OCR update and Other HIPAA Issues to Keep You Up At Night!

Presented by:
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Vice President of Audit Strategy

Meeting Agenda

1. OCR update
2. Privacy and Security Vendor Management Risks
3. Compliance and Privacy Key Considerations in Incident Response
4. Questions

OCR UPDATE

OCR Activities

• Proposed policy update
• The changing landscape of data compromises
• The past findings and future process for the audit program
Proposed HIPAA Policy Activity

- Notice of Proposed Rulemaking on Good Faith Disclosures by Health Care Providers to Address Opioid Crisis

- Request for Information on Improving Care Coordination and Reducing Regulatory Burden
  - Notice of Privacy Practices
  - Required Provider to Provider Information Sharing
  - Accounting of Disclosures

- Request for Information on Civil Monetary Penalties or Monetary Settlements to Harmed Individuals

- HIPAA/FERPA

500+ Breaches by Type

<table>
<thead>
<tr>
<th>Category Name</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theft</td>
<td>12%</td>
</tr>
<tr>
<td>Loss</td>
<td>4%</td>
</tr>
<tr>
<td>Improper Disposal</td>
<td>2%</td>
</tr>
<tr>
<td>Unauthorized Access/Disclosure</td>
<td>27%</td>
</tr>
<tr>
<td>Other</td>
<td>14%</td>
</tr>
<tr>
<td>Unknown</td>
<td>1%</td>
</tr>
<tr>
<td>Improper Disposal</td>
<td>3%</td>
</tr>
</tbody>
</table>

September 23, 2009 through December 31, 2017

January 1, 2018 through September 30, 2018
What Went Wrong

Anthem, Inc. - $16,000,000

- 78.8m individuals affected
  - Largest health data breach in U.S.
- Gained access through spear fishing in Feb. 2014
- Data extracted from Dec. 2014 to Jan. 2015
  - Included names, addresses, dates of birth, email addresses, SSNs, medical ID numbers and employment information
- Issues with risk analysis, information system activity review, security incident response and reporting, and access controls
- 2 other settlements –
  - National Association of Insurance Commissioners (December 2016)
  - Class Action (August 2018)
What went Wrong

**ABC Cases $999,000**

- Boston Medical Center - $100,000
- Brigham and Women’s Hospital - $384,000
- Massachusetts General Hospital - $515,000
  - BWH and MGH are members of Partners Healthcare - an integrated health care delivery system that includes community hospitals, primary care and specialty physicians, specialty facilities, community health centers and other health-related entities
- All three involved filming for “Save My Life: Boston Trauma”
- Similar to another ABC TV show – “NY Med”
  - “NY Med” resulted in a 2016 settlement with NY Presbyterian for $2.2m

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AND IT’S NOT JUST HIPAA …..

- **All 50 States now have some type of data breach notification statute**
  - Alabama added in April 2018
  - All but 8 concern electronic data only
- **In June, New Jersey AG announced formation of a new data privacy & cybersecurity section**
- **Also in June, the New California Consumer Privacy Act was passed**
- **In September, the Massachusetts AG signed a $250,000 settlement agreement with UMass Memorial Medical Center for a privacy violation**
- **And let’s not forget about GDPR!**
OCR Audit Findings

- Total covered entities audited: 166
  - 103 for Privacy and Breach Rule compliance
  - 63 for Security Rule compliance
  - Break down of covered entities
    - 9% Health Plans
    - 1% Clearinghouses
    - 90% Providers
- Business associates audited: 41
  - All assessed for Breach Notification and Security Rule compliance

OCR Audit Findings

- OCR comments about the audit process: Under OCR’s separate, broad authority to open compliance reviews, OCR could decide to open a separate compliance review in circumstances were significant threats to the privacy and security of PHI are revealed through the audit.
OCR Compliance Rating Scale

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The audit results indicate the entity is in compliance with both goals and objectives of the selected standards and implementation specifications.</td>
</tr>
<tr>
<td>2</td>
<td>The audit results indicate that the entity substantially meets criteria; it maintains appropriate policies and procedures; and, documentation and other evidence of implementation meets requirements.</td>
</tr>
<tr>
<td>3</td>
<td>Audit results indicate entity efforts minimally address audited requirements; analysis indicates that entity has made attempts to comply, but implementation is inadequate, or some efforts indicate misunderstanding of requirements.</td>
</tr>
<tr>
<td>4</td>
<td>Audit results indicate the entity made negligible efforts to comply with the audited requirements (e.g. policies and procedures submitted for review are copied directly from an association template; evidence of training is poorly documented and generic).</td>
</tr>
<tr>
<td>5</td>
<td>The entity did not provide OCR with evidence of serious attempt to comply with the Rules and enable individual rights with regard to PHI.</td>
</tr>
</tbody>
</table>

CEs: Privacy, Security and Breach Notification Rules

<table>
<thead>
<tr>
<th></th>
<th>Rating at each end of the rankings for all entities (103)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breach Rule</td>
<td>5 Rating</td>
</tr>
<tr>
<td>Timeliness of Notification</td>
<td>15</td>
</tr>
<tr>
<td>Content of Notification</td>
<td>9</td>
</tr>
<tr>
<td>Privacy Rule</td>
<td>11</td>
</tr>
<tr>
<td>Access</td>
<td>16</td>
</tr>
<tr>
<td>NPP Content</td>
<td>15</td>
</tr>
<tr>
<td>Electronic NPP</td>
<td>13</td>
</tr>
<tr>
<td>Security Rule</td>
<td>17</td>
</tr>
<tr>
<td>Risk Analysis</td>
<td>13</td>
</tr>
<tr>
<td>Risk Management</td>
<td>17</td>
</tr>
</tbody>
</table>
### CEs: Privacy, Security and Breach Notification Rules

#### Rankings of the covered entities audited (103)

<table>
<thead>
<tr>
<th>Breach Rule</th>
<th>5</th>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timeliness of Notification</td>
<td>11%</td>
<td>9%</td>
<td>2%</td>
<td>6%</td>
<td>65%</td>
<td>7%</td>
</tr>
<tr>
<td>Content of Notification</td>
<td>7%</td>
<td>37%</td>
<td>23%</td>
<td>14%</td>
<td>14%</td>
<td>5%</td>
</tr>
</tbody>
</table>

#### Privacy Rule
- Provision of the NPP | 15% | 6% | 4% | 15% | 57% |
- NPP Content | 15% | 11% | 39% | 33% | 2% |
- Access right | 11% | 54% | 27% | 10% | 1% |

#### Security Rule
- Risk Analysis | 13% | 23% | 19% | 8% | 0% |
- Risk Management | 17% | 29% | 13% | 3% | 1% |

### BAs: Security and Breach Notification Rules

#### Rankings of the business associate audited (41)

<table>
<thead>
<tr>
<th>Breach Rule</th>
<th>5</th>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notification to CE</td>
<td>0%</td>
<td>7%</td>
<td>10%</td>
<td>5%</td>
<td>0%</td>
<td>78%</td>
</tr>
</tbody>
</table>

#### Security Rule
- Risk Analysis | 15% | 29% | 39% | 10% | 7% | 0% |
- Risk Management | 17% | 51% | 20% | 12% | 0% | 0% |
CE and BA Risk Analysis Comparison

CE and BA Risk Management Comparison
Industry Take-Away

**Best Outcomes**
- Providing timely notice of breach
- Posting of NPP on website
- Providing required NPP content

**Most Room for Improvement**
- Risk Management
- Risk Analysis
- Enabling Individual Access

OCR will examine entity practices for lessons learned that can be shared in technical assistance

Review OCR guidance and technical assistance

OCR is working to enhance technical assistance in those areas

Enforcement Highlights

60 OCR enforcement actions
$100 Million
In settlements & CMPs
13 settlements in 2016
10 settlements in 2017
6 settlement in 2018
41 of 60 enforcement actions arose from breach reports to HHS

4 Civil Money Penalty Actions
$3,021,950
Average settlement amount

55
9
Required internal monitor

5
Required external monitor

10
Monitor required in 10 out of 56
Vendor Management
Risks

Healthcare Vendors in the News

Nuance

eClinicalWorks

Allscripts
Vendor Security Must Improve

- Requirements definition
- Pre-Contract due diligence
- Contract security specifications
- Performance monitoring
- Breach Notification
- Contract termination
- Documentation

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Breach Notification

- Contract language regarding
  - Security incident notification
  - Breach notification
- Timeliness of notifications
- Assistance in investigation/risk assessment
- Indemnification for certain costs
- Notifications to public
Compliance and Privacy Key Considerations Incident Response

Understanding who is in charge, the hierarchy.

- Who is in charge?
- Who are the key stakeholders?
- What are their priorities?
- When are they needed?
- How do you communicate?
- When or if do you engage legal?
Specifically, Who To Involve

- Core team members
  - CIO
    - Multiple specialist across IT and IS
  - Compliance Leadership
    - CCO
    - CPO
    - CISO
  - General Counsel
  - Designated member of the senior leadership team
    - Business Unit Leaders
    - Clinical Leadership

- Key stakeholders representing other functions
  - Media relations
  - Patient relations
  - Procurement
  - Human Resources
  - Impacted business owners
  - Other senior leaders of your organization
    - CEO, CFO, CNO, CMO, & CMIO
    - Senior leaders of a parent organization
Specifically, Who To Involve

- Key outside stakeholders who may need to be involved
  - Cybersecurity insurance company
  - External counsel
  - Key vendors
    - Forensics firms
    - Support for response and recovery
  - Law enforcement
    - Local
    - Federal
  - Impacted business partners such as affiliated healthcare providers

Developing a Successful IRP

Develop repeatable, efficient, and effective incident response processes

Use these to identify, analyze, and correct hazards to prevent future occurrences

Four primary work components will help this initiative:
- Initiate and Organize: Establish Incident Response Project Governance
- Measure: Conduct Incident Response Workflow Analysis
- Standardize & Align: Develop Incident Response Program and Processes
- Perform & Inform: Post-Incident Activity
What is Often Missing From IRPs

- Executive Buy-in for planning and execution of IRP
- Governance Council Involvement in Planning & execution of IRP
- Breach notification and compliance
- Thorough communication plans (internal and external)
- Involvement beyond IT and IS departments
- Regular Exercises and updates
- Up-to-date phone trees

Notification to Covered Entities & Business Partners

- In addition to regulatory obligations to notify there may also be other obligations
  - Contractual obligations
    - Are you a BA to another covered entity?
    - Does the organization have contracts that require notification regarding a data incident or breach
Plenty of Ways to Get Ahead During the Attack

• Anticipate having to defend against legal consequences
  - Engage your GC early, especially if litigation is anticipated
  - Determine if Privilege is needed as soon as possible
  - Assign a scribe – who discovered what, when, & how
• Do not rush to reimage – it destroys evidence that can be used to support your conclusions
• Start documenting for the after action report now

Thank You!

Questions?

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