Updates in Privacy, Security, and Breach Enforcement

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

Danielle Archuleta, Supervisory Equal Opportunity Specialist
Nikki Levy, Equal Opportunity Specialist (Contractor)
June 7, 2019

Updates

• Breach Notification
• Enforcement
• Audit
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 March 31, 2019
- Theft: 15%
- Unauthorized Access/Disclosure: 21%
- Hacking/IT: 63%
- Improper Disposal: 1%
- Unrelated: 3%
- Unauthorized Access/Disclosure: 29%
- Loss: 7%

#### Jan 1, 2019 through March 31, 2019
- Theft: 15%
- Unauthorized Access/Disclosure: 21%
- Hacking/IT: 63%
- Improper Disposal: 1%
- Unknown: 1%
- Unauthorized Access/Disclosure: 29%
**500+ Breaches by Location of Breach**

- **Sept 23, 2009 through March 31, 2019**
  - Paper Records: 21%
  - Desktop Computer: 10%
  - Laptop: 14%
  - Network Server: 18%
  - Email: 14%
  - EMR: 6%
  - Other: 9%

- **Jan 1, 2019 through March 31, 2019**
  - Paper Records: 34%
  - [CATEGORY NAME]: 7%
  - Laptop: 7%
  - Network Server: 27%
  - Portable Electronic Device: 1%
  - Other: 9%
  - EMR: 7%
  - Desktop Computer: 8%

**Breaches Affecting 500 or More Individuals Reports Received Involving the Theft of PHI**

<table>
<thead>
<tr>
<th>Calendar Years 2014 - 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
</tr>
<tr>
<td>121</td>
</tr>
</tbody>
</table>
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
2018 Enforcement Actions

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

Total $28,683,400

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


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
http://www.hhs.gov/hipaa

Join us on Twitter @hhsocr