Lessons Learned from OCR Privacy and Security Audits

Program Overview & Initial Analysis

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Presentation to IAPP Global Privacy Summit
March 7, 2013
Program Mandate

HITECH Act, Section 13411 - Audits

- This section of The American Recovery and Reinvestment Act of 2009, requires HHS to provide for periodic audits to ensure covered entities and business associates are complying with the HIPAA Privacy and Security Rules and Breach Notification Standards.

Program Opportunity

- Examine mechanisms for compliance
- Identify best practices
- Discover risks and vulnerabilities that may not have come to light through complaint investigations and compliance reviews
- Encourage renewed attention to compliance activities
# Multi-year Audit Plan

<table>
<thead>
<tr>
<th>Description</th>
<th>Vendor</th>
<th>Status/Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audit program development study</td>
<td>Booz Allen Hamilton</td>
<td>Closed 2010</td>
</tr>
<tr>
<td>Covered entity identification and cataloguing</td>
<td>Booz Allen Hamilton</td>
<td>Closed 2011</td>
</tr>
<tr>
<td>Develop audit protocol and conduct audits</td>
<td>KPMG, Inc.</td>
<td>Closed 2011-2012</td>
</tr>
<tr>
<td>Evaluation of audit program</td>
<td>PWC, LLP</td>
<td>Open Conclude in 2013</td>
</tr>
</tbody>
</table>
2012 Implementation

Audit Protocol Design

- Created a comprehensive, flexible process for analyzing entity efforts to provide regulatory protections and individual rights

Resulting Audit Program

- Conducted 115 performance audits through December 2012 to identify findings in regard to adherence with standards. Two phases:
  - Initial 20 audits to test original audit protocol
  - Final 95 audits using modified audit protocol
What is a Performance Audit?

- An audit service conducted in accordance with GAGAS, Generally Accepted Government Auditing Standards (The Yellow Book)
- Provides findings, observations, or conclusions based on an evaluation of sufficient, appropriate evidence against established audit criteria
- Can include a limitless range of objectives driven by the needs of users
- Can entail objective assessments of a variety of attributes:
  - Program effectiveness, economy, and efficiency
  - Internal control
  - Compliance
  - Other questions of interest to management (e.g. value of assets, determination of pension benefits)
Performance Audit Objective

To analyze the key processes, controls, and policies of the auditee relative to selected requirements of the Rules as specified in an OCR audit protocol and provide findings or observations.

The audit objective *did not* include a determination of the effectiveness of implementation of the selected requirements in OCR’s audit protocol.
Who Can Be Audited?

Any Covered Entity

For 2011-2012, OCR sought wide range of types and sizes
- Health plans of all types
- Health care clearinghouses
- Individual and organizational providers

Any Business Associate

TBD after September 23, 2013 (HITECH Final Rule compliance date)
Auditee Selection Criteria

OCR identified a pool of covered entities

- Public versus Private
- Entity’s size, e.g., level of revenues/assets, number of patients or employees, use of HIT
- Affiliation with other health care organizations
- Geographic location
- Type of entity

Specific criteria includes but is not limited to:
Breakdown of Auditees

**Level 1 Entities**
- Large Provider / Health Plan
- Extensive use of HIT - complicated HIT enabled clinical/business work streams
- Revenues and or assets greater than $1 billion

**Level 2 Entities**
- Large regional hospital system (3-10 hospitals/region) / Regional Insurance Company
- Paper and HIT enabled work flows
- Revenues and or assets $300 million to $1 billion

**Level 3 Entities**
Community hospitals, outpatient surgery, regional pharmacy / All Self-Insured entities that don’t adjudicate their claims
- Some but not extensive use of HIT – mostly paper based workflows
- Revenues $50 Million to $300 million

**Level 4 Entities**
- Small Providers (10 to 50 Provider Practices, Community or rural pharmacy)
- Little to no use of HIT – almost exclusively paper based workflows
- Revenues less than $50 million
# Auditees by Type & Size

<table>
<thead>
<tr>
<th></th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Level 4</th>
<th>Total</th>
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<tbody>
<tr>
<td><strong>Health Plans</strong></td>
<td>13</td>
<td>12</td>
<td>11</td>
<td>11</td>
<td>47</td>
</tr>
<tr>
<td><strong>Health Care Providers</strong></td>
<td>11</td>
<td>16</td>
<td>10</td>
<td>24</td>
<td>61</td>
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<tr>
<td><strong>Health Care Clearinghouses</strong></td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>26</td>
<td>31</td>
<td>22</td>
<td>36</td>
<td>115</td>
</tr>
</tbody>
</table>

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Audit Process
Audit Timeline

- **1 Business Day**: Notification Letter Sent to Covered Entities
- **20-60 Business Days**: Receiving and Reviewing Documentation and Planning the Audit Field Work
- **3-5 Business Days**: Onsite Field Work
- **10-20 * Business Days**: Draft Audit Report
- **10 Business Days**: Covered Entity Provides Management Responses
- **30-90 * Business Days**: Final Audit Report

* Duration varies based on several factors such as, the volume and complexity of findings noted

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Planning the Audit

1. Complete Covered Entity selection process to:
   - Determine auditee universe;
   - Determine independence from entity;
   - Determine entity size and type; and
   - Select the entity.

2. Send notification letter to the selected Covered Entity including:
   - Information Request List; and
   - Entity Survey.

3. Make Initial contact to:
   - Confirm Notification Letter receipt;
   - Respond to any questions/concerns; and
   - Confirm due date for documentation requests.
1. Conduct kick-off call to:
   – Confirm Covered Entity type (provider, clearinghouse, fully insured
group health plan, etc.), applicable scope, audit location(s); and
   – Discuss on-site visit and logistics.
2. Perform analysis of documentation provided by the Covered
   Entity to determine:
   – What documents have been received; and
   – What documents are missing?
3. Begin audit testing procedures surrounding the review of
documentation.
4. Send field work start date reminder email.
Field Work

1. Conduct an entrance conference with the Covered Entity to discuss:
   - Performance audit concept, scope, objective, and approach; and
   - Set expectations with the auditee.

2. Execute and document all applicable audit procedures (see Audit Protocol Walkthrough):
   - Complete onsite testing;
   - Conduct interviews;
   - Review documentation; and
   - Observe appropriate facilities/workstations.

3. Conduct an exit conference with the Covered Entity to discuss:
   - Preliminary identified issues; and
   - Discuss next steps for the audit process.
1. Document results of the audit.
2. Finalize draft identified findings.
4. Submit draft audit report and supporting evidence for Quality Assurance (QA) Review.
5. Provide draft findings to Covered Entity for management response.
6. Incorporate findings with management responses into draft report and Clarify management responses with Covered Entity.
7. Submit draft audit report and results for secondary QA Review.
8. Provide OCR with draft audit report for comments.
10. Issue the final audit report.
Audit Process Walkthrough
Audit Protocol—11 Modules

Breach Notification

Security
- Administrative Safeguards
- Physical Safeguards
- Technical Safeguards

Privacy
- Notice of Privacy Practices
- Rights to Request Privacy Protection of PHI
- Access of Individuals to PHI
- Administrative Requirements
- Uses and Disclosures of PHI
- Amendment of PHI
- Accounting of Disclosures
Audit Protocol Components

Established Criteria - Privacy, Security, and Breach Notification Rule criteria against which compliance is to be evaluated and assessed.

Audit Testing Procedures – Procedures executed to assess compliance with the criteria.

Workpaper Reference – Reference to workpaper documenting results of testing for the corresponding criteria.

Applicability - Whether or not the criteria/audit procedures are applicable for the Covered Entity.
Protocol Example - Authorizations

The following slides walk through the protocol for § 164.508 – Uses & Disclosures. Process is repeated for each applicable section of the rule, listed in Appendices A & B.

1) Criteria

2) Audit Testing Procedures

3) W/P Ref.

4) Applicability
Audit Testing Procedure - Inquiry

- The audit team would execute this audit step through an interview with, for example, the Privacy Officer:
  - Inquire of management as to whether a process exists to determine when authorization is required.

| Inquire of management as to whether a process exists to determine when authorization is required. | EF-350.FF1 |
| Obtain and review a sample of instances where authorization is required to determine if a valid authorization was obtained: | EF-350.FF2 |
| - Evidence that an authorization was valid. | |
| For providers only: obtain and review all patient intake forms for both inpatient and outpatient services, including consent and authorization forms, if any. | EF-350.FF3 |
The audit team would execute this audit step through review of documentation:

- Obtain and review a sample of instances where authorization is required to determine if a valid authorization was obtained:
  - Evidence that an authorization was valid.
Audit Testing Procedure - Review

<table>
<thead>
<tr>
<th>Inquire of management as to whether a process exists to determine when authorization is required.</th>
<th>EF-350.FF1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obtain and review a sample of instances where authorization is required to determine if a valid authorization was obtained:</td>
<td>EF-350.FF2</td>
</tr>
<tr>
<td>-Evidence that an authorization was valid.</td>
<td></td>
</tr>
<tr>
<td>For providers only: obtain and review all patient intake forms for both inpatient and outpatient services, including consent and authorization forms, if any.</td>
<td>EF-350.FF3</td>
</tr>
</tbody>
</table>

- The audit team would execute this audit step through review of documentation:
  - For providers only: obtain and review all patient intake forms for both inpatient and outpatient services, including consent and authorization forms, if any.
Workpaper – Authorizations

- **Results of Audit Testing Procedure**
  - Documentation of the procedures performed and audit evidence obtained

- **Summary of Results**
  - Documentation of whether the Covered Entity addressed the requirements outlined within the criteria.
  - Documentation of a reference to a finding.

<table>
<thead>
<tr>
<th>Results of audit testing procedure:</th>
<th>EF-150 FE:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Inquire of management as to whether a process exists to determine when authorization is required.</td>
<td>A. [INSERT DESCRIPTION OF TESTING PERFORMED AND RESULTS]</td>
</tr>
<tr>
<td></td>
<td>Obtain and review a sample of instances where authorization is required to determine if a valid authorization was obtained:</td>
</tr>
<tr>
<td></td>
<td>- Evidence that an authorization was valid.</td>
</tr>
<tr>
<td></td>
<td>A. [INSERT DESCRIPTION OF TESTING PERFORMED AND RESULTS]</td>
</tr>
<tr>
<td>3. For providers only: obtain and review all patient intake forms for both inpatient and outpatient services, including consent and authorization forms, if any.</td>
<td>A. [INSERT DESCRIPTION OF TESTING PERFORMED AND RESULTS]</td>
</tr>
<tr>
<td></td>
<td>[INSERT DESCRIPTION OF TESTING PERFORMED AND RESULTS]</td>
</tr>
</tbody>
</table>

**Summary of results:**

Based on the procedures performed above...

In instances where a finding has been identified, make reference to the Notice of Finding(s) and Recommendation(s) work paper here.
Appendix A – Tested Privacy & Breach Notification Protocol
# Privacy Audit Protocol

<table>
<thead>
<tr>
<th>Section</th>
<th>Key Activity</th>
<th>W/P Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$164.520 Provision of Notice – Health Plans</td>
<td>EF-321.AA</td>
</tr>
<tr>
<td></td>
<td>$164.520 Provision of Notice – Certain Covered Health Care Providers</td>
<td>EF-322.AA</td>
</tr>
<tr>
<td></td>
<td>$164.520 Provision of Notice – Electronic Notice</td>
<td>EF-323.AA</td>
</tr>
<tr>
<td></td>
<td>$164.520 Joint Notice by Separate Covered Entities</td>
<td>EF-324.AA</td>
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<tr>
<td>BB. Rights to Request Privacy Protection for PHI - §164.522</td>
<td>$164.522 Confidential Communication Requirements</td>
<td>EF-325.BB</td>
</tr>
<tr>
<td>CC. Access of Individuals to PHI - §164.524</td>
<td>$164.524 Right to Access</td>
<td>EF-330.CC</td>
</tr>
<tr>
<td></td>
<td>$164.524 Review of Denial of Access</td>
<td>EF-331.CC</td>
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<tr>
<td>DD. Administrative Requirements - §164.530</td>
<td>$164.530 Privacy Training</td>
<td>EF-335.DD</td>
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<td></td>
<td>$164.530 Complaints to the Covered Entity</td>
<td>EF-336.DD</td>
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<tr>
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<td>$164.530 Sanctions of Workforce Regarding failure to Comply with the Privacy Policies and Procedures</td>
<td>EF-337.DD</td>
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<tr>
<td></td>
<td>$164.530 Policies and Procedures</td>
<td>EF-338.DD</td>
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<tr>
<td>Section</td>
<td>Key Activity</td>
<td>W/P Ref.</td>
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<tr>
<td>---------</td>
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<td>---------------</td>
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<tr>
<td>FF. Uses and Disclosures§164.502, 504, 508, 510, 512, and 514</td>
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<td>§164.502</td>
<td>Deceased Individuals</td>
<td>EF-345.FF</td>
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<td>§164.502</td>
<td>Personal Representatives</td>
<td>EF-346.FF</td>
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<td>§164.504</td>
<td>Business Associate Contracts</td>
<td>EF-347.FF</td>
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<td>§164.504</td>
<td>Requirements for Group Health Plans</td>
<td>EF-348.FF</td>
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<tr>
<td>§164.506</td>
<td>Permitted Uses and Disclosures</td>
<td>EF-349.FF</td>
</tr>
<tr>
<td>§164.508</td>
<td>Obtaining Authorization as Required for Internal Use and Disclosure of Protected Health Information</td>
<td>EF-350.FF</td>
</tr>
<tr>
<td>§164.508</td>
<td>Authorization for Uses and Disclosures is Required</td>
<td>EF-351.FF</td>
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<tr>
<td>§164.510</td>
<td>Limited Uses and Disclosures when the Individual is Not Present</td>
<td>EF-352.FF</td>
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<tr>
<td>§164.512</td>
<td>Disclosures for Judicial and Administrative Proceedings</td>
<td>EF-353.FF</td>
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<tr>
<td>§164.512</td>
<td>Uses and Disclosures for Research Purposes</td>
<td>EF-354.FF</td>
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<td>§164.512</td>
<td>Re-Identification</td>
<td>EF-355.FF</td>
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<td>§164.514</td>
<td>Minimum Necessary Uses of PHI</td>
<td>EF-356.FF</td>
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<tr>
<td>§164.514</td>
<td>Minimum Necessary Disclosures of PHI</td>
<td>EF-357.FF</td>
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<td>§164.514</td>
<td>Uses and Disclosures for Fundraising</td>
<td>EF-358.FF</td>
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<td>§164.514</td>
<td>Uses and Disclosures for Underwriting and Related Purposes</td>
<td>EF-359.FF</td>
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<tr>
<td>§164.514</td>
<td>Verification of the Identity of Those Requesting PHI</td>
<td>EF-360.FF</td>
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# Breach Notification Rule

<table>
<thead>
<tr>
<th>Section</th>
<th>Key Activity</th>
<th>W/P Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>EE. Breach Notification- §164.404 and 414</td>
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<tr>
<td>§164.404</td>
<td>Notification to Individuals</td>
<td>EF-340.EE</td>
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<tr>
<td>§164.404</td>
<td>Timeliness of Notification</td>
<td>EF-341.EE</td>
</tr>
<tr>
<td>§164.404</td>
<td>Methods of Individuals Notification</td>
<td>EF-342.EE</td>
</tr>
<tr>
<td>§164.414</td>
<td>Burden of Proof</td>
<td>EF-343.EE</td>
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</table>
Appendix B – Tested Security Protocol
## Security Audit Protocol

<table>
<thead>
<tr>
<th>Section</th>
<th>Key Activity</th>
<th>W/P Ref.</th>
<th>Implementation Specification</th>
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<tbody>
<tr>
<td><strong>A. Administrative Safeguards - §164.308</strong></td>
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<tr>
<td>§164.308(a)(1)</td>
<td>Conduct Risk Assessment</td>
<td>EF-301.A</td>
<td>Required</td>
</tr>
<tr>
<td>§164.308(a)(7)</td>
<td>Develop Contingency Planning Policy</td>
<td>EF-305.A</td>
<td>Required</td>
</tr>
<tr>
<td><strong>A. Physical Safeguards - §164.310</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>§164.310(c)</td>
<td>Identify All Methods of Physical Access to Workstations</td>
<td>EF-310.B</td>
<td>Required</td>
</tr>
<tr>
<td>§164.310(c)</td>
<td>Implement Methods for Final Disposal of ePHI</td>
<td>EF-311.B</td>
<td>Required</td>
</tr>
<tr>
<td>§164.310(d)(1)</td>
<td>Maintain Accountability for Hardware and Electronic Media</td>
<td>EF-312.B</td>
<td>Addressable</td>
</tr>
<tr>
<td>§164.310(d)(1)</td>
<td>Develop Data Backup and Storage Procedures</td>
<td>EF-313.B</td>
<td>Addressable</td>
</tr>
<tr>
<td><strong>C. Technical Safeguards - §164.312</strong></td>
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<td></td>
</tr>
<tr>
<td>§164.312(a)(1)</td>
<td>Encryption and Decryption</td>
<td>EF-315.C</td>
<td>Addressable</td>
</tr>
<tr>
<td>§164.312(b)</td>
<td>Determine the Activities that Will be Tracked or Audited</td>
<td>EF-316.C</td>
<td>Required</td>
</tr>
<tr>
<td>§164.312(b)</td>
<td>Implement the Audit/System Activity Review Process</td>
<td>EF-317.C</td>
<td>Required</td>
</tr>
<tr>
<td>§164.312(c)(1)</td>
<td>Identify All Users Who Have Been Authorized to Access ePHI</td>
<td>EF-318.C</td>
<td>N/A</td>
</tr>
<tr>
<td>§164.312(c)(1)</td>
<td>Implement a Mechanism to Authenticate ePHI</td>
<td>EF-319.C</td>
<td>Addressable</td>
</tr>
</tbody>
</table>
Potholes along the way

Entity verification
• Old addresses, no contacts
• CE’s that aren’t
• Nonresponsive

Documents for review
• Newly minted and not trained on (i.e., not implemented)

Interaction and representation to KPMG
• Intentional misrepresentation
• Disavowing staff statements
• GAGAS standards for trusted sources
# Program Deliverables

<table>
<thead>
<tr>
<th>Final Audit Reports</th>
<th>Leading Practices</th>
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</thead>
<tbody>
<tr>
<td>• Scope and methodology of the audits</td>
<td></td>
</tr>
<tr>
<td>• Findings and observations</td>
<td></td>
</tr>
<tr>
<td>• Covered Entity responses</td>
<td></td>
</tr>
</tbody>
</table>
Exceptions Affect Audit Scope

• What did we audit? Varied by type of entity.
• Exceptions to certain requirements applied to several audited entities
  • 6 of the 7 clearinghouses asserted they only act as a business associate to other covered entities; in accordance with §164.500(b) few privacy procedures applied
  • 8 of the 47 health plans asserted they were fully insured group health plans, so only one privacy procedure applied.
  • 2 of the 61 providers and 4 of the 47 health plans asserted they do not create, receive or retain electronic Protected Health Information (ePHI), so security protocol was not executed.
Overall Findings & Observations

No findings or observations for 13 entities (11%)
- 2 Providers, 9 Health Plans, 2 Clearinghouses

Security accounted for 60% of the findings and observations—although only 28% of potential total.

Providers had a greater proportion of findings & observations (65%) than reflected by their proportion of the total set (53%).

Smaller, Level 4 entities struggle with all three areas

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Audit Findings & Observations By Level

Audit Findings and Observations by Level of Entity

- Level 1: 41%
- Level 2: 20%
- Level 3: 19%
- Level 4: 20%
Proportional by Entity Type

Audit Findings and Observations by Type of Covered Entity

- Provider: 65%
- Health Plan: 32%
- Clearinghouse: 3%
Proportional Findings by Rule

Audit Findings and Observations by Rule

- Security: 60%
- Privacy: 30%
- Breach: 10%

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Element Exposure by Entity Type

Audit Findings and Observations Distribution

Total Number of Audit Findings and Observations

- 0
- 1-5
- 6-10
- 11-20
- >20

Number of Auditees

- Clearinghouse
- Health Plan
- Provider

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Privacy Findings & Observations

PERCENTAGE OF FINDINGS AND OBSERVATIONS BY AREA OF FOCUS

- Notice of Privacy Practices for PHI: 44%
- Right to Request Privacy Protection for PHI: 18%
- Access of Individuals to PHI: 16%
- Administrative Requirements: 20%
- Uses and Disclosures of PHI: 2%
Privacy Results by Entity Type

Findings and Observations by Area and Type of Entity

- Providers: 43% Uses and Disclosures of PHI, 19% Administrative Requirements, 16% Access of Individuals to PHI, 2% Right to Request Privacy Protection for PHI, 20% Notice of Privacy Practices for PHI
- Health Plans: 43% Uses and Disclosures of PHI, 18% Administrative Requirements, 18% Access of Individuals to PHI, 1% Right to Request Privacy Protection for PHI, 20% Notice of Privacy Practices for PHI
- Clearinghouses: 75% Uses and Disclosures of PHI, 25% Administrative Requirements
Privacy Results by Entity Size

FINDINGS AND OBSERVATIONS BY LEVEL

![Bar graph showing the findings and observations by level for different areas of focus.](image)

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Privacy Administrative Elements

Administrative Requirements Findings and Observations

- 26% Training
- 47% Policies and Procedures
- 15% Complaints
- 11% Sanctions
Privacy -- Uses and Disclosures

Uses and Disclosures of PHI Findings and Observations

- Business Associates: 18%
- Identity Verification: 17%
- Minimum Necessary: 8%
- Authorizations: 7%
- Deceased Individuals: 9%
- Personal Representatives: 11%
- Judicial and Administrative Procedures: 4%
- Group Health Plan Requirements: 2%
Individual HIPAA Privacy Area of Focus – Audit Findings and Observations

Notice of Privacy Practices for PHI Findings and Observations

*The graph on the bottom includes an analysis of observations from additional areas of the Notice of Privacy Practice content requirements that were not included in the audit protocol at the time. Notice of Privacy Practices Letters were provided to covered entities indicating deficiencies noted in the content.
Security Results

58 of 59 providers had at least one Security finding or observation.

No complete & accurate risk assessment in two thirds of entities:
- 47 of 59 providers,
- 20 out of 35 health plans and
- 2 out of 7 clearinghouses

Security addressable implementation specifications: Almost every entity without a finding or observation met by fully implementing the addressable specification.
Security Elements

Percentage of Audit Findings and Observations by Area of Focus

- Risk Analysis: 14%
- Access Management: 14%
- Security Incident Procedures: 14%
- Contingency Planning and Backups: 14%
- Workstation Security: 9%
- Media Movement and Destruction: 7%
- Encryption: 8%
- Audit Controls and Monitoring: 4%
- Integrity Controls: 18%
Security by Entity Type

Total Audit Findings and Observations by Area of Focus and Entity Type

Area of Focus

- Risk Analysis
- Access Management
- Security Incident Procedures
- Contingency Planning and Backups
- Media Movement and Destruction
- Encryption
- Audit Controls and Monitoring
- Integrity Controls

Number of Audit Findings and Observations

- Clearinghouses
- Health Plans
- Providers

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Security Results by Entity Size

Total Security Audit Findings and Observations by Area of Focus and Level of Entity

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Breach Notification by Entity Type

Audit Findings and Observations by Requirement and Type of Entity

- Notification to Individuals: 58% (Providers), 42% (Clearinghouses)
- Timeliness of Notification: 57% (Providers), 43% (Clearinghouses)
- Methods of Individuals Notification: 63% (Providers)
- Burden of Proof: 52% (Providers), 44% (Clearinghouses)
Breach Notification by Entity Size

Audit Findings and Observations by Requirement and Level of Entity

- Notification to Individuals: 53%, Level 4; 26%, Level 3; 11%, Level 2; 11%, Level 1
- Timeliness of Notification: 43%, Level 4; 26%, Level 3; 17%, Level 2; 13%, Level 1
- Methods of Individuals Notification: 41%, Level 4; 22%, Level 3; 19%, Level 2; 19%, Level 1
- Burden of Proof: 40%, Level 4; 28%, Level 3; 12%, Level 2; 20%, Level 1

IAPP - March 7, 2013
Overall Cause Analysis

• For every finding and observation cited in the audit reports, audit identified a “Cause.”

• Most common across all entities: entity unaware of the requirement.
  • in 30% (289 of 980 findings and observations)
    • 39% (115 of 293) of Privacy
    • 27% (163 of 593) of Security
    • 12% (11) of Breach Notification
  • Most of these related to elements of the Rules that explicitly state what a covered entity must do to comply.

• Other causes noted included but not limited to:
  • Lack of application of sufficient resources
  • Incomplete implementation
  • Complete disregard
## Cause Analysis – Top Elements

**Unaware of the Requirement**

<table>
<thead>
<tr>
<th>Privacy</th>
<th>Security</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Notice of Privacy Practices;</td>
<td>• Risk Analysis;</td>
</tr>
<tr>
<td>• Access of Individuals;</td>
<td>• Media Movement and Disposal;</td>
</tr>
<tr>
<td>• Minimum Necessary; and,</td>
<td>and,</td>
</tr>
<tr>
<td>• Authorizations.</td>
<td>• Audit Controls and Monitoring.</td>
</tr>
</tbody>
</table>
Next Steps for OCR

Formal Program Evaluation 2013

Internal analysis for follow up and next steps
- Creation of technical assistance based on results
- Determine where entity follow up is appropriate
- Identify leading practices

Revise Protocol to reflect Omnibus Rule

Ongoing program design and focus
- Business Associates
- Accreditation /Certification correlations?
Want More Information?

HIPAA Audit Webpage
http://www.hhs.gov/ocr/privacy/hipaa/enforcement/audit/index.html

OCR offers a wide range of helpful information about health information privacy including educational resources, FAQ’s, rule text and guidance for the Privacy, Security, and Breach Notification Rules
http://www.hhs.gov/ocr/privacy/

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