

<p>U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES</p> <p>OFFICE FOR CIVIL RIGHTS</p>	<h2>OCR Audits of HIPAA Privacy, Security and Breach Notification, Phase 2</h2>
<p>Linda Sanches, MPH Senior Advisor, Health Information Privacy</p>	
<p>HCCA Compliance Institute March 31, 2014</p>	

<p>U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES</p> <p>OFFICE FOR CIVIL RIGHTS</p>	<h2>Agenda</h2>
<ul style="list-style-type: none">•Background•Audit Phase 1<ul style="list-style-type: none">•Design•2012 Findings•Evaluation—major recommendations•Audit Phase 2<ul style="list-style-type: none">•Approach•Size•Timing•Focus•Entity selection•Guidance	<p>Office for Civil Rights, DHHS March 2014</p>
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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

- OCR sought a comprehensive, flexible process for analyzing entity efforts to provide regulatory protections and individual rights.
- Identify best practices and uncover risks and vulnerabilities not identified through other enforcement tools
- Encourage consistent attention to compliance activities

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Multi-year Phase 1

Description	Vendor	Status/Timeframe
Audit program development study	Booz Allen Hamilton	Closed 2010
Covered entity identification and cataloguing	Booz Allen Hamilton	Closed 2011
Develop audit protocol and conduct audits	KPMG	Closed 2011-2012
Evaluation of audit program	PWC, LLP	Closed 2013

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	<h2>Phase 1 Building Blocks</h2>	<p style="writing-mode: vertical-rl; transform: rotate(180deg);">March 2014</p>
<ul style="list-style-type: none"> • Comprehensive audit protocol and associated set of audit program work papers • Databases of covered entities • Methodology for entity selection • Survey of entity attributes for audit planning • Program evaluation • Other foundational materials –Include templates for notification letters, final reports, document requests 		

	<h2>Phase 1, Pilot 2011 -- 2012</h2>	<p style="writing-mode: vertical-rl; transform: rotate(180deg);">March 2014</p>
<div style="border: 1px solid black; border-radius: 10px; padding: 5px; margin-bottom: 10px;"> <h3>Audit Protocol Design</h3> <ul style="list-style-type: none"> • Created a comprehensive, flexible process for analyzing entity efforts to provide regulatory protections and individual rights </div> <div style="border: 1px solid black; border-radius: 10px; padding: 5px;"> <h3>Resulting Audit Program</h3> <ul style="list-style-type: none"> • Conducted 115 performance audits through December 2012 to identify findings in regard to adherence with standards. Two phases: <ul style="list-style-type: none"> • Initial 20 audits to test original audit protocol • Final 95 audits using modified audit protocol </div>		

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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

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Overall Findings & Observations

No findings or observations for 13 entities (11%)

- 2 Providers, 9 Health Plans, 2 Clearinghouses

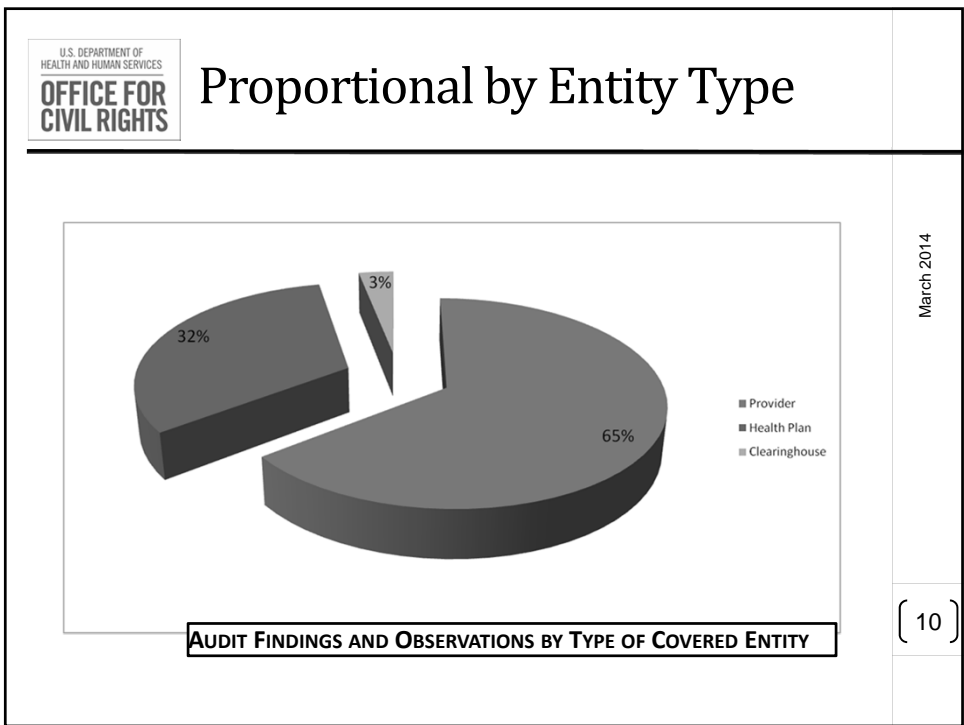
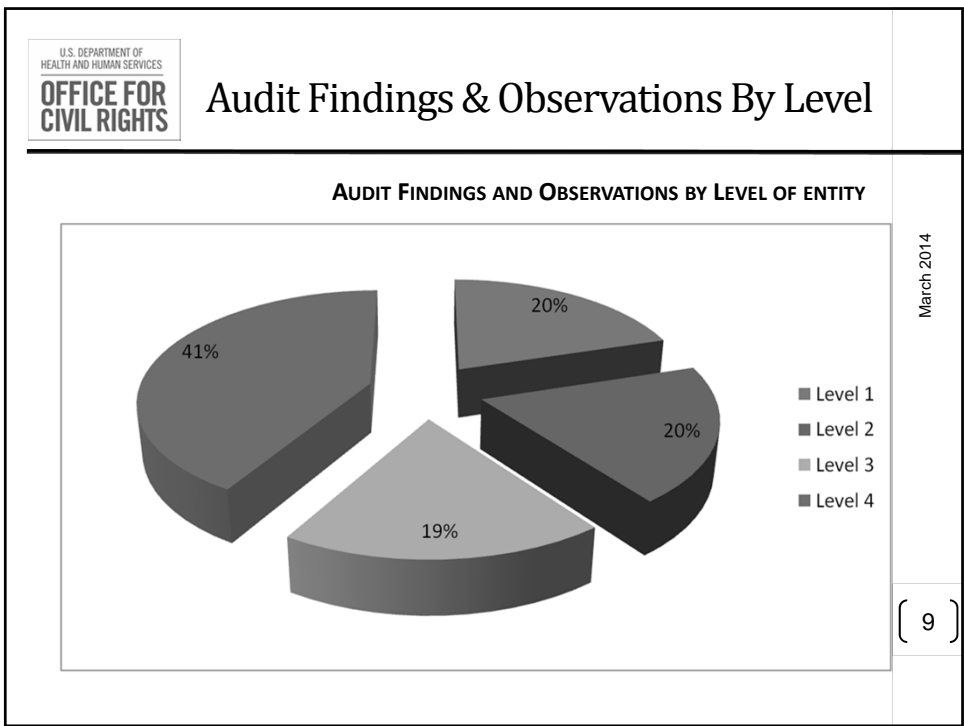
Security accounted for 60% of the findings and observations—although only 28% of potential total.

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

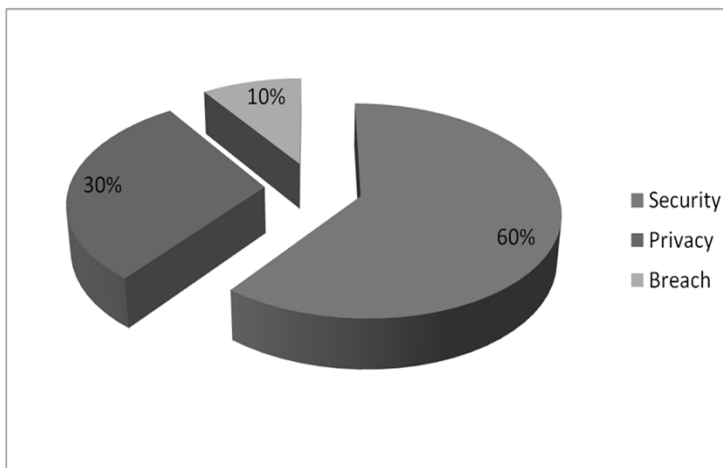
Smaller, Level 4 entities struggle with all three areas

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Proportional Findings by Rule



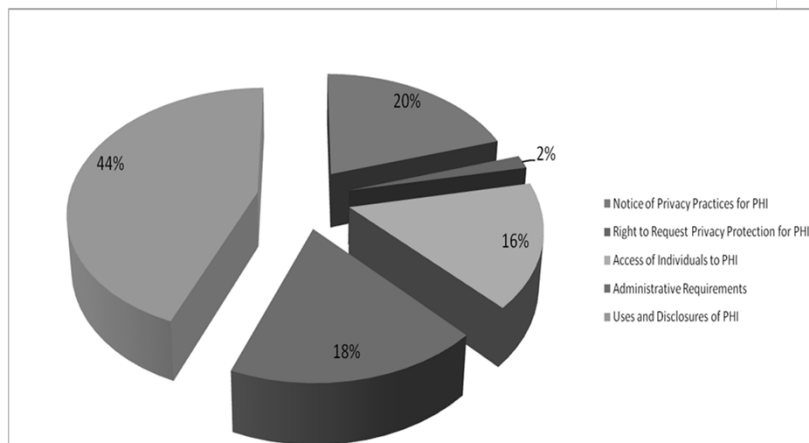
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Audit Findings and Observations by Rule

Privacy Findings & Observations

PERCENTAGE OF FINDINGS AND OBSERVATIONS BY AREA OF FOCUS



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Security Results

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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: most entities without a finding or observation met the standard by fully implementing the addressable specification.

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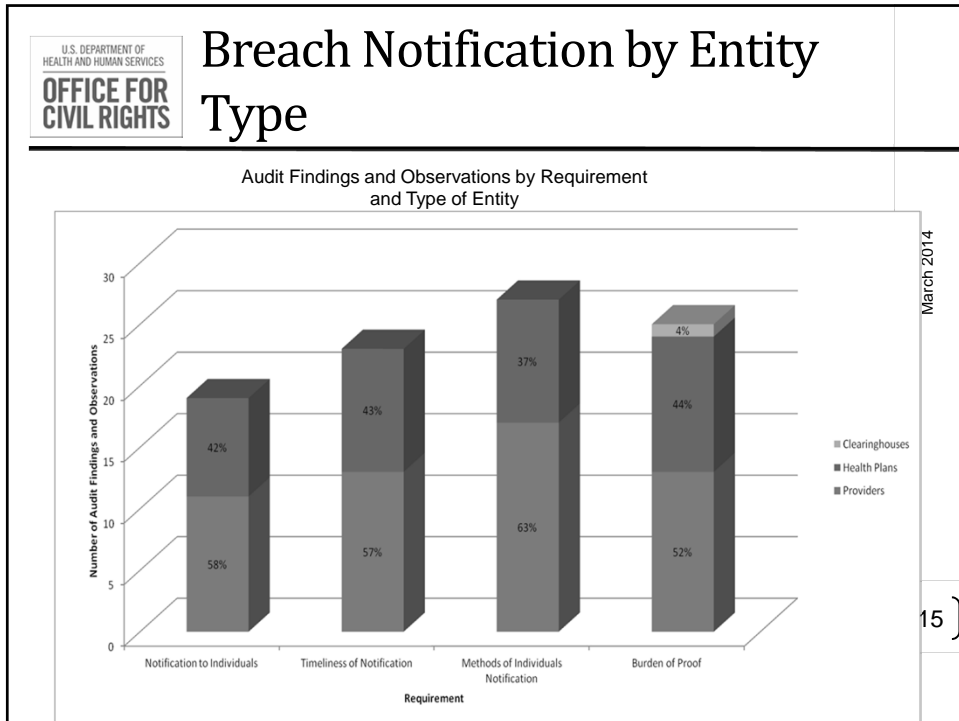
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Security Elements

Percentage of Audit Findings and Observations by Area of Focus

Area of Focus	Percentage
Risk Analysis	12%
Access Management	14%
Security Incident Procedures	14%
Contingency Planning and Backups	7%
Workstation Security	18%
Media Movement and Destruction	4%
Encryption	8%
Audit Controls and Monitoring	14%
Integrity Controls	9%
(Unlabeled)	14%



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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


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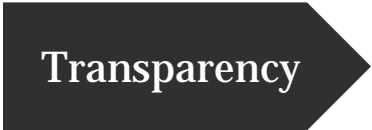
<p>U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE FOR CIVIL RIGHTS</p>	<h3>Cause Analysis – Top Elements</h3> <p><i>Unaware of the Requirement</i></p>	<p>March 2014</p>				
<table border="1"><thead><tr><th data-bbox="568 466 695 508">Privacy</th></tr></thead><tbody><tr><td data-bbox="467 556 787 886"><ul style="list-style-type: none">• Notice of Privacy Practices;• Access of Individuals;• Minimum Necessary; and,• Authorizations.</td></tr></tbody></table>	Privacy		<ul style="list-style-type: none">• Notice of Privacy Practices;• Access of Individuals;• Minimum Necessary; and,• Authorizations.	<table border="1"><thead><tr><th data-bbox="966 466 1112 508">Security</th></tr></thead><tbody><tr><td data-bbox="873 556 1177 835"><ul style="list-style-type: none">• Risk Analysis;• Media Movement and Disposal; and,• Audit Controls and Monitoring.</td></tr></tbody></table>	Security	<ul style="list-style-type: none">• Risk Analysis;• Media Movement and Disposal; and,• Audit Controls and Monitoring.
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<p>Objectives Communications Entity Selection Protocols</p>	<p>March 2014</p>
<h3>PHASE ONE PROGRAM EVALUATION</h3>	


	<h2>Evaluation Objective</h2>	
<p>To determine if the implementation objectives of the audit plan and program were achieved. The assessment:</p> <ul style="list-style-type: none"> • Looked at the effectiveness of the protocol & auditing process in identifying compliance challenges; • Methods applies included: <ul style="list-style-type: none"> • the review of audit data; • surveys of the audited covered entities; and, • interviews with audited covered entities • Focused on what activities and resources facilitated the audit program, and understanding the barriers and/or problems that may have been encountered in the program. 		<p>Office for Civil Rights, DHHS March 2014</p> <p>(19)</p>

	<h2>Communication & Outreach Results</h2>	
<div style="border: 1px solid black; border-radius: 10px; padding: 10px; margin-bottom: 10px;"> <p>Audited covered entities generally felt positive about communications during the course of the audit:</p> <ul style="list-style-type: none"> • 90% agreed that communications prior to the onsite visit clearly explained the purpose of the audit • 71% agreed that communications prior to the onsite visit clearly explained what would happen during the audit process • 56% became aware of additional HIPAA regulations which apply to their organizations </div> <div style="border: 1px solid black; border-radius: 10px; padding: 10px;"> <p>However, 59% of responding covered entities were <i>not</i> aware of the audit program prior to receiving notification of selection. Most of these entities were also not aware that the audit protocol was available on the OCR website</p> </div>		<p>Office for Civil Rights, DHHS March 2014</p> <p>(20)</p>

	<h2>Communication and Outreach Recommendations</h2>	
<h3>Ongoing Publicity of the Audit Program</h3>	<ul style="list-style-type: none"> • OCR should continue to widely publicize the audit program and overall results to prompt covered entities to proactively attempt to identify and correct potential compliance issues. • For smaller entities, OCR may want to focus additional attention on forums and journals • After each year of audits, OCR should evaluate areas of high risk and pervasive non-compliance and consider the creation and delivery of training on leading practices 	<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Office for Civil Rights, DHHS March 2014</p> <p style="text-align: center;">(21)</p>

	<h2>Selection Process</h2>	
<h3>Results</h3>	<ul style="list-style-type: none"> • Some surveyed audited entities indicated that the selection methodology should be published so that entities can understand the selection criteria. 	<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Office for Civil Rights, DHHS March 2014</p>
<h3>Recommendation</h3>	<ul style="list-style-type: none"> • OCR should consider this request. 	
	<p style="text-align: center;">(22)</p>	

	<h2>Recommendations: Protocol Modifications</h2>	
<p>Consider updating the protocol to include test procedures that specifically address the review of specific types of documentation needed to meet the audit objective</p>	<p>Add steps to guide auditors in tailoring the protocol to the specific covered entity type</p>	<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Office for Civil Rights, DHHS March 2014</p>
<p>Revise the protocol to include the Omnibus Final Rule and reassess priority areas based on program audit results and industry feedback</p>	<p style="text-align: center;">(23)</p>	

	<h2>Selection of Requirements to Audit-- Recommendations</h2>	
<h3>Implement a Risk-Based Approach</h3>		<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Office for Civil Rights, DHHS March 2014</p>
<ul style="list-style-type: none"> • A risk-based approach for applying audit protocols would allow OCR to determine areas of the Rules which require implementation of controls which, if not implemented effectively, pose the greatest risk to the protection of PHI. • OCR should consider a multi-tiered audit approach which can be tailored based on entity type, area or a hybrid. 		

Requested Documentation Results

Survey results from responding covered entities regarding the documents and data requested of them:

<p>• 87%</p> <p>The documents and data requested were communicated clearly during the onsite visit</p>	<p>• 82%</p> <p>The documents and data requested were clearly outlined in the original request</p>	<p>• 79%</p> <p>The documents and data requested were sufficient for assessing compliance at their type of entity</p>
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Requested Documentation

Results

- Survey comments and follow-up interviews also indicated some inconsistency in the document collection process:
 - Electronic vs. hard copy submission
 - Issues with the document repository causing resubmission
 - Misdirection of audit notification letters

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Timing and Staffing Levels

Recommendation--Implement a Centralized Staffing Tracker

Benefits:

- Captures historical data to identify the appropriate number of staff required for an audit
- More even distribution of man hours, which would likely decrease the range in time of testing
- Staff assigned based on the nature of the entity being reviewed
- Assign people with proper backgrounds
- Plan for and complete audits more easily
- Enhanced program oversight

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Work Papers Recommendations

- **Use an Electronic Work Paper System (EWPS)**
- An EWPS system would provide a centralized mechanism for capturing documentation to support standards related to audit planning, fieldwork, reporting, and monitoring. This includes documentation for the following areas:

Independence, both on an organizational and individual level	Professional judgment and competence (ex. auditor resumes)
Support for conclusions (ex. Documentation provided by covered entities)	Planning (ex. agreed upon protocols, sampling methodologies)
Quality Control and Assurance	Clear supervisory review evidence
Audit work papers/narrative	Audit reports and referencing

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Work Paper Recommendations

- **Use Representative Sampling Methods**
 - Representative sampling will help OCR to understand the degree to which an entity is compliant for a given focus area.
 - *Yellow Book section 6.64: random sampling* is the preferred method when a representative sample is needed. This method produces unbiased estimates of the population, as each unit has an equal probability of being chosen.

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Final Report: Results

Survey results from responding covered entities regarding the audit report issued to them:

• **80%**

The report was clear and easy to read

• **79%**

The report provided an actionable basis for bringing the entity into HIPAA compliance

• **71%**


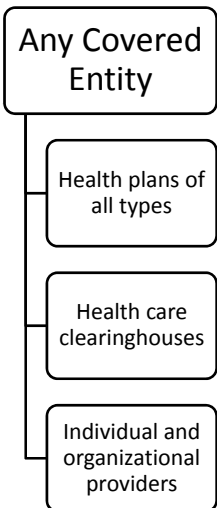
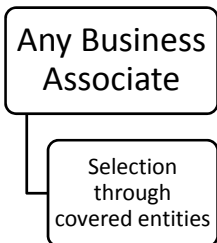
The report adequately identified gaps between HIPAA requirements and entity operations


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Who will be audited & selection What will be audited Approach Timeline Outreach Electronic management system	March 2014
PHASE 2 2014 -- 2015	(31)

	Who Can Be Audited?	March 2014
		(32)

	<h2>Phase 2 Covered Entity Pool</h2>	
<ul style="list-style-type: none"> • Have selected a pool of covered entities eligible for audit • Used resources developed through Booz Allen Hamilton contract <ul style="list-style-type: none"> • Health care providers selected through NPI database • Clearinghouses & Health Plans from external databases (e.g., AHIP) • Random selection used when possible w/in types • Wide range (e.g., group health plans, physicians and group practices, behavioral health, dental, hospitals, laboratories) 	<p>March 2014</p> <p>(33)</p>	

	<h2>Pre-audit Survey</h2>	
<ul style="list-style-type: none"> • Available entity databases lack data for entity stratification • Survey currently going through the Paperwork Reduction Act clearance process • Questions address size measures, location, services, best contacts • OCR will conduct address verification with entities this spring • Entities will receive link to on-line screening “pre-survey” this summer • Expect to contact 550-800 entities • OCR will use results of survey to select a projected 350 covered entities to audit 	<p>March 2014</p> <p>(34)</p>	

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Audit Phase 2 Approach

- Primarily internally staffed
- Selected entities will receive notification and data requests in fall 2014
- Entities will be asked to identify their business associates and provide their current contact information
- Will select business associate audit subjects for 2015 first wave from among the BAs identified by covered entities
- Desk audits of selected provisions
- Comprehensive on-site audits as resources allow

DHHS, OCR April 2014

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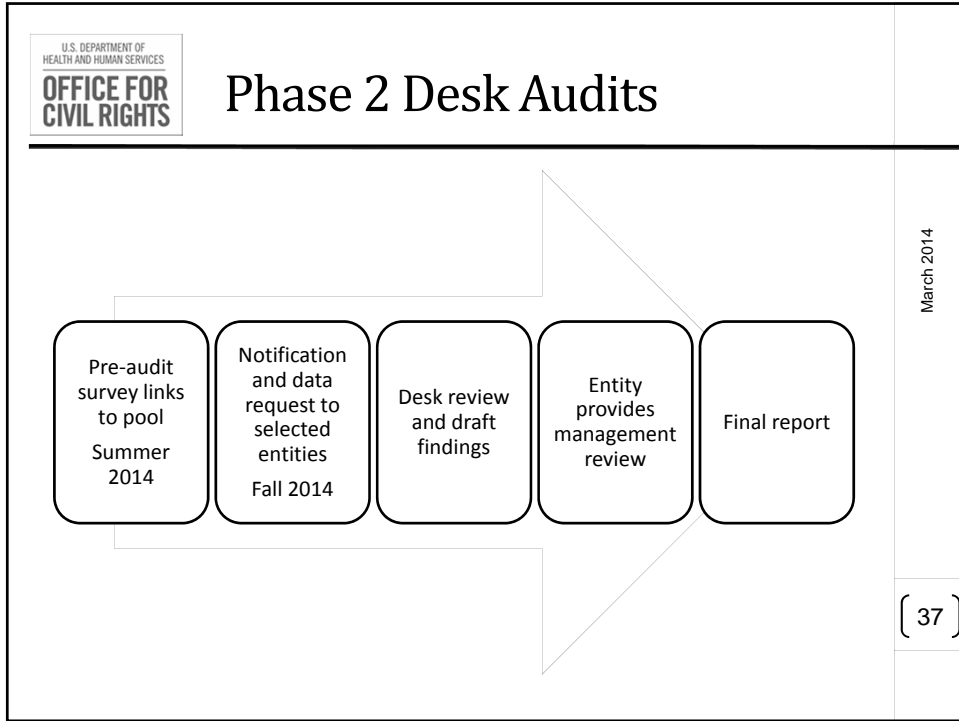
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Phase 2 Audit Distribution Projections

Entity Type	Privacy	Breach	Security
Covered Entities	100	100	150
• Health Plans	33	31	45
• Providers	67	65	100
• Clearinghouses	-	4	5
Business Associates	0	0	50
• IT Related	-	-	35
• Non-IT Related (eg, TPAs, claims)	-	-	15
Total Audits by Protocol	100	100	200

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The table provides a detailed timeline for the Phase 2 Desk Audits process, mapping specific periods to key activities.

Period	Activity
Spring 2014	CE address verification
Summer 2014	Pre-audit surveys link sent to covered entity pool
Fall 2014	Notification and data request letters to selected entities
Two weeks	Period for entity response
October 2014 -- June 2015	CE Audit Reviews
2015	Business Associates

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Phase 2 Timing


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<p>U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE FOR CIVIL RIGHTS</p>	<h2>Desk Audit Expectations</h2>	<p>March 2014</p>
<p>Data request will specify content & file organization, file names, and any other document submission requirements</p>		
<p>Only requested data submitted on time will be assessed.</p>		
<p>All documentation must be current as of the date of the request.</p>		
<p>Auditors will not have opportunity to contact the entity for clarifications or to ask for additional information, so it is critical that the documents accurately reflect the program.</p>		
<p>Submitting extraneous information may increase difficulty for auditor to find and assess the required items.</p>		
<p>Failure to submit response to requests may lead to referral for regional compliance review</p>		<p>{ 39 }</p>

<h2>Electronic Management System</h2>		<p>March 2014</p>
<ul style="list-style-type: none"> • All communication electronic—entities will receive and respond to pre-audit survey, notification and document requests through email, or other electronic media (eg, CD) 	<p>Audit management system for</p> <ul style="list-style-type: none"> • Document retention • Auditor assignments • Work papers • Audit manager review • Referral for regional compliance review 	
		<p>{ 40 }</p>


	<h2>Phase 2 Protocol Criteria</h2>	<p>March 2014</p>
<ul style="list-style-type: none"> • Auditors will assess entity efforts through an updated protocol; new criteria reflect omnibus rule changes and more specific test procedures • Uses sampling methodology in a number of provisions to assess compliance efforts • Desk audits will target particular provisions that were the source of a high number of compliance failures in the pilot audits • Updated protocol will be available on web site so that entities can use it for internal compliance assessments 		
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	<h2>Phase 2 Audit Focus</h2>	<p>March 2014</p>
<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;">2014 – Covered Entities</div> <ul style="list-style-type: none"> • Security--Risk analysis and risk management • Breach—Content and timeliness of notifications • Privacy—Notice and Access <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;">2015</div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"><i>Round 1 Business Associates</i></div> <ul style="list-style-type: none"> • Security--Risk analysis and risk management • Breach--Breach reporting to CE <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"><i>Round 2 Covered Entities (Projected)</i></div> <ul style="list-style-type: none"> • Security--Device and media controls , transmission security • Privacy--Safeguards, training to policies and procures <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;">2016 (Projected)</div> <ul style="list-style-type: none"> • Security: Encryption and decryption), facility access control (physical); other areas of high risk as identified by 2014 audits, breach reports and complaints 		
<p>{ 42 }</p>		

	<h2>EHR & HIPAA on Medscape</h2>	
<ul style="list-style-type: none"> • New! 6th module EHRs and HIPAA: Steps for Maintaining the Privacy and Security of Patient Information." • For physicians, nurses, and other healthcare professionals; free Continuing Medical Education (CME) and Continuing Education (CE) credits. Steps to safeguard patient data on electronic health records (EHRs), to plan appropriate communication for patients about how their data will be stored and used on EHRs, and to evaluate Meaningful Use criteria related to data security and privacy required as part of the EHR Incentive Program. • OCR's Medscape destination page at http://www.medscape.org/sites/advances/patients-rights. 	<p>March 2014</p> <p>{ 43 }</p>	

	<h2>Medscape Education Tools</h2>	
<ul style="list-style-type: none"> • <i>Patient Privacy: A Guide for Providers</i> http://www.medscape.org/viewarticle/781892?src=ocr2 • <i>HIPAA and You: Building a Culture of Compliance</i> http://www.medscape.org/viewarticle/762170?src=ocr2 • <i>Examining Compliance with the HIPAA Privacy Rule</i> http://www.medscape.org/viewarticle/763251?src=ocr2 • These Medscape modules offer free Continuing Medical Education (CME) credits for physicians and Continuing Education (CE) credits for health care professionals. 	<p>March 2014</p> <p>{ 44 }</p>	

	<h2>Security Rule Compliance Aides</h2>	
<ul style="list-style-type: none"> • New! Risk Analysis tool for small providers from ONC, find at http://healthit.gov • HHS Mobile Device Security Resource Kit <ul style="list-style-type: none"> • http://healthit.gov/mobiledevices • Vast Array of Guidance Material <ul style="list-style-type: none"> • http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/securityruleguidance.html 		<p>March 2014</p> <p>(45)</p>

	<h2>More Information</h2>	
<p>HIPAA Audit Webpage http://www.hhs.gov/ocr/privacy/hipaa/enforcement/audit/index.html</p> <p>Wide range of other 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/</p>		<p>March 2014</p> <p>(46)</p>