



**Connecting  
Healthcare**<sup>®</sup>  
*Engaging Patients*<sup>™</sup>

**HIPAA Success - Physician Education Series**

**HIPAA Security – What Does it Require?**

# Your Faculty:

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- President and Founder, Connecting Healthcare®
- Host and Producer, Medical Update Show
- Served as Technical and Operations Lead, HIE Project Manager Florida Health Information Exchange
- Served as the State of Florida - Technical SME for the ONC State Health Policy Consortium, Southeast Regional HIT-HIE Collaboration (SERCH)
- Founding Executive Director, ePrescribe Florida and President, ePrescribe America
- Founding Chair of the Southern Healthcare Administrative Regional Process (SHARP), a regional collaborative workgroup alliance of private and public health care organizations and HHS, HRSA and CMS
- Founding Co-Chair of the CMS Sponsored Southern Insurance Commissioner Task Force, a regional collaborative workgroup alliance for State-level HIPAA Education
- Founding Security and Privacy Co-Chair for the Workgroup for Electronic Data Interchange (WEDi) Strategic National Implementation Process (SNIP)



# Agenda

- Introduction to HIPAA Security
- HIPAA Security Requirements
- Security Policies and Procedures
- Meeting HIPAA Security Compliance



# Security is a P.A.I.N.

**P**rivacy is what you have to secure

**A**uthentication identifying those sending & receiving information and accessing systems

**I**ntegrity guaranteeing non-altered information

**N**on-Repudiation being able to prove that the sender did in fact send the information



# Final Security Rules – Part 1

- The initial Security Rule was published February 20, 2003 with a final compliance date of April 21, 2005
- The Security Rule specifies a series of administrative, technical, and physical security procedures for covered entities to use to assure the confidentiality, integrity, and availability of e-PHI
  - Protect data against *reasonably* anticipated threats or hazards
  - Addresses security from both administrative and technical perspective to safeguard
    - Integrity of data
    - Confidentiality of information



## Final Security Rules – Part 2

- As part of the Health Information Technology for Economic and Clinical Health (HITECH) Act, the initial HIPAA Security rule was amended by the Omnibus Rule on January 25, 2013
- It included provisions that change several important aspects of the rule
- The Omnibus Rule requires the compliance of business associates (BAs) and their subcontractors
- It also requires the Office for Civil Rights (OCR) to perform audits that include stiffer penalties for non-compliance



# Who is Covered?

- Who must comply?
  - Health plans
  - Clearinghouses
  - Any healthcare provider who transmits any health information in electronic form in connection with a standard transaction
- Business associates (BAs) and their subcontractors
- Covered Entities must obtain assurances regarding security from their agents and chain of trust (Business Associate Agreements)



## Security Applies to ALL Electronic Data

- Provides ***standards*** for security but does not mandate specific technology
- Applies to data electronically transmitted or maintained
- Scalable and flexible and technology neutral
  - Allows entity to implement standards in best way to meet business requirements
  - Implement requirements differently in large versus small organizations



# Security Requires Documentation

- Documentation is a core component of the Security requirements:
  - Analyze security risks and document
  - Document how will mitigate risks to protect data and meet security standards
  - If do not implement a requirement, use documentation to justify why
  - Document administrative policies and procedures will follow to enforce security requirements



# Security Rule Requirements

- Security requirements in four areas:
  - Administrative procedures
  - Physical safeguards
  - Technical services
  - Technical mechanisms (networks)
- 75 - 80% of requirements are administrative rather than technical



# Security Covers ALL

- While most of the HIPAA EDI provisions apply only to electronically transmitted claims and related transactions, the security provisions cover *all* electronic health data
  - Standards cover information transmitted over networks, stored in a database or maintained on PCs
  - Security standards make little distinction between internal or external communications
  - All covered entities that electronically maintain or transmit identifiable health information must comply

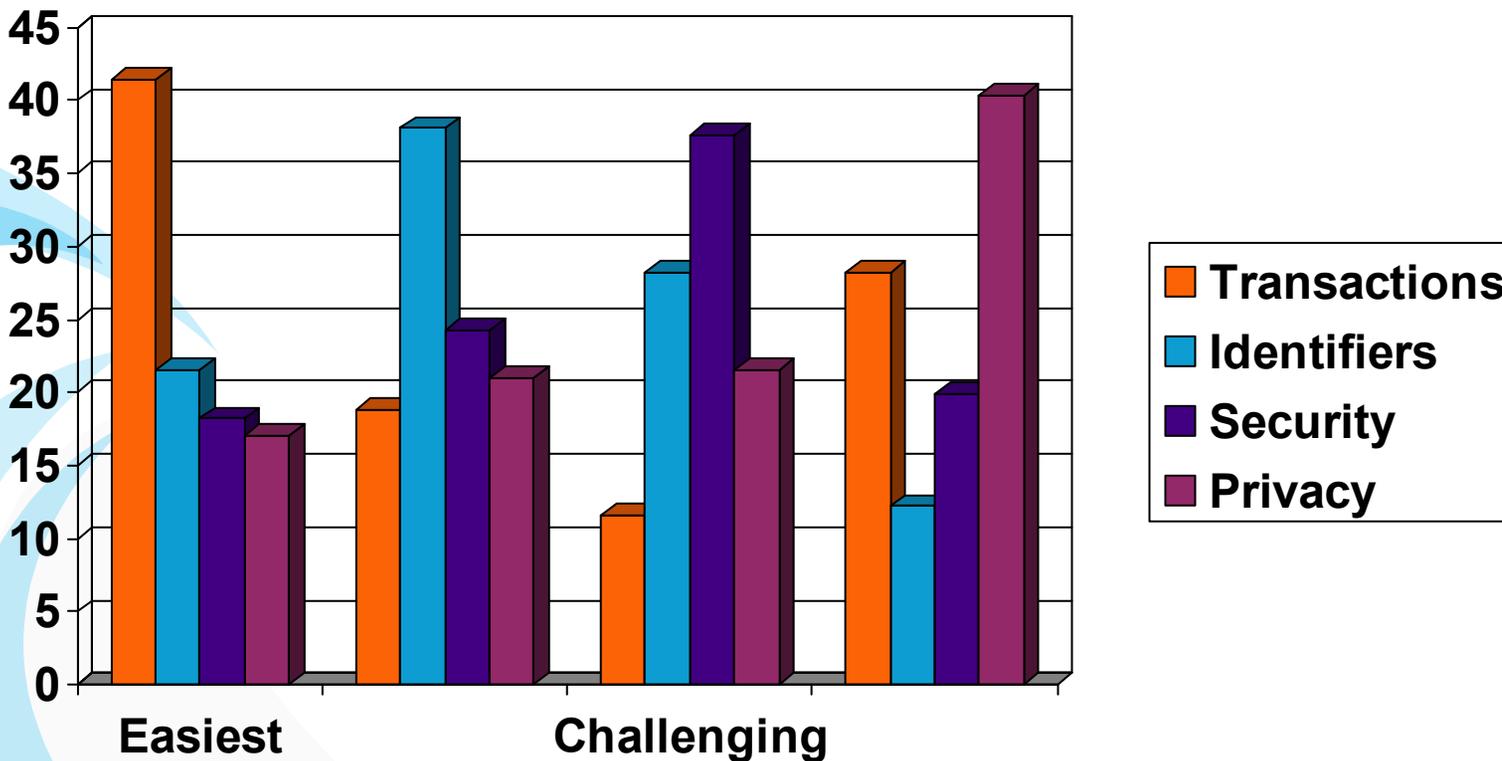


# Security Facts

- The HIPAA security requirements are very comprehensive and extend far beyond the information technology environment
- Most security requirements impact administrative areas and cannot be solved merely by technology
- To meet HIPAA compliance, many organizations will have to make major system, workflow, policy and procedure modifications



# The CIO's View of HIPAA Rules



Source: Faulkner and Gray 2000 Survey of Healthcare CIOs



# Security Effects

- Because they were designed to be very broad, the effects and implementation issues of HIPAA will vary across the industry from providers to payers
- Implementation issues will vary dramatically in each organization based minimally on:
  - Size and structure
  - Technology foundations
  - Business and trading partner arrangements
  - Role of identified healthcare information



# Impact of the Security

- The major impact areas of the security provisions include:
  - Requirement for Security Certification
  - Assessment of risks
  - Implementation of a written Security Plan
  - Implementation of specific personnel, physical and operational security measures
  - Use of access control rules
  - Development and maintenance of audit trails
  - Use of “approved” security technologies



# HIPAA Security Requirements



# HIPAA's “Cure” for P.A.I.N.

- Administrative Procedures
  - Formal practices to manage security and personnel
- Physical Safeguards
  - Protection of computer systems
- Technical Security Services
  - Control and monitor information access (data-at-rest)
- Technical Security Mechanisms
  - Includes technology to secure data-in-transit



# Administrative Procedures

- Largest category of standards
- Relates primarily to policies, procedures and organizational practices dealing with the behavioral side of security
- Will require representatives and input from all areas of the organization



# Administrative Procedure Requirements

## Certification Requirement

### Contingency Planning

Each organization will be required to have a plan of response to system emergencies

<sup>1</sup> These features must be implemented

## Implementation

- Internal or external review
- Applications and data criticality analysis <sup>1</sup>
- Data backup plan <sup>1</sup>
- Disaster recovery plan<sup>1</sup>
- Emergency mode operation plan<sup>1</sup>
- Testing and revision<sup>1</sup>



# Administrative Procedure Requirements

## Information Access Control

<sup>1</sup> These features must be implemented

## Formal Mechanism for Processing Records

Routine and non-routine receipt, manipulation, storage, dissemination and/or disposal of health information

## Implementation

- Access authorization <sup>1</sup>
- Access establishment <sup>1</sup>
- Access modification <sup>1</sup>
- Documented policies and procedures



# Administrative Procedure Requirements

## Security Configuration Management

Implementation of measures, practices, and procedures for the security of information systems

<sup>1</sup> These features must be implemented

## Implementation

- Documentation <sup>1</sup>
- Hardware/software installation & maintenance review and testing for security features <sup>1</sup>
- Inventory <sup>1</sup>
- Security testing <sup>1</sup>
- Virus checking <sup>1</sup>



# Administrative Procedure Requirements

## Security Incident Procedures

<sup>1</sup> These features must be implemented

## Security Management Process

<sup>1</sup> These features must be implemented

## Implementation

- Report procedures <sup>1</sup>
- Response procedures <sup>1</sup>
  
- Risk analysis <sup>1</sup>
- Risk management <sup>1</sup>
- Sanction policy <sup>1</sup>
- Security policy <sup>1</sup>



# Administrative Procedure Requirements

## Termination Procedures

<sup>1</sup> These features must be implemented

## Chain of Trust Agreement

<sup>2</sup> These features must be implemented

## Implementation

- Combination locks changed <sup>1</sup>
- Removal from access lists <sup>1</sup>
- Removal of user account(s) <sup>1</sup>
- Turn in keys, tokens, or cards that allow access <sup>1</sup>
- Training <sup>1</sup>
- Binding legal agreements <sup>2</sup>



# Administrative Procedure Requirements

## Training

A security training program should be established for all employees and certain third parties with access to health information, e.g. consultants and temps

<sup>1</sup> These features must be implemented

## Implementation

- Awareness training for all personnel including management <sup>1</sup>
- Periodic security reminders <sup>1</sup>
- User education concerning virus protection <sup>1</sup>
- User education in importance of monitoring log-in success/failure and reporting discrepancies <sup>1</sup>
- User education in password management <sup>1</sup>



# Administrative Procedure Requirements

## Internal Audit

Ongoing in-house audit & review of records of system activity

## Implementation

- Procedures for review of logins, file accesses, security incidents



# Administrative Procedure Requirements

## Personnel Security

<sup>1</sup> These features must be implemented

## Implementation

- Ensure supervision of maintenance personnel by authorized, knowledgeable personnel <sup>1</sup>
- Maintain access authorizations records <sup>1</sup>
- Ensure that operating and maintenance personnel have proper access <sup>1</sup>
- Employ personnel clearance procedures <sup>1</sup>
- Employ personnel security procedures <sup>1</sup>
- Ensure that system users, including maintenance personnel, are trained in system security <sup>1</sup>



# Physical Safeguards

- Protection of computer systems
- Documented policies on the receipt and removal of hardware and software
- Policies and procedures for ensuring authorized physical access
- Policies and procedures for ensuring authorized use and location of work stations
- Security Awareness training for all employees, agents and contractors



# Physical Safeguard Requirements

## Assigned Security Responsibility

<sup>1</sup> Documented assignment of security responsibility

## Media Controls

<sup>2</sup> Documented policies on the receipt and removal of hardware and software. These features must be implemented

## Implementation

- Use of Security Measures <sup>1</sup>
- Conduct of personnel in relation to protecting data <sup>1</sup>
  
- Access control <sup>2</sup>
- Accountability (tracking)<sup>2</sup>
- Data backup <sup>2</sup>
- Data storage <sup>2</sup>
- Disposal <sup>2</sup>



# Physical Safeguard Requirements

## Physical Access Controls

Policies and procedures for ensuring authorized physical access

All listed features must be implemented

## Implementation

- Disaster recovery
- Emergency mode operation
- Equipment control (into and out of site)
- Facility security plan
- Maintenance records
- Need-to-know procedures for personnel access
- Procedures for verifying authorizations prior to physical access
- Sign-in for visitors and escort, if appropriate
- Testing and revision



# Physical Safeguard Requirements

Policy/guideline on  
Work Station Use

Secure Work  
Station Location

Security Awareness  
Training

## Implementation

- Documented work station instructions and procedures
- Physical safeguards to minimize the possibility of unauthorized access to information
- Training required for all employees, agents and contractors



# Technical Security Services

- Relates to the processes that must be put in place to protect, control, and monitor information access
  - Procedures to assess and maintain security programs and identify suspect data access
  - Procedures to control access to information based on user identity or role
  - Procedures to corroborate non-altered data and proper disposal



# Technical Security Service Requirements

## Access Control

<sup>1</sup> Procedure for emergency access must be implemented

<sup>2</sup> At least one of these features must be implemented

<sup>3</sup> Encryption is optional

## Implementation

- Procedure for emergency access <sup>1</sup>
- Context-based access <sup>2</sup>
- Role-based access <sup>2</sup>
- User-based access <sup>2</sup>
- Encryption <sup>3</sup>



# Technical Security Service Requirements

## Audit Controls

<sup>1</sup> Procedures to assess and maintain security programs and identify suspect data access

## Authorization Control

<sup>2</sup> At least one of these features must be implemented

## Implementation

- Mechanisms to record and examine system activity <sup>1</sup>
- Role-based access <sup>2</sup>
- User-based access <sup>2</sup>



# Technical Security Service Requirements

## Data Authentication

Procedures to corroborate non-altered data and proper disposal

<sup>1</sup> Examples may include these features

## Entity Authentication

<sup>2</sup> These features must be implemented

<sup>3</sup> At least one of these features must be implemented

## Implementation

- check sum, double keying, message authentication code, digital signature <sup>1</sup>
- Automatic logoff <sup>2</sup>
- Unique user identification <sup>2</sup>
- Biometrics <sup>3</sup>
- Password <sup>3</sup>
- PIN <sup>3</sup>
- Telephone callback <sup>3</sup>
- Token <sup>3</sup>



# Technical Security Mechanisms

- Technical security requirements to guard Data Integrity, Confidentiality, and Availability
- Relates to the “data-in-transit” processes that are to be implemented in order to prevent unauthorized access to data that is transmitted over a communications network



# Technical Security Mechanisms

## Requirement

<sup>1</sup> If communications or networking is employed these must be implemented and either <sup>2</sup> access controls or encryption

<sup>3</sup> These features must be implemented if using a network

## Implementation

- Integrity controls <sup>1</sup>
- Message authentication <sup>1</sup>
- Access controls <sup>2</sup>
- Encryption <sup>2</sup>
- Alarm <sup>3</sup>
- Audit trail <sup>3</sup>
- Entity authentication <sup>3</sup>
- Event reporting <sup>3</sup>



# Digital Signature

## Requirement

<sup>1</sup> Optional at this time. If digital signature is employed these must be implemented

<sup>2</sup> These features are optional

## Implementation

- Message Integrity <sup>1</sup>
- Non-repudiation <sup>1</sup>
- User Authentication <sup>1</sup>
- Ability to add new attributes <sup>2</sup>
- Continuity of signature capability <sup>2</sup>
- Counter signatures <sup>2</sup>
- Independent Verifiability <sup>2</sup>
- Interoperability <sup>2</sup>
- Multiple signatures <sup>2</sup>
- Transportability <sup>2</sup>



# Security Policies and Procedures



# Security Policies and Procedures

- Access control
- Records processing
- Security configuration - documentation, testing, inventory, virus control
- Security incident procedures - reporting and response



# Security Policies and Procedures

- Security management - prevention, detection, containment, correction of breaches
- Termination procedures - physical and system access of terminated users
- Personnel security - supervision, authorization and clearance, training, record keeping
- Media controls - Receipt and removal of hardware/software and media



# Security Policies and Procedures

- Physical access controls - limit access but ensure proper access for disaster recovery and emergency operation, control of equipment, facility security, maintenance records, need-to-know procedures, visitor access, on-going testing and revision
- Workstation use - proper use and log off procedures



# Security Policies and Procedures

- Contingency planning - criticality analysis, backup, disaster recovery, emergency mode operation, on-going security verification
- Internal audits of system activity
- Training - for all employees, agents and contractors - awareness training and user education related to security, virus protection, login problems, password management





# Meeting HIPAA Security Compliance

# Security Recommendations

- Generate awareness
  - Establish a framework for management buy-in
  - Develop an awareness program
  - Establish a security implementation team
  - Establish security training tailored to types of staff
- Determine the magnitude of the compliance effort with a Business Impact Analysis
  - Organizations need to determine scope of BIA, narrow focus on compliance or business opportunity



# Security Organization

- Maintain a project governance structure
- Identify key stakeholders
- Identify project manager(s)
- Determine workgroups
- Develop communications plan
- Identify vendor and business associate relationships



# Security Awareness and Training

- Identify resources to participate
- Evaluate Security Assessment tools and resources
- Develop training materials
- Conduct educational sessions
- Schedule frequent update sessions



## Why Perform an Assessment?

- HIPAA is an enterprise-wide issue that will impact each organization differently
- Establishing budget levels and effectively understanding future capital and resource needs requires a base-line level of analysis
- There is no magic formula to reach these conclusions
- You need to evaluate your unique environment
- An assessment positions your organization to make informed decisions about how you will address HIPAA



# Evaluate Compliance Requirements

- Baseline Assessment
  - Inventory of current security with respect to policies, processes and technology
- Gap Analysis
  - Current environment versus regulatory requirements
- Risk Assessment
  - Characterize your business process
  - Value the Asset
  - Determine how current controls mitigate the risk
  - Assess the vulnerability or the threat
  - Assess the probability that the threat will happen



# Perform an Assessment and Analysis

- Conduct a Security Tactical Analysis
  - Start with a High-level review
  - Conduct a Business Impact Analysis and Assessment
  - Conduct Security Gap Analysis
- Strategic Assessment
  - Identify business strategy
  - Identify IT strategy
  - Identify business initiatives (i.e., e-Business)
  - Develop HIPAA approach statement
  - Identify benefits and costs of HIPAA approach
  - Obtain executive and board of directors buy-in
  - Develop an internal compliance team



# Security Gap Analysis Overview

- ◆ Organizational structure
  - ◆ Information Technology across all platforms
  - ◆ Security
- ◆ Systems environment
  - ◆ Platforms
  - ◆ Operating systems
  - ◆ Security mechanisms
  - ◆ Access paths
- ◆ Security management and administration
  - ◆ Policy and procedures
  - ◆ Control processes



# Security Assessment & Gap Analysis

## Administrative Procedures

	Responsibility	Procedures	Operations	Gap	Risk	Solution
<b>Certification</b>		<input type="radio"/>	<input checked="" type="radio"/>	Periodic Security evaluation and certification	high	Currently high-level evaluation, can be external or internal
<b>Chain of Trust</b>		<input type="radio"/>	<input type="radio"/>	Chain of Trust Partner agreements	mod	Need to be created, Chain of Trust agreements with all business partners mandatory
<b>Contingency Plan</b>		<input type="radio"/>	<input checked="" type="radio"/>	Contingency Plan	low	Disaster recovery plan is established and tested
<b>Rcords Processing</b>		<input type="radio"/>	<input type="radio"/>	Formal mechanism for Processing records	high	Formal documented policy required for processing health information organizationally
<b>Access Control</b>		<input type="radio"/>	<input checked="" type="radio"/>	Information Access Control	high	Need formal policy, access control policy must be in place, at least departmentally
<b>Incident Procedures</b>		<input checked="" type="radio"/>	<input checked="" type="radio"/>	Security Incident Response Procedures	mod	Need formal incident response policies and procedures
<b>Security Process</b>		<input checked="" type="radio"/>	<input checked="" type="radio"/>	Security Management Process	mod	Policy and implementation not consistent
<b>Termination Procedures</b>		<input type="radio"/>	<input checked="" type="radio"/>	Termination Procedures	mod	Notice currently inconsistent, drawn from untimely source
<b>Training</b>		<input type="radio"/>	<input checked="" type="radio"/>	Training	high	Development of mandatory security training for all individuals is required



# Security Assessment & Gap Analysis

## Security Services

	Responsibility	Policies & Procedures	Operations	Gap	Risk	Solution
<b>Security Official</b>	☒	○	○	There is a security official	none	
<b>Access Procedures</b>	☒	○	◐	Access Control: Procedures for emergency access	low	Amend documentation, Covered in departmental policy.
<b>Access Controls</b>	☒	◐	◐	Access/Authorization Control: Either context-based, role-based, or user-based access control	high	Role-based, access control based on being "like" another user; menu access is not consistent or always rational.
<b>Authentication</b>	☒					see Security assessment
<b>Audit</b>	☒	●	◐	Audit Controls	low	Application audit functionality is not sufficient. Audit policy needs to be approved and implemented.
<b>Data</b>	☒	○	○	Data Authentication	low	Role-based access by job function but sensitive data is not properly segmented within application.
<b>Entity</b>		●	●	Entity Authentication	low	Amend P&P to acknowledge duty and assign responsibility. This is not a high exposure or high risk concern.
<b>Device</b>	☒	○	○	Automatic Logoff	low	All user have a 5 min. timeout, except departments with pre-authorization.



# Solution Design and Development

- Analyze solution alternatives
- Develop cost/benefit analysis
- Consider effect on business partners
- Present solutions paths to management
- Select appropriate solution
- Develop implementation plan
- Identify resources for implementation

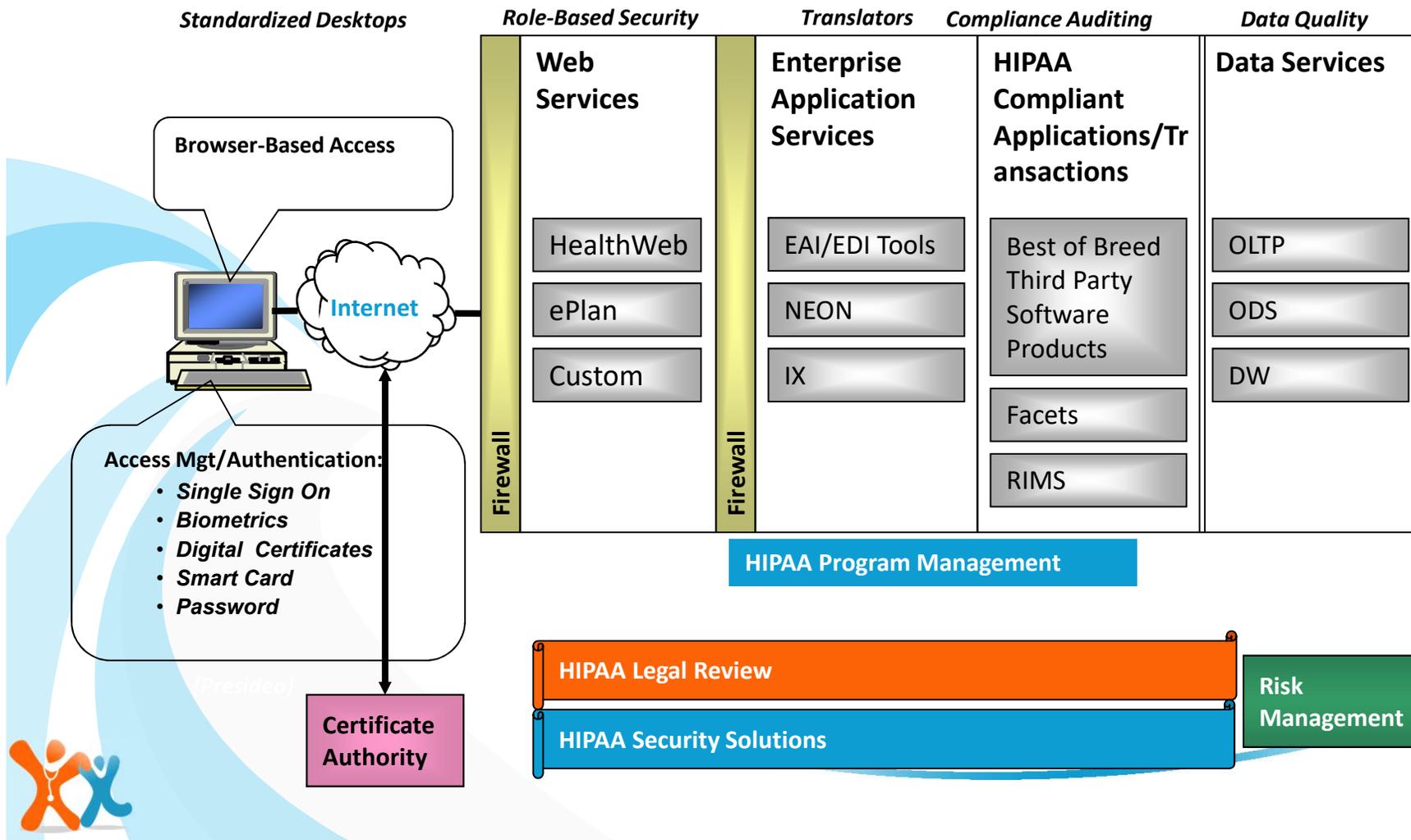


# Solution Implementation

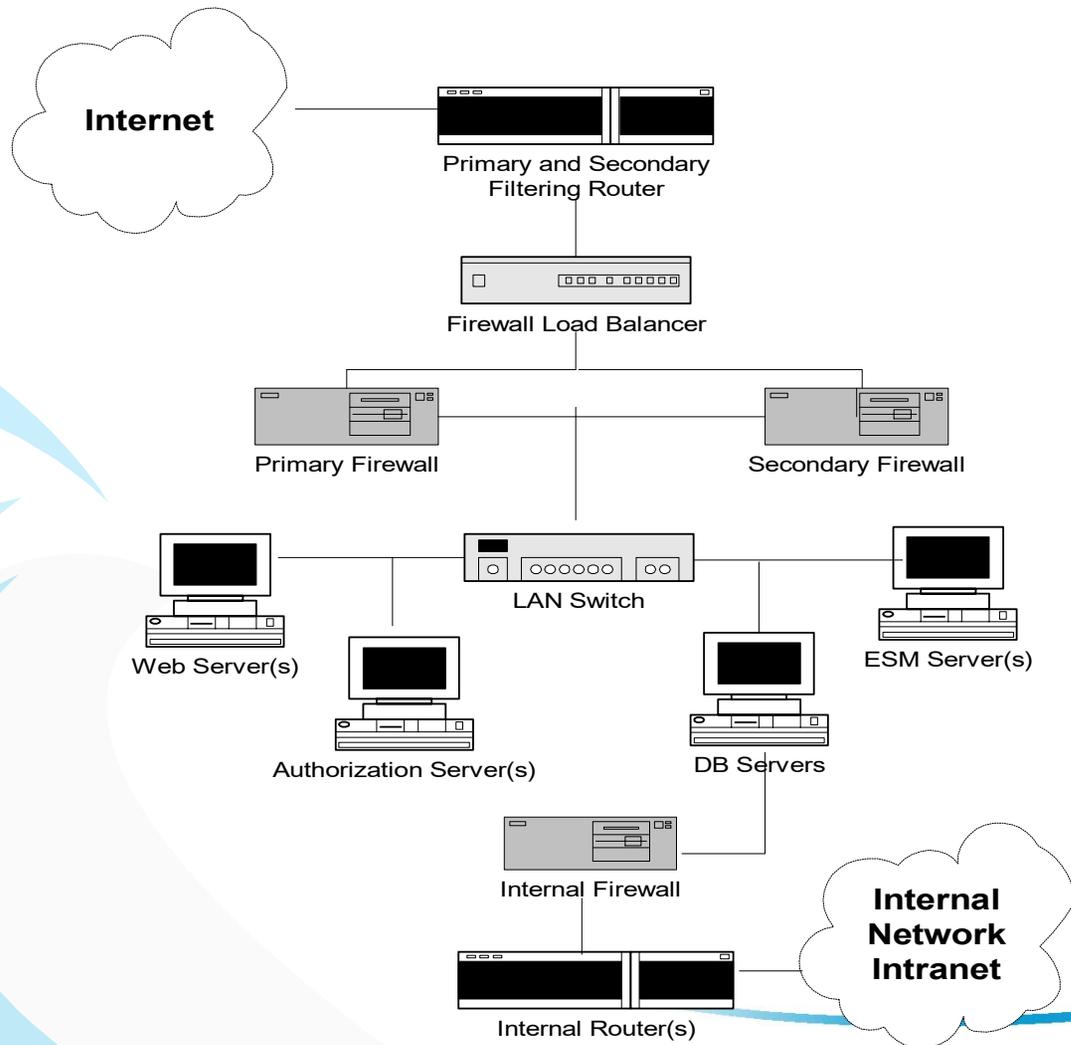
- Execute implementation plan
- Monitor status of progress
- Identify project risks
- Develop mitigation strategies
- Test and perform quality assurance
- Train users



# HIPAA Architecture Example



# Detailed Security Architecture



# Security Impacts

- ◆ Administrative Changes
  - ◆ Certification/testing of computer network security
  - ◆ Chain of trust agreements with business partners
  - ◆ Data backup procedures and contingency planning



# Security Impacts

- ◆ Physical Building and Access Changes
  - ◆ Facility and workstation security
  - ◆ Physical control of storage media use and disposal
  - ◆ Visitor/maintenance authorization and escort



# Security Impacts

- ◆ Personnel Changes
  - ◆ Awareness training for all system users
  - ◆ Breach reporting and sanctions
  - ◆ Assignment of security responsibility



# Security Impacts

- ◆ Operational Changes
  - ◆ User authentication
  - ◆ Audit trails and periodic review
  - ◆ Incident alarms and reporting
  - ◆ Internal audit procedures and controls
  - ◆ Change controls





# Have Questions?

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