OCR/HHS HIPAA/HITECH Audit Preparation

Who are we

EHR 2.0 Mission: To assist healthcare organizations develop and implement practices to secure IT systems and comply with HIPAA/HITECH regulations.

- *Education*
- *Consulting*
- *Toolkit(Tools, Best Practices & Checklist)*

Goal: To make compliance an enjoyable and painless experience

Webinar Objective

Understand OCR/HHS HIPAA/HITECH audit program and steps required to prepare for an audit

Glossary

1. HHS, OCR, DOJ and SAG:

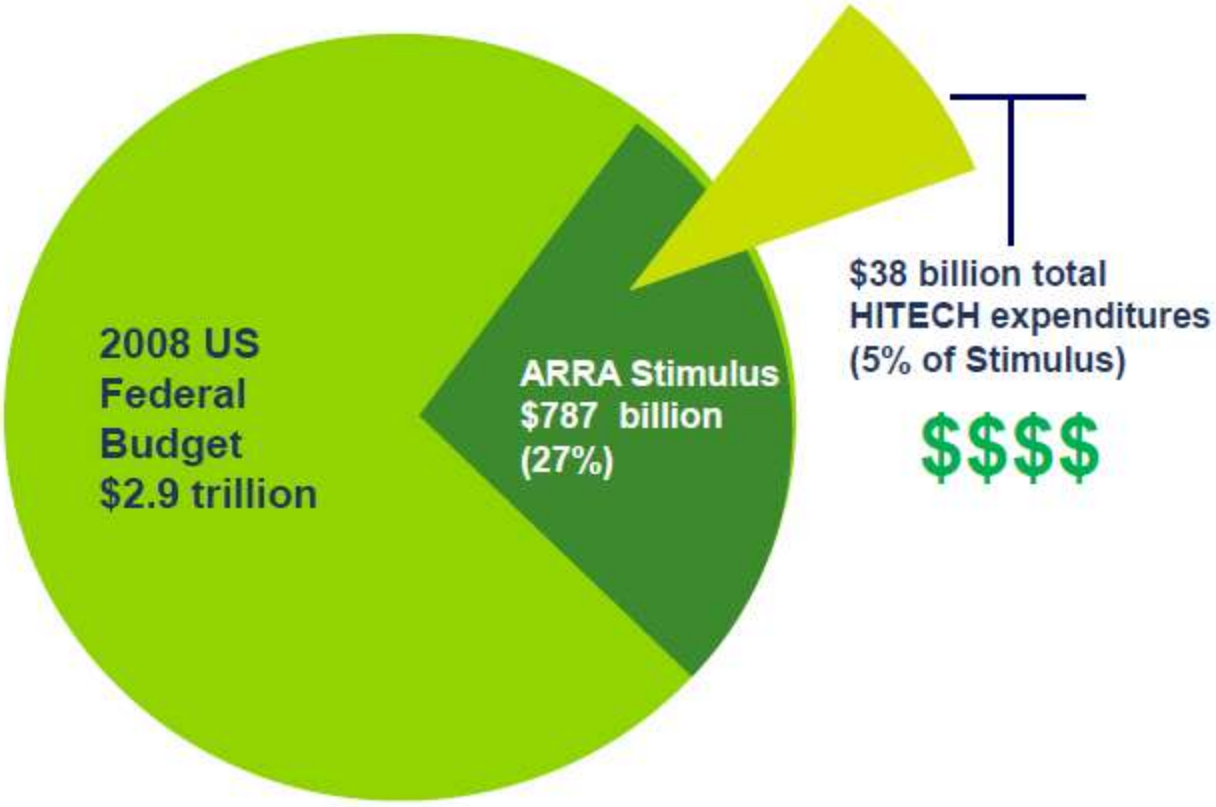
2. Covered Entity:

3. Assessment:

4. Findings:

5. Risk Analysis:

The American Recovery and Reinvestment Act of 2009 and HITECH



Federal Spending for ARRA includes federal tax cuts, expansion of unemployment benefits and other social welfare provisions, and domestic spending in education, health care, and infrastructure, including the energy sector.

HITECH Act

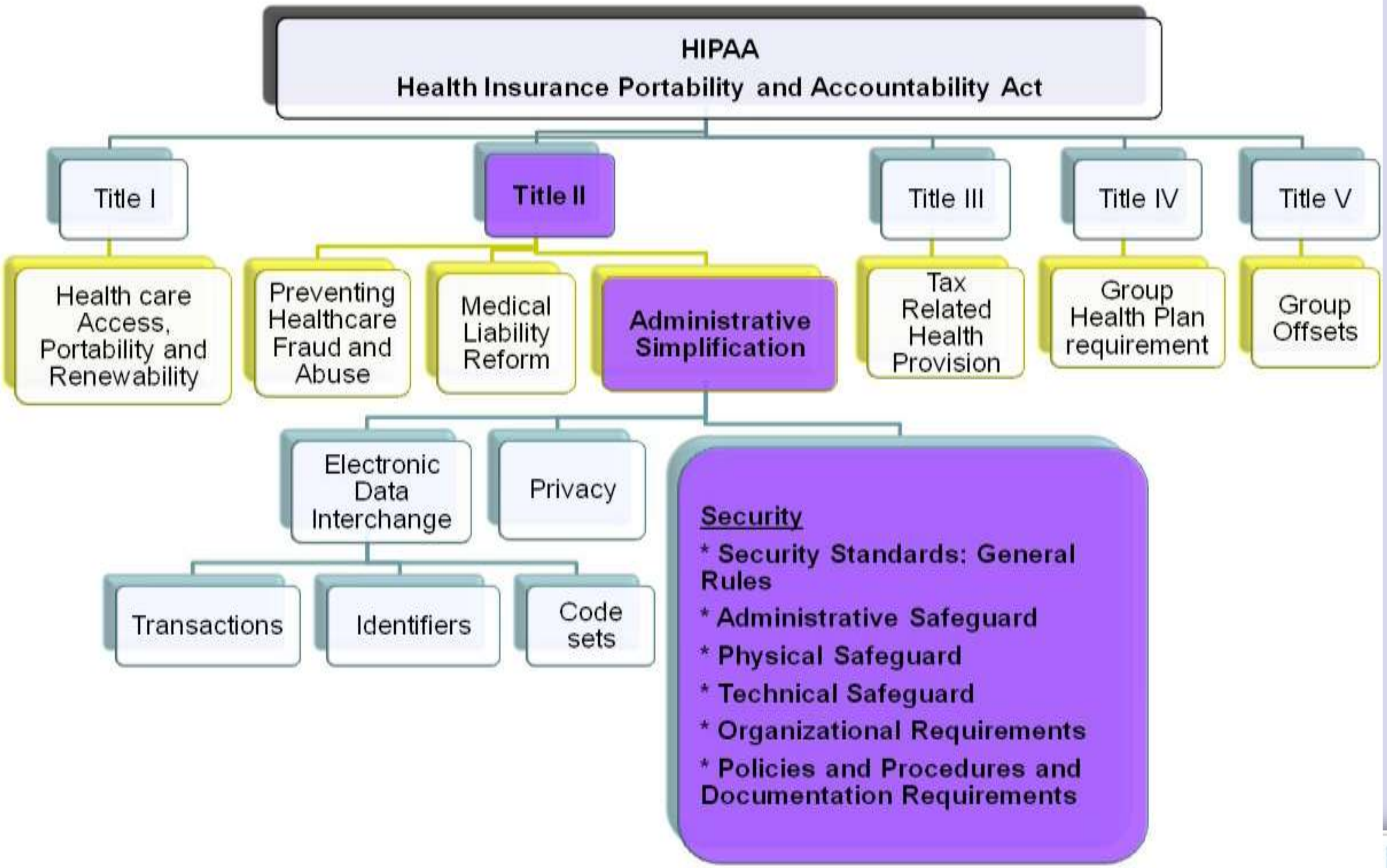
The Health Information Technology for Economic and Clinical Health (“HITECH”) provisions of the American Recovery and Reinvestment Act of 2009 (“ARRA”, also referred to as the “Stimulus Bill”) codify and expand on many of the requirements contained in the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and its regulations to protect the privacy and **security of protected health information** (“PHI”).

HITECH

HITECH **modifications to HIPAA** including**:**

- Creating incentives for developing a meaningful use of **electronic health records**
- Changing the liability and responsibilities of **Business Associates**
- Redefining what a **breach** is
- Creating stricter **notification** standards
- Tightening **enforcement**
- Raising the **penalties** for a violation
- Creating **new code and transaction sets** (HIPAA 5010, ICD10)

HIPAA Titles - Overview



HIPAA
Health Insurance Portability and Accountability Act

Title I

Health care Access, Portability and Renewability

Title II

Preventing Healthcare Fraud and Abuse

Medical Liability Reform

Administrative Simplification

Electronic Data Interchange

Transactions

Identifiers

Code sets

Privacy

Security

* Security Standards: General Rules

* Administrative Safeguard

* Physical Safeguard

* Technical Safeguard

* Organizational Requirements

* Policies and Procedures and Documentation Requirements

Title III

Tax Related Health Provision

Title IV

Group Health Plan requirement

Title V

Group Offsets

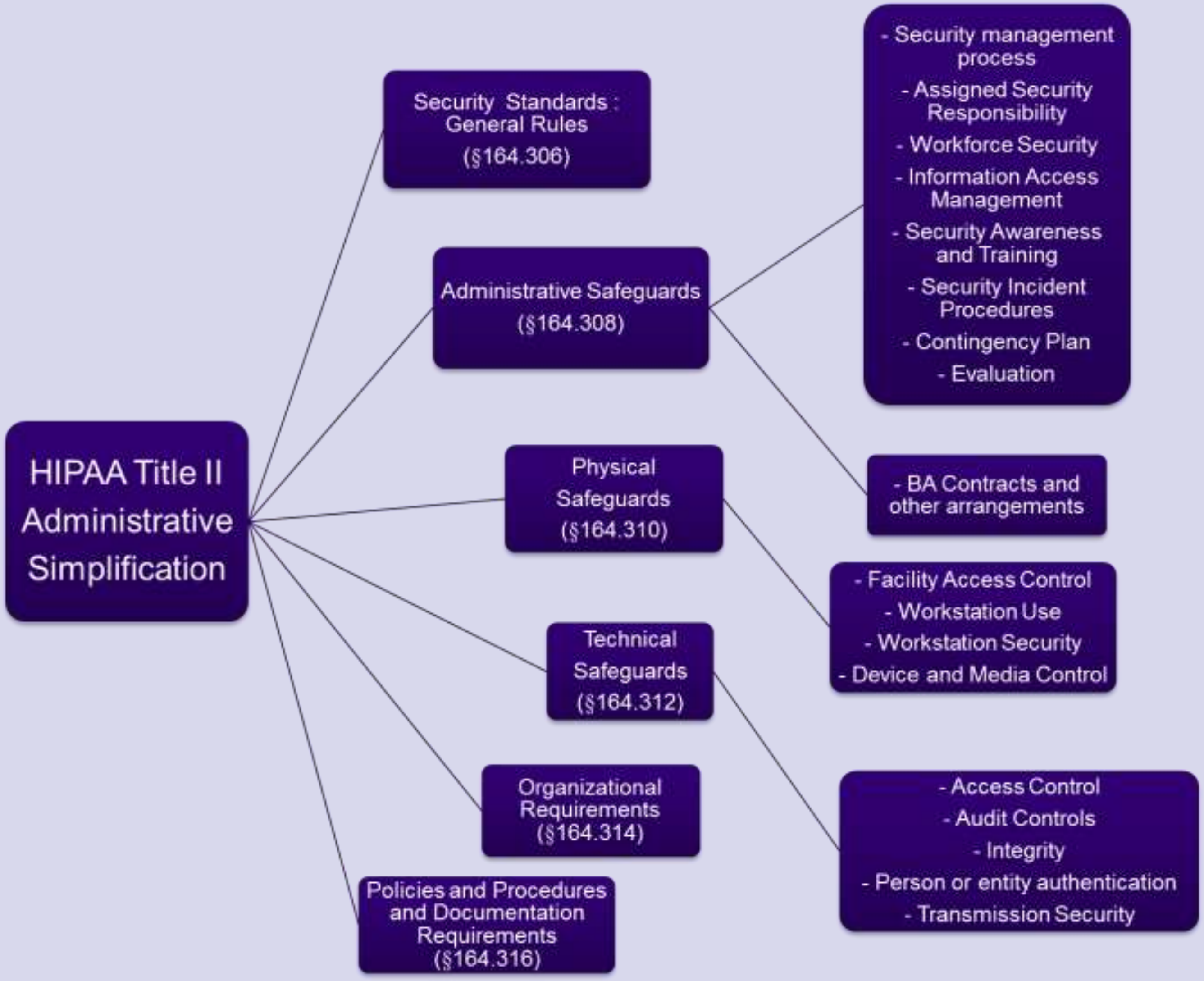
HIPAA

The two main rules of HIPAA are:

- **Privacy Rule**: Organizations must identify the uses and disclosures of protected health information (PHI) and put into effect appropriate safeguards to protect against an unauthorized use or disclosure of that PHI. When material breaches or violations of privacy are identified, the organizations must take reasonable steps to solve those problems in order to limit exposure of PHI.
- **Security Rule**: Defines the administrative, physical and technical safeguards to protect the confidentiality, integrity and availability of electronic protected health information.

(45 CFR Part 160 and Subparts A and C of Part 164)

HIPAA Security Rule



HIPAA Title II Administrative Simplification

Security Standards : General Rules (§164.306)

Administrative Safeguards (§164.308)

- Security management process
- Assigned Security Responsibility
- Workforce Security
- Information Access Management
- Security Awareness and Training
- Security Incident Procedures
- Contingency Plan
- Evaluation

- BA Contracts and other arrangements

Physical Safeguards (§164.310)

- Facility Access Control
- Workstation Use
- Workstation Security
- Device and Media Control

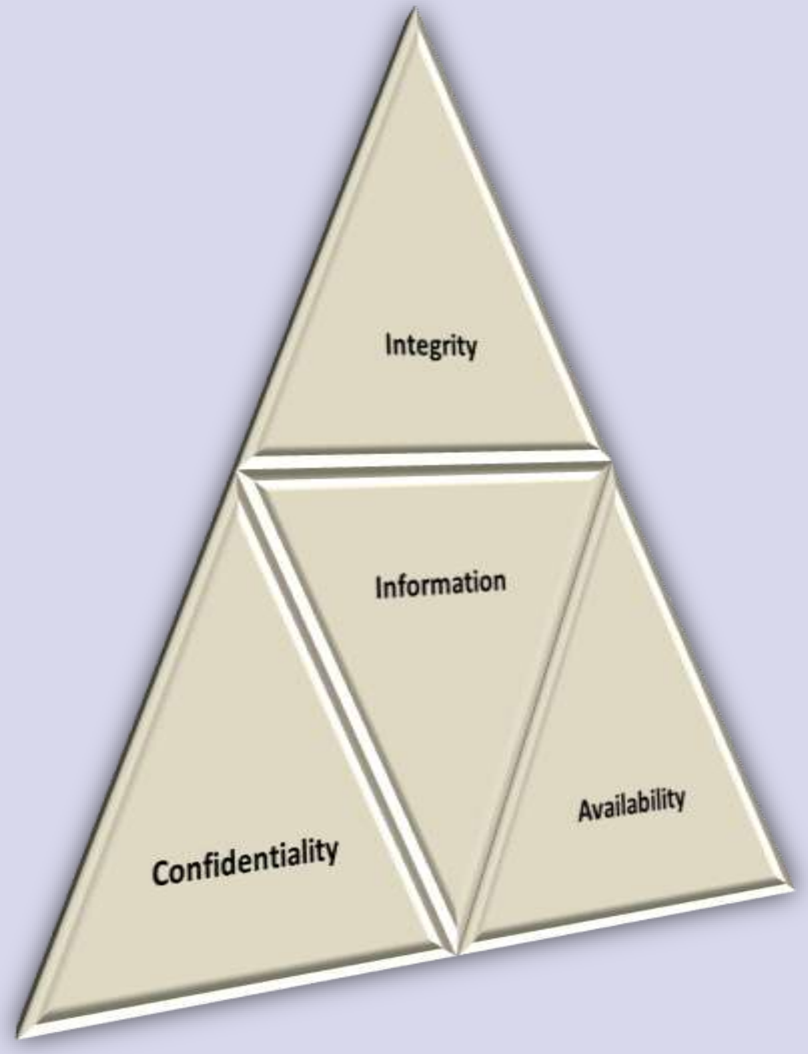
Technical Safeguards (§164.312)

- Access Control
- Audit Controls
- Integrity
- Person or entity authentication
- Transmission Security

Organizational Requirements (§164.314)

Policies and Procedures and Documentation Requirements (§164.316)

Information Security Model



Confidentiality

Limiting information access and disclosure to authorized users (the right people)

Integrity

Trustworthiness of information resources (no inappropriate changes)

Availability

Availability of information resources (at the right time)

Covered Entity

- HIPAA applies to any entity that is a
  - **Health care provider** - of services as a provider of medical or other health services, and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business
  - **Health care clearinghouse** - public or private entity that does billing services, re-pricing companies, community health management information systems or community health information systems, etc
  - **Health plan** - means an individual or group plan that provides, or pays the cost of, medical care

https://www.cms.gov/hipaageninfo/downloads/CoveredEntityCharts.pdf

Business Associates

- a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity. A member of the covered entity's workforce is not a business associate.

Examples:

- A third party administrator that assists a health plan with claims processing.
- A CPA firm whose accounting services to a health care provider involve access to protected health information.
- An attorney whose legal services to a health plan involve access to protected health information.
- A consultant that performs utilization reviews for a hospital.
- A health care clearinghouse that translates a claim from a non-standard format into a standard transaction on behalf of a health care provider and forwards the processed transaction to a payer.
- An independent medical transcriptionist that provides transcription services to a physician.
- A pharmacy benefits manager that manages a health plan's pharmacist network.

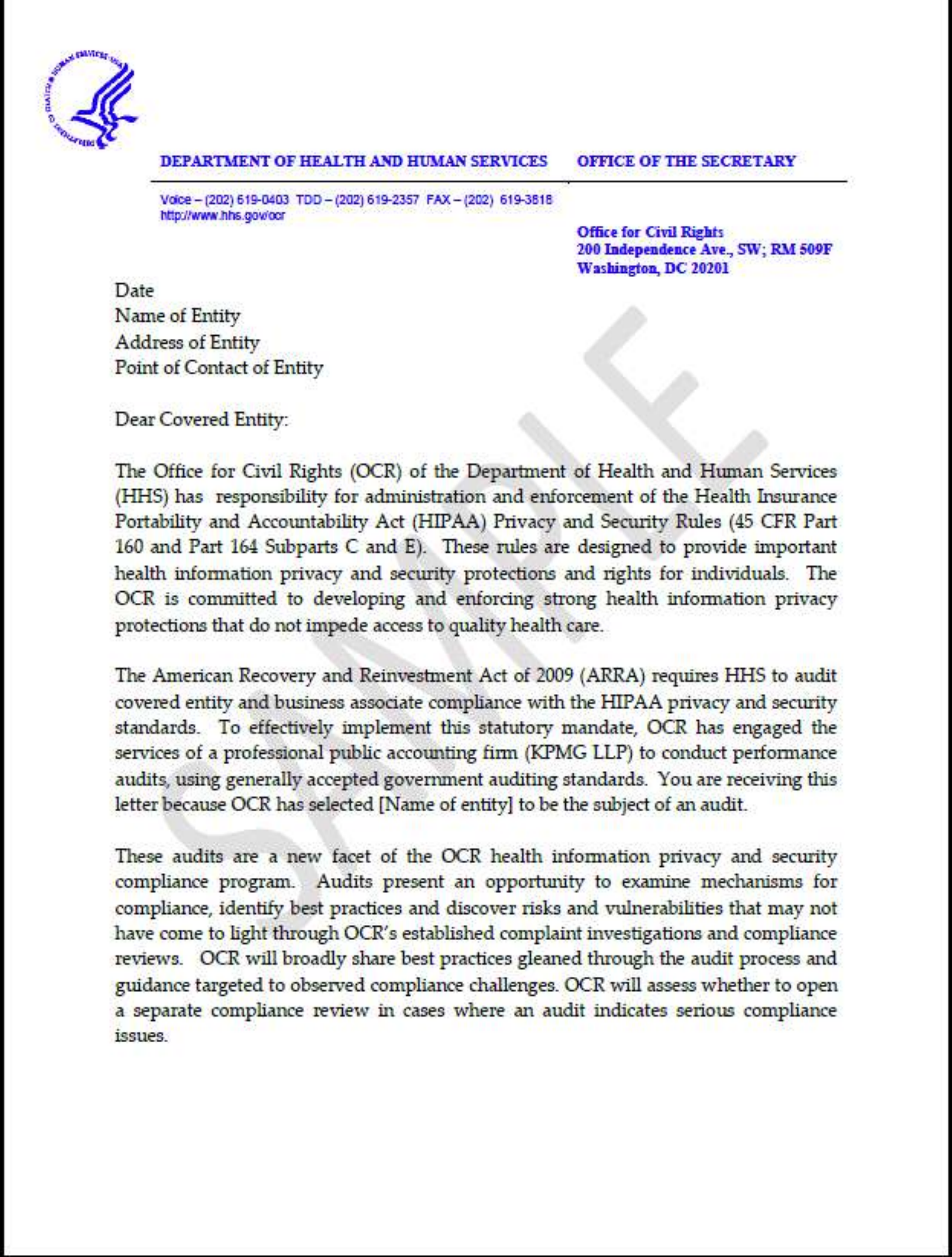
Enforcement Authorities

- Office for Civil Rights (OCR)
  - Investigating complaints filed with HHS
  - Impose civil money penalities
- Department of Justice (DOJ)
  - Investigates criminal violations
- State Attorney General (SAG)
  - Civil actions on behalf of state residents
  - Civil Money Penalties

OCR HITECH Audit

- KPMG to conduct 150 during 2012
- 20 scheduled during January – May 2012
  - In the pilot phase, OCR is auditing eight *health plans*, two claims *clearinghouses* plus 10 *provider* organizations, including three *hospitals*, three *physicians' offices*, and a *laboratory*, a *dental* office, a *nursing/custodial facility* and a *pharmacy*.

Sample letter



DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF THE SECRETARY

Voice – (202) 619-0403 TDD – (202) 619-2357 FAX – (202) 619-3818
http://www.hhs.gov/ocr

Office for Civil Rights
200 Independence Ave., SW; RM 509F
Washington, DC 20201

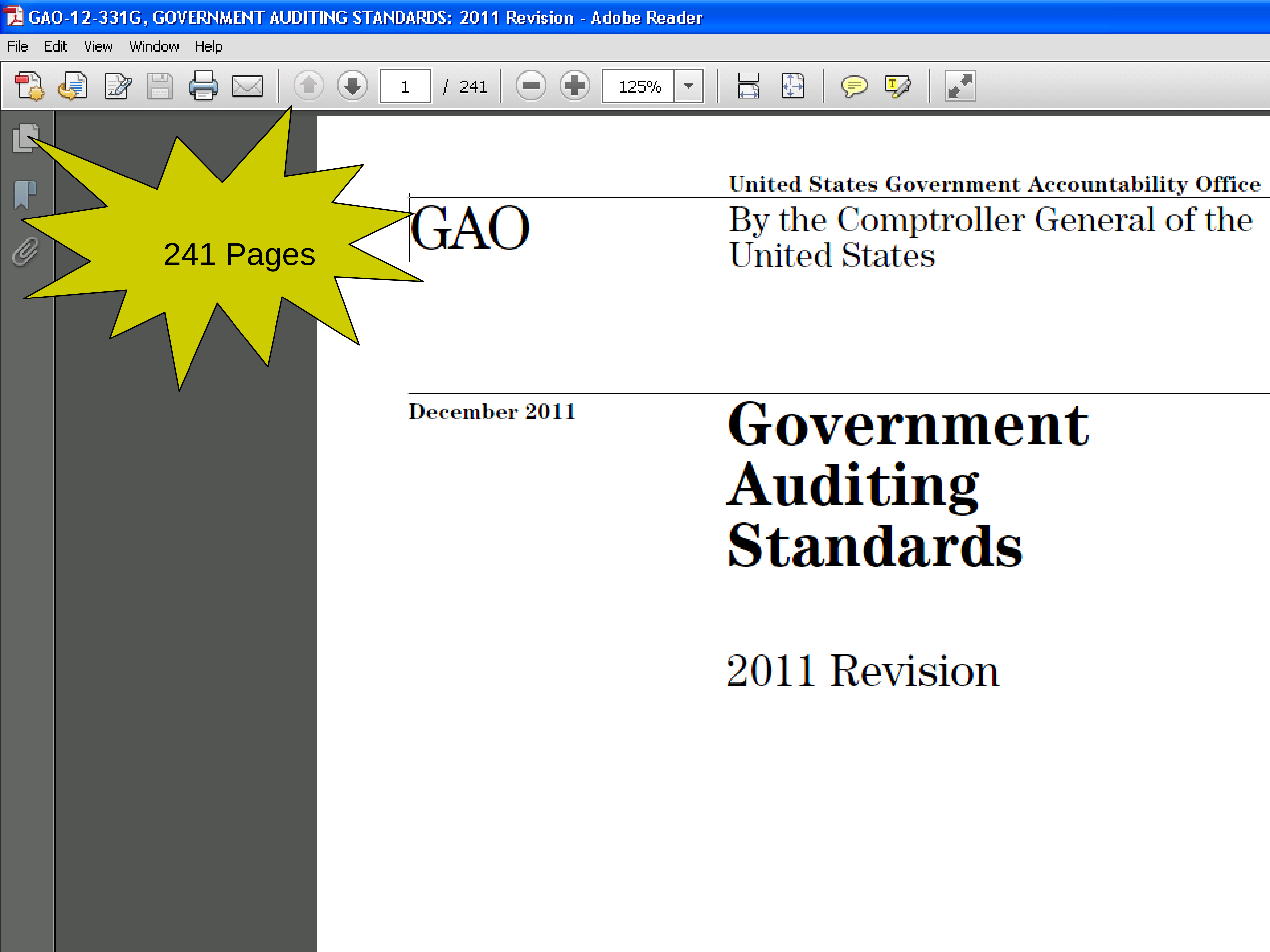
Date
Name of Entity
Address of Entity
Point of Contact of Entity

Dear Covered Entity:

The Office for Civil Rights (OCR) of the Department of Health and Human Services (HHS) has responsibility for administration and enforcement of the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules (45 CFR Part 160 and Part 164 Subparts C and E). These rules are designed to provide important health information privacy and security protections and rights for individuals. The OCR is committed to developing and enforcing strong health information privacy protections that do not impede access to quality health care.

The American Recovery and Reinvestment Act of 2009 (ARRA) requires HHS to audit covered entity and business associate compliance with the HIPAA privacy and security standards. To effectively implement this statutory mandate, OCR has engaged the services of a professional public accounting firm (KPMG LLP) to conduct performance audits, using generally accepted government auditing standards. You are receiving this letter because OCR has selected [Name of entity] to be the subject of an audit.

These audits are a new facet of the OCR health information privacy and security compliance program. Audits present an opportunity to examine mechanisms for compliance, identify best practices and discover risks and vulnerabilities that may not have come to light through OCR's established complaint investigations and compliance reviews. OCR will broadly share best practices gleaned through the audit process and guidance targeted to observed compliance challenges. OCR will assess whether to open a separate compliance review in cases where an audit indicates serious compliance issues.


GAO-12-331G, GOVERNMENT AUDITING STANDARDS: 2011 Revision - Adobe Reader
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241 Pages

United States Government Accountability Office

GAO

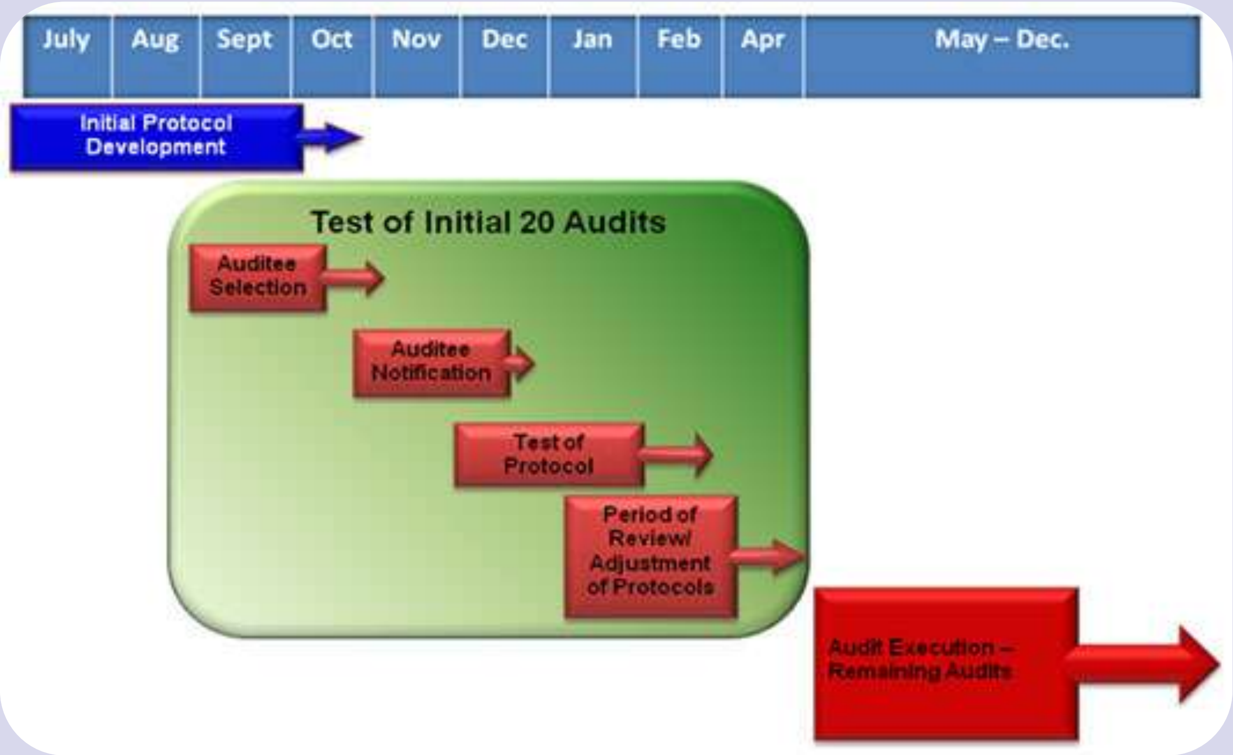
By the Comptroller General of the United States

December 2011

Government Auditing Standards

2011 Revision

OCR Audit Timeline



July Aug Sept Oct Nov Dec Jan Feb Apr May – Dec.

Initial Protocol Development

Test of Initial 20 Audits

Auditee Selection

Auditee Notification

Test of Protocol

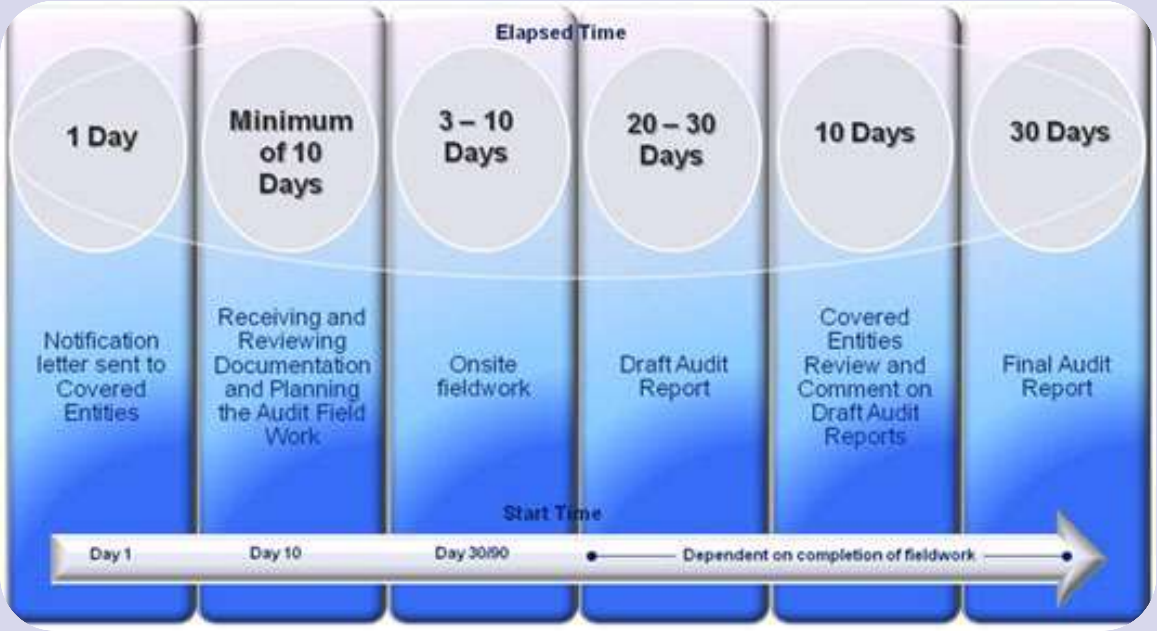
Period of Review/ Adjustment of Protocols

Audit Execution – Remaining Audits

Every covered entity and business associate is eligible for an audit.

From HHS.gov site

OCR Audit Schedule



1 Day	Minimum of 10 Days	3 – 10 Days	20 – 30 Days	10 Days	30 Days
Notification letter sent to Covered Entities	Receiving and Reviewing Documentation and Planning the Audit Field Work	Onsite fieldwork	Draft Audit Report	Covered Entities Review and Comment on Draft Audit Reports	Final Audit Report

OCR: Audits are primarily a compliance improvement activity

From HHS.gov site

HIPAA Complaint Process

OCR enforces the Privacy and Security Rules in several ways:

1. by investigating complaints filed with it
2. conducting compliance reviews(audit) to determine if covered entities are in compliance
3. performing education and outreach to foster compliance with the rules' requirements

Resolution

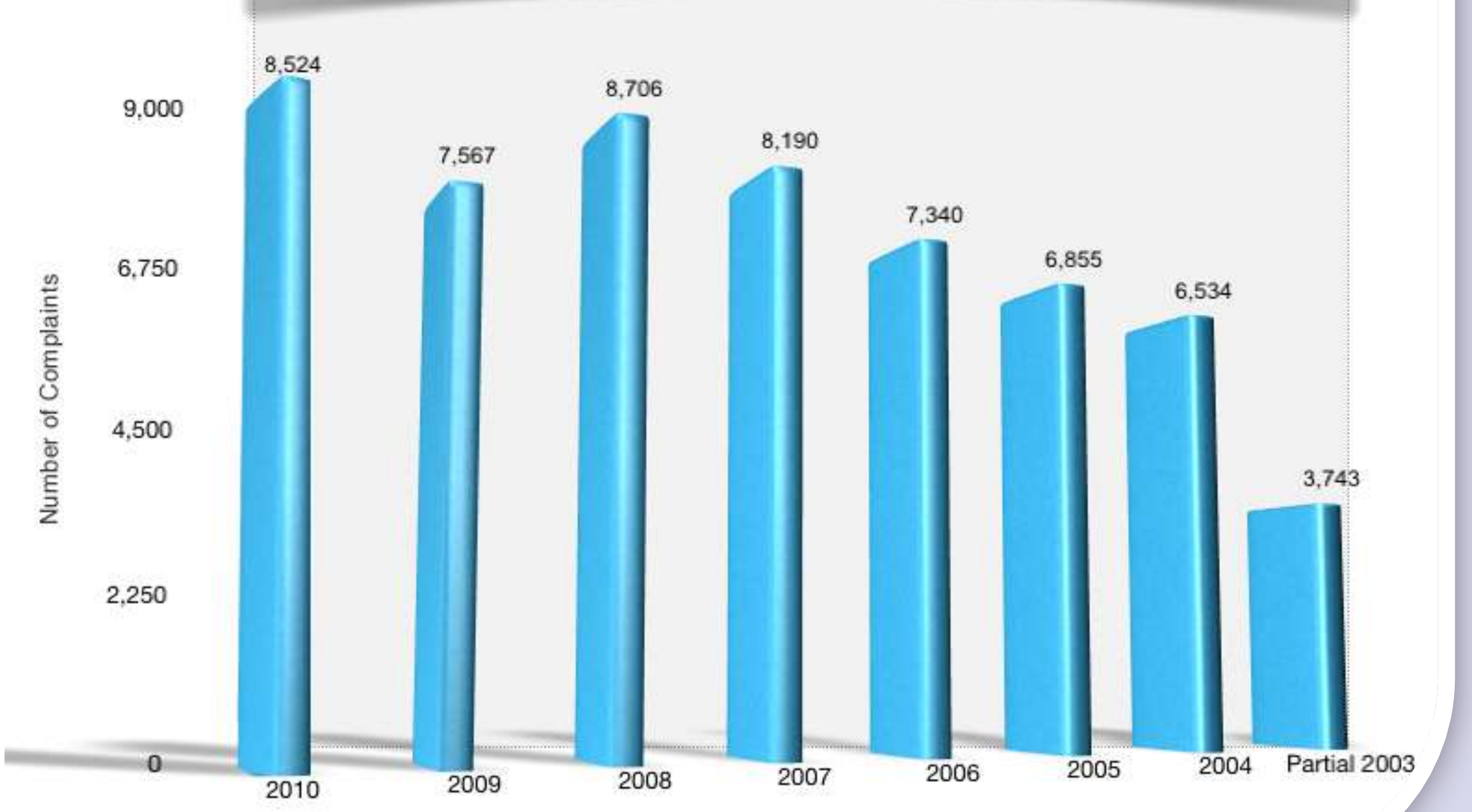
OCR will attempt to resolve the case with the covered entity by obtaining:

1. Voluntary compliance
2. Corrective action which might include penalty
3. Resolution agreement

Common fallacies related to OCR audit

- “Our compliance officer handles everything – there’s no need to involve anyone else.” “We’re compliant; therefore, we’re secure.”
- “The last time we had an audit they didn’t find anything of concern.”
- “We have a security policy to keep our systems protected.”
- “Even if we mess up, the regulators aren’t going to come after us.”

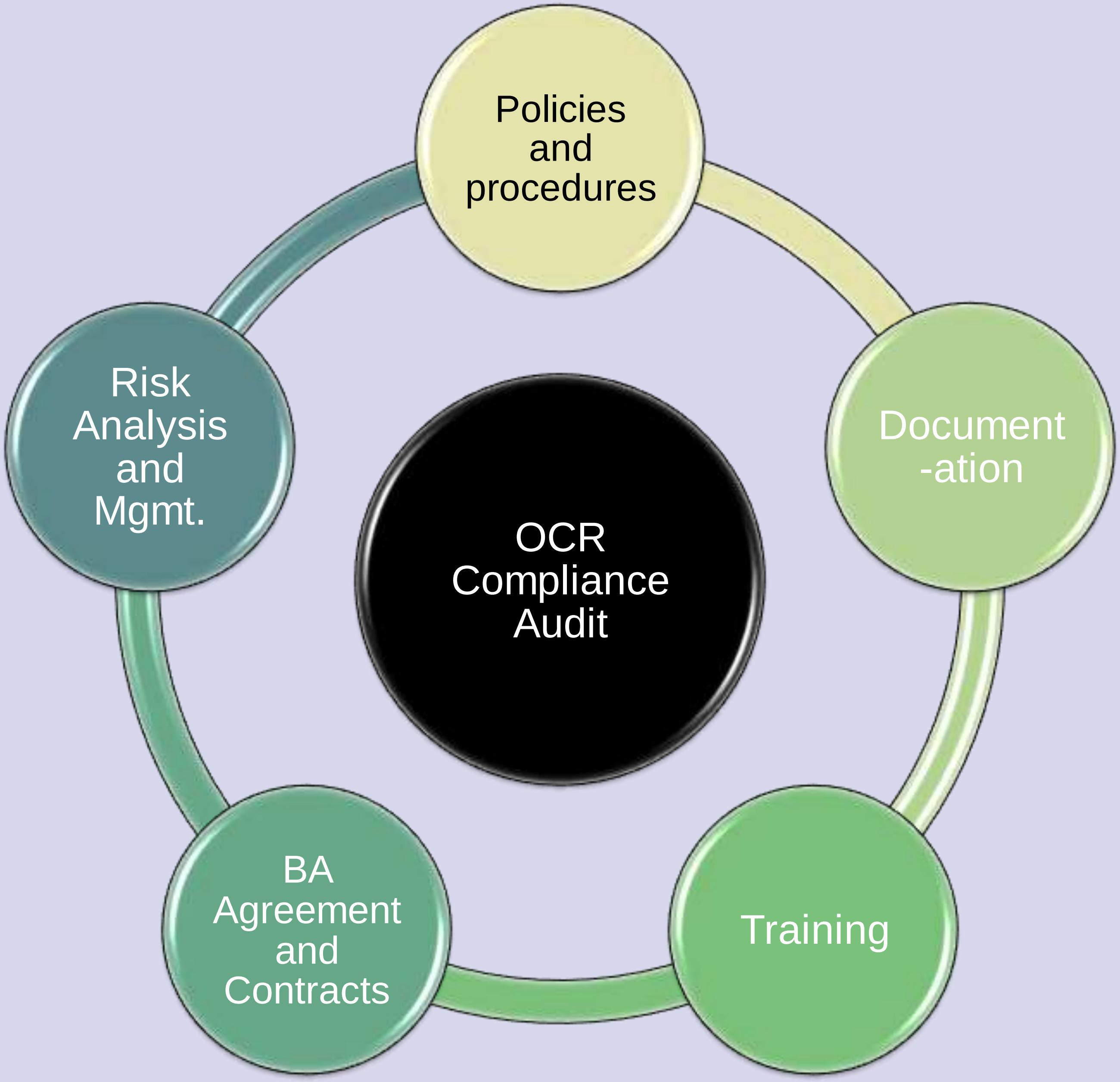
Complaints Received by Calendar Year



Top 5 issues investigated

Year	Issue 1	Issue 2	Issue 3	Issue 4	Issue 5
2010	Impermissible Uses & Disclosures	Safeguards	Access	Minimum Necessary	Notice
2009	Impermissible Uses & Disclosures	Safeguards	Access	Minimum Necessary	Complaints to Covered Entity
2008	Impermissible Uses & Disclosures	Safeguards	Access	Minimum Necessary	Complaints to Covered Entity

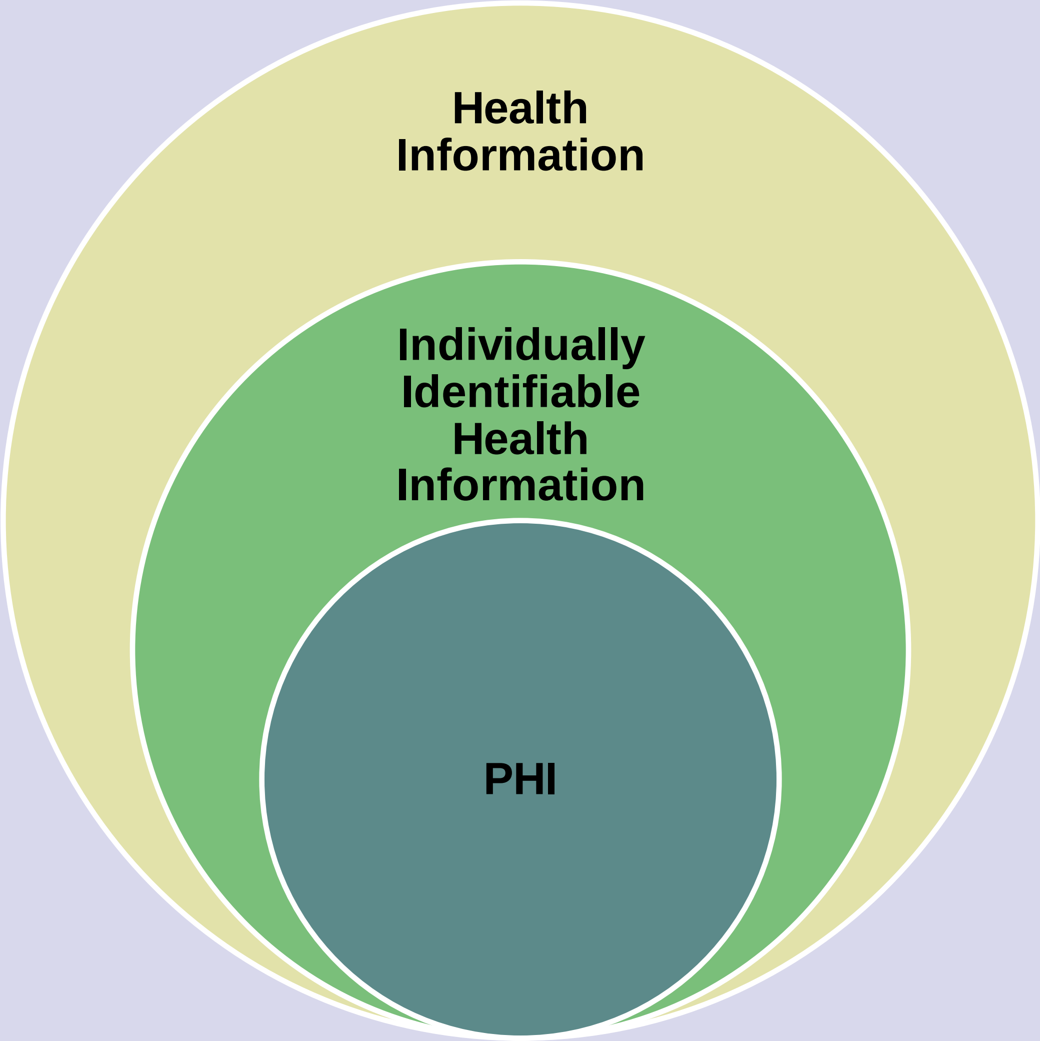
OCR Compliance Audit Review



OCR Compliance Audit Review(Contd.)

- Off-site access and use of ePHI from remote locations
- Implementation of minimum necessary standard
- Storage of ePHI on portable devices and media
- Provision of Notices of Privacy Practices
- Disposal of equipment containing ePHI
- Executing proper authorization forms
- Physical security of facilities and mobile devices
- Technical safeguards in place to protect ePHI
- Data encryption
- Virus protection
- Monitoring of access to ePHI

PHI


Health Information

Individually Identifiable Health Information

PHI

ePHI – 18 Elements

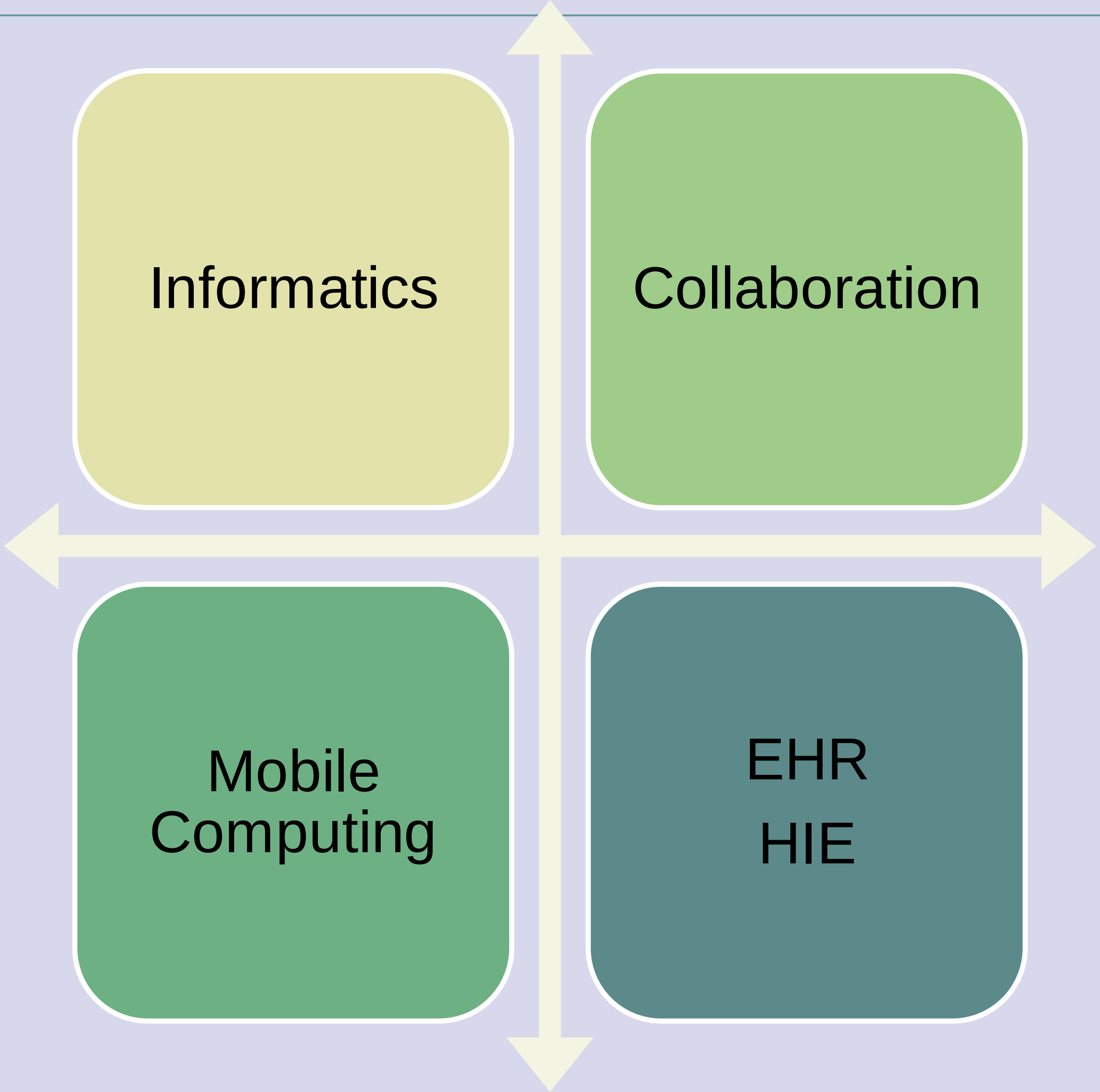
Elements	Examples
Name	Max Bialystock
Address	1355 Seasonal Lane (all geographic subdivisions smaller than state, including street address, city, county, or ZIP code)
Dates related to an individual	Birth, death, admission, discharge
Telephone numbers	212 555 1234, home, office, mobile etc.,
Fax number	212 555 1234
Email address	LeonT@Hotmail.com, personal, official
Social Security number	239-68-9807
Medical record number	189-88876
Health plan beneficiary number	123-ir-2222-98
Account number	333389
Certificate/license number	3908763 NY
Any vehicle or other device serial number	SZV4016
Device identifiers or serial numbers	Unique Medical Devices
Web URL	www.rickymartin.com
Internet Protocol (IP) address numbers	19.180.240.15
Finger or voice prints	finger.jpg
Photographic images	mypicture.jpg
Any other characteristic that could uniquely identify the individual	

Infrastructure

Any device that electronically stores or transmits information using a software program

- Computers
- Storage Devices
- Networking devices (Routers, Switches & Wireless)
- Medical Devices
- Scanners, fax and photocopiers
- VoIP
- Smart-phones, Tablets (ipad, PDAs)
- Cloud-based services

Trends in Healthcare IT



Informatics

Collaboration

Mobile Computing

EHR

HIE

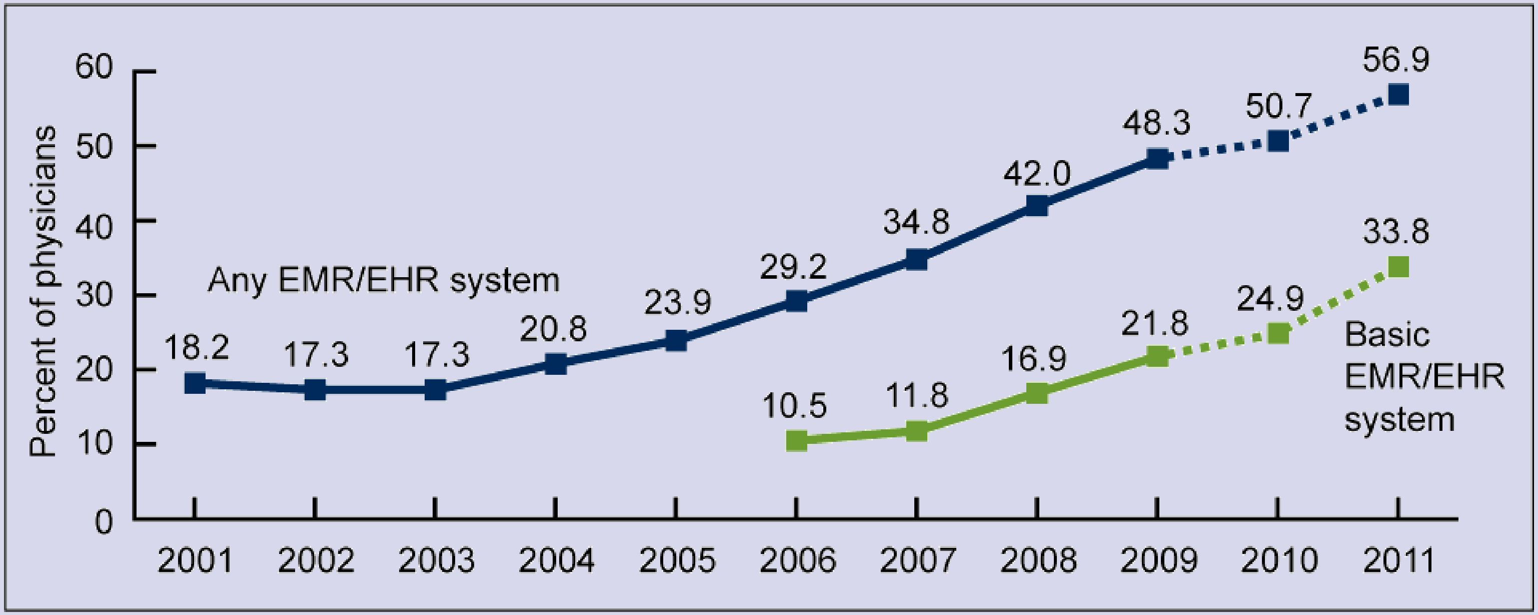
Handheld Usage in Healthcare

- 25% usage with providers
- Another 21% expected to use
- 38% physicians use medical apps
- 70% think it is a high priority
- 1/3 use hand-held for accessing EMR/EHR

compTIA 2011 Survey

EMR and EHR systems

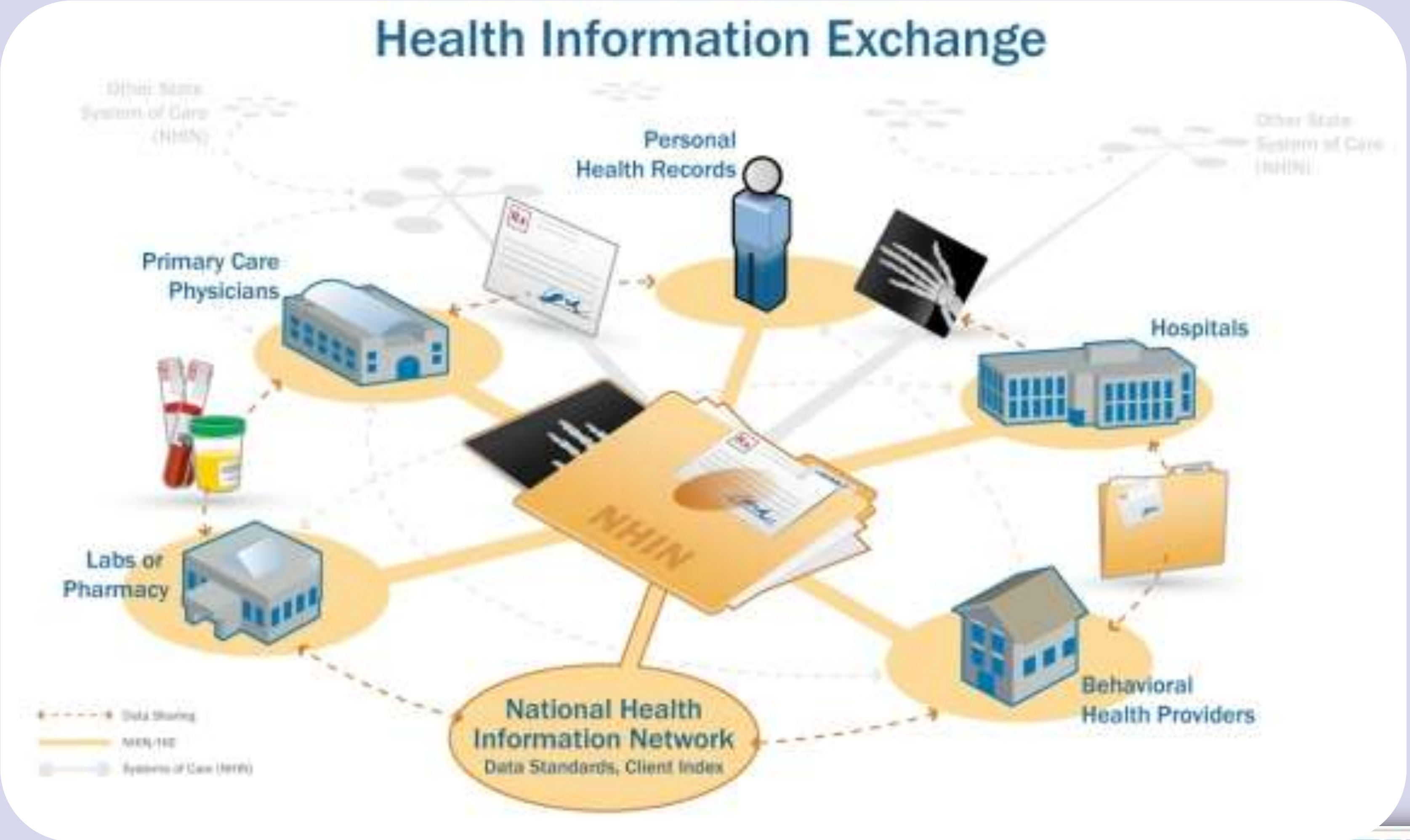
Figure 1. Percentage of office-based physicians with EMR/EHR systems: United States, 2001–2009, and preliminary 2010–2011



NOTES: EMR/EHR is electronic medical record/electronic health record. "Any EMR/EHR system" is a medical or health record system that is all or partially electronic (excluding systems solely for billing). Data for 2001–2007 are from the in-person National Ambulatory Medical Care Survey (NAMCS). Data for 2008–2009 are from combined files (in-person NAMCS and mail survey). Data for 2010–2011 are preliminary estimates (dashed lines) based on the mail survey only. Estimates through 2009 include additional physicians sampled from community health centers. Estimates of basic systems prior to 2006 could not be computed because some items were not collected in the survey. Data include nonfederal, office-based physicians and exclude radiologists, anesthesiologists, and pathologists.

SOURCE: CDC/NCHS, National Ambulatory Medical Care Survey.

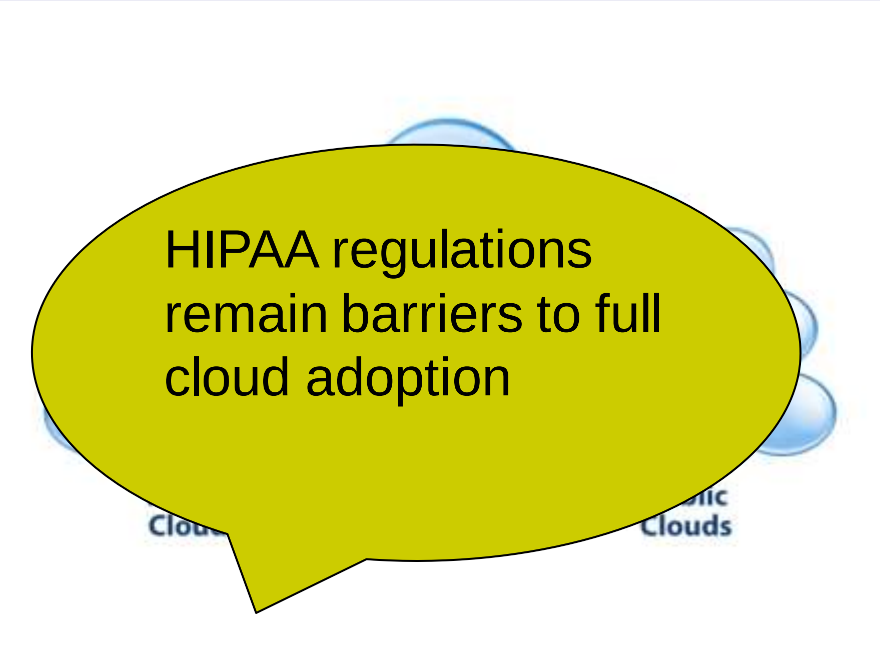
Health Information Exchange (HIE)


Health Information Exchange
Other State System of Care (NHIN)
Personal Health Records
Other State System of Care (NHIN)
Primary Care Physicians
Hospitals
NHIN
Labs or Pharmacy
Behavioral Health Providers
National Health Information Network
Data Standards, Client Index
Data Sharing
NHIN/HIE
Systems of Care (NHIN)

Social Media

- How does your practice use it?
- How do your employees use it?
- Do you have policies?

Cloud-based services

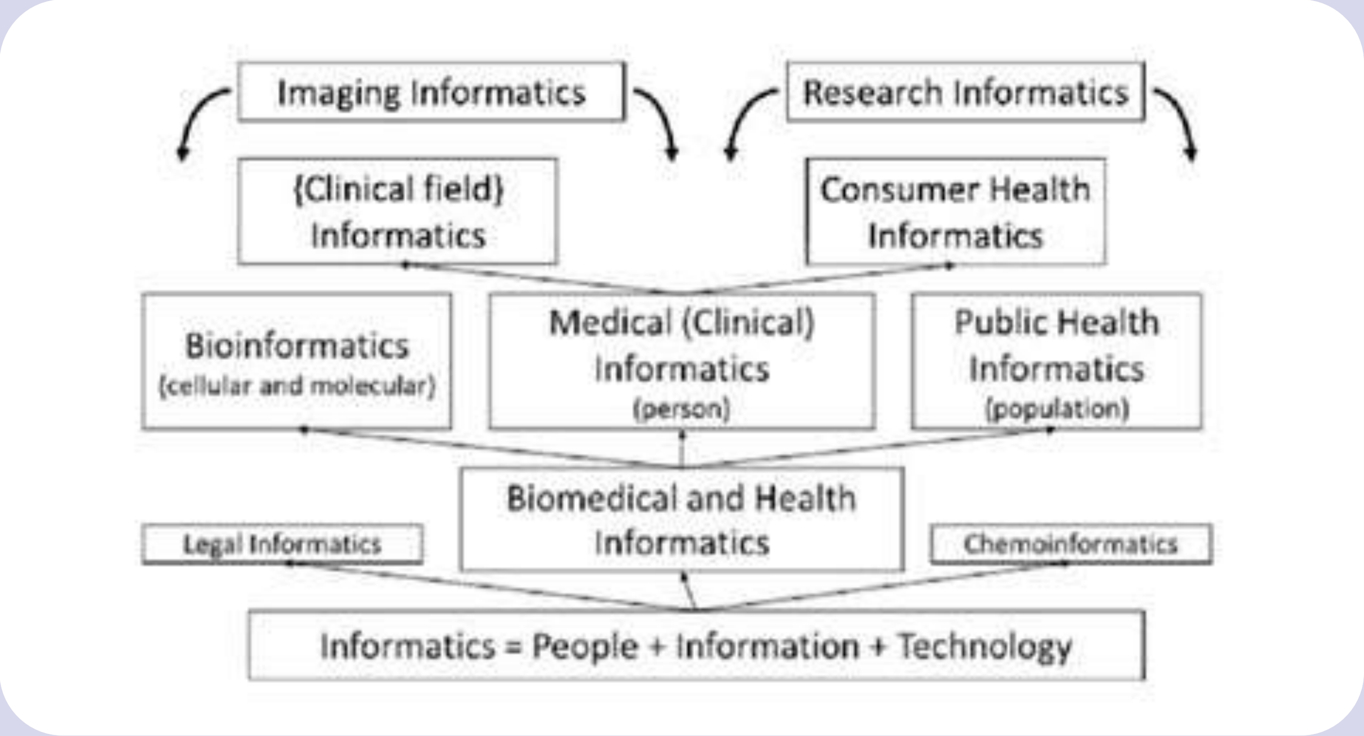


HIPAA regulations remain barriers to full cloud adoption

Cloud Computing is taking all batch processing, and farming it out to a huge central or virtualized computers.

- **Public Cloud**
  - EHR Applications
  - Private-label e-mail
- **Private Cloud**
  - Archiving of Images
  - File Sharing
  - On-line Backups
- **Hybrid**

Informatics


Imaging Informatics
Research Informatics
{Clinical field} Informatics
Consumer Health Informatics
Bioinformatics (cellular and molecular)
Medical (Clinical) Informatics (person)
Public Health Informatics (population)
Biomedical and Health Informatics
Legal Informatics
Chemoinformatics
Informatics = People + Information + Technology

Sample Risk Analysis Template

		Likelihood		
		High	Medium	Low
Impact	High	Unencrypted laptop ePHI	Lack of auditing on EHR systems	Missing security patches on web server hosting patient information
	Medium	Unsecured wireless network in doctor's office	Outdated anti-virus software	External hard drives not being backed up
	Low	Sales presentation on USB thumb drive	Web server backup tape not stored in a secured location	Weak password on internal document server

Top 5 Recommendations to Survive an OCR Audit

1. Ensure encryption on all protected health information in storage and transit.(at least de-identification)
2. Implement a mobile device security program.
3. Strengthen information security user awareness and training programs.
4. Ensure that business associate due diligence includes clearly written contract, a periodic review of implemented controls.
5. Minimize sensitive data capture, storage and sharing.

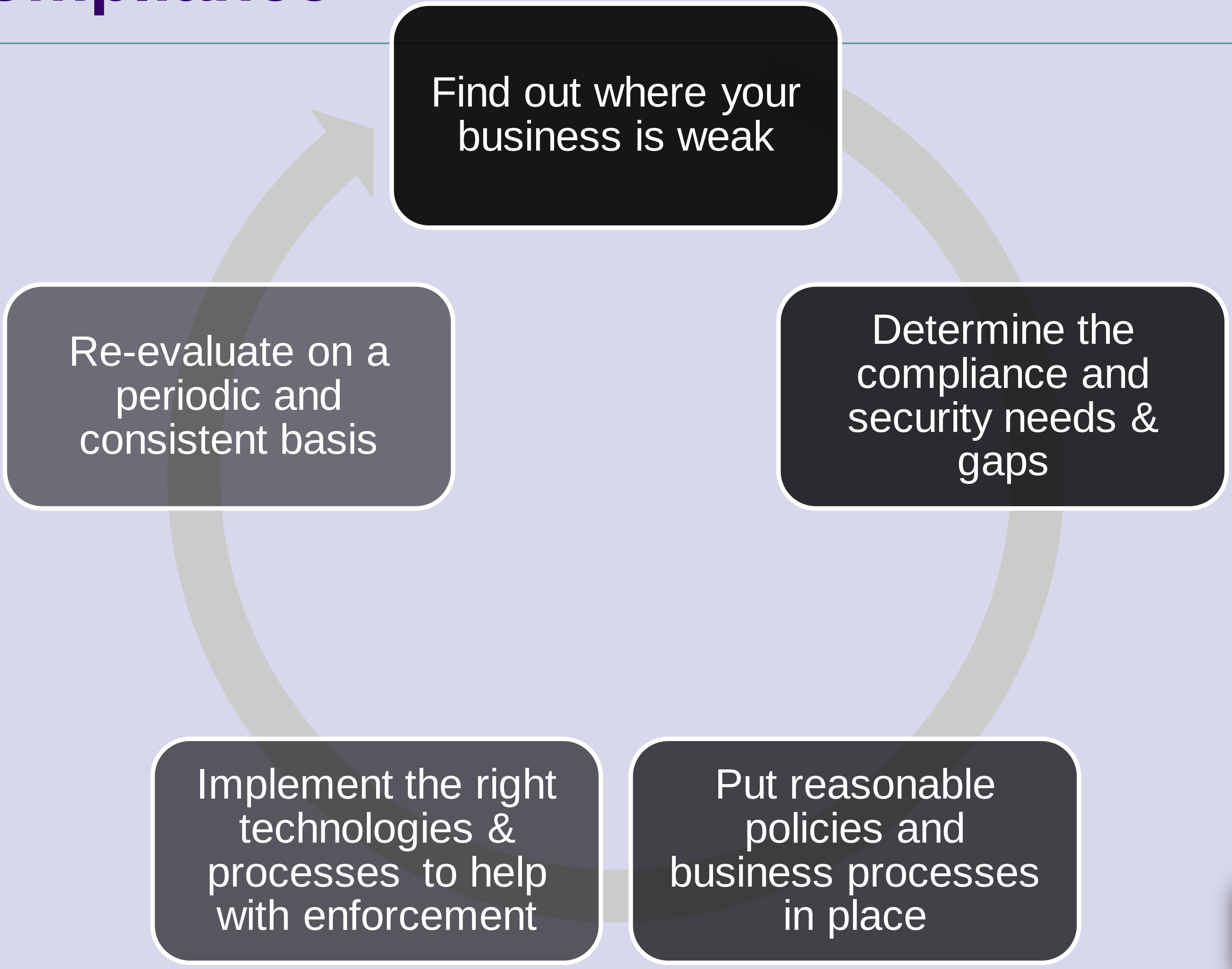
Questions to your auditors

- Do you have an audit plan?

- Do you have detail audit objectives documented?

- Do you recommend action to correct deficiencies?

Effective Management of Security and Compliance



Find out where your business is weak

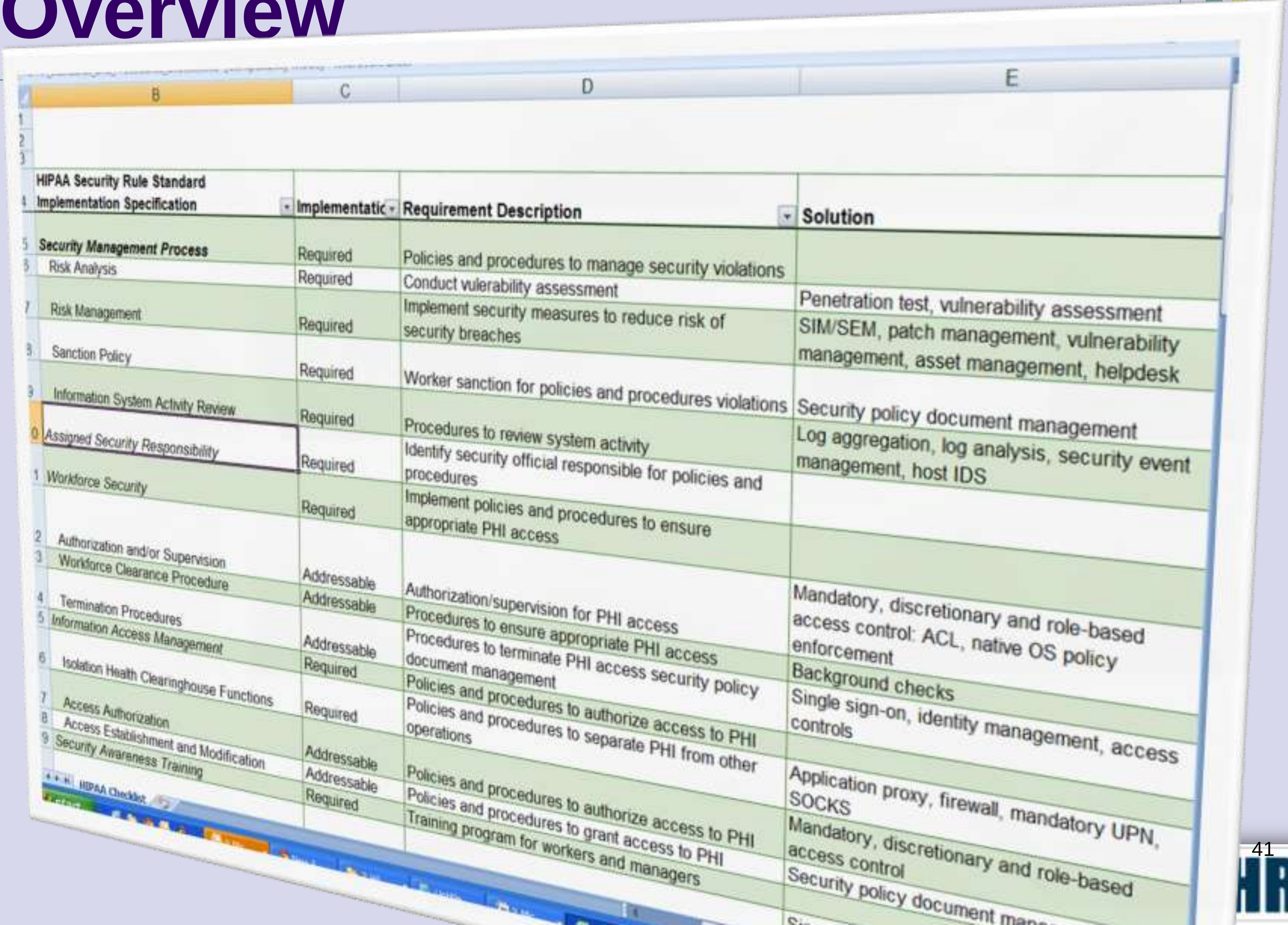
Determine the compliance and security needs & gaps

Put reasonable policies and business processes in place

Implement the right technologies & processes to help with enforcement

Re-evaluate on a periodic and consistent basis

HIPAA Security Checklist Overview



HIPAA Security Rule Standard Implementation Specification	Implementatic	Requirement Description	Solution
Security Management Process	Required	Policies and procedures to manage security violations	
Risk Analysis	Required	Conduct vulerability assessment	Penetration test, vulnerability assessment
Risk Management	Required	Implement security measures to reduce risk of security breaches	SIM/SEM, patch management, vulnerability management, asset management, helpdesk
Sanction Policy	Required	Worker sanction for policies and procedures violations	Security policy document management
Information System Activity Review	Required	Procedures to review system activity	Log aggregation, log analysis, security event management, host IDS
Assigned Security Responsibility	Required	Identify security official responsible for policies and procedures	
Workforce Security	Required	Implement policies and procedures to ensure appropriate PHI access	
Authorization and/or Supervision	Addressable	Authorization/supervision for PHI access	Mandatory, discretionary and role-based access control: ACL, native OS policy enforcement
Workforce Clearance Procedure	Addressable	Procedures to ensure appropriate PHI access	Background checks
Termination Procedures	Addressable	Procedures to terminate PHI access security policy document management	Single sign-on, identity management, access controls
Information Access Management	Required	Policies and procedures to authorize access to PHI	
Isolation Health Clearinghouse Functions	Required	Policies and procedures to separate PHI from other operations	Application proxy, firewall, mandatory UPN, SOCKS
Access Authorization	Addressable	Policies and procedures to authorize access to PHI	Mandatory, discretionary and role-based access control
Access Establishment and Modification	Addressable	Policies and procedures to grant access to PHI	Security policy document mana
Security Awareness Training	Required	Training program for workers and managers	

EHR 2.0 Toolkit for Planning & Documentation

- http://ehr20.com/toolkit/

Key Takeaways

- HITECH act enforces HIPAA guidelines with new audit, penalties, notifications requirements etc.,

- ePHI elements drives the security and compliance requirements

- There is no silver bullet for audit issues. It is a journey of continuous assessment and improvement

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- Follow-us on social media
  facebook.com/ehr20 (Like)
  linkedin.com/company/ehr-2-0 (Follow us)
  https://twitter.com/#!/EHR_20 (Follow)

- Next Webinar on Meaningful Use Risk Analysis (3/14)

- http://ehr20.com/ocr-audit-advisory-services/

We sincerely appreciate your referrals!

Thank you!!