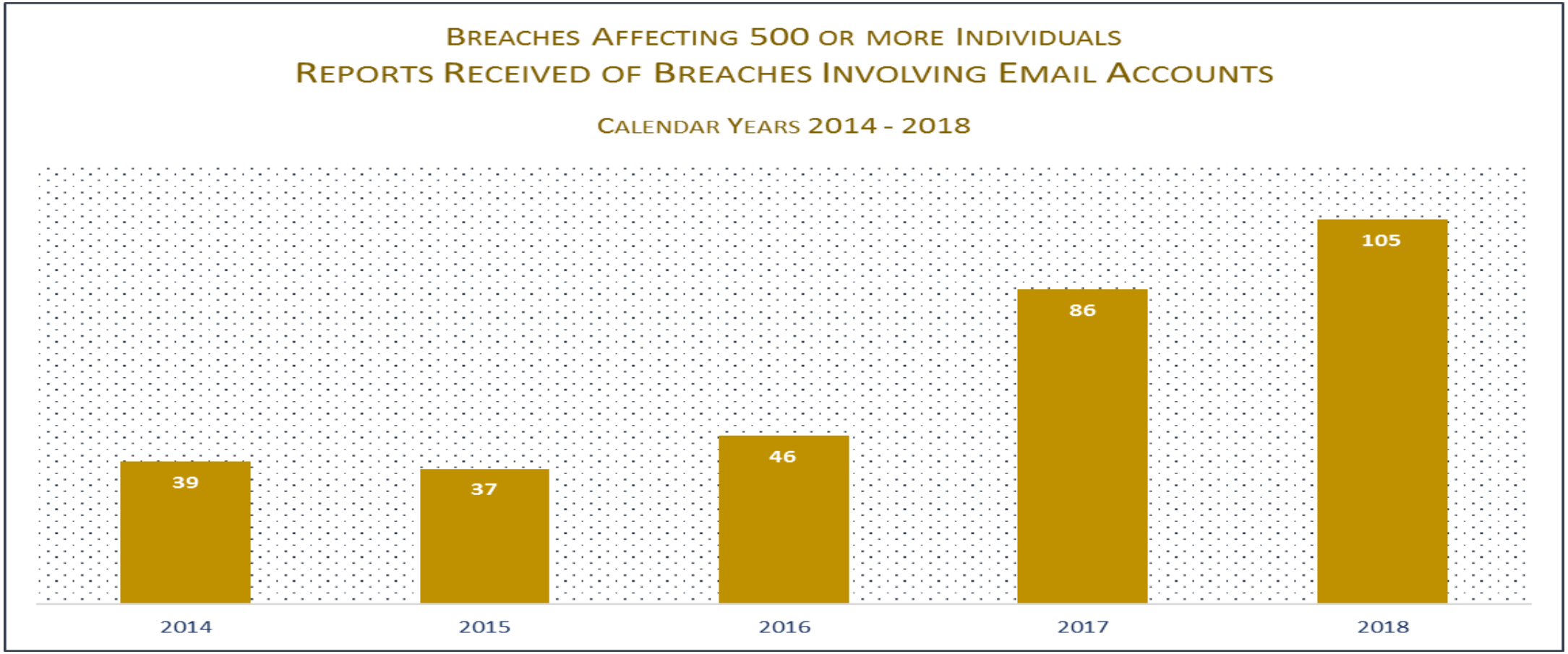
Calendar Years 2014 - 2018



Breaches Affecting 500 or more Individuals
Reports Received of Breaches of Laptop Computers

Calendar Years 2014 - 2018




Breaches Affecting 500 or more Individuals
Reports Received of Breaches Involving Email Accounts
Calendar Years 2014 - 2018
39
37
46
86
105
2014
2015
2016
2017
2018

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
  - 64 settlement agreements that include detailed corrective action plans and monetary settlement amounts
- 5 civil money penalties

As of October 31, 2019

Recent Enforcement Actions

10/2018	Allergy Associates of Hartford	$125,000
10/2018	Anthem	$16,000,000
11/2018	Pagosa Springs Medical Center	$111,400
12/2018	Cottage Health	$3,000,000
4/2019	Touchstone Medical Imaging	$3,000,000
4/2019	Medical Informatics Engineering	$100,000
9/2019	Bayfront Health St. Petersburg	$85,000
10/2019	Elite Dental Associates	$10,000
10/2019	Jackson Health System	$2,154,000

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

Corrective Action

Corrective Actions May Include:

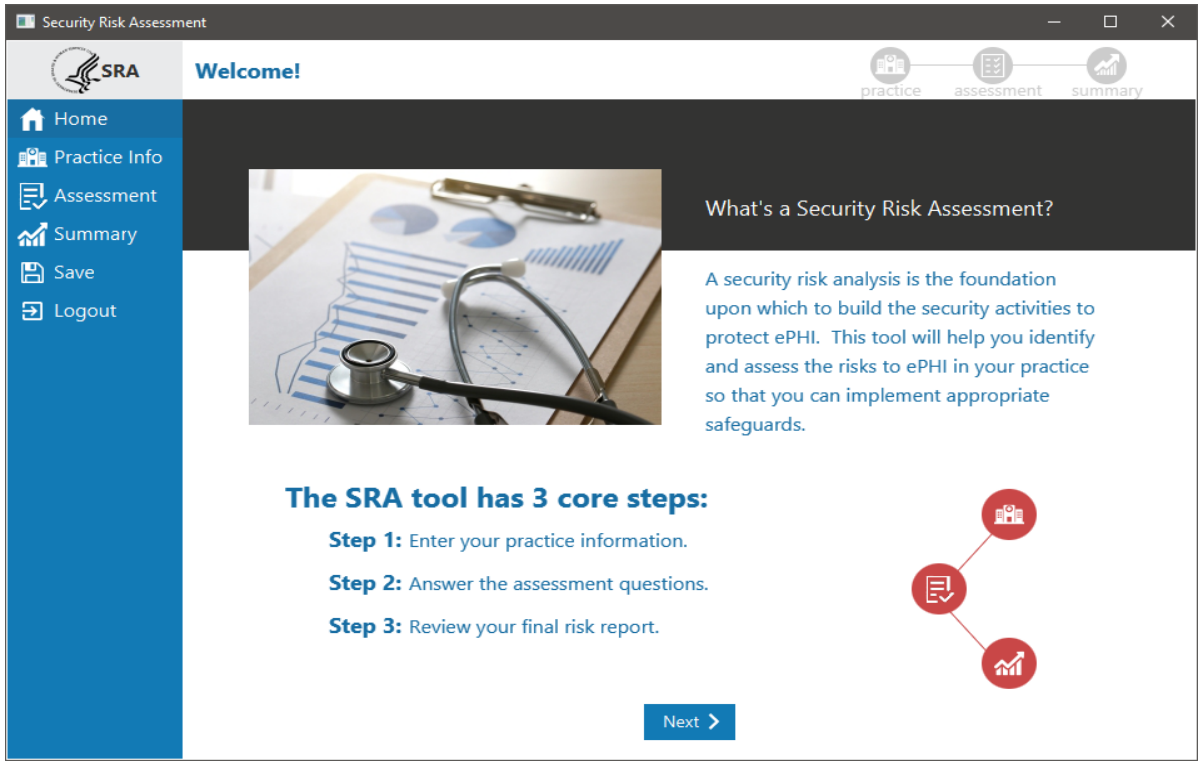
- Updating risk analysis and risk management plans
- Updating policies and procedures
- Training of workforce
- CAPs may include 3rd party or outside monitoring

Best Practices

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
- 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

SRA Tool



https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool

Designed to assist small to medium sized organizations in conducting an internal security risk assessment to aid in meeting the security risk analysis requirements of the HIPAA Security Rule and the CMS EHR Incentive Program.

The SRA tool guides users through a series of questions based on standards identified in the HIPAA Security Rule. Responses are sorted into Areas of Success and Areas for Review.

Not all areas of risk may be captured by the tool. Risks not identified and assessed via the SRA Tool must be documented elsewhere.

Provider Education:
An Individual's Right to Access and Obtain their Health Information Under HIPAA

- Web-based Video Training for Free Continuing Medical Education and Continuing Education Credit for Health Care Professionals via Medscape
- 70,000+ health care providers and allied health professionals trained

http://www.medscape.org/viewarticle/876110

Cybersecurity Newsletters

- Began in January 2016
- Past Topics Include
  - Risk Analyses v. Gap Analyses
  - Workstation Security
  - Software Vulnerabilities and Patching
  - Guidance on Disposing of Electronic Devices and Media
  - Considerations for Securing Electronic Media and Devices
  - Sign up for the OCR Listserv:

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

http://www.hhs.gov/hipaa

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