HIPAA Security Compliance Reviews

Elizabeth S. Holland, MPA
Office of E-Health Standards and Services
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

What is HIPAA?

- Administrative Simplification
  - Transactions and Codes Sets
  - Unique Identifiers
  - Security
  - Privacy

Covered Entities under HIPAA

- The Administrative Simplification standards adopted by HHS under HIPAA apply to any entity that is:
    - a health care provider that conducts certain transactions in electronic form
    - a health care clearinghouse, or
    - a health plan

Role of CMS/OESS

- OESS is responsible for
  - E-Health including e-prescribing, personal health records, Recovery Act coordination re: electronic health record incentives
  - HIPAA:
    - Regulatory/Policy Interpretation (5010 and ICD-10)
    - Outreach and Education
    - Enforcement

HIPAA Security Rule

- Security Standards for the protection of Electronic Protected Health Information (ePHI)
- Applies to ePHI that a covered entity creates, receives, maintains, or transmits
- Published February 20, 2003
- Compliance Date April 20, 2005 (April 20, 2006 for small health plans)

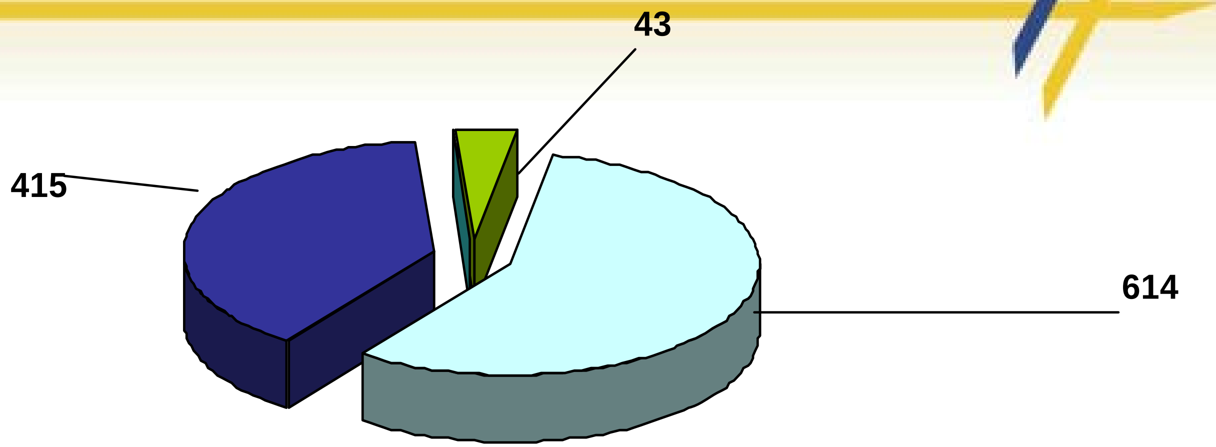
HIPAA Security Rule – Security Standards

- Three categories of safeguards:
  - Administrative
  - Physical
  - Technical

HIPAA Enforcement

- Secretary of HHS delegated to the Administrator of CMS the authority to investigate complaints of non-compliance with HIPAA regulations
- Office for Civil Rights (OCR), HHS has responsibility for privacy
- Enforcement efforts are complaint based

CMS Enforcement Statistics Report
Open and Closed Cases by Type
As of April 30, 2009



Complaint Type	Total	Open	Closed
Transactions and Code Sets (TCS)	614	43	571
Security	415	74	341
National Provider Identifier (NPI)	43	4	39
Total	1,072	121	951

Open – Outstanding issues remain. Entity may be under a corrective action plan or additional information from either the complainant, the filed against entity, or both is being sought.

Closed – No further action required. All issues have been sufficiently resolved. Please note that 47 of the 341 security cases have been closed via corrective action plans.

Most Common Complaints

Security Rule Section	**Security Type Description**	**Number of complaints**
164.308(a)(4)(i)	Information Access Management	159
164.312(a)(1)	Access Control	158
164.308(a)(5)(i)	Security Awareness and Training	127
164.308(a)(6)(i)	Security Incident Procedures	103
164.310(d)(1)	Device and Media Control	73

HIPAA Security Compliance

- Expanded our work to build voluntary HIPAA compliance
- Began to conduct compliance reviews on covered entities
- Contracted with Price Waterhouse Coopers (PWC) for 10 reviews in 2008

HIPAA Security Compliance

- Selection of entities:
  - Entities against whom a complaint has been filed
  - Media reports of potential security violations
- Reviews focused:
  - on the allegations in the complaint or
  - Information in the media report
  - how the covered entity resolved the issues

HIPAA Security Compliance

- Issues included:
  - Risk analysis and management
  - Security training;
  - Physical security of facilities and mobile devices;
  - Off-site access and use of ePHI from remote locations;
  - Storage of ePHI on portable devices and media;
  - Disposal of equipment containing ePHI;
  - Business associate agreements and contracts;
  - Data encryption;
  - Virus protection;
  - Technical safeguards in place to protect ePHI; and
  - Monitoring of access to ePHI.

HIPAA Security Compliance Reviews-2008

- Reviews were conducted in New York, Florida, California, Oregon, New Hampshire, North Carolina, Pennsylvania, Maryland
- Nine were of providers and one was a health plan
- Seven were hospitals, one pharmacy, and one home care/hospice provider

HIPAA Security Compliance Reviews-2008

- Compliance reviews revealed areas where covered entities appeared to struggle:
  - Risk assessment
  - Currency of Policies and Procedures
  - Security Training
  - Workforce Clearance
  - Workstation Security
  - Encryption

HIPAA Security Compliance Reviews-2008

- Prepared Report: HIPAA Compliance Review Analysis and Summary of Results-2008 Reviews
- Outlines the six overarching compliance issues and provides recommended solutions as a guide to help improve compliance

HIPAA Security Compliance Reviews-2008

- Posted Compliance Review Examples
  - Related to Loss of Portable Device
  - Related to Theft of Backup Tapes
  - Related to Theft of Workstation and Backup Hard Drive
  - Related to Theft of Laptop
  - Related to a Computer Virus Infection
  - Related to Theft of Workstation and Backup Hard Drive

HIPAA Security Compliance Reviews

- Reviews have resulted in Corrective Action Plans (CAPs) that include:
  - Policies and procedures for remote use/access
  - Designation of internal security audit personnel
- CAPs are monitored by CMS
- Compliance review cases are generally closed when CMS verifies completion of CAP.

HIPAA Security Compliance Reviews-2009

- Contracted with Quality Software Services, Inc (QSSI) to do compliance reviews in 2009
- Six have been conducted or scheduled
- Not complaint based reviews
- Selected by covered entity type and location

HIPAA Security Compliance Reviews-2009

- Reviews in Florida, California, New York, Illinois, Minnesota, and Washington
- Three health plans, one clearinghouse, two providers (one federally qualified health center and one skilled nursing facility)

HIPAA Security Compliance Reviews-2009

- Reviews are not meant to be punitive
- Improve compliance
  - Determine things that the entity is doing well (possible best practices that can be shared)
  - Determine areas where the covered entity can improve their compliance

HIPAA Security Compliance Reviews-2009

- Contact covered entity via letter sent by certified mail
  - Propose review dates
  - Propose date for pre-entrance conference call with CMS, QSSI and covered entity
  - Request working space with electricity, phone with outside access and internet connectivity for at least five business days

HIPAA Security Compliance Reviews-2009

- Request documents
- Receive documents on a flow-basis
- Assess documents for compliance with the HIPAA regulations
- Periodic pre-review conference calls
- Formulate questions based on review of policies and procedures

HIPAA Security Compliance Reviews-2009

- On-site review:
  - Interview staff
  - Review additional documentation
  - Review technical controls
  - Review results of past reviews and audits
- Draft report
- Final report of findings
- Creation of corrective action plans, if needed

HIPAA Security Compliance Reviews-2009-Interviews

- Director of Covered Entity (CE) organization under review.
- **VP IT Security and Compliance**
- **SVP, Chief Compliance Officer**
- **VP Infrastructure**
- **IT Security Manager**
- **Direct Line Supervisor of individual or area where breach/incident occurred.**
- **Developer Executing the File Transfer During the Security Incident**

HIPAA Security Compliance Reviews-2009-Interviews

- Lead systems manager or director.
- Systems security officer
- Computer Hardware specialist.
- Disaster recovery specialist or person in charge of backup tapes.
- Facility access control coordinator (physical security).

HIPAA Security Compliance Reviews-2009-Interviews

- Lead network engineer.
  - Individuals responsible for administration of platforms that store, transmit, or process ePHI.
  - Individuals responsible for administration of the site network (wired and wireless).
  - Individuals responsible for monitoring of platforms that store, transmit, or process ePHI.
  - Individuals responsible for monitoring the network (if different from above).

HIPAA Security Compliance Reviews-2009-Interviews

- Human resources representative.
- Director of training.
- Individual responsible for policy and procedure management
- Incident response team leader.
- Access to all members of workforce.

HIPAA Security Compliance Reviews-2009-Sample Request

- **All policies and procedures designed to demonstrate compliance with the HIPAA Security Rule Administrative Safeguards mapped to the specific HIPAA Security Administrative Safeguard.**
- Policies and procedures to prevent, detect, contain, and correct security violations.
- Policies and procedures address setting up a user's access profile.
- Policies and procedures that address detecting, reporting, and responding to security incidents (if not in the security plan).
- Physical security policies.

HIPAA Security Compliance Reviews-2009-Sample Request

- Policies and procedures that address encryption and decryption of electronic PHI.
- Policies and procedures that address mechanisms to ensure integrity of data during transmission - including portable media transmission (i.e. laptops, cell phones, blackberries, thumb drives).
- Policies outlining the entity's monitoring of system usage - authorized and unauthorized attempts.
- Policies regarding the use of wireless networks in the environment..

HIPAA Security Compliance Reviews-2009-Sample Request

- **Templates and/or documents used to record the acknowledgement of use of wireless networks, mobile computing, as well as remote access to systems.**
- Periodic vulnerability scanning policy and procedure.
- Periodic network penetration testing policy and procedure.
- Access to security violation monitoring reports.
- **Security violation monitoring reports templates.**

HIPAA Security Compliance Reviews-2009-Sample Request

- Access to reports developed related to follow up action taken from violations that have occurred**.**
- **Security violation follow-up action log/report templates.**
- Policies and procedures that address granting, approving, and monitoring emergency access IDs during an emergency situation.
- Policies and procedures that outline hiring and termination procedures.
- Policies related to employee background checks and confidentiality agreements.

HIPAA Security Compliance Reviews-2009-Sample Request

- **Templates and/or documents used to record the processing of background checks and confidentiality agreements.**
- Policies related to periodic reviews of appropriateness for personnel with access to PHI.
- Policies for granting system access (for example, by level, role, and job function.
- Polices and procedures that address creating, changing, and safeguarding passwords.
- **Templates and/or documents used to record the creating, changing, and safeguarding passwords.**

HIPAA Security Compliance Reviews-2009-Sample Request

- Policies related to the timely removal of personnel from the system environment.
- Policies and procedures regarding secure workstation use are documented and address specific guidelines for each class of workstation (i.e., on site, laptop, and home system usage).
- Policies and procedures that address the secure disposal of hardware, software, and the electronic PHI data.

HIPAA Security Compliance Reviews-2009-Sample Request

- **Templates and/or documentation used to record the secure disposal of hardware, software, and the electronic PHI data.**
- Most recent high-level risk assessment. Review risk assessment policies**.**
- **Risk assessment template documentation**
- Other documents: http://www.cms.hhs.gov/Enforcement/09_HIPAAComplianceReviewInformationandExamples.asp

HIPAA Security Compliance Reviews-2009

- Vulnerabilities identified:
  - HIPAA Security Policies and Procedures
  - Business Associate Agreements
  - Encryption of ePHI on mobile devices
  - HIPAA Security Training

HIPAA Compliance

- Looking to the future – continuation a three-pronged approach:
  - Complaint management
  - Compliance reviews
  - Outreach and Education