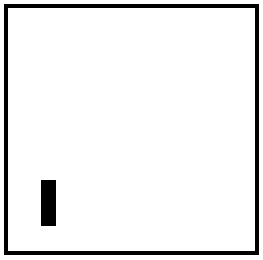
December 8, 2005

Security Manual

Alabama Department of Public Health

Contents



Introduction

I.A. Overview of the HIPAA (Health Insurance Portability and Accountability Act) Security Rule and web link to access the Rule

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the US Department of Health and Human Services (HHS) to adopt national standards for safeguards to protect the Confidentiality, Integrity, and availability of Protected Health Information (PHI).

Title II of the HIPAA Act, Administrative Simplification, defines three sets of standards:

- Privacy Standards, with an implementation deadline of April 14, 2003;
- Electronic Data Interchange (EDI) Standards, with an implementation deadline of October 16, 2003; and
- Security Standards, with an implementation deadline of April 21, 2005 (or 2006 due to a one-year extension for small Plans, those with less than $5M in receipts).

HHS issued the Final HIPAA Security Rule, referred to throughout this Manual as the HIPAA Security Rule, on February 20, 2003, detailing requirements for the protection of Electronic Protected Health Information (e-PHI) for health plans, Health Care clearinghouses, and Health Care providers (known as Covered Entities). Covered Entities must comply with the HIPAA Security Rule of Title II by April 21, 2005 or April 21, 2006, depending on the size of the Plan.

The requirements of the HIPAA Security Rule are scalable and flexible. The HIPAA Security Rule defines standards that make good business sense. The HIPAA Security Rule has 18 standards and 42 implementation specifications. The HIPAA Security Rule's requirements are contained in three major security safeguard sections:

- Administrative Safeguards,
- Physical Safeguards, and
- Technical Safeguards

The HIPAA Security Rule and this Manual are effective on and after April 21, 2005

The HIPAA Privacy Standards required that PHI be safeguarded. They primarily address:

who can have access to PHI; and
how PHI can be used and disclosed.

The Privacy Standards apply to all PHI regardless of whether it is in oral, written, or in electronic form.

The HIPAA Security Rule protects only e-PHI, whether it is:

- electronically created;
- electronically received;
- "at rest" or maintained in a storage device, such as a computer hard drive, disk, CD, or tape; or
- "in transit" via the Internet, dial-up lines, etc. (for example, email, FTP, EDI, IVR, and fax-back Systems that transmit PHI).

PHI that was not in electronic form before transmission is not e-PHI. This includes information shared by person-to-person telephone calls, copy machines, paper-to-paper fax machines, or voice mail. De-identified information is not e-PHI.

The HIPAA Security Rule requires Covered Entities to implement processes to safeguard e-PHI against unauthorized access or modification. ADPH has developed Administrative, Physical, and Technical Safeguards that will reasonably protect e-PHI from intentional and unintentional uses or Disclosures that violate the HIPAA Security Rule.

As with PHI under the Privacy Rule, under the HIPAA Security Rule, ADPH must protect the e-PHI of its participants and their family members in accordance with HIPAA and state law. ADPH generally will use e-PHI only for health plan payment activities and operations, and in other limited circumstances, such as when it is required for law enforcement and public health activities.

When e-PHI is shared with Business Associates providing services to the Plan, they are required to agree in writing to maintain procedures that protect the e-PHI from improper uses and Disclosures in accordance with HIPAA.

I.B. Purpose of the Security Policy Manual

The purpose of this manual is to define the ADPH policies relevant to HIPAA security as well as general security policies so as to provide employees and supervisors with clear guidelines for protecting information.

This Manual consists of eight (8) sections as follows:

Section 1—Introduction. Presents an overview of the HIPAA Security Rule, the purpose of this Manual and its organization.

Section 2—Administrative Safeguards. Describes the Security Policies for Administrative Safeguards.

Section 3—Physical Safeguards. Describes the Security Policies for Physical Safeguards.

Section 4—Technical Safeguards. Describes the Security Policies for Technical Safeguards.

Sections 5—Other ADPH Security Policies. Provides other relevant ADPH policies.

Section 6—Security Rule. Contains the text of the HIPAA Security Rule.

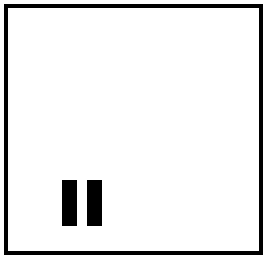
Section 7—Glossary. Defines key terms that are used in this Manual.

Section 8—Appendix. Contains related documents.

The Manual will be accessible to ADPH workforce members who have access to e-PHI. Workforce Members can obtain more information from the ADPH Information Security Officer.

I.C. How to obtain a copy of the manual

This manual is available on the ADPH Website. Contact the Information Security Officer if you need assistance.



Administrative Safeguards

II.A. Overview

The HIPAA Security Rule Administrative Safeguards require documented policies and procedures governing day-to-day operations; managing the behavior of employees in relation to electronic protected health information (e-PHI); and managing the selection, development, implementation, and use of security controls.

In the following sections, we discuss each of the nine standards included under the Administrative Safeguards. Note that each of the standards may contain one or more implementation specifications, and that the implementation specifications may be either required or addressable.

Section II.B – Security Management Process
The Security Management Process forms the foundation for all of the other standards by requiring a covered entity to prevent, detect, and correct security violations. This standard requires a risk analysis, ongoing risk management, implementation of a sanction policy to address violations of the entity's policies and procedures, and an information services activity review.

Section II. C – Assigned Security Responsibility
This standard requires that a covered entity designate a single individual with overall responsibility for the development and implementation of the policies and procedures governing the security of its e-PHI.

Section II. D – Workforce Security
A covered entity must implement workforce security measures to assure that all personnel with access to e-PHI have the appropriate access authority and clearances, and to prevent access by those who do not.

Section II.E – Information Access Management

This standard requires establishment, adoption, and maintenance of documented policies and procedures defining access control for all personnel authorized to access e-PHI and prescribing how access is granted and modified.

Section II.F – Security Awareness and Training
This standard requires that the covered entity implement a security awareness and training program for all personnel with access to e-PHI.

Section II.G – Security Incident Procedures
This standard requires the implementation of policies and procedures to handle security incidents.

Section II.H – Contingency Plan
This standard requires that the covered entity have a contingency plan for responding to emergencies that affect systems containing e-PHI, as well as related facilities and operations.

Section II.I – Evaluation
This standard requires that the covered entity demonstrate and document ongoing compliance with its security policy through periodic technical and non-technical evaluations. These evaluations are based on the requirements of the HIPAA Security Rule, and also address the covered entity's response to environmental or operational changes.

Section II.J – Business Associate Contracts and Other Arrangements
As defined in the HIPAA Security Rule, a covered entity may permit a business associate to create, receive, maintain, or transmit e-PHI on its behalf, only if the covered entity obtains a written contract or other documented arrangement with the business associate. The contract or documented arrangement must provide satisfactory assurances that the business associate will appropriately safeguard the protected information. While many covered entities developed business associate agreements while pursuing HIPAA privacy compliance, it is likely that these agreements will need to be reviewed and perhaps revised to achieve HIPAA security compliance.

Each of these standards and the associated implementation specifications are outlined in detail in the following sections.

II.B. Security Management Process

II.B.1 Risk Analysis Policy

Version Number

V1

Applies To

Computer Systems Center

Effective Date

April 21, 2005

Purpose

The purpose of the Risk Analysis Policy is to empower the ADPH Information Security Officer (ISO) to perform periodic security Risk Assessments (RAs) to identify areas of vulnerability, and to initiate appropriate remediation.

The information ADPH gathers through the security risk assessment (RAs) provides insight for determining the measures needed to eliminate or minimize all types of risks and vulnerabilities: natural, environmental, technical, or human.

Scope

The procedures for RAs will be conducted on any information system, including applications, servers, and networks, and on any process or procedure by which these systems are administered and/or maintained. HIPAA security RAs must consider all hardware and software used to store or transmit e-PHI.

Policy

It is the policy of the Alabama Department of Public Health to conduct assessments of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of e-PHI held by the ADPH periodically, as warranted by changes in environmental, technological, or operational conditions.

Procedural Responsibilities

Computer Systems Center

Procedure(s)

1. A risk assessment will be performed by the ISO and the owning CSC division(s) for all new applications or systems during the system design phase to identify security requirements. All systems or applications repositories containing e-PHI must be identified and documented; potential threats or vulnerabilities must be

identified; each repository must be assigned a level of risk; and, as appropriate, the risk must be mitigated.

2. A risk assessment will be performed by the ISO and the owning CSC division(s) for all existing applications or systems to identify potential threats or vulnerabilities. Each repository containing e-PHI must be assigned a level of risk; and, as appropriate, the risk must be mitigated.
3. ADPH Computer Systems Center will contract with an outside consultant to perform a system-wide risk analysis every two years. The analysis will include, but not be limited to:
    a) External Auditing
        i) Foot printing – To gather and develop information to create a complete profile of ADPH's security posture.
        ii) Penetration testing – To test the ability of the network to withstand or thwart and attack.
        iii) Vulnerability Mapping – To map specific security attributes of a system or network to an associated vulnerability or potential vulnerability. Techniques used will include, but not be limited to: manually mapping specific system attributes against publicly available sources of vulnerability information, using public exploit code posted to various security mailing list and hacker sites, and using automated vulnerability scanning tools to identify true vulnerabilities.
    b) Internal Auditing
        i) Logical Security Controls
            (1) Network boundaries (subnets)
            (2) Routing boundaries
                (a) Corporate network
                (b) Internet access
                (c) Dial-in access
            (3) VLAN's
        ii) Logical Access Controls
            (1) Preventative controls – uniquely identify every authorized user and deny unauthorized users
            (2) Detective controls – log and report activities to systems, programs, and data
        iii) Firewall Rules
            (1) Directions of traffic
            (2) Traffic origin
            (3) IP address
            (4) Port numbers
            (5) Authentication
            (6) Application content
        iv) Network Services
            (1) Email
            (2) Telnet
            (3) DNS

(4) Others

Form(s)

None

Reference(s):

HIPAA Security Rule, CFR §164.308(a) (1) Standard: Security Management Process, Implementation Specification: Risk Analysis (Required)

Contact

Send e-Mail to CSC – Security Team

II.B.2 Risk Management Policy

Version Number

V1

Applies To

Computer Systems Center

Effective Date

April 21, 2005

Purpose

To implement policies and procedures for risk management related to the implementation of security measures. Risk management activities must be sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level.

Scope

The procedure for risk management is for overall security review, risk assessment (RA), selection and evaluation of safeguards, cost benefit analysis, management decision-making, implementation of safeguards, and review of the effectiveness of safeguards.

Policy

It is the policy of the Alabama Department of Public Health to implement changes based on findings and recommendations from the RA review, including information on correction of any deficiencies or recently completed corrections or upgrades.

Procedural Responsibilities

Computer Systems Center

Procedure(s)

1. The ISO will schedule risk assessments on all systems and review findings from the risk assessments.
2. The ISO will make recommendations to mitigate any risk identified by the risk assessment.
3. The ISO will work with the owning CSC division to remediate these risks.
4. The ISO will monitor progress toward mitigation on a quarterly basis.
5. The ISO will maintain an inventory of all e-PHI repositories.
6. The ISO will maintain records of all risk assessments performed. These will include the date the risk assessment was conducted, who performed the assessment, the methods used in the assessment, a statement of how any identified risks relate to the requirements for e-PHI confidentiality, integrity, and availability determined for the system, and findings or recommendations from the review,

including information on correction of any deficiencies or recently completed corrections or upgrades.

Form(s)

None

Reference(s):

HIPAA Security Rule, CFR §164.308(a) (1), Standard: Security Management Process, Implementation Specification: Risk Management (Required)

Contact

Send e-Mail to CSC – Security Team

II.B.3 Sanction Policy

Version Number

V1

Applies To

All ADPH Employees and Contractors

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to outline sanctions for noncompliance with the ADPH security policies and procedures.

Scope

The procedures cover sanctions against workforce members who fail to comply with the security policies and procedures; sanctions may be progressive, escalating from verbal to written warnings or other disciplinary measures followed by suspension or termination.

Policy

It is the policy of the Alabama Department of Public Health that all employees and all persons working under contract with the Alabama Department of Public Health shall abide by all policies included in the Alabama Department of Public Health Security Policy Manual. Workforce members who fail to comply with the security policies and procedures will be in disciplined in accordance with ADPH Policy 03-08, Alabama Department of Public Health Discipline Policy. Contract employees who fail to comply with security policies and procedures will be handled in accordance with the contract governing their services.

ADPH will not apply sanctions against employees who file a complaint with an entity about a security violation or risk.

Procedural Responsibilities

All ADPH Employees and Contractors

Procedure(s)

1. Any employee desiring to report suspected violation or risk of any policy within the ADPH Security Policy Manual should contact their immediate supervisor. The ADPH Information Security Officer (ISO) may be contacted directly if the employee is concerned about retaliation by their immediate supervisor.
2. The supervisor will contact the ISO.

3. The ISO or their designee will investigate the suspected violation or risk.
4. The ISO will offer suggestions to the party/parties involved and their supervisors to mitigate the problem.
5. The ISO will maintain records of all suspected violations.

Form(s)

Employee Relations Checklist, ADPH-PER-48 (02/03) (Appendix B)

Reference(s):

HIPAA Security Rule, CFR § 164.308(a) (1), Standard: Security Management Process, Implementation Specification: Sanction Policy (Required)
ADPH Discipline Policy, #03-08

Contact

Send e-Mail to CSC – Security Team

II.B.4 Information System Activity Review Policy

Version Number

V1

Applies To

Computer Systems Center

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to protect data from accidental or malicious alteration or destruction and implement measures to monitor and identify such risks. Once security events are detected, the key elements and pertinent information regarding the potential breach must be reported to the ADPH Security Officer.

Scope

The procedures address the regular review of records of information system activity, such as audit logs, access reports, and security incident tracking reports to identify security events.

Policy

It is the policy of the Alabama Department of Public Health to monitor all computer systems for security related events.

Security-related events include, but are not limited to:

Port-scan attacks;
Evidence of unauthorized access to privileged accounts; and
Occurrences that are not related to specific applications.

Procedural Responsibilities

Computer Systems Center

Procedure(s)

1. Each system administrator is responsible for reviewing logs weekly for security-related events.
2. System administrator will notify the Information Security Officer (ISO) if they suspect a security-related event has occurred.
3. The ISO will investigate the suspected security-related event.
4. The ISO will record the suspected event and recommendations and report to IT Management.
5. Corrective measures will be prescribed as needed.

6. All security-related events on critical or sensitive systems must be logged and audit trails saved as follows:
7. All security related logs will be kept online for a minimum of 1 week.
8. Weekly full backups of electronic logs will be retained for at least 1 month.
9. Monthly full backups will be retained for a minimum of 2 years.

Form(s)

None

Reference(s):

HIPAA Security Rule, CFR §164.308(a) (1), Standard: Security Management Process, Implementation Specification: Information System Activity Review (Required)

Contact

Send e-Mail to CSC – Security Team

II.C. Assigned Security Responsibility

Version Number
V1
Applies To
ADPH Administration
Effective Date
April 21, 2005

Purpose
The purpose of this policy is to designate a Security Official who will be responsible for enforcement of the HIPAA Security Rule within ADPH, including developing, implementing, and maintaining policies and procedures that meet the requirements of the HIPAA Security Rule.

Scope
An Information Security Officer and an alternate will be designated as Computer Systems Center's focal points for all information security issues. Specific questions about the policies described here can be directed to the Information Security Officer.

Policy
It is the policy of the Alabama Department of Public Health to appoint a primary and alternate security official to be responsible for enforcement of the HIPAA Security Rule within ADPH, including developing, implementing, and maintaining policies and procedures that meet the requirements of the HIPAA Security Rule.
A job description for this position is in Appendix A of this Manual.

Procedural Responsibilities
State Health Officer

Procedure(s)
1. The State Health Officer will sign a letter appointing a primary and alternate Information Security Officer.
2. If the ADPH Security Official is unable to meet the requirements or responsibilities under the Security Rule, or is no longer affiliated with ADPH, then the State Health Officer will assign a new Security Official.

Form(s)
None

Reference(s):

HIPAA Security Rule CFR §164.308(a) (2), Standard: Assigned Security Responsibility (Required)

Contact

Send e-Mail to CSC – Administration

II.D. Workforce Security

II.D.1 Authorization and/or Supervision

Version Number

V1

Applies To

All ADPH Employees
All ADPH Supervisors

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures for the authorization and/or supervision of workforce members who work with e-PHI or who work in locations where e-PHI might be accessed.

Scope

This policy addresses control of individuals who have access to systems with e-PHI.

Policy

It is the policy of the Alabama Department of Public Health to ensure that all workforce members be adequately supervised and/or have authorization when working with e-PHI or in locations where e-PHI resides.

Procedural Responsibilities

All ADPH Supervisors

Procedure(s)

1. Supervisors will ensure that all employees/workforce members are granted appropriate authorization when working with e-PHI or in locations where e-PHI resides.
2. Supervisors will periodically review authorization and withdraw or modify authorization when necessary.
3. Supervisors will frequently monitor employees and contractors to ensure that e-PHI is not compromised.
4. Supervisors or their designee will be present when maintenance work is being performed by non-ADPH personnel in a secured area or an area where PHI resides.

Form(s)

None

Reference(s):

HIPAA Security Rule, CFR §164.308(a) (3)(ii)(A), Standard: Workforce Security, Implementation Specification: Authorization and/or Supervision (Addressable)

Contact

Send e-Mail to CSC – Administration

II.D.2 Workforce Clearance Procedure

Version Number

V1

Applies To

All ADPH Supervisors

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures to determine that the access of a workforce member to e-PHI is appropriate, and to ensure measures to prevent workforce members from obtaining unauthorized access to e-PHI.

Scope

The procedure applies to all types of information generated, used or held by ADPH that are used within the scope of ADPH business processes in all formats, including electronic, magnetic, paper or other.

Policy

It is the policy of The Alabama Department of Public Health to verify applicant/employee information and perform reference checks on individuals hired to perform work pertaining to e-PHI.

All individuals who have been granted access to ADPH information systems, including but not limited to full-and part-time employees, contractors, temporary workers, those employed by others to perform ADPH work, and others granted access are covered by this policy and shall comply with this and associated policies, procedures and guidelines.

Most of the positions in the ADPH are in the "classified service" category. All employees in the classified service category are under the State Merit System, and recruitment of employees for positions in the classified service must be accomplished in accordance with the Rules for the State Personnel Board. Applicants are interviewed by the supervisor in the section where the position exists. It is the responsibility of each supervisor to verify the information on the applicant's application. Information may be verified through reference checks and by verifying the applicant's credentials (e.g., educational degrees earned, prior job history).

Procedural Responsibilities

ADPH Supervisors

Procedure(s)

1. Supervisors will verify the information on the applicant's/employee's application through reference checks and by verifying the applicant's credentials (e.g., educational degrees earned, prior job history) before granting access to e-PHI.
2. Supervisors may want to verify information on existing employees, depending on the level of access required.
3. Supervisors will continue to monitor behavior and performance of employees and will withdraw access to e-PHI for high risk individuals.
4. Supervisors will check references on all other contractors and temporary workers before granting access to e-PHI.

Form(s)

None

Reference(s):

HIPAA Security Rule CFR §164.308(a) (3) (i) Standard: Workforce Security, (ii) Implementation specifications: Workforce Clearance Procedure (Addressable)
ADPH Policy #93-86, Utilization of Volunteer Workers
ADPH Policy #04-17, Policy Summaries for Volunteers

Contact

Send e-Mail to Personnel

II.D.3 Termination Procedures

Version Number

V1

Applies To

All ADPH Employees
Contract Employees
SOBRA Workers

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures for terminating access to e-PHI when the employment of a workforce member ends, or as required by determinations specified in the ADPH Workforce Clearance Procedure. Termination procedures are important because of the potential risks associated with unauthorized acts by former employees or contractors, such as acts of retribution or use of proprietary information for personal gain.

Scope

The procedures apply to any ADPH workforce member whose employment is terminated.

Policy

It is the policy of the Alabama Department of Public Health to terminate computer access for any employee leaving the service of the Alabama Department of Public Health. This applies to merit employees, contract workers, and Medicaid SOBRA workers.

Procedural Responsibilities

All ADPH Supervisors
All Security Coordinators
Information Security Officer
Computer Systems Center

Procedure(s)

When a worker leaves employment with the Alabama Department of Public Health or transfers within the Alabama Department of Public Health:

1. The appointing authority or designee must complete a Computer Access Removal Form and submit to the CSC - Security Team when an employee's resignation has been accepted. The Computer Access Removal Form is located in Section VIII, Appendix C, of the ADPH Security Policy Manual.

2. When personnel receives a Form 11 indicating a transfer or resignation, they must complete a Computer Access Removal Form and submit it to the CSC – Security Team.
3. The CSC Security Team will route the form to the appropriate CSC units to remove access to all computer files. If an employee is transferring within the department, access will be removed from the current unit and, upon receipt from the unit they are transferring to, appropriate access will be granted.
4. The Information Security Officer or designee will maintain records of completed Computer Access Removal Forms. These will be available to the initiating office upon request.
5. The Information Security Officer or designee will review the monthly personnel report which provides a listing of all terminated personnel in the department to determine if users' access should be terminated, and will notify the responsible security coordinator to obtain a removal form.
6. All employees and employers must follow the responsibilities defined in the Policy for Processing Separation of Employment, ADPH Policy #03-06, upon the termination of an employee.

Form(s)

Computer Access Removal Form (Appendix C)

Reference(s):

- HIPAA Security Rule CFR § 164.308(a) (3) (i) Standard: Workforce Security, (ii) Implementation specifications: Termination Procedures (Addressable)
- ADPH Policy for Processing Separation of Employment, ADPH Policy ID #03-06

Contact

Send e-Mail to CSC – Security Team

II.E. Information Access Management

II.E.1 Isolating Health Care Clearinghouse Functions

Not applicable; ADPH does not perform clearinghouse functions.

Reference(s):

HIPAA Security Rule CFR § 164.308(a) (4) (i) Standard: Information Access Management, (ii) Implementation specifications: Isolating Health Care Clearinghouse Functions (Required)

II.E.2 Access Authorization

Version Number

V1

Applies To

ADPH Supervisors
Local Security Coordinators
CSC Support Desk
Systems Administrators
System Owners

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement policies and procedures for granting or denying access to e-PHI and other electronic data, e.g., through access to a workstation, transaction, program, process, or other mechanism. Access authorization involves system controls that limit and monitor who has access to a system and the level of access an individual has to the information contained within the system.

Access authorization policies and procedures will include proper security and controls to ensure data, system, network, and application integrity and security, as well as data, system, network and application availability to the staff responsible for e-PHI.

Scope

The Systems Administrators will grant access privileges to electronic information based on an individual's "need to know" as approved by the Owner of the information. The default universal access for all datasets will be NONE.

Policy

It is the policy of The Alabama Department of Public Health to limit access of electronic information only to individuals who have a need to use or view the information.

Procedural Responsibilities

ADPH Supervisors
Local Security Coordinators
CSC Support Desk
Systems Administrators
System Owners

Guidelines

1. Supervisor submits request for computer access or removal of access to the local security coordinator. When job duties change, supervisor should reassess the access needs of the employee to ensure that the employee has proper access for their job duties.
2. Local security coordinator submits request to the CSC Support Desk.
3. CSC Support Desk sends request to the System Administrator.
4. System Administrator requests approval from the Owner.
5. System Administrator grants access if approved by Owner.
6. System Administrator notifies the local security coordinator when access is granted.
7. It is the responsibility of the ADPH employees, contractors, vendors and agents with remote access privileges to the ADPH network to ensure that their remote access connection is protected in the same manner as the user's on-site connection to the ADPH.
8. The ADPH employee bears responsibility for the consequences should the access be misused.
9. The ADPH employees and contractors with remote access privileges must ensure that their the ADPH-owned or personal computer or workstation, which is remotely connected to the ADPH network, is not connected to any other network at the same time, with the exception of personal networks that are under the complete control of the user.
10. The ADPH employees and contractors with remote access privileges to the ADPH network must not use non-ADPH email accounts (i.e., Hotmail, Yahoo, AOL), or other external resources to conduct the ADPH business, thereby ensuring that official business is never confused with personal business.
11. Reconfiguration of a home user's equipment for the purpose of split-tunneling or dual homing is not permitted at any time.
12. Frame Relay must meet minimum authentication requirements of DLCI standards.
13. Non-standard hardware configurations must be approved by Remote Access Services, and Information Security must approve security configurations for access to hardware.
14. All hosts that are connected to the ADPH internal networks via remote access technologies must use the most up-to-date anti-virus software, this includes personal computers. Third party connections must comply with requirements as stated in the Third Party Agreement.
15. Personal equipment that is used to connect to the ADPH networks must meet the requirements of the ADPH-owned equipment for remote access.
16. Organizations or individuals who wish to implement non-standard Remote Access solutions to the ADPH production network must obtain prior approval from Remote Access Services and Information Security.

Form(s)

Computer Systems Access Form (Appendix D)

Reference(s):

HIPAA Security Rule, CFR § 164.308(a) (4) (i) Standard: Information Access Management, (ii) Implementation specifications: Access Authorization Policy (Addressable)

Contact

Send e-Mail to CSC – Security Team

II.E.3 Access Establishment and Modification

Version Number

V1

Applies To

ADPH Supervisors
Local Security Coordinators
CSC Support Desk
Systems Administrators
System Owners

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement policies and procedures (based on ADPH's access authorization policies) to establish, document, review, and modify a User's right of access to a workstation, transaction, program, or process including maintenance personnel.

Scope

The procedures are for granting appropriate access to e-PHI, such as granting access upon employment, job classification, changes in job classification, and maintaining a record of access authorizations.

Policy

It is the policy of the Alabama Department of Public Health to assign one unique user ID to each employee and to grant a level of access to the level needed to do their job. This will be done through assignment of roles. System administrators will assign user roles for each User ID so each user will be able to accomplish the functions they are authorized to perform.

Procedural Responsibilities

ADPH Supervisors
Local Security Coordinators
CSC Support Desk
Systems Administrators
System Owners

Procedure(s)

1. To Request a User ID
    a. The employee's supervisor contacts the Security Coordinator assigned to their section and provides information as to what access the employee requires.
    b. The Security Coordinator contacts the support desk.

c. The Support Desk forwards the Computer Access Authorization Form to the Security Coordinator.
d. The Security Coordinator completes the form and returns the form, via e-mail, to the Support Desk.
e. The Support Desk assigns the request to the appropriate work unit.
f. System Administrator requests approval from the Owner.
g. System Administrator grants access if approved by Owner.
h. System Administrator notifies the local security coordinator when access is granted.

2. Adding a User (CSC Only)
   a. Log onto the domain as an administrator or account operator.
   b. Using User Manger for Domains, copy an existing user from the same group as the new user. The following fields will be copied from the existing user to the new user: description, groups, logon script name, home directory location, and logon hours.
   c. Enter the username and full name. Change the description if necessary. If the user needs to print to a different printer from the existing user's printer, add the user to the corresponding printer group and remove the user from the existing printer group.
3. Miscellaneous (CSC Only)
   a. One user ID will be assigned per client.
   b. The Information Security Officer or their designee will assign all new users of systems one standard User ID that will be used for every system the individual accesses, including PHALCON, AS/400, ISD Mainframe, Oracle database, Lotus Notes, and the network.
   c. Previously assigned User IDs will be changed as system upgrades occur to bring them into conformance with this policy.
   d. All User IDs will be logged and assigned from the primary domain server to avoid duplication.
   e. The User ID will always have six or more digits.
   f. The System Administrator will add new User IDs to the network domain server, AS/400, and ISD Mainframe as required by the user.
   g. The System Administrator will provide the User ID to the Oracle Database Administrator and the Lotus Notes Administrator.
   h. System administrators will also assign user roles for each User ID so each user will be able to accomplish the functions they are authorized to perform.

4. Moving a User to a New Location (CSC Only)
   a. Log onto the domain as an administrator or account operator.
   b. Using User Manager for Domains, remove the user from their existing departmental and printer groups and add them to their new groups.
   c. Change the location of the user's home directory to the new server.

d. Move any existing files from the user's old home directory to their new home directory.

5. Creating a New Departmental Group (CSC Only)
   a. Log onto the domain as an administrator or account operator.
   b. Using User Manger for Domains, create a new Global Group for the new department.
   c. Add all users to the new group and remove them from their existing group.
   d. Add the new departmental group to all appropriate local/resource groups.
   e. Edit the logon script and add the group name to the "IF MEMBER" statement for the local server.

Form(s)

Computer Systems Access Form (Appendix D)

Reference(s):

HIPAA Security Rule CFR § 164.308(a) (4) (i) Standard: Information Access Management, (ii) Implementation specifications: Access Establishment and Modification (Addressable)

Contact

Send e-Mail to CSC – Security Team

II.F. Security Awareness and Training

II.F.1 Security Reminders

Version Number

V1

Applies To

All ADPH Employees
Contract Employees
SOBRA Workers

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to provide security training and periodic security updates/reminders to all members of the workforce.

Scope

The procedure applies to all workforce members.

Policy

It is the policy of the Alabama Department of Public Health to provide security training for all employees and contractors utilizing a variety of methods to remind and inform individuals of their security responsibilities (e.g., e-mail reminders, pamphlets, or copies of security policies and procedures). ADPH will distribute security reminders at appropriate intervals, such as notification regarding possible viruses, and procedures for reporting potential security incidents.

Procedural Responsibilities

ISO
CSC Support Desk Manager
CSC Technical Support

Procedure(s)

1. All employees and contractors will be required to view security training videos and may be required to take a test regarding security issues.
2. All employees will be given refresher training on security policies and procedures during their annual appraisal and will be required to sign the Departmental Rules & Policies for Review at Annual Performance Appraisal form (Form ADPH-PER-63) stating that they have reviewed these policies and procedures.

3. The Information Security Officer (ISO) will develop and provide frequent reminders concerning security and use media such as Satellite Training, Alabama's Health, E-Mail, videos, webcasts, etc.

Form(s)

None

Reference(s):

HIPAA Security Rule CFR §164.308(a) (5) (i) Standard: Security Awareness and Training, (ii) Implementation Specifications, Security Reminders (Addressable)

Contact

Send e-Mail to CSC – Security Team

II.F.2 Protection from Malicious Software

Version Number

V1

Applies To

Computer Systems Center

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures for guarding against and detecting malicious software.

Scope

The procedures are for providing, maintaining, and ensuring that workforce members use appropriate and updated virus protection software.

Policy

It is the policy of the Alabama Department of Public Health to install and maintain enterprise-wide virus protection software.

Procedural Responsibilities

CSC Technical Support
CSC Virus Team

Procedure(s)

Technical Guidelines for Systems Development

1. All software development and software maintenance activities performed by in-house staff must subscribe to CSC standards and conventions. Among other things, these standards and conventions include the proper testing, training, and documentation. Systems Development will develop and update their standards and conventions to keep them current at all times.
2. Systems Development workers will review these standards and conventions annually as part of continued training.

Technical Guidelines for CSC Technical Support

1. Operating System configuration should be in accordance with approved Information security guidelines.
2. Services and applications that will not be used must be disabled where practical.
3. Access to services should be logged and/or protected through access-control methods.

4. The most recent security patches and hot fixes must be installed on the system as soon as practical, the only exception being when immediate application would interfere with business requirements.
5. Trust relationships between systems are a security risk, and their use should be avoided. Do not use a trust relationship when some other method of communication will do.
6. Always use standard security principles of least required access to perform a function.
7. If a methodology for secure channel connection is available (i.e., technically feasible), privileged access must be performed over secure channels, (e.g., encrypted network connections using SSH or IPSec).
8. Servers should be physically located in an access-controlled environment.

Form(s)

None

Reference(s):

HIPAA Security Rule, CFR § 164.308(a) (5) (i) Standard: Security Awareness and Training, (ii) Implementation Specifications, Protection from Malicious Software (Addressable)

Contact

Send e-Mail to CSC – Technical Support

II.F.3 Log-in Monitoring

Version Number

V1

Applies To

ADPH Computer Systems Center

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures for the monitoring of log-in attempts, the reporting of discrepancies, and the correct safeguards to take in regard to ADPH system User IDs.

Scope

The procedures are to ensure that all ADPH system User IDs are used in an authorized manner.

Policy

It is the policy of the Alabama Department of Public Health to monitor log-in attempts on ADPH systems weekly, monthly, and quarterly utilizing system audit reports.

Procedural Responsibilities

CSC Technical Support
Lotus Notes Administrator
AS/400 Administrator
Data Operations Manager

Procedure(s)

1. Each system administrator will review logs weekly, monthly, quarterly, for security events.
2. If an event(s) is identified, the system administrator will notify the Information Security Officer (ISO) to investigate.
3. All findings will be submitted in writing for management review.

Form(s)

None

Reference(s):

HIPAA Security Rule CFR § 164.308(a) (5) (i) Standard: Security Awareness and Training, (ii) Implementation Specifications, Log-in Monitoring (Addressable)

Contact

Send e-Mail to CSC – Security Team

II.F.4 Password Management

Version Number

V1

Applies To

CSC Technical Support
CSC Systems Development
CSC Database Administration

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures for creating, changing, and safeguarding Passwords.

Scope

The procedures apply to passwords used by workforce members to access electronic systems maintaining e-PHI and the networks, servers, databases, back-up systems, and other technical systems and mechanisms supporting the storage, transmission, or utilization of e-PHI.

Policy

It is the policy of the Alabama Department of Public Health for employees of the ADPH to create secure passwords for logging in to electronic systems and for changing passwords every sixty days. All individuals must safeguard this information to ensure system integrity. CSC will implement procedures in which passwords will expire sixty days after creation.

Procedural Responsibilities

All ADPH employees
Chuck Langley

Guidelines

General

All system-level passwords (e.g., root, enable, administrator, application administration accounts, etc.) must be changed at least every six [6] months. User accounts that have system-level privileges granted through group memberships or programs such as “pseudo” must have unique user identification from all other accounts held by that user. All user-level passwords must be changed at least every 60 days.

a. Passwords must not be inserted into e-mail messages or other forms of electronic communication.
b. Where SNMP (Simple Network Management Protocol) is used, the community strings must be defined as something other than the standard defaults of "public," "private", and "system" and must be different from the passwords used to log in interactively. A keyed hash must be used where available (e.g., SNMPv2).
c. All user-level and system-level passwords must conform to the guidelines described below.

Remote Access Requirements

1. Secure remote access must be strictly controlled. Control will be enforced via one-time password authentication or public/private keys with strong pass-phrases.

Storage of Data Base User Names and Passwords

1. Database user names and passwords may be stored in a file separate from the executing body of the program's code. This file must be encrypted.
2. Database credentials may reside on the database server. In this case, a hash number identifying the credentials may be stored in the executing body of the program's code.
3. Database credentials may be stored as part of an authentication server (i.e., an entitlement directory), such as an LDAP server used for user authentication. Database authentication may occur on behalf of a program as part of the user authentication process at the authentication server. In this case, there is no need for programmatic use of database credentials.
4. Database credentials may not reside in the documents tree of a web server.
5. Pass through authentication (i.e., Oracle OPS$ authentication) must not allow access to the database based solely upon a remote user's authentication on the remote host.

Retrieval of Database User Names and Passwords

1. If stored in a file that is not source code, then database user names and passwords must be read from the file immediately prior to use. Immediately following database authentication, the memory containing the user name and password must be released or cleared.
2. The scope into which you may store database credentials must be physically separated from the other areas of your code, (e.g., the credentials must be in a separate source file). The file that contains the credentials must contain no other code but the credentials (i.e., the user name and password) and any functions, routines, or methods that will be used to access the credentials.
3. For languages that execute from source code, the credentials' source file must not reside in the same searchable or executable file directory tree in which the executing body of code resides.

Access to Database User Names and Passwords

1. Every program or every collection of programs implementing a single business function must have unique database credentials. Sharing of credentials between programs is not allowed.
2. Database passwords used by programs are system-level passwords.
3. Developer groups must have a process in place to ensure that database passwords are controlled. This process must include a method for restricting knowledge of database passwords to a need-to-know basis.

Account Policy

Parameter	**Setting**
Maximum Password Age (system-level) Maximum Password Age (user-level)	6 Months 60 Days
Minimum Password Age	None
Minimum Password Length	8 alphanumeric characters/symbols
Password Uniqueness (history)	13
Account Lockout Threshold	Lockout after 3 bad attempts
Lockout Duration	2 Hours
Reset account lockout counter after	2 Hours

*Waivers may be granted for certain passwords to be unexpiring based on their rights and permissions.

Form(s)

None

Reference(s):

HIPAA Security Rule CFR § 164.308(a) (5) (i) Standard: Security Awareness and Training, (ii) Implementation Specifications, Password Management (Addressable)

Contact

Send e-Mail to CSC – Technical Support

II.G. Security Incident Procedures

II.G.1 Security Incident Response and Reporting

Version Number

V1

Applies To

All ADPH Employees and Contractors

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to establish a formal procedure for: identifying and responding to suspected or known security incidents; mitigating, to the extent practicable, harmful effects of security incidents that are known to ADPH; and documenting security incidents and their outcomes.

Scope

The procedures are for reporting security incidents and establishing feedback processes to ensure that persons reporting incidents are notified of results after the incident has been resolved and closed.

Policy

It is the policy of the Alabama Department of Public Health for all employees to report violations, or suspected violations, of computer policy. All computer policy violations will be investigated.

Procedural Responsibilities

All ADPH employees and contractors
Information Security Officer
CSC Technical Support Staff
CSC Virus Team
CSC Network Manager
CSC Network Engineers
CSC Director
ADPH General Counsel

Procedure(s)

1. Report suspected cyber criminal attacks, virus attacks, or physical compromises to the CSC Security Team via e-mail, telephone, or work order.
   E-mail address: CSC – Security Team
   Main Telephone Number: 334-206-5264
   Support Desk Telephone Number: 334-206-5268

2. Information Security Officer determines which procedure should be implemented.
3. In the event of a security incident, the Information Security Manager (or his or her designee will:
    a. assess the severity of the compromise;
    b. if feasible, make a backup of the infected system(s) or application(s) to prevent attacker from removing evidence of his or her activities;
    c. if feasible, determine if the hacker has left any programs or files on the infected system(s); and
    d. check all logs for any suspicious activity.
4. For Cyber Attack:
    a. Information Security Officer will notify the Technical Security Manager
    b. Technical Security Manager will access the IDS upon notification of suspicious network activity
    c. Technical Security Manager will monitor security logs for servers
    d. Technical Security Manager will identify any unusual activity
    e. Technical Security Manager will gathers data on activity
    f. Technical Security Manager will initiates security measures to identify and neutralize attack
    g. Technical Security Manager will prepares report on actions taken and results achieved
    h. Technical Security Manager will present report to Security Management
5. For Virus Infection:
    a. Virus team leader will utilize antivirus console to inspect servers and systems at least once a week
    b. Systems not cleared from antivirus console are noted and given to the respective network team
    c. Network team members will make a visit to “uncleared” system and resolve problem
    d. Network team members will get advanced support from the Antivirus Team leader for unusual situations or those events that span more than one area of responsibility
    e. Virus Team leader will present report to Security Management
6. For Physical Compromise:
    a. Computer Security Team will meet with Network manager for Tower (or County) to lay out plan of action
    b. Network management and their engineers will investigate to ascertain the facts of the situation and report back to the Computer Security Team
    c. Based on discoveries of network management, the Computer Security Team will brief the Technical Support director and CSC director
    d. Computer Security Team will contact the General Counsel and notify them of the situation and provide all relevant facts
    e. General Counsel will contact the individual’s immediate supervisor and any other personnel in that person’s chain of command
    f. General Counsel will determine if any outside law enforcement authorities should be alerted

g. Present Report to Security Management

7. Noncompliance with ADPH's employee computer policy may result in discipline up to, and including, termination. Employees that report violations or suspected violations of company policy will be protected from termination, discrimination, harassment, and any other form of retaliation. Hackers, snoopers, password stealers, virus installers, data erasers, and anyone involved in such activity will be disciplined.

Form(s)

Information Systems Administrator's Incident Reporting Form (Appendix E)

Reference(s):

HIPAA Security Rule CFR § 164.308(a) (6) (i) Standard: Security Incident Procedures, (ii) Implementation Specification, Response and Reporting (Required)

Contact

Send e-Mail to CSC – Security Team

II.H. Contingency Plan

II.H.1 Data Backup Plan

Version Number

V1

Applies To

CSC Data Operations

Effective Date

April 21, 2004

Purpose

The purpose of this policy is to implement procedures to create and maintain retrievable exact copies of e-PHI and all other computer systems.

Scope

The procedures are to backup and maintain retrievable exact copies of e-PHI when there is a need to do so.

Policy

It is the policy of the Alabama Department of Public Health to create and maintain retrievable backups of all electronic files. Further, the Computer Systems Center has responsibility for the backup of centralized systems and the counties and/or individual users have responsibility for backup of self-maintained systems/files.

Procedural Responsibilities

CSC – Data Operations

Procedure(s)

1. To protect CSC's information resources from loss or damage, microcomputer users are responsible for backing-up the information on their microcomputers.
2. For multi-user computer and communication systems, Data Operations is responsible for making periodic back-ups.
3. If requested, the CSC Technical Support Division will install, or provide technical assistance for the installation of back-up hardware and/or software.
4. All CONFIDENTIAL, valuable, or critical information residing on CSC computer systems and networks must be periodically backed-up. Owners must define which information and which machines are to be backed-up, the frequency of back-up, and the method of back-up based on the following guidelines:

a. If the system supports more than one individual and contains data that is critical to the day-to-day CSC operations, then back-up is required daily.
b. If the system is used to support job-related functions and contains key data critical to the day-to-day operation of that job, then back-up is required weekly.
c. If the system is primarily used as a personal productivity tool and contains no data that would be classified as job or departmental in nature, then back-up is at the discretion of the individual user.

5. Save files containing e-PHI or critical data to a designated location on the server. Servers are regularly backed up, so this will ensure that the e-PHI/critical data will be retrievable.

Form(s)

None

Reference(s):

HIPAA Security Rule CFR § 164.308(a) (7) (i) Standard: Contingency Plan, (ii) Implementation Specifications, and Data Backup Plan (Required)
See also Section III.E.4 (Data Backup and Storage).

Contact

Send e-Mail to CSC – Data Operations

II.H.2 Disaster Recovery Plan

Version Number

V1

Applies To

Computer Systems Center

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to document how ADPH disaster recovery planning addresses the preservation of data, systems, applications, and networks in the face of major disruptions to normal business operations.

Scope

The procedures are for emergency response, extended back-up operation, and post-disaster recovery in the event that a computer installation experiences a partial or total loss of computer resources and physical facilities.

Policy

It is the policy of the Alabama Department of Public Health to create and maintain a disaster recovery plan addressing the preservation of data, systems, applications, and networks.

Procedural Responsibilities

Computer Systems Center
Bureau Directors
Area Administrators
County Administrators

Guidelines

1. A disaster is an event, or set of events, that result in the inability of CSC to provide the information services needed for ongoing operations. Disaster conditions can occur at a variety of levels ranging from the "very minor" isolated hardware outage to the complete loss of services.
2. Owners are responsible for the compilation, regular maintenance, and testing of contingency plans for systems handling information for which they are responsible. The Data Management Division will prepare, maintain, and test the Contingency Plan for recovery and continued data processing service after a disaster or emergency.
3. The Information Security Manager is responsible for providing technical guidance for all information systems contingency planning efforts.

4. Data Management will train all workers in the Computer System Center on their responsibilities in case of activation this plan.
5. Each Bureau/Area/County leadership must have a written contingency plan to cover the following disaster definitions.

The degree of the outage experienced, Level 1, Level 2, or Level 3 directly corresponds to the impact on information services. The definition of levels is as follows:

- Level 1 – the outage involves a limited portion of the business function and usually revolves around the malfunction of an isolated piece of hardware with the expectation of having full function restored in a time frame not to exceed one – three working days.
- Level 2 – the outage involves a significant portion of a business function. The damage incurred is minor to moderate, but the time frame until serviceability can be restored for critical applications may continue for up to 24 calendar days.
- Level 3 – the outage involves major damage or the complete destruction of information services in the RSA Tower (Tower) or a county.

Form(s)

None

Reference(s):

- HIPAA Security Rule CFR § 164.308(a) (7) (i) Standard: Contingency Plan,
- (ii) Implementation Specifications, and Disaster Recovery Plan (Required)
- Disaster Recovery Plan (Appendix K)

Contact

Send e-Mail to CSC – Data Administration

II.H.3 Emergency Mode Operation Plan

Version Number

V1

Applies To

Bureau Directors and Area Administrators

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to establish (and implement as needed) procedures to enable continuation of critical ADPH business processes for protection of the security of e-PHI while operating in emergency mode.

Scope

The procedures are for the Disaster Response Team to follow in the case of an emergency.

Policy

It is the policy of the Alabama Department that, in the event of a disaster, the Disaster Response Team (DRT) will be initiated to assess the current situation and develop an action plan to rectify existing problems. The protection of e-PHI must be a consideration while operating in emergency mode.

Procedural Responsibilities

Bureau Directors
Area Administrators
Disaster Response Team (DRT)

Procedure(s)

1. When an outage is detected that affects the service levels of CSC, the Disaster Response Team (DRT) will convene in Suite 800 of the Tower or an off-site location, such as the Folsom Building, determined by the Director of Information Services.
2. The team will review conditions surrounding the outage, the type and degree of outage, and information concerning the criticality and number of application functions impacted to determine the impact on the Department.
3. This information will be passed to the State Health Officer who will, if needed, declare a disaster and announce the current "Disaster Level" based on the DRT's report.

4. The Disaster Response team will coordinate this information with the Bureau and Office Directors to ensure all are involved in responding properly to the disaster.
5. The DRT will develop a "Current Operations Plan" to restore operations based on the criticality and severity of the disaster. They will estimate the time frame necessary to recover the systems. This Current Operations Plan will be based upon the situation and the pre-developed contingency information in this plan.
6. Once the Current Operations Plan is completed, the DRT will carry out the actions specified in the plan.
7. The DRT will meet as required to update status, direct new actions, and inform the State Health Officer, Bureau and Office Director, Area and County Administrators, etc. until operations are returned to normal.

Form(s)

None

Reference(s):

- HIPAA Security Rule CFR § 164.308(a) (7) (i) Standard: Contingency Plan, (ii) Implementation Specifications, and Emergency Mode Operation Plan (Required)
- ADPH Contact List for Emergency Personnel

Contact

Send e-Mail to CSC – Administration

II.H.4 Testing and Revision Procedures

Version Number

V1

Applies To

Computer Systems Center

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures for the periodic testing and revision of Contingency Plans. Contingency Plans permit continuity of mission-critical functions in the event of a catastrophic event.

Scope

The procedures are to ensure that all critical functions can be recovered in the event of a disaster situation.

Policy

It is the policy of the Alabama Department of Public Health to review and test the Computer Systems Center contingency plan on an annual basis.

Procedural Responsibilities

Computer Systems Center Team Leaders

Procedure(s)

1. Computer Systems Center staff will create a scenario in order to test the contingency plan.
2. CSC will conduct desktop planning and discussion sessions to address what would be done for that scenario by following the contingency plan.
3. The following method(s) may be used to test the plan:
    a. **Checklist Test.** Copies of the plan are distributed to each involved functional area.
    b. **Simulation Test**. All operational and support personnel expected to perform during an actual emergency meet in a practice session.
    c. **Parallel Test**. Full test of the recovery plan. However, processing at the main data processing facility does not stop.
    d. **Full-Interruption Test**. Full test in which a disaster is simulated and data processing at the main facility stops.
4. CSC will perform a self review following the exercise to note lessons learned and modify the contingency plan accordingly.

Form(s)

None

Reference(s):

HIPAA Security Rule CFR § 164.308(a) (7) (i) Standard: Contingency Plan, (ii) Implementation Specifications, Testing and Revision Procedures (Addressable) III.B.1, Contingency Operations Policy

Contact

Send e-Mail to CSC – Security Team

II.H.5 Applications and Data Criticality Analysis

Version Number

V1

Applies To

All Data Owners

Effective Date

April 21, 2005

Purpose

This policy addresses assessing the relative criticality of specific applications and data in support of other Contingency Plan components.

Scope

The procedure is to identify the specific locations/sites and criticality of systems statewide.

Policy

It is the policy of the Alabama Department of Public Health to review all program areas to determine the "Mission Critical" systems and the impact if the system is lost and to maintain a Mission Criticality Spreadsheet.

Each system/application will be rated using the following:

- Essential – Loss would cause interruptions to service but the Department could continue to operate successfully.
- Critical – Loss would severely impair the ability of the Department to provide services.
- Fatal – Loss would stop the Department from providing services.

Procedural Responsibilities

Area Administrators
Bureau Directors
CSC Data Management Division

Procedure(s)

1. CSC will identify, with the aid of Area Administrators and Bureau Directors, all systems and assist them with determining criticality of an application function or system to determine the order of emergency restoration and recovery.
2. CSC will maintain a spreadsheet of all applications/systems deemed mission critical, the criticality, and the impact if that application/system is lost.

Form(s)

Mission Criticality Spreadsheet (Appendix F)

Reference(s):

HIPAA Security Rule CFR § 164.308(a) (7) (i) Standard: Contingency Plan, (ii) Implementation Specifications, Applications and Data Criticality Analysis (Addressable)

Contact

Send e-Mail to CSC – Data Operations

II.I. Evaluation

Version Number

V1

Applies To

All ADPH Supervisors
All ADPH Directors
CSC Technical Support

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to ensure that ADPH conducts periodic technical and non-technical evaluations to establish the extent to which ADPH's security policies and procedures meet the requirements of the Security Rule.

Scope

The procedure encompasses assessing whether all vulnerabilities have been addressed and verifying that all compliance requirements have been met.

Policy

It is the policy of the Alabama Department of Public Health to perform periodic technical and non-technical evaluations, based on the standards set forth in the HIPAA Security Rule, to ensure that the ADPH's policies and procedures are updated as warranted by changes in the ADPH's environmental or operational conditions affecting the security of e-PHI.

Procedural Responsibilities

All ADPH Supervisors
All ADPH Directors
CSC Technical Support
Information Security Officer

Procedure(s)

1. The ADPH Information Security Officer will have oversight over the HIPAA Security compliance evaluations.
2. Supervisors will report any changes to their environment that have impact on the security rule.
3. Technical Guidelines for CSC

   The types of operational changes that would typically call for an updated evaluation include: new purchases of computers, servers, IT lines or other

connections to a system; changes to systems or hardware housing e-PHI; changes in the Owners or Custodians of the e-PHI; and changes to the law or regulations of the HIPAA Security Rule.

a. The ADPH Information Security Officer will randomly test security measures statewide.
b. CSC Technical Support will perform technical evaluations on all computer systems (see II.B.1, Risk Analysis Policy).

Form(s)

Violation Tracking Form (listing the violation, date, corrective measures, and comments) (Appendix G)

Reference(s):

HIPAA Security Rule CFR § 164.308(a) (8) Standard: Evaluation (Required)

Contact

Send e-Mail to CSC – Security Team

II.J. Business Associate Contracts and Other Arrangements Policy

II.J.1 Written Contracts or Other Arrangements

Version Number

V1

Applies To

General Counsel
All ADPH Supervisors
All ADPH Directors

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures for the review and update of all ADPH Business Associate Agreements to document satisfactory assurances that the Business Associate(s) will appropriately safeguard e-PHI created, received, maintained, or transmitted on ADPH's behalf. In addition all Business Associate Agreements must specify that security incidents must be reported to ADPH.

Scope

The procedures encompass all ADPH Business Associate Agreements and written contracts with Business Associates that create, receive, maintain, or transmit e-PHI on behalf of ADPH.

Policy

It is the policy of the Alabama Department of Public Health to ensure that all business associates properly safeguard e-PHI created, received, maintained, or transmitted on ADPH's behalf by inserting the HIPAA Clause contained in the "Standard Clauses Required for Professional Services Contract" document in all Business Associate Agreements.

Procedural Responsibilities

Bureau/Office with contracts
General Counsel

Procedure(s)

1. The responsibility for the security of the equipment deployed by external service providers will be specified in the contract with the service provider and security contacts, and escalation procedures documented. Contracting departments are responsible for third party compliance with this policy.

2. At minimum, contracts with third parties who are “Business Associates” of ADPH or any of its component parts, will include provisions requiring the Business Associate to do the following:
    a. Implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of e-PHI that it creates, receives, maintains, or transmits on behalf of ADPH.
    b. Ensure that any agent, including a subcontractor, to whom it provides such information agrees to implement reasonable and appropriate safeguards to protect it.
    c. Report to ADPH any security incident of which it becomes aware.
    d. Authorize termination of the contract by ADPH if ADPH determines that Business Associate has violated a material term of the contract.

Form(s)

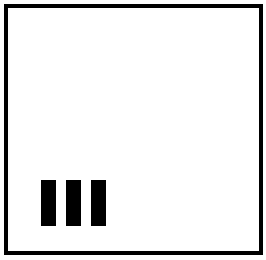
Standard Clauses Required for Professional Services Contracts (Appendix H)

Reference(s):

HIPAA Security Rule CFR §164.308(a) (8) (b) (1) Standard: Business Associate Contracts and Other Arrangements (Required)

Contact

Send e-Mail to General Counsel



Physical Safeguards

III.A. Overview

Purpose

Physical Safeguards include security measures, policies, and procedures that ADPH implements to protect its electronic Information Systems and related facilities and equipment from natural and environmental hazards, unauthorized intrusion, and other threats. These physical safeguards are in addition to standard safeguards that address fire, water damage, utility failure, and structural damage to a facility.

Physical Safeguards define the physical operations (processes) that control access to the Facility when ADPH is implementing the plans developed under the Administrative Safeguards outlined in the Security Rule at CFR § 164.308.

Standards

Physical Safeguards include four standards. These standards are detailed in following sections of this Manual and include:

Section III.B – Facility Access Controls
Policies and procedures that limit physical access to electronic Information Systems and the facilities in which they are housed, while ensuring that properly authorized access is allowed.

Section III.C – Workstation and State Electronic Equipment Use
Policies and procedures that specify the proper Workstation functions to be performed, the manner in which those functions are to be performed, and the characteristics of the physical surroundings of Workstations that can access e-PHI.

Section III.D – Workstation Security
Physical Safeguards for all Workstations that can access e-PHI designed to restrict access to authorized Users.

Section III.E – Device and Media Controls
Policies and procedures that govern the receipt and removal of hardware and electronic media that contain e-PHI into and out of a Facility, and the movement of these items within the Facility.

III.B. Facility Access Control

III.B.1 Contingency Operations

Version Number

V1

Applies To

Area Administrators
Bureau Directors

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures that allow ADPH facility access in support of restoration of lost data under the Disaster Recovery and Emergency Mode Operations Plans.

Scope

The procedures are to be used by workforce members in the event that ADPH facilities and/or operational systems are unavailable for use due to an emergency or a natural disaster.

Policy

It is the policy of the Alabama Department of Public Health to allow the Disaster Response Team (DRT) to have access to facilities during emergency mode operations.

Procedural Responsibilities

Area Administrators
Bureau Directors

Procedure(s)

1. Refer to section II.H Contingency Plan of this policy manual for policy on Contingency Operations. Specifically within that section refer to II.H.2 Disaster Recovery Plan and II.H.3 Emergency Mode Operation Plan.
2. All facilities managers will be notified as to whom will be aiding them in the recovery process.

Form(s)

None

Reference(s):

HIPAA Security Rule, CFR §164.310(a) (1) Standard: Facility Access Controls; Implementation Specifications: Contingency Operations (Addressable)

Contact

Send e-Mail to CSC – Administration

III.B.2. Facility Security Plan

Version Number

V1

Applies To

Facilities Managers

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures to safeguard ADPH facilities and their equipment from unauthorized physical access, tampering, and theft by utilizing such things as fences, security guards, security cameras, and locking mechanisms.

Scope

The procedures cover limiting access to facilities and equipment therein.

Policy

It is the policy of the Alabama Department of Public Health to safeguard ADPH facilities and their equipment from unauthorized physical access, tampering, and theft.

Procedural Responsibilities

Facilities Managers

Guidelines

All ADPH facilities must have written procedures.
Facility security procedures include, but are not limited to, the following items:

- Protection of mobile and portable systems, such as laptops or handheld devices including items including, but not limited to:
  - secure storage of e-PHI;
  - access to system(s), application(s), and data in the event of theft; and
  - encryption of data, passwords, and other sensitive information.
- Locking doors during non-business hours with limited access
- Locking buildings
- Use of personal password for building access by each individual with authorization to access e-PHI
- Use and distribution of keys to the building

- No duplication of keys
- Use of fence, well lit with security lights
- Use of security guards or cameras for fence
- Use of combination locks
- Monitor security alarm systems (e.g., by Simplex)
- Secure equipment access
- Security monitoring
- Security system – access limited to personnel with keyless coded entries
- Issue log of keys
- Issue log of passwords

Form(s)

None

Reference(s):

HIPAA Security Rule, CFR §164.310(a) (1) Standard: Facility Access Controls, Implementation Specification: Facility Security Plan (Addressable)
II.F.2, Protection from Malicious Software Policy
II.H.1, Data Backup Policy
II.H.2, Disaster Recovery Plan Policy
III.C, Workstation and State Electronic Equipment Use Policy
Memorandum dated March 26, 1997, Information and Rules at the RSA Tower

Contact

Send e-Mail to Facilities Management Administration

III.B.3. Physical Access Control and Validation Procedures

Version Number

V1

Applies To

Facilities Managers
All ADPH Employees
All Contractors

Effective Date

April 21, 2005

Purpose

The purpose is to implement procedures to control and validate ADPH workforce personnel's access to facilities based on their role or function, including visitor control and control of access to software programs for testing and revision.

Scope

The procedures are to make employees need to be aware of the ADPH protocol for accessing facilities and electronic systems.

Policy

It is the policy of the Alabama Department of Public Health to limit access to ADPH facilities and access to software programs.

Procedural Responsibilities

Facilities Managers
All ADPH Employees

Procedure(s)

1. Physical security is key to protecting computer and computer information from loss and damage.
    a. Store floppy disks and other sensitive information in a locked drawer.
    b. Office doors must be locked after work hours or during prolonged absences of 1 day or more.
    c. All file servers will be locked when not in use.
    d. Server rooms must have a door and be locked at all times and only have limited access by authorized IT personnel. If the servers are not in a lockable room, they must have the ability to be physically locked (either by door built on server or locked in a cabinet).
2. Theft Protection
    a. All offices are secured after duty hours.

    b. During normal duty hours, workers will be aware of visitors and will challenge anyone appearing to take equipment from the offices.
    c. Computer and network gear may not be removed from offices except by authorized personnel.
3. All ADPH employees and contractors must wear external badges on their outer garments so that both the picture and information on the badge are clearly visible when in Public Health buildings or facilities.
4. All visitors must show proper identification and sign in prior to gaining access to restricted areas controlled by the department. Visitors must be escorted at all times by an authorized employee, consultant, or contractor. Visitors may be issued Visitor ID badges.
5. Any manuals/documentation containing e-PHI or privileged information must be kept in locked cabinets when not in use.
6. All workers should challenge any strangers you see on the premises that are not properly identified. (i.e. no badge). If you notice and unescorted visitor inside a restricted area, the visitor must be immediately questioned about the purpose for being in restricted areas. The visitor must then be directly accompanied to a manager, a guard station, or the person they came to see. If they cannot promptly produce a valid badge, they must be escorted to the proper authorities.
7. *CSC Only* - All systems development documentation and manuals must be stored in the Systems Development office and the doors to the Center will be locked after duty hours. This documentation must be regarded as CONFIDENTIAL and protected from unauthorized access. Only employees with a "need to know" will be allowed to access the documentation. During normal duty hours, workers will be aware of visitors and will challenge anyone who is not authorized to do so taking documentation from the offices. Documentation may not be removed from CSC offices unless the involved person has first obtained a property pass from the Systems Development Director.
8. *CSC Only* - The doors to the operations room will be kept locked at all times. Employees who regularly require access into the operations room will be issued a card key. Visitors include anyone else who enters the operations room. Visitors will be escorted within the operations room by authorized personnel at all times until they depart.
9. *All Departments/Divisions* - Physical access control and validation procedures are to include, at minimum, the following items:
    a. Use of ADPH employee ID badges;
    b. Requirements for passwords/codes limiting access to computers with e-PHI;
    c. Secure computers by employees when away from work areas;
    d. Watch for visitors and monitor exits;
    e. Escort of visitors to the designated area or person, where applicable;
    f. Keys to be signed for by the cleaning crew;
    g. Require all persons entering the building to stop at the front office;
    h. Performance of maintenance only during business hours;

i. All repair and maintenance crews to be required to report to the front office upon arrival and to be verified by Office Manager (e.g., with their packing slips, etc.);
j. Limited distribution of alarm keys for alarm systems;
k. Employees of outside agencies to provide ID upon arrival;
l. Control of access to software;
m. Use of door codes;
n. Access to be given by supervisor;
o. Use of keyless entry at doorways;
p. Issue log of keys;
q. Issue log of passwords;
r. Front entrance to be monitored;
s. All doors to be kept locked except front and back entrances.

Form(s)

None

Reference(s):

HIPAA Security Rule, CFR § 164.310(a) (1), Standard: Facility Access Controls, Implementation Specification: Access Control and Validation Procedures (Addressable)

Contact

Send e-Mail to Facilities Management Administration

III.B.4. Maintenance Records

Version Number

V1

Applies To

Facilities Managers

Effective Date

April 21, 2005

Purpose

Formal procedures need to be established to address documentation of repairs and modifications to the physical components of a facility (for example, hardware, walls, doors, alarm systems, and locks).

Scope

The procedures are for all facilities managers to maintain logs of when maintenance is performed at their facilities.

Policy

It is the policy of the Alabama Department of Public Health that facilities managers will maintain records of all maintenance performed at their facility.

Procedural Responsibilities

Facilities Managers

Procedure(s)

1. Tower

   Procedures for Maintenance Requests are addressed in "The Retirement Systems of Alabama, Montgomery Properties Tenant Handbook."

   Maintenance requests are made through Facilities Management. If there is an emergency maintenance situation, a building staff person may be paged during or after regular business hours. The Building Maintenance Service Request form records the request for service work. The invoice prepared at the completion of the work describes the services performed and will serve as the maintenance long.

2. County Facilities

   Facility managers will keep records on file of any maintenance performed. These records should include the date, the time, a description of the work performed, and the person(s) performing the work.

Form(s)

None

Reference(s):

HIPAA Security Rule, CFR §164.310(a) (1), Standard: Facility Access Controls, Implementation Specification: Maintenance Records (Addressable)

Contact

Send e-Mail to Facilities Management Administration

III.C. Workstation and State Electronic Equipment Use Policy

Version Number

V1

Applies To

All ADPH Employees and Contractors

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures for the proper use of ADPH workstations and ADPH provided information technology resources by workforce members.

The intent of this policy is to assure that:

- The uses of IT resources are related to, or for the benefit of ADPH,
- State-provided IT resources are used productively,
- Disruptions to ADPH activities, because of inappropriate use of state-provided IT resources are avoided.

It is also the intent is to create an environment where communication can flow freely and with a minimum of policing. This policy should not discourage the Department from using these resources.

Effective use of IT resources is important to the Alabama Department of Public Health. To help improve the effectiveness of your use of these resources, incidental and occasional personal use is permitted, as long as such use does not;

- Adversely affect the employee's performance of duties,
- Interfere with existing rules or policies pertaining to the agency,
- Overburden the communications system,
- Create significant additional cost to the Department of Public Health,
- Involve a for-profit personal business activity,
- Has the potential to harm or reflect adversely on the state, including but not limited to uses involving pornography, chain letters or jokes, advertising, soliciting or selling, improper handling of confidential information, or
- Involve illegal activities.

If it is unclear about the acceptable "personal" use of a state-provided resource or wish to use the resource for what may be considered as a good cause, seek authorization from your Computer System Center (CSC) representative.

Scope

The scope of this policy is to define what the proper use of ADPH workstations and other ADPH provided information technology resources are for workforce members. Proper use includes security measures, e-mail use, Internet access, and installation of computer software.

Policy

It is the policy of the Alabama Department of Public Health to implement procedures for the proper use of ADPH workstations and ADPH provided information technology resources by workforce members.

Procedural Responsibilities

All ADPH Employees and Contractors

Procedure(s)

1. Use of Personal Computer (PC) Software/Hardware
   The Alabama Department of Public Health licenses the use of copies of computer software from a variety of outside companies. The Alabama Department of Public Health does not own the copyright to this software or its related documentation and, except for a single copy for backup purposes or unless expressly authorized by the copyright owner(s), does not have the right to reproduce it for use on more than one computer. With regard to software usage on local area networks, the Alabama Department of Public Health shall use the software only in accordance with the applicable agreement.

   The Alabama Department of Public Health employees are not permitted to install their own copies of any software onto the Alabama Department of Public Health computers.

   The Alabama Department of Public Health employees are not permitted to install their own hardware of any kind without exclusive written permission from Senior Management of the Alabama Department of Public Health. The ADPH employees are not permitted to copy software from the ADPH computers and install it on personally owned computers, or any other computers.

   ADPH employees learning or knowing of any improper use of software or related documentation within the department shall notify CSC Technical Support. According to U.S. Copyright law, unauthorized reproduction of software is a federal offense. Offenders can be subject to civil damages, criminal penalties, and imprisonment.

   Any ADPH employee who knowingly makes, acquires or uses unauthorized copies of computer software on equipment owned or leased by the ADPH shall be subject to immediate termination of employment.

The ADPH does not condone and specifically forbids the unauthorized duplication of software.

2. Internet Access and Use

   In compliance with law and the guidelines provided in this policy, employees of the Alabama

   Department of Public Health are encouraged to use the Internet to its fullest potential to further the ADPH mission, to provide customer service of the highest quality, to discover new ways to use resources, to enhance customer services, and to promote staff development.

   For employees that receive access to the Internet, the following guidelines should be observed:

   a. The ADPH employees should use the Internet, when appropriate, to accomplish job responsibilities more effectively. The Internet provides access to a wide variety of information resources that can aid the ADPH employees in the performance of their jobs.
   b. Use of the Internet by the ADPH employees is a privilege, not a right. This privilege may be revoked at any time for inappropriate conduct. The ADPH employees have an obligation to use their Internet access in a responsible and informed way, conforming to a network etiquette (e.g., netiquette), customs and courtesies. Use of the Internet encompasses many different interconnected networks and computer systems. Many of these systems are provided free of charge by universities, public service organizations and commercial companies. Each system has its own rules and limitations, and guests on these systems have an obligation to learn and abide by the rules. Users should identify themselves properly when using any Internet service. They should also be careful about how they represent themselves, given that what they say or do could be interpreted as the ADPH opinion or policy. Users should be aware that their conduct could reflect on the reputation of the ADPH and its employees. Examples of inappropriate conduct include, but not limited to:
      - use of the Internet for unlawful activities;
      - misrepresentation of oneself or the ADPH; and
      - employees shall respect intellectual property rights at all times when obtaining information over the Internet. Illegal or unauthorized downloading, uploading, copying or distribution of copyrighted works is strictly prohibited. Employees should be aware that such actions could result in legal liability for the ADPH.
   c. Employees should take all necessary steps to prevent unauthorized access to Internet/Intranet/Extranet-related systems information.

d. Keep passwords secure and do not share accounts. Authorized users are responsible for the security of their passwords and accounts. System level passwords should be changed every six months; user level passwords should be changed every sixty days.
e. All PCs, laptops, workstations, PDAs, and any other electronic equipment will be secured with a password-protected screensaver with the automatic activation feature set at 15 minutes or less, or by logging-off when the host will be unattended.
f. Because information contained on portable computers is especially vulnerable, special care should be exercised. [See III.D Workstation Security Policy, Item 2, Laptop Security]
g. Postings by employees from ADPH e-mail address to newsgroups should contain a disclaimer stating that the opinions expressed are strictly their own and not necessarily those of the ADPH, unless posting is in the course of business duties.
h. All hosts used by the employee that are connected to the ADPH Internet/Intranet/Extranet, whether owned by the employee or the ADPH, shall be continually executing approved virus-scanning software with a current virus database. Unless overridden by departmental or group policy.
i. Users must have their own internet provider to access email via i-Notes. The department does not provide personal internet services.

3. E-mail Use Guidelines
    a. Employees should check e-mail daily.
    b. If a message could be perceived as ADPH's business or opinion, add a disclaimer to the signature block when not officially representing the ADPH. An example of a disclaimer is: "the opinions expressed herein are my own and do not necessarily represent those of the ADPH."
    c. Use signature blocks at the bottom of electronic mail messages. Signature blocks should be short; preferably not more than six lines, and should include the user's name, e-mail address, phone number and postal address. Anything additional, such as pictures, personal notes, quotations, etc, is not allowed.
    d. Be aware that e-mail is not private communication. Others may be able to read or access e-mail. E-mail may be best regarded as a postcard rather than as a sealed letter.
    e. Delete unwanted messages or files immediately because they take up valuable disk storage space.
    f. Keep e-mail messages stored in mailboxes to a minimum.
    g. Keep e-mail messages short and to the point. Generally limit messages to one subject.
    h. Act in a professional and courteous manner. Avoid gossip and remember that statements about others may find their way back to them. Be patient with new users.

i. Be clear and concise. Re-read and spell check messages before sending them to be sure they will not be misunderstood. Read all messages carefully before replying.
j. Be aware of the potential audience in any discussion group and address them accordingly.
k. Be careful when using sarcasm and humor. Identify intended humor with standard statements (e.g., "only joking"), and through the use of emotions (e.g., ☺ happy face for humor).
l. Give cites and credit for all quotations, references and sources. Do not engage in plagiarism. Give proper credit to the correct sources to avoid potential legal issues surrounding information ownership.
m. Do not violate the privacy of individual users by reading e-Mail or private communications unless you are specifically authorized to maintain and support the system.
n. Do not represent yourself as someone else, fictional or real.
o. The maximum size of an e-mail with attachments will be 10 Megabytes.
p. E-Mail will be blocked when it contains certain file extensions, including .exe.
q. All e-Mail will be scanned for viruses and spyware. E-mail will be deleted if a virus or spyware is detected.

4. General IT Resource Guidelines
    a. Leave the "mattress tag" as installed by CSC.
    b. Leave the desktop settings as installed by CSC.
    c. Access only files and data that are your own, are necessary for the performance of your duties, are publicly available, or to which you have been given authorized access.
    d. Use IT resources efficiently and productively. Refrain from monopolizing systems, overloading networks with excessive data, or wasting computer time, connect time, disk space, printer paper, or other IT resources.
    e. Be responsible for the use of your program data files. Under no condition should you give your passwords to another person. Guard yourself against unauthorized access to your system. When you are away from your desk, take precautions to protect your data files. Print out and file paper copy of documents needed for long-term records.
    f. Report to your supervisor and the CSC IT representative for your area if you:
        i. Receive or obtain information to which you are not entitled (Note: Also notify the owner or sender of such information),
        ii. Become aware of breaches of security, or
        iii. Know of any inappropriate use of state-provided IT resources.
    g. Seek the advice of your CSC IT representative for any state-provided IT resource if you are in doubt concerning your authorization to access that resource.

h. Adhere to copyright law regarding use of software, information and attributions of authorship.
i. Conduct yourself as a representative of both the state agency and state government as a whole. As a minimum, this means that you will not use IT resources to:
    i. Distribute offensive or harassing statements, disparage others based on race, national origin, sex, sexual orientation, age, disability or political or religious beliefs.
    ii. Distribute statements which might incite violence or describe or promote the use of weapons or devices associated with terrorist activities.
    iii. Distribute or solicit sexually oriented messages or images.
j. Any documents stored encrypted on any ADPH owned equipment must also be stored on a server. This is to ensure that the data/documents are accessible and can be recovered in the event of emergency.

Form(s)

None

Reference(s):

HIPAA Security Rule CFR §164.310(b), Standard: Workstation Use (Required)

Contact

Send e-Mail to CSC - Administration

III.D. Workstation Security Policy

Version Number

V1

Applies To

All ADPH Employees and Contractors

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures for physical safeguards for all ADPH workstations that access e-PHI, and restrict workstation access only to authorized Users.

Scope

Procedures for Workstation Security define what measures workforce members must take to ensure the safety and security of workstations and laptops that they are responsible for.

Policy

It is the policy of the Alabama Department of Public Health that all ADPH employees and contractors will implement procedures for securing workstations having access to e-PHI or other sensitive data.

Procedural Responsibilities

All ADPH Employees, Contractors, and Visitors

Procedure(s)

1. Security and Proprietary Information
    a. Employees should take all necessary steps to prevent unauthorized access to Internet/Intranet/Extranet-related systems information.
    b. Keep passwords secure and do not share accounts. Authorized users are responsible for the security of their passwords and accounts. System level passwords must be changed every six months; user level passwords must be changed every sixty days.
    c. All PCs, laptops and workstations will be secured with a password-protected screensaver with the automatic activation feature set at 15 minutes or less, or by logging-off (control-alt-delete for NT users) when the host will be unattended.
    d. Because information contained on portable computers is especially vulnerable, special care should be exercised.

e. Postings by employees from ADPH e-mail address to newsgroups should contain a disclaimer stating that the opinions expressed are strictly their own and not necessarily those of the ADPH, unless posting is in the course of business duties.
f. All hosts used by the employee that are connected to the ADPH Internet/Intranet/Extranet, whether owned by the employee or the ADPH, shall be continually executing approved virus-scanning software with a current virus database. Unless overridden by departmental or group policy.
g. Employees must use extreme caution when opening e-mail attachments received.
h. Electronic data vital to the department stored on laptops must be encrypted and transmitted in an encrypted state.
i. All laptops must have firewalls installed.
j. Department, bureau, section property managers will be responsible for seeing that loaner systems are logged into the master database at least once a month and checking the current status of antivirus and security patches.
k. Users of laptops are responsible for logging into the master database at least once a month, checking the current status of antivirus and security patches on laptops assigned to them.
l. Property managers are responsible for updating the antivirus and security patches on laptops before issuing them to a user.
m. Once per month users and property managers will connect to the network and update the master inventory database.
    i. This is done by double-clicking the "Logit" icon which writes to a log file on the system and updates the master database.
    ii. Next, open the antivirus program and check the date of the Virus definitions. If more than a month old, leave the laptop connected to the network for thirty minutes and recheck the date. If date has not changed, submit a work order to the Support Desk to have system examined.
    iii. Last, select "Windows Update" from Start Menu and let Microsoft website scan system to determine which security patches need to be upgraded.
    iv. When asked what type of install desired, select "Express Install". Any security patches in black letters will be installed when the "Install" button is clicked. Any service packs listed in RED are <u>not to be installed.</u>

2. Laptop Security

Users are responsible for damage to and/or loss or theft of loaned laptop units. In order to avoid loss or theft, please follow these guidelines:

- Airports: Never leave the laptop unattended. Do not check the laptop as baggage. Exercise diligence in watching the laptop as it is passed through any x-ray devices.

- Cars: Keep the car locked and the laptop out of view. Ensure that the laptop is securely stored so that it does not slide while driving. Avoid storage of the laptop in a car during very hot or very cold weather.

If the laptop is lost or stolen, a written claim must be filed within 24 hours to CSC and notice given to the appropriate police authorities. If a laptop is lost, damaged, or stolen, the employee responsible for that laptop must attend an investigative disciplinary hearing where the circumstances surrounding the loss, damage, or theft will be discussed in depth. Losing or severely damaging a laptop, or failing to take appropriate action to prevent its theft, is a dismissible offence.

Users are responsible for performing their own data backups. CSC is not responsible for any files left on any laptop or for loss of, or damage to, a user's files during the loan period.

3. Visiting Laptops

Employees may wish to use a privately owned laptop computer at the ADPH. Visiting laptops must have permission from CSC to connect to any network port since it could be disruptive or destructive to the network. Violation could result in permanent ban of visiting laptop use. If an employee chooses to bring in a visiting laptop, be prepared to provide the following information:

- computer type;
- planned location for use; and
- plans for current and future use.

Short-term contract workers or consultants in the employ of the ADPH will be provided with a laptop for the duration of their stay if required. If they wish to provide their own laptop, the same visiting laptop rules apply. In the event of laptop lease from CSC, the lease of a laptop must be sponsored by a current ADPH employee overseeing the work of the contract worker or consultant and that employee may be held partially responsible for any damages incurred.

In general, visiting laptops are not supported by CSC. This does not include visiting units owned by the ADPH from branch locations within the company. CSC will attempt to support visiting laptops owned by short-term contract workers or consultants in the employ of the ADPH, but does not guarantee support.

Form(s)

None

Reference(s):

HIPAA Security Rule, CFR §164.310(c), Standard: Workstation Security (Required)

Contact

Send e-Mail to CSC – Technical Support

III.E. Device and Media Controls

III.E.1. Device and Media Disposal

Version Number

V1

Applies To

Computer Systems Center Technical Support Division

Effective Date

April 21, 2005

Purpose

Implement policies and procedures to address the final disposition of e-PHI, and/or the hardware or electronic media on which it is stored.

Scope

The procedures deal with the process of disposing of hard drives and magnetic tapes from desktops, laptops, and minicomputers owned by the ADPH. The media fall within two broad categories, those that contain no e-PHI and those that do have e-PHI stored on them.

Policy

It is the policy of the Alabama Department of Public Health to dispose of media containing e-PHI. This can include moving data to another system, archiving, discarding, destroying data, or destroying hard drives.

Procedural Responsibilities

CSC Technical Support

Procedure(s)

Process for CSC

Before a computer system, desktop, or laptop is salvaged, the user will inform Technical Support staff if it contains e-PHI or not.

1. If the system **does not contain e-PHI** and is to be salvaged, then software such as Partition Magic will be used to destroy the operating system and data partitions. A statement to that effect shall be attached to the property transfer form and sent with the system to the Warehouse.
2. If the system **does contain e-PHI** and is to be salvaged, then Symantec Ghost 7.5 or similar product shall be used to erase the hard drive according to DoD 5220.22-M standards.
3. Tapes used on the AS400 that are deemed beyond their useful service life shall be erased with a magnetic bulk eraser before they are discarded. A log will be

kept of the erasure and will contain the tape label, date of erasure, and name of the person who did the erasing. The log will be maintained for two years for audit purposes. The above process is applicable to tape cartridges user for server backups and mainframe backups.

Form(s)

Property Transfer Form (Appendix I)

Reference(s):

- HIPAA Security Rule CFR §164.310(d) (1), Standard: Device and Media Controls, Implementation Specification: Disposal (Required)
- DoD 5220.22-M, Section C5.7 Disposition and Retention, Department of Defense National Industrial Security Program Operating Manual (http://www.dtic.mil/whs/directives/corres/pdf2/p522022m.pdf)

Contact

Send e-Mail to CSC – Technical Support

III.E.2. Media Re-use

Version Number

V1

Applies To

All ADPH Users and Contractors
CSC Technical Support Division

Effective Date

April 21, 2005

Purpose

To address removal of e-PHI from electronic devices before the media are made available for re-use; e.g., scrubbing data off a tape, hard drive, CD, etc.

Scope

The procedure is to prepare electronic devices for reuse.

Policy

It is the policy of the Alabama Department of Public Health to remove all e-PHI from electronic devices before the device is made available for reuse.

Procedural Responsibilities

CSC Technical Support
All Users

Procedure(s)

Before a computer system, desktop, or laptop is transferred, the user will inform Technical Support staff if it contains e-PHI or not.

Process for CSC

- If the system **does not contain e-PHI** and is to be transferred, then software such as Partition Magic will be used to destroy the operating system and data partitions. A statement to that effect shall be attached to the property transfer form and sent with the system to the Warehouse. If the system is to be transferred to another division or section, then the hard disk will be reimaged under the current procedures now used by the Technical Support Division.
- If the system **does contain e-PHI** and is to be transferred to another work unit, then such system will be reimaged under the current Technical Support procedures.
- Tapes used on the ISD 3270 Mainframe will be reinitialized before reuse.

Form(s)

Property Transfer Form (Appendix I)

Reference(s):

- HIPAA Security Rule CFR §164.310(d) (1), Standard: Device and Media Controls, Implementation Specification: Media Re-use (Required)
- DoD 5220.22-M, Section C5.7 Disposition and Retention, Department of Defense National Industrial Security Program Operating Manual (http://www.dtic.mil/whs/directives/corres/pdf2/p522022m.pdf)

Contact

Send e-Mail to CSC – Technical Support

III.E.3. Media Accountability

Version Number

V1

Applies To

All ADPH Employees and Contractors
CSC Data Operations

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures to maintain a record of the physical movements of media as well as any person responsible for those movements.

Scope

The procedures identify processes that workforce members must follow to account for the distribution of e-PHI that is stored on electronic media.

Policy

It is the policy of the Alabama Department of Public Health to maintain a record of location and movement of all media containing e-PHI.

Procedural Responsibilities

All ADPH Employees
CSC Data Operations

Procedure(s)

Technical CSC Guidance

All internal servers deployed at the ADPH must be owned by an operational group that is responsible for system administration. Approved server configuration guides must be established and maintained by each operational group, based on business needs and approved by CSC Technical Support. Operational groups should monitor configuration compliance and implement an exception policy tailored to their environment. Each operational group must establish a process for changing the configuration guides, which includes review and approval by CSC Technical Support.

1. Servers must be registered within the ADPH Computer Systems Center. At a minimum, the following information is required to positively identify the point of contact:
    a. Server contact(s) and location, and a backup contact
    b. Hardware and Operating System/Version
    c. Main functions and applications, if applicable

2. Information in the ADPH enterprise management system must be kept up-to-date.
3. Configuration changes for production servers must follow the appropriate change management procedures.

General Guidance

1. Any media containing e-PHI must be labeled and the location logged.
2. All computer storage media such as CDs, memory sticks, smart media, etc, must be purchased by the department and are departmental property. These items must be returned upon employee departure. Privately owned storage media is strictly forbidden.

Form(s)

None

Reference(s):

HIPAA Security Rule, CFR §164.310(d) (1), Standard: Device and Media Accountability, Implementation Specification: Accountability (Addressable)

Contact

Send e-Mail to CSC – Data Operations

III.E.4. Data Backup and Storage

Version Number

V1

Applies To

All ADPH Employees

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures for the backup and storage of e-PHI used by ADPH workforce members.

Scope

The procedures are to provide guidance for workforce members to follow for the backup and storage of e-PHI.

Policy

It is the policy of the Alabama Department of Public Health to backup all critical systems and to maintain off-site storage of these systems.

Procedural Responsibilities

All ADPH Employees
CSC Data Operations

Procedure(s)

1. All personnel are responsible for backing up local PC hard drive files.
2. Any documents, whether e-PHI or otherwise, that are critical to the department, must be stored on a designated location on the server.
3. All County main offices will rotate their Friday tapes once a week with their fallback location (every Monday).

CSC Only

1. Management shall designate a non-IT person or persons to be responsible for the rotation of backup tapes of critical systems and to courier the tapes to the designated location for safe storage. When requested, and for the purpose of performing an audit, any access needed will be provided to evaluate that procedures are being followed properly for tape backup rotation Form(s).

This access may include:

a. Access to information (electronic, hardcopy, etc.) to verify tape backup process documentation or tapes are located in proper location and fireproof container.
b. Media Rotation
   CSC Data Management Division will use at least three (3) sets of back-up storage media (tapes, CD-ROMs, etc.) to be used in rotation. Periodic archival back-up copies should also be made every few months; these copies should be stored for one month, depending upon the Owner's requirements, and may be used to help recover from system problems or data loss problems.
c. Media Storage
   Secure storage of back-up media is the responsibility of the microcomputer user or multi-user machine Systems Administrator involved in the back-up process. Storage media from multi-user systems should be stored in fireproof safes, at a separate location several city blocks away from the system being backed-up. All back-up media stored off-site must be physically protected against unauthorized access.

2. The Tower will rotate their backup storage tapes off-site on a daily basis to secured fire-proof container secured at a secure location located more than 1 mile from the Tower.
3. CSC will do a special backup on the 1st day of each month and mark it with Month/Year on the label. This will be permanently stored in a fire proof container.

Tape rotation will be as followed (Tower)

Monday 1 (used on odd week of month)	Monday 2 (used on even week of month)
Tuesday 1 (used on odd week of month)	Tuesday 2 (used on even week of month)
Wednesday 1 (used on odd week of month)	Wednesday 2 (used on even week of month)
Thursday 1 (used on odd week of month)	Thursday 2 (used on even week of month)
Friday 1 – (used on 1st Friday of month)	Friday 2 – (used on 2nd Friday of month)
Friday 3 – (used on 3rd Friday of month)	Friday 4 – (used on 4th Friday of month)
Friday 5 – (used on 5th Friday of month)	
1st of each month – Special backup (permanent)	

Reference(s):

HIPAA Security Rule CFR §164.310(d) (1), Standard: Device and Media Controls, Implementation Specification: Data Backup and Storage

Forms

None

Contact

Send e-Mail to CSC – Data Operations

IV

Technical Safeguards

IV.A. Overview

Purpose

Technical Safeguards address technology and the policies and procedures for its use that protect e-PHI and control access to it.

Technical Safeguards are designed to guard against unauthorized access to e-PHI maintained in a system or transmitted over a communications network. The Technical Safeguards contain the following five security standards that specify how to use technology to protect e-PHI and, in particular, to control access to e-PHI.

Standards

The five standards contained in the Technical Safeguards are detailed in the following sections and include:

Section IV.B – Access Control
Technical policies and procedures for electronic Information Systems that maintain e-PHI to grant and allow access only to those persons or software programs that have appropriate access rights.

Section IV.C – Audit Controls
Procedural mechanisms and/or processes that record and examine activity in Information Systems that contain or use e-PHI.

Section IV.D – Integrity
Policies and procedures to protect e-PHI from improper or unauthorized alteration or destruction.

Section IV.E – Person or Entity Authentication
Procedures to verify that a person or entity seeking access to e-PHI is who they/it claims to be.

Section IV.F – Transmission security
Technical security measures to guard against unauthorized access to e-PHI transmitted over an electronic communications network.

IV.B. Access Control

IV.B.1. Unique User Identification

Version Number

V1

Applies To

Security Coordinators
CSC Data Management
CSC Technical Support

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures to assign a unique name and/or number for identifying and tracking ADPH systems user identity.

Scope

The procedures include guidelines for unique user identification, User ID maintenance, and password construction.

Policy

It is the policy of the Alabama Department of Public Health to assign a unique user ID and password for each employee requiring access to ADPH computer systems.

Procedural Responsibilities

Security Coordinators
CSC Data Management
CSC Technical Support

Procedure(s)

1. User ID Construction – Network User ID
    - RSA Tower – The Network ID will be the first two letters the bureau the employee is assigned plus a number, followed by the first letter of the employee's first name and the first four letters of the last name.
    - County – The Network ID will be "H" plus the county number, followed by the first letter of the user's first name and the first four letters of the last name.
    - Non-departmental Users – The Network ID sill be "H" plus a two-letter identifier, followed by the first letter of the user's first name and the first four letters of the last name.

2. User ID Construction - RACF IDs
    - RSA Tower – The RACF ID will be "PHX" plus four random numbers.
    - County – The RACF ID will be "PH" plus the county number plus four random numbers.
3. User ID Construction - AS/400
    - The first two positions identify the work unit; the third position is a number, followed by the first letter of the user's name, and the first four letters of the last name.
4. General Password Construction

    All ADPH personnel with access to e-PHI are subject to the following requirements: Passwords are used for various purposes at the ADPH. Some of the more common uses include: user level accounts, web accounts, e-mail accounts, screen saver protection, voice-mail password, and local router logins. Since very few systems have support for one-time tokens (i.e., dynamic passwords which are only used once), everyone should be aware of how to select strong passwords.

    ADPH standard passwords will be configured as the following:

    - Contain both upper and lower case characters (e.g., a-z, A-Z)
    - Have digits and punctuation characters as well as letters e.g., 0-9, !@#$%^&*()_+|~-=\`{}[]:";'<>?,./)
    - Are at least eight alphanumeric characters long.
    - Should not be a variation on the username.
    - Is not a word in any language, slang, dialect, jargon, either forward or backward, etc.
    - Are not based on personal information, names of family, etc.
    - Passwords should never be written down or stored on-line. Try to create passwords that can be easily remembered. One way to do this is create a password based on a song title, affirmation, or other phrase. For example, the phrase might be: "This May Be One Way To Remember" and the password could be: "TmB1w2R!" or "Tmb1W>r~" or some other variation. How about your ISO's favorite quote: "All for one and one for all"? The password could be: "All41&14All"!

        - NOTE: Do not use these examples as passwords!

Form(s)

Computer Systems Access Form (Appendix D)

Reference(s):

HIPAA Security Rule, CFR §164.312(a) (1), Standard: Unique User Identification (Required)

Contact

Send e-Mail to CSC – Security Team

IV.B.2. Emergency Access Procedure

Version Number

V1

Applies To

Bureau Directors
Area Administrators
Disaster Response Team
Computer Systems Center

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures for obtaining e-PHI during an emergency.

Scope

The procedures provide guidance regarding emergency access to e-PHI by ADPH workforce members before an emergency arises. Periodic review and updates are required.

Policy

It is the policy of the Alabama Department of Public Health for the Data Management Division to maintain, plan, and test the continuity plan for recovering and continuing data processing service before/after an emergency has occurred.

Policy for Emergency Access is contained in the policy for Contingency/Emergency Planning in section II.H.2 Disaster Recovery Plan.

Procedural Responsibilities

Bureau Directors
Area Administrators
Disaster Response Team
Computer Systems Center

Procedure(s)

1. The Disaster Recovery Team (DRT) will be initiated to access the current situation and develop and action plan.
2. The Information Security Officer is responsible for providing security guidance for all information systems contingency planning efforts.
3. The Technical Support manager is responsible for providing technical guidance for all information systems contingency planning efforts.

4. Data Management will train all workers in the Computer System Center on their responsibilities in case of activation this plan.
5. Each Bureau/Area/County leadership must provide CSC with a contingency plan to cover the following disaster definitions.
6. CSC will maintain, at the central office, a file of all Bureau/Area/County contingency plans.
7. Emergency Access Procedures are covered in II.H.2 and II.H.3.

Form(s)

None

Reference(s):

- HIPAA Security Rule, CFR § 164.312(a) (1), Standard: Access Control, Implementation Specification: Emergency Access Procedure (Required)
- II.H.2 Disaster Recovery Plan
- II.H.3 Emergency Mode Operation Plan

Contact

Send e-Mail to CSC - Administration

IV.B.3. Automatic Logoff

Version Number

V1

Applies To

All ADPH Employees
CSC Technical Support

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement electronic procedures that terminate an electronic session after a predetermined time of inactivity.

Scope

ADPH logoff procedures apply to all workforce members.

Policy

It is the policy of the Alabama Department of Public Health to automatically disconnect electronic sessions after 15 minutes of inactivity.

Procedural Responsibilities

CSC Technical Support

Guidance

1. All PCs, laptops and workstations will be secured with a password-protected screensaver with the automatic activation feature set at 15 minutes or less, or by logging-off when the workstation is left unattended.
2. The VPN concentrator is limited to an absolute connection time of 24 hours.

Procedures

- CSC will configure all workstations to automatically lock after 15 minutes of inactivity.

Form(s)

None

Reference(s):

HIPAA Security Rule CFR §164.312(a) (1), Standard: Access Control, Implementation Specification: Automatic Logoff (Addressable)

Contact

Send e-Mail to CSC – Technical Support

IV.B.4. Encryption and Decryption

Version Number

V1

Applies To

All ADPH Employees
CSC Technical Support

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures and mechanisms to encrypt and decrypt e-PHI.

Scope

The procedures are for encryption/decryption of e-PHI to deny unauthorized users access to information in that file and establishing control of data files at rest or in transit.

Policy

It is the policy of the Alabama Department of Public Health that for the purpose of access control of transient data or data at rest, the use of encryption will be determined on a file to file basis.

Procedural Responsibilities

All ADPH Employees
CSC Technical Support

Guidelines

1. E-PHI contained on site (e.g., in servers and workstations) generally will not be encrypted, but will be protected via the many other various safeguards applied to ADPH premises and system access (see Facility Access Controls, Workstation Use, Workstation Security, and Access Controls).
2. As appropriate and consistent with guidelines established by the ISO, e-PHI stored on laptops will be encrypted during storage, and decrypted for use, in order to reduce the vulnerability of information contained in these portable media devices.

Procedure(s)

1. CSC will purchase and load software to enable encryption and decryption of data.
2. ADPH will utilize SSL(Secure Socket Layers) and VPN (Virtual Private Network) procedures to protect e-PHI transmission.
3. Technical Guidelines (CSC Only)
   SSL uses RSA encryption. Symmetric cryptosystem key lengths must be at least 56 bits. Asymmetric crypto-system keys must be of a length that yields equivalent strength. ADPH's key length requirements will be reviewed annually and upgraded as technology allows.

   The use of proprietary encryption algorithms is not allowed for any purpose, unless reviewed by qualified experts outside of the vendor in question and approved by the Information Security Officer. Be aware that the export of encryption technologies is restricted by the U.S. Government. Residents of countries other than the United States should make themselves aware of the encryption technology laws of the country in which they reside.

   To comply with this policy, wireless implementations must: Maintain point-to-point hardware encryption of at least 56 bits. Maintain a hardware address that can be registered and tracked, i.e., a MAC address. Support strong user authentication which checks against an external database such as TACACS+, RADIUS or something similar.

   Exception

   A limited-duration waiver to this policy for Aironet products has been approved; specific implementation instructions are followed for ADPH.

Form(s)

None

Reference(s):

HIPAA Security Rule, CFR §164.312(a) (1), Standard: Access Control, Implementation Specification: Encryption (Addressable)

Contact

Send e-Mail to CSC – Technical Support

IV.C. Audit Controls

Version Number

V1

Applies To

ADPH Data Owners
CSC Data Management

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement hardware, software, and/or procedural mechanisms that record and examine activity in Information Systems that contain or use e-PHI.

Scope

The procedures are to establish audit controls to record any alterations of patient information, including changes, deletions, modifications, creations, and additions and to provide an internal mechanism to track and report access to ADPH e-PHI.

Policy

It is the policy of the Alabama Department of Public Health to implement audit controls to record any alterations, changes, deletions, modifications, creations, and/or additions to records containing e-PHI.

Procedural Responsibilities

ADPH Data Owners
CSC Data Management

Procedure(s)

1. Audit logs will be reviewed bi-annually by data owners.
2. Data owners will report any irregularities to CSC Data Management.
3. Audit Controls will be specific to each system or application and specific to each type of User activity. An audit process systematically tracks and reports, minimally, the following events:
   a. Log-on and log-off;
   b. File and object access;
   c. Use of user rights;
   d. User and group management;
   e. Security policy changes;
   f. Restart and/or shutdown; and
   g. System process tracking.

Form(s)

Sample of Audit Logs (Appendix J)

Reference(s):

HIPAA Security Rule, CFR § 164.312(b), Audit Controls (Required)

Contact

Send e-Mail to CSC – Security Team

IV.D. Integrity Controls

IV.D.1. Mechanism to Authenticate e-PHI

Version Number

V1

Applies To

CSC Technical Support

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement, as needed, electronic mechanisms to corroborate that ADPH e-PHI has not been altered or destroyed in an unauthorized manner.

Scope

The procedure covers the different mechanisms used by ADPH to authenticate e-PHI.

Policy

It is the policy of the Alabama Department of Public Health to employ data reconciliation routines to examine e-PHI for evidence of tampering, errors and omissions.

Procedural Responsibilities

CSC Technical Support

Procedure(s)

1. Data reconciliation routines will be deployed at the level of the server housing e-PHI or at an application-specific level.
2. ADPH will use RAID 5 storage and backup methodologies to assist in ensuring the integrity of its e-PHI.
3. Users will verify via reports (i.e. reconciliation program reports) that data is accurate and has not been altered.

Form(s)

None

Reference(s):

HIPAA Security Rule, CFR §164.312(c) (1), Standard: Integrity, Implementation Specification: Mechanism to Authenticate Electronic Protected Health Information (Addressable)

Contact

Send e-Mail to CSC – Technical Support

IV.E. Person or Entity Authentication

Version Number

V1

Applies To

CSC Technical Support

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement procedures to verify that a person or entity seeking access to e-PHI is the one claimed.

Scope

The procedures cover the different mechanisms used by ADPH to authenticate entities.

Policy

It is the policy of the Alabama Department of Public Health to authenticate all users and entities seeking access to the ADPH computer systems.

Procedural Responsibilities

CSC Technical Support

Guidelines

1. Dial-in access should be strictly controlled, using one-time password authentication.
2. Analog and non-GSM digital cellular phones cannot be used to connect to the ADPH network, as their signals can be readily scanned and/or hijacked by unauthorized individuals. Systems on the ADPH network cannot be connected to other networks via analog and non-GSM digital cellular phones due to the same risk factors. Only GSM standard digital cellular phones are considered secure enough for connection to the ADPH network.
3. Approved ADPH employees and authorized third parties (customers, vendors, etc.) may utilize the benefits of VPNs, which are a “user managed” service. This means that the user is responsible for selecting an Internet Service Provider (ISP), coordinating installation, installing any required software, and paying associated fees.
4. Other entities will utilize ADPH’s public FTP site to transfer files to our network. If the information contains e-PHI, the files must be encrypted as self-extracting executable. The entity must provide ADPH with the password to decrypt.

5. It is the responsibility of employees with VPN privileges to ensure that unauthorized users are not allowed access to the ADPH internal networks.
6. Dual (split) tunneling is NOT permitted; only one network connection is allowed.
7. Only Information security-approved VPN clients may be used.
8. By using VPN technology with personal equipment, users must understand that their machines are a de facto extension of the ADPH network, and as such are subject to the same rules and regulations that apply to the ADPH-owned equipment, i.e., their machines must be configured to comply with ADPH security policies.

Procedure(s)

1. VPN use is to be controlled using either a one-time password authentication such as a token device or a public/private key system with a strong pass phrase.
2. When actively connected to the ADPH network, VPNs will force all traffic to and from the PC over the VPN tunnel: all other traffic will be dropped.
3. VPN gateways will be set up and managed by the ADPH network operational groups.
4. Users of computers that are not the ADPH-owned equipment must configure the equipment to comply with the ADPH VPN and Network policies.

Form(s)

None

Reference(s):

HIPAA Security Rule, CFR §164.312(d), Standard: Person or Entity Authentication, (Required)

Contact

Send e-Mail to CSC – Technical Support

IV.F. Transmission Security

IV.F.1. Transmission Integrity Controls

Version Number

V1

Applies To

CSC Technical Support

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement security measures to ensure that electronically transmitted e-PHI is not improperly modified without detection until disposed of.

Scope

The procedures cover the electronic transmission of sensitive information such as e-PHI and other business information, by all employees, vendors, and agents operating on behalf of ADPH.

Policy

It is the policy of the Alabama Department of Public Health to secure the electronic transmission of sensitive information.

Procedural Responsibilities

CSC Technical Support

Guidelines

1. ADPH uses SSL (Secure Sockets Layer) and VPN protocols to secure Web-based client or browser and server traffic.
2. Only approved ADPH employees and authorized third parties may utilize the benefits of VPNs, which are “user managed” services.

Procedure(s)

- ADPH will prohibit the installation of an unauthorized wireless access point.

Form(s)

None

Reference(s):

HIPAA Security Rule, CFR §164.312(e) (2)(i), Standard: Transmission Security, Implementation Specification: Integrity Controls (Addressable)
IV.B.4 Encryption and Decryption Policy

Contact

Send e-Mail to CSC – Technical Support

IV.F.2. Encryption

Version Number

V1

Applies To

CSC Technical Support

Effective Date

April 21, 2005

Purpose

The purpose of this policy is to implement, as needed, a mechanism to encrypt e-PHI whenever deemed appropriate.

Scope

The procedure is for ADPH to protect e-PHI, while at rest or in transit, using encryption to protect the confidentiality, integrity, authentication, non-repudiation, and availability of e-PHI.

Policy

It is the policy of the Alabama Department of Public Health to use encryption to protect the confidentiality, integrity, authentication, non-repudiation, and availability of e-PHI.

Procedural Responsibilities

CSC Technical Support

Procedure(s)

See IV.B.4 Encryption and Decryption

Form(s)

None

Reference(s):

HIPAA Security Rule, CFR §164.312(e) (2)(ii), Standard: Transmission Security, Implementation Specification: Encryption (Addressable)
IV.B.4 Encryption and Decryption Policy

Contact

Send e-Mail to CSC – Technical Support

V

Other ADPH Security Policies

V.A. Overview

Purpose

This section is reserved for additional ADPH security policies that do not correlate directly to the Standards and Implementation Specifications outlined in the HIPAA Security Rule.

Policies

The following additional security policies addressed in this section include:

Section V.B – Electronic Signature
An electronic signature is accomplished through the use of an authentication control, such as a password, token, or biometric.

V.B. Electronic Signature

V.B.1. Electronic Signature

Version Number

V1

Applies To

CSC Technical Support

Effective Date

April 21, 2005

Purpose

Electronic signature is the attribute that is affixed to an electronic document to bind it to a particular entity. Electronic signature may be an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record. An electronic signature process secures the user authentication (proof of claimed identity, such as by biometrics (fingerprints, retinal scans, hand written signature verification, etc.), tokens or passwords) at the time the signature is generated; creates the logical manifestation of signature (including the possibility for multiple parties to sign a document and have the order of application recognized and proven) and supplies additional information such as time stamp and signature purpose specific to that user; and ensures the integrity of the signed document to enable transportability, interoperability, independent verifiability, and continuity of signature capability. Verifying a signature on a document verifies the integrity of the document, associated attributes, and verifies the identity of the signer. There are several technologies available for user authentication, including passwords, cryptography, and biometrics. (ASTM 1762-95, as cited in the HISB draft Glossary of Terms Related to Information Security in Health care Information Systems)

Scope

The procedure is for the Department to generate/receive documents of all types filed physically or utilizing electronic media, to control the integrity of the data submitted, to reduce processing costs and processing times, to facilitate accuracy and reduce complexities of manual processing and to accept electronic signatures and other such authentication methods.

Policy

It is the policy of the Alabama Department of Public Health to adopt electronic signature standards as outlined in the Alabama Uniform Electronic Transactions Act.

Procedural Responsibilities

CSC Technical Support

Guidance

ADPH will adhere to the Alabama Administrative Code which states that the digital signature must be:

- Unique to the person using it
- Capable of verification
- Under the sole control of the person using it
- Linked to a document in such a manner that the digital signature is invalidated if any data in the document is changed.

Procedures

Employees will sign a letter of "Receipt and Acknowledgement" stating that they acknowledge the receipt of a personal identification number ("PIN") for use exclusively with the Alabama Department of Public Health's automated systems. The use of this PIN in the System is the legal equivalent to the employee's signature and divulging the PIN to any other person allows such person to use the PIN in their place and affirms that any action taken using such PIN as though the action were taken by that employee.

Note: In most cases, the PIN will be the employee's User ID and password.

Form(s)

Sample of Receipt and Acknowledgement (Appendix L)

Reference(s):

II.E.3 Access Establishment and Modification

Contact

Send e-Mail to CSC – Security Team

VI

Security Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160, 162, and 164

[CMS-0049-F]

RIN 0938-AI57

Health Insurance Reform: Security Standards

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule adopts standards for the security of electronic protected health information to be implemented by health plans, health care clearinghouses, and certain health care providers. The use of the security standards will improve the Medicare and Medicaid programs, and other Federal health programs and private health programs, and the effectiveness and efficiency of the health care industry in

providers, and health plans) that the integrity, confidentiality, and availability of electronic protected health information they collect, maintain, use, or transmit is protected. The confidentiality of health information is threatened not only by the risk of improper access to stored information, but also by the risk of interception during electronic transmission of the information. The purpose of this final rule is to adopt national standards for safeguards to protect the confidentiality, integrity, and availability of electronic protected health information. Currently, no standard measures exist in the health care industry that address all aspects of the security of electronic health information while it is being stored or during the exchange of that information between entities.

This final rule adopts standards as required under title II, subtitle F, sections 261 through 264 of the Health

health care providers. These statutory sections are discussed in the Transactions Rule, at 65 FR 50312, on pages 50312 through 50313, and in the final rules adopting Standards for Privacy of Individually Identifiable Health Information, published on December 28, 2000 at 65 FR 82462 (Privacy Rules), on pages 82470 through 82471, and on August 14, 2002 at 67 FR 53182. The reader is referred to those discussions.

Section 1173(d) of the Act requires the Secretary of HHS to adopt security standards that take into account the technical capabilities of record systems used to maintain health information, the costs of security measures, the need to train persons who have access to health information, the value

general by establishing a level of protection for certain electronic health information. This final rule implements some of the requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). **DATES**: Effective Date: These regulations are effective on April 21, 2003. Compliance Date: Covered entities, with the exception of small health plans, must comply with the requirements of this final rule by April 21, 2005. Small health plans must comply with the requirements of this final rule by April 21, 2006. **I. Background** The Department of Health and Human Services (HHS) Medicare Program, other Federal agencies operating health plans or providing health care, State Medicaid agencies, private health plans, health care providers, and health care clearinghouses must assure their customers (for example, patients, insured individuals,	Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191. These standards require measures to be taken to secure this information while in the custody of entities covered by HIPAA (covered entities) as well as in transit between covered entities and from covered entities to others. The Congress included provisions to address the need for safeguarding electronic health information and other administrative simplification issues in HIPAA. In subtitle F of title II of that law, the Congress added to title XI of the Social Security Act a new part C, entitled "Administrative Simplification" (hereafter, we refer to the Social Security Act as "the Act"; we refer to the other laws cited in this document by their names). The purpose of subtitle F is to improve the Medicare program under title XVIII of the Act, the Medicaid program under title XIX of the Act, and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements to enable the electronic exchange of certain health information. Part C of title XI consists of sections 1171 through 1179 of the Act. These sections define various terms and impose requirements on HHS, health plans, health care clearinghouses, and certain	of audit trails in computerized record systems, and the needs and capabilities of small health care providers and rural health care providers. Section 1173(d) of the Act also requires that the standards ensure that a health care clearinghouse, if part of a larger organization, has policies and security procedures that isolate the activities of the clearinghouse with respect to processing information so as to prevent unauthorized access to health information by the larger organization. Section 1173(d) of the Act provides that covered entities that maintain or transmit health information are required to maintain reasonable and appropriate administrative, physical, and technical safeguards to ensure the integrity and confidentiality of the information and to protect against any reasonably anticipated threats or hazards to the security or integrity of the information and unauthorized use or disclosure of the information. These safeguards must also otherwise ensure compliance with the statute by the officers and employees of the covered entities. **II. General Overview of the Provisions of the Proposed Rule** On August 12, 1998, we published a proposed rule (63 FR 43242) to establish a minimum standard for security of electronic health information. We proposed that the standard would require the safeguarding of all electronic health information by covered entities. The proposed rule also proposed a

standard for electronic signatures. This final rule adopts only security standards. All comments concerning the proposed electronic signature standard, responses to these comments, and a final rule for electronic signatures will be published at a later date. A detailed discussion of the provisions of the August 12, 1998 proposed rule can be found at 63 FR 43245 through 43259. We originally proposed to add part 142, entitled "Administrative Requirements," to title 45 of the Code of Federal Regulations (CFR). It has now been determined that this material will reside in subchapter C of title 45, consisting of parts 160, 162, and 164. Subpart A of part 160 contains the general provisions applicable to all the Administrative Simplification rules; other subparts of part 160 will contain other requirements applicable to all standards. Part 162 contains the standards for transactions and code sets and will contain the identifier standards. Part 164 contains the standards relating to privacy and security. Subpart A of part 164 contains general provisions applicable to part 164; subpart E contains the privacy standards. Subpart C of part 164, which is adopted in this final rule, adopts standards for the security of electronic protected health information. **III. Analysis of, and Responses to, Public Comments on the Proposed Rule**	Rule, and the Privacy Rule. Within the comment and response portion of this final rule, for purposes of continuity, however, we use "requirement" and "implementation feature" when we are referring specifically to matters from the proposed rule. In all other instances, we use "standard" and "implementation specification." The proposed rule would require that each covered entity (as now described in § 160.102) engaged in the electronic maintenance or transmission of health information pertaining to individuals assess potential risks and vulnerabilities to such information in its possession in electronic form, and develop, implement, and maintain appropriate security measures to protect that information. Importantly, these measures would be required to be documented and kept current. The proposed security standard was based on three basic concepts that were derived from the Administrative Simplification provisions of HIPAA. First, the standard should be comprehensive and coordinated to address all aspects of security. Second, it should be scalable effectively implemented by covered entities of all types and sizes. Third, it should not be linked to specific technologies, allowing covered entities to make use of future technology advancements. The proposed standard consisted of four categories of requirements that a covered	overwhelmingly validated our basic assumptions that the entities affected by this regulation are so varied in terms of installed technology, size, resources, and relative risk, that it would be impossible to dictate a specific solution or set of solutions that would be useable by all covered entities. Many commenters also supported the concept of technological neutrality, which would afford them the flexibility to select appropriate technology solutions and to adopt new technology over time. 1. Security Rule and Privacy Rule Distinctions As many commenters recognized, security and privacy are inextricably linked. The protection of the privacy of information depends in large part on the existence of security measures to protect that information. It is important that we note several distinct differences between the Privacy Rule and the Security Rule. The security standards below define administrative, physical, and technical safeguards to protect the confidentiality, integrity, and availability of electronic protected health information. The standards require covered entities to implement basic safeguards to protect electronic protected health information from unauthorized access, alteration, deletion, and transmission. The Privacy Rule, by contrast, sets standards for how protected health information should be controlled by setting forth what uses and disclosures are

We received approximately 2,350 timely public comments on the August 12, 1998 proposed rule. The comments came from professional associations and societies, health care workers, law firms, health insurers, hospitals, and private individuals. We reviewed each commenter's letter and grouped related comments. Some comments were identical. After associating like comments, we placed them in categories based on subject matter or based on the section(s) of the regulations affected and then reviewed the comments.

In this section of the preamble, we summarize the provisions of the proposed regulations, summarize the related provisions in this final rule, and respond to comments received concerning each area.

It should be noted that the proposed HIPAA Security Rule contained multiple proposed "requirements" and "implementation features." In this final rule, we replace the term "requirement" with "standard." We also replace the phrase "implementation feature" with "implementation specification." We do this to maintain consistency with the use of those terms as they appear in the statute, the Transactions

We received a number of comments that pertained to privacy issues. These issues were considered in the development of the Privacy Rule and many of these comments were addressed in

entity would have to address in order to, so that it can be safeguard the integrity, confidentiality, and availability of its electronic health information pertaining to individuals: administrative procedures, physical safeguards, technical security services, and technical mechanisms. The implementation features described the requirements in greater detail when that detail was needed. Within the four categories, the requirements and implementation features were presented in alphabetical order to convey that no one item was considered to be more important than another.

The four proposed categories of requirements and implementation features were depicted in tabular form along with the electronic signature standard in a combined matrix located at Addendum 1. We also provided a glossary of terms, at Addendum 2, to facilitate a common understanding of the matrix entries, and at Addendum 3, we mapped available existing industry standards and guidelines to the proposed security requirements.

A. General Issues

The comment process

(c)implement a combination of both; or (d) not implement either an addressable implementation specification or an alternative security measure. In all cases, the covered entity must meet the standards, as explained below.

authorized or required and what rights patients have with respect to their health information.

As is discussed more fully below, this rule narrows the scope of the information to which the safeguards must be applied from that proposed in the proposed rule, electronic health information pertaining to individuals, to protected health information in electronic form. Thus, the scope of information covered in this rule is consistent with the Privacy Rule, which addresses privacy protections for "protected health information. "However, the scope of the Security Rule is more limited than that of the Privacy Rule. The Privacy Rule applies to protected health information in any form, whereas this rule applies only to protected health information in electronic form. It is true that, under section 1173(d) of the Act, the Secretary has authority to cover "health information," which, by statute, includes information in other than electronic form. However, because the proposed rule proposed to cover only health information in electronic form, we do not include security standards for health information in non-electronic form in this final rule.

under the information access management standard, an access establishment and modification implementation specification reads: "implement policies and procedures that, based upon the entity's access authorization policies, establish, document, review, and modify a user's right of

the preamble of the Privacy Rule. Therefore, we are referring the reader to that document for a discussion of those issues. **2. Level of Detail** We solicited comments as to the level of detail expressed in the required implementation features; that is, we specifically wanted to know whether commenters believe the level of detail of any proposed requirement went beyond what is necessary or appropriate. We received numerous comments expressing the view that the security standards should not be overly prescriptive because the speed with which technology is evolving could make specific requirements obsolete and might in fact deter technological progress. We have accordingly written the final rule to frame the standards in terms that are as generic as possible and which, generally speaking, may be met through various approaches or technologies. **3. Implementation Specifications** In addition to adopting standards, this rule adopts implementation specifications that provide instructions for implementing those standards. However, in some cases, the standard itself includes all the necessary instructions for implementation. In these instances, there may be no corresponding implementation specification for the standard specifically set forth in the regulations text. In those instances, the standards	The entity must decide whether a given addressable implementation specification is a reasonable and appropriate security measure to apply within its particular security framework. This decision will depend on a variety of factors, such as, among others, the entity's risk analysis, risk mitigation strategy, what security measures are already in place, and the cost of implementation. Based upon this decision the following applies: (a) If a given addressable implementation specification is determined to be reasonable and appropriate, the covered entity must implement it. (b) If a given addressable implementation specification is determined to be an inappropriate and/or unreasonable security measure for the covered entity, but the standard cannot be met without implementation of an additional security safeguard, the covered entity may implement an alternate measure that accomplishes the same end as the addressable implementation specification. An entity that meets a given standard through alternative measures must document the decision not to implement the addressable implementation specification, the rationale behind that decision, and the alternative safeguard implemented to meet the standard. For example, the addressable implementation specification for the integrity standard calls for electronic mechanisms to corroborate that data have not been	access to a workstation, transaction, program, or process" (45 CFR 164.308(a)(4)(ii)(c)). It is possible that a small practice, with one or more individuals equally responsible for establishing and maintaining all automated patient records, will not need to establish policies and procedures for granting access to that electronic protected health information because the access rights are equal for all of the individuals. a. Comment: A large number of commenters indicated that mandating 69 implementation features would result in a regulation that is too burdensome, intrusive, and difficult to implement. These commenters requested that the implementation features be made optional to meet the requirements. A number of other commenters requested that all implementation features be removed from the regulation. Response: Deleting the implementation specifications would result in the standards being too general to understand, apply effectively, and enforce consistently. Moreover, a number of implementation specifications are so basic that no covered entity could effectively protect electronic protected health information without implementing them. We selected 13 of these mandatory implementation specifications based on (1) the expertise of Federal security experts and generally accepted industry practices and, (2) the recommendation

themselves also serve as the implementation specification. In other words, in those instances, we are adopting one set of instructions as both the standard and the implementation specification. The implementation specification would, accordingly, in those instances be required. In this final rule, we adopt both "required" and "addressable" implementation specifications. We introduce the concept of "addressable implementation specifications" to provide covered entities additional flexibility with respect to compliance with the security standards. In meeting standards that contain addressable implementation specifications, a covered entity will ultimately do one of the following: (a) Implement one or more of the addressable implementation specifications; (b) implement one or more alternative security measures; communication among trading partners. These include the Strategic National Implementation Process (SNIP) developed under the auspices of the Workgroup for Electronic Data Interchange (WEDI), an organization named in the HIPAA statute to consult with the Secretary of HHS on HIPAA issues. Some of these organizations have developed white papers, tools, and recommended best practices addressing a number of HIPAA issues, including security. Covered entities may wish to examine these products to determine if they	altered or destroyed in an unauthorized manner (see 45 CFR 164.312(c)(2)). In a small provider's office environment, it might well be unreasonable and inappropriate to make electronic copies of the data in question. Rather, it might well be more practical and afford a sufficient safeguard to make paper copies of the data. (c) A covered entity may also decide that a given implementation specification is simply not applicable (that is, neither reasonable nor appropriate) to its situation and that the standard can be met without implementation of an alternative measure in place of the addressable implementation specification. In this scenario, the covered entity must document the decision not to implement the addressable specification, the rationale behind that decision, and how the standard is being met. For example, http://www.snip.wedi.org. We believe that these and other future industry- developed guidelines and/or models may provide valuable assistance to covered entities implementing these standards but must caution that HHS does not rate or endorse any such guidelines and/or models and the value of its content must be determined by the user. **4. Examples** Comment: We received a number of comments that demonstrated confusion regarding the purpose of the examples of security solutions that were included throughout the proposed rule. Commenters stated that they	for immediate implementation of certain technical and organizational practices and procedures described in Chapter 6 of For The Record: Protecting Electronic Health Information, a 1997 report by the National Research Council (NRC). These mandatory implementation specifications are referred to as required implementation specifications and are reflected in the NRC report's recommendations. Risk Analysis and Risk management are found in the NRC recommendation title System Assessment; Sanction Policy is required in the Sanctions recommendation; Information system Activity Review is discussed in Audit Trails; Response and Reporting circumstances. In addition, a number of voluntary national and regional organizations have been formed to address HIPAA implementation issues and to facilitate external to the corporate entity. Electronic transmissions would include transactions using all media, even when the information is physically moved from one location to another using magnetic tape, disk, or other machine readable media. Transmissions over the Internet (wide-open), extranet (using Internet technology to link a business with information only accessible to collaborating parties), leased lines, dial-up lines, and private networks would be included. We proposed that telephone voice response and "faxback" systems (a request for

are relevant and useful in their own implementation efforts. A partial list of these organizations can be found at http://www.wedi/snip./org. We believe that these and other future industry-developed guidelines and/or models may provide valuable assistance to covered entities implementing these standards but must caution that HHS does not rate or endorse any such guidelines and/or models and the value of its content must be determine by the user. b. Comment: Many commenters asked us to develop guidelines and models to aid in complying with the Security Rule. Several commenters either offered to participate in the development of guidelines and models or suggested entities that should be invited to participate. Response: We agree that creation of compliance tools and guidelines for different business environments could assist covered entities to implement the HIPAA Security Rule. We plan to issue guidance documents after the publication of this final rule. However, it is critical for each covered entity to establish policies and procedures that address its own unique risks and circumstances. In addition, a number of voluntary national and regional organizations have been formed to address HIPAA implementation issues and to facilitate communication among trading partners. These include the Strategic National Implementation Process (SNIP) developed under the auspices of the Workgroup for	could not, or did not wish to, adopt various security measures suggested in examples. Other commenters asked that we include additional options within the examples. Some commenters referred specifically to the example provided in the proposed rule demonstrating how a small or rural provider might comply with the standards. One commenter asked for clarification that the examples are not mandatory measures that are required to demonstrate compliance, but are merely meant as a guide when implementing the security standards. Another commenter expressed support for the use of examples to clarify the intent of text descriptions. Response: We wish to clarify that examples are used only as illustrations of possible approaches, and are included to serve as a springboard for ideas. The steps that a covered entity will actually need to take to comply with these regulations will be dependent upon its own particular environment and circumstances and risk assessment. The examples do not describe mandatory measures, nor do they represent the only, or even the best, way of achieving compliance. The most appropriate means of compliance for any covered entity can only be determined by that entity assessing its own risks and deciding upon the measures that would best mitigate those risks. **B. Applicability (§164.302)** We proposed that the security	information made via voice using a fax machine and requested information returned via that same machine as a fax) would not be included but we solicited comments on this proposed exclusion. This final rule simplifies the applicability statement greatly. Section 164.302 provides that the security standards apply to covered entities; the scope of the information covered is specified in § 164.306 (see the discussion under that section below regarding the changes and revisions to the scope of information covered). 1. Comment: A number of commenters requested clarification of who must comply with the standards. The preamble and proposed § 142.102 and §142.302 stated: "Each person described in section 1172(a) of the Act who maintains or transmits health information shall maintain reasonable and appropriate administrative, technical, and physical safeguards." Commenters suggested that this statement is in conflict with the law, which defines a covered entity as a health plan, a clearinghouse, or a health care provider that conducts certain transactions electronically. The commentors apparently did not realize that section 1172(a) of the Act contains the definition of covered entities. Response: Section 164.302 below makes the security standards applicable to "covered entities." The term "covered entity" is defined at § 160.103 as one of the following: (1) A health plan; (2) a health care clearinghouse;

Electronic Data Interchange (WEDI), an organization named in the HIPAA statute to consult with the Secretary of HHS on HIPAA issues. Some of these organizations have developed white papers, tools, and recommended best practices addressing a number of HIPAA issues, including security. Covered entities may wish to examine these products to determine if they are relevant and useful in their own implementation efforts. A partial list of these organizations can be found at 2. Comment: Several commenters recommended expansion of applicability, either to other specific entities, or to all entities involved in health care. Others wanted to know whether the standards apply to entities such as employers, public health organizations, medical schools, universities, research organizations, plan brokers, or non-EDI providers. One commenter asked whether the standards apply to State data organizations operating in capacities other than as plans, clearinghouses, or providers. Still other commenters stated that it was inappropriate to include physicians and other health care professionals in the same category as plans and clearinghouses, arguing that providers should be subject to different, less burdensome requirements because they already protect health information. Response: The statute does not cover all health care entities that transmit or maintain individually	standards would apply to health plans, health care clearinghouses, and to health care providers that maintain or transmit health information electronically. The proposed security standards would apply to all electronic health information maintained or transmitted, regardless of format (standard transaction or a proprietary format). No distinction would be made between internal corporate entity communication or communication between what needs to be secured external to a corporation versus the security of data movement within an organization. Another stated that complying with the security standards for internal communications may prove difficult and costly to monitor and control. In contrast, one commenter stated that the existence of requirements should not depend on whether use of information is for internal or external purposes. Another commenter argued that the regulation goes beyond the intent of the law, and while communication of electronic information between entities should be covered, the law was never intended to mandate changes to an entity's internal automated systems. One commenter requested that raw data that are only for the internal use of a facility be excluded, provided that reasonable safeguards are in place to keep the raw data under the control of the facility. Response: Section 1173(d)(2) of the Act states: Each person described in section 1172(a)	(3) a health care provider who transmits any health information in electronic form in connection with a transaction covered by part 162 of title 45 of the Code of Federal Regulations (CFR). The rationale for the use and the meaning of the term “covered entity” is discussed in the preamble to the Privacy Rule (65 FR 82476 through 82477). As that discussion makes clear, the standards only apply to health care providers who engage electronically in the transactions for which standards have been adopted. other tests that determine whether a particular transaction is subject to those standards (see the discussion in the Transactions Rule at 65 FR 50316 through 50318). We also note that the Privacy Rule regulates a covered entity's use, as well as disclosure, of protected health information. 6. Comment: One commenter stated that research would be hampered if proposed §142.306(a) applied. The commenter believes that research uses of health information should be excluded or the standard should be revised to allow appropriate flexibility for research depending on the risk to patients or subjects (for example, if the information is anonymous, there is no risk, and it would not be necessary to meet the security standards). Response: If electronic protected health information is de- identified (as truly anonymous information would

identifiable health information. Section 1172(a) of the Act provides that only health plans, health care clearinghouses, and certain health care providers (as discussed above) are covered. With respect to the comments regarding the difference between providers and plans/clearinghouses, we have structured the Security Rule to be scalable and flexible enough to allow different entities to implement the standards in a manner that is appropriate for their circumstances. Regarding the coverage of entities not within the jurisdiction of HIPAA, see the Privacy Rule at 82567 through 82571. 3. Comment: One commenter asked whether the standards would apply to research organizations, both to those affiliated with health care providers and those that are not. Response: Only health plans, health care clearinghouses, and certain health care providers are required to comply with the security standards. Researchers who are members of a covered entity's work force may be covered by the security standards as part of the covered entity. See the definition of "workforce" at 45 CFR 160.103. Note, however, that a covered entity could, under appropriate circumstances, exclude a researcher or research division from its health care component or components (see §164.105(a)). Researchers who are not part of the covered entity's	who maintains or transmits health information shall maintain reasonable and appropriate administrative, technical, and physical safeguards–(A) to ensure the integrity and confidentiality of the information; (B) to protect against any reasonably anticipated–(i) threats or hazards to the security or integrity of the information; and (ii) unauthorized uses or disclosures of the information; and (C) otherwise to ensure compliance with this part by the officers and employees of such person. This language draws no distinction between internal and external data movement. Therefore, this final rule covers electronic protected health information at rest (that is, in storage) as well as during transmission. Appropriate protections must be applied, regardless of whether the data are at rest or being transmitted. However, because each entity's security needs are unique, the specific protections determined appropriate to adequately protect information will vary and will be determined by each entity in complying with the standards (see the discussion below). 5. Comment: Several commenters found the following statement in the proposed rule (63 FR 43245) at section II.A. confusing and asked for clarification: "With the exception of the security standard, transmission within a corporate entity would not be required to comply with the standards." Response: In the final	be), it is not covered by this rule because it is no longer electronic protected health information (see 45 CFR 164.502(d) and 164.514(a)). Electronic protected health information received, created, or maintained by a covered entity, or that is transmitted by covered entities, is covered by the security standards and must be protected. To the extent a researcher is a covered entity, the researcher must comply with these standards with respect to electronic protected health information. Otherwise, the conditions for release of such information to researchers is governed by the Privacy Rule. See, for example, 45 CFR 164.512(i), 164.514(e) and 164.502(d). These standards would not apply to the researchers as such in the latter circumstances. 7. Comment: One commenter asked to what extent individual patients are subject to the standards. For example, some telemedicine practices support the use of diagnostic systems in the patient's home, which can be used to conduct tests and send results to a remote physician. In other cases, patients may be responsible for the filing of insurance claims directly and will need the ability to verify facts, confirm receipt of claims, and so on. The commenter asked if it is the intent of the rule to include electronic transmission to or from the patient. Response: Patients are not covered entities and, thus, are not subject to these standards. With respect to transmissions from covered entities, covered

workforce and are not themselves covered entities are not subject to the standards. 4. Comment: Several commenters stated that internal networks and external networks should be treated differently. One commenter asked for further clarification of the difference **C. Transition to the Final Rule** The proposed rule included definitions for a number of terms that have now already been promulgated as part of the Transactions Rule or the Privacy Rule. Comments related to the definitions of "code set," "health care" clearinghouse," "health plan," "health care provider," "small health plan," "standard" and "transaction," are addressed in the Transactions Rule at 65 FR 50319 through 50320. Comments concerning the definition of "individually identifiable health information" are discussed below, but are also addressed in the Privacy Rule at 65 FR 82611 through 82613. In addition, a few terms were redefined in the final Standards for Privacy of Individually Identifiable Health Information (67 FR 53182), issued on August 14, 2002 (Privacy Modifications). Certain terms that were defined in the proposed rule are not used in the final rule because they are no longer necessary. Other terms defined in the proposed rule are defined within the explanation of the standards in the final rule and are discussed in the preamble	Transactions Rule, we revised our approach concerning the transaction and code set exemptions, replacing this concept with media" is used in the definition of "protected health information." Both the privacy and security standards apply to information "at rest" as well as to information being transmitted. We note that we have deleted the reference to § 162.103 in paragraph (1)(ii) of the definition of "protected health information," since both definitions, "electronic media" and "protected health information," have been moved to this section. Also, it is unnecessary, because the definitions of § 160.103 apply to all of the rule in parts 160, 162, and 164. We have also clarified that the physical movement of electronic media from place to place is not limited to magnetic tape, disk, or compact disk. This clarification removes a restriction as to what is considered to be physical electronic media, thereby allowing for future technological innovation. We further clarified that transmission of information not in electronic form before the transmission, for example, paper or voice, is not covered by this definition. § 164.103: The following term "plan sponsor" now appears in the new § 164.103, which consists of definitions of terms common to both subpart C and subpart E (the privacy standards). This definition was moved, without substantive	entities must protect electronic protected health information when they transmit that information. See also the discussion of encryption in section III.G. apply to both security and privacy, their definitions have been moved to § 164.103 without change. Those terms are discussed in the Privacy Rule at 65 FR 82502 through 82503 and at 67 FR 53203 through 53207. 1. Covered Entity (§ 160.103) Comment: One commenter asked if transcription services were covered entities. The question arose because transcription is often the first electronic or printed source of clinical information. Concern was expressed about the application of physical safeguard standards to the transcribers working for transcription companies or health care providers, either as employees or as independent contractors. Another commenter expressed concern that scalability was limited to only small providers. The commenter explained that Third Party Administrators (TPAs) allow claim processors to work at home. Some TPAs have noted that it would be impossible to comply with the security standards for home-based claims processors. Response: A covered entity's responsibility to implement security standards extends to the members of its workforce, whether they work at home or on-site. Because a covered entity is responsible for ensuring the security of the

discussions in § 164.308 through § 164.312. Definitions of terms relevant to the security standards now appear in the regulations text provisions as indicated below: § 160.103: Definitions of the following terms relevant to this rule appear in § 160.103: "business associate," "covered entity," "disclosure," "electronic media," "electronic protected health information," "health care," "health care clearinghouse," "health care provider," "health information," "health plan," "individual," "individually identifiable health information," "implementation specification," "organized health care arrangement," "protected health information," "standard," "use," and "workforce." These terms were discussed in connection with the Transaction and Privacy Rules and with the exception of the terms "covered entity" "disclosure" "electronic protected health information," "health information," "individual," "organized health care arrangement," "protected health information," and "use," we will not discuss them in this document. We note that the definition of those terms are not changed in the final rule. § 162.103: We have moved the definition of "electronic media" at § 162.103 to § 160.103 and have modified it to clarify that the term includes storage of information. The term "electronic 3. Health Information and Individually Identifiable Health Information 160.103) We note that the definitions of "health information" and	change, from § 164.501 and has the meaning given to it in that section, and comments relating to this definition are discussed in connection with that section in the Privacy Rule at 65 FR 82607, 82611 through 82613, 82618 through 82622, and 82629. § 164.304: Definitions specifically applicable to the Security Rule appear in § 164.304, and these are discussed below. These definitions are from, or derived from, currently accepted definitions in industry publications, such as, the International Organization for Standards (ISO) 7498-2 and the American Society for Testing and Materials (ASTM) E1762-95. The following terms in § 164.304 are taken from the proposed rule text or the glossary in Addendum 2 of the proposed rule (63 FR 43271), were not commented on, and/or are unchanged or have only minor technical changes for purposes of clarification and are not discussed below: "access," "authentication," "availability," "confidentiality," "encryption," "password," and "security." § 164.314: Four terms were defined in § 164.504(a) of the Privacy Rule ("common control," "common ownership," "health care component," and "hybrid entity"). Because these terms identifiable health information. Another stated that in § 142.306(b) of the proposed rule, "health information pertaining to an individual" should be changed to	information in its care, the covered entity must include "at home" functions in its security process. While an independent transcription company or a TPA may not be covered entities, they will be a business associate of the covered entity because their activities fall under paragraph (1)(i)(a) of the definition of that term. For business associate provisions see proposed preamble section III.E.8. and § 164.308(b)(1) and § 164.314(c) of this final rule. 2. Health Care and Medical Care (§ 160.103) Comment: One commenter asked whether "medical care," which is defined in the proposed rule, and "health care," which is not, are synonymous. Response: The term "medical care," as used in the proposed rule (63 FR 43242), was intended to be synonymous with "health care." The term ldquo;medical care" is not included in this final rule. It is, however, included in the definition of "health plan," where its meaning is not synonymous with "health care." For a full discussion of this issue and its resolution, see the Privacy Rule (65 FR 82578). asking that this term be defined. Response: This final rule defines "Security incident" in § 164.304 as "the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system."

"individually identifiable health information" remain unchanged from those published in the Transactions and Privacy Rules. a. Comment: A number of commenters asked that the definition of "health information" be expanded to include information collected by additional entities. Several commenters wanted the definition to include health information collected, maintained, or transmitted by any entity, and one commenter suggested the inclusion of aggregated information not identifiable to an individual. Several commenters asked that eligibility information be excluded from the definition of information. Several commenters wanted the definition broadened to include demographics. Response: Our definition of health information is taken from the definition in section 1171(4) of the Act, which provides that health information relates to the health or condition of an individual, the provision of health care to an individual, or payment for the provision of health care to an individual. The statutory definition also specifies the entities by which health information is created or received. We note that, because "individually identifiable health information" is a subset of "health information" and by statute includes demographic information, "health information" necessarily includes demographic information. We think this is	"individually identifiable health information," as nonidentifiable information can be used for utilization review and other purposes. As written, the regulation text could limit the ability to use data, for example, from a clearinghouse for compliance monitoring. Response: In general, we agree with these commenters, and note that these comments are largely mooted by the decision, reflected in § 164.306 below and discussed in section III.D.1. of this final rule, to cover only electronic protected health information in this final rule. c. Comment: Several commenters stated that the definition of "individually identifiable health information" is not in the regulations and should be added. Response: We note that the definition of "individually identifiable health information" appears at § 160.103, which applies to this final rule. 4. Protected Health Information (§160.103) This term is moved from § 164.501 to § 160.103 because it applies to both subparts C (security) and E (privacy). See 67 FR 53192 through 531936 regarding the definition of "protected health information." Also, the term "electronic media" is included in paragraphs (1)(i) and (ii) of the definition of "protected health information," as specified in this section. In addition, we added the definitions of "covered functions," "plan sponsor," and "Required by law" to §	8. System (§ 164.304) Comment: One commenter asked that "system" be defined. Response: This final rule defines "system," in the context of an information system, in § 164.304 as "an interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware, software, information, data, applications, communications, and people." 9. Workstation (§164.304) Comment: One commenter expressed concern that the use of the term "workstation" implied limited applicability to fixed devices (such as terminals), excluding laptops and other portable devices. Response: We have added a definition of the term "workstation" to clarify that portable devices are also included. This final rule defines workstation as "an electronic computing device, for example, a laptop or desktop computer, or any other device that performs similar functions, and electronic media stored in its immediate environment." 10. Definitions Not Adopted Several definitions in the proposed regulations text and glossary are not adopted as definitions in the final rule: " participant," "contingency plan," " risk," " role-based access control," and " user-based access control." The terms " participant," " role-based access control," and " user-based access control" are not used in this final rule and

clear as a matter of statutory construction and does not require further regulatory change. b. Comment: Several commenters asked that we clarify the difference between "health information" and "individually identifiable" and "health information pertaining to an individual" as used in the August 12, 1998 proposed rule (63 FR 43242). Additionally, commenters asked that we be more consistent in the use of these terms and recommended use of the term "individually identifiable health information." Two commenters stated that it is important to distinguish between "health information pertaining to an individual" and "individually identifiable health information," as in reporting statistics at various levels there will always be a need to bring forth information pertaining to an individual. One commenter recommended that the standards apply only to individually to providers. We received an equal number of comments stating that there is no need to define these terms. One commenter stated that definitions for these terms would be necessary only if special exemptions existed for small and rural providers. Several commenters suggested initiation of a study to determine limitations and potential barriers small and rural providers will have in implementing these regulations. Response: The statute	164.103. 5. Breach (§ 164.304) Comment: One commenter asked that "breach" be defined. Response: The term "breach" has been deleted and therefore not defined. Instead, we define the term "security incident," which better describes the types of situations we were referring to as breaches. 6. Facility (§ 164.304) This new term has been added as a result of changing the name of the "physical access control" standard to "facility access control." This change was made based on comments indicating that the original term was not descriptive. We have defined the term "facility" as the physical premises and interior and exterior of a building. 7. Security Incident (§ 164.304) Comment: We received comments **D. General Rules (§ 164.306)** In the proposed rule, we proposed to cover all health information maintained or transmitted in electronic form by a covered entity. We proposed to adopt, in § 142.308, a nation-wide security standard that would require covered entities to implement security measures that would be technology-neutral and scalable, and yet integrate all the components of security (administrative procedures, physical safeguards, technical security	thus are not defined. " Risk" is not defined as its meaning is generally understood. While we do not define the term, we address " contingency plan" as a standard in §164.308(a)(7) below. a. Comment: We received comments requesting that we define the following terms: " token" and " documentation." Response: These terms were defined in Addendum 2 of the proposed rule. In this final rule, we do not adopt a definition for " token" because it is not used in the final rule. " Documentation" is discussed in § 164.316 below. b. Comment: We received several comments that "small" and "rural" should be defined as those terms apply the standards. The administrative, physical, and technical safeguards a covered entity employs must be reasonable and appropriate to accomplish the tasks outlined in paragraphs (1) through (4) of § 164.306(a). Thus, an entity's risk analysis and risk management measures required by § 164.308(a)(1) must be designed to lead to the implementation of security measures that will comply with § 164.306(a). It should be noted that the implementation of reasonable and appropriate security measures also supports compliance with the privacy standards, just as the lack of adequate security can increase the risk of violation of the privacy standards. If, for example, a particular

requires that we address the needs of small and rural providers. We believe that we have done this through the provisions, which require the risk assessment and the response to be assessment based on the needs and capabilities of the entity. This scalability concept takes the needs of those providers into account and eliminates any need to define those terms. c. Comment: In the proposed rule, we proposed the following definition for the term "Access control": "A method of restricting access to resources, allowing only privileged entities access. Types of access control include, among others, mandatory access control, discretionary access control, time-of-day, classification, and subject- object separation." One commenter believed the proposed definition is too restrictive and requested revision of the definition to read: "Access control refers to a method of restricting access to resources, allowing access to only those entities which have been specifically granted the desired access rights." Another commenter wanted the definition expanded to include partitioned rule-based access control (PRBAC). Response: We agree with the commenter who suggested that the definition as proposed seemed too restrictive. In this case, as in many others, a number of commenters believed the examples given in the proposed rule provided the only acceptable compliance actions. As previously noted, in order to clarify that the	services, and technical security mechanisms) that must be in place to preserve health information confidentiality, integrity, and availability (three basic elements of security). Since no comprehensive, scalable, and technology-neutral set of standards currently exists, we proposed to designate a new standard, which would define the security requirements to be fulfilled. The proposed rule proposed to define the security standard as a set of scalable, technology-neutral requirements with implementation features that providers, plans, and clearinghouses would have to include in their operations to ensure that health information pertaining to an individual that is electronically maintained or electronically transmitted remains safeguarded. The proposed rule would have required that each affected entity assess its own security needs and risks and devise, implement, and maintain appropriate security to address its own unique security needs. How individual security requirements would be satisfied and which technology to use would be business decisions that each entity would have to make. In the final rule we adopt this basic framework. In § 164.306, we set forth general rules pertaining to the security standards. In paragraph (a), we describe the general requirements. Paragraph (a) generally reflects section 1173(d)(2) of the Act, but makes explicit the connection between the security	safeguard is inadequate because it routinely permits reasonably anticipated uses or disclosures of electronic protected health information that are not permitted by the Privacy Rule, and that could have been prevented by implementation of one or more security measures appropriate to the scale of the covered entity, the covered entity would not only be violating the Privacy Rule, but would also not be in compliance with § 164.306(a)(3) of this rule. Paragraph (d) of § 164.306 establishes two types of implementation specifications, required and addressable. It provides that required implementation specifications must be met. However, with respect to implementation specifications that are addressable, § 164.306(d)(3) specifies that covered entities must assess whether an implementation specification is a reasonable and appropriate safeguard in its environment, which may include consideration of factors such as the size and capability of the organization as well as the risk. If the organization determines it is a reasonable and appropriate safeguard, it must implement the specification. If an addressable implementation specification is determined not to be a reasonable and appropriate answer to a covered entity's security needs, the covered entity must do one of two things: implement another equivalent measure if reasonable and appropriate; or if the standard can otherwise be met, the covered entity may choose to

examples listed were not to be considered all-inclusive, we have generalized the proposed requirements in this final rule. In this case, we have also generalized the requirements and placed the substantive provisions governing access control at § 164.308(a)(4), § 164.310(a)(1), and § 164.312(a)(1). With respect to PRBAC, the access control standard does not exclude this control, and entities should adopt it if appropriate to their circumstances. implemented by reviewing and modifying the measures as needed to continue the provision of reasonable and appropriate protections, for example, as technology moves forward, and as new threats or vulnerabilities are discovered. 1. Scope of Health Information Covered by the Rule (§ 164.306(a)) We proposed to cover health information maintained or transmitted by a covered entity in electronic form. We have modified, by narrowing, the scope of health information to be safeguarded under this rule from that which was proposed. The statute requires the privacy standards to cover individually identifiable health information. The Privacy Rule covers all individually identifiable information except for: (1) Education records covered by the Family and Educational Rights and Privacy Act (FERPA); (2) records described in 20 U.S.C. 1232g(a)(4)(B)(iv); and (3) employment records. (see the Privacy Rule at 65 FR 82496.	standards and the privacy standards (see § 164.306(a)(3)). In § 164.306(a)(1), we provide that the security standards apply to all electronic protected health information the covered entity creates, receives, maintains, or transmits. In paragraph (b)(1), we provide explicitly for the scalability of this rule by discussing the flexibility of the standards, and paragraph (b)(2) of § 164.306 discusses various factors covered entities must consider in complying with the standards. The provisions of § 164.306(c) provide the framework for the security standards, and establish the requirement that covered entities must comply with meaning of these rules and, thus, does not come within the definition of "protected health information." It accordingly is not covered by this final rule. For a full discussion of the issues of de-identification and re-identification of individually identifiable health information see 65 FR 82499 and 82708 through 82712 and 67 FR 53232 through 53234. b. Comment: Several commenters asked whether systems that determine eligibility of the covered entity for insurance coverage under broad categories such as medical coverage groups are considered health information. One commenter asked that we specifically exclude eligibility information from the standards. Response: We cannot accept the latter suggestion. Eligibility information will typically be	not implement the implementation specification or any equivalent alternative measure at all. The covered entity must document the rationale behind not implementing the implementation specification. See the detailed discussion in section II.A.3. Paragraph (e) of § 164.306 addresses the requirement for covered entities to maintain the security measures those systems included, on the grounds that inclusion is necessary for consistency and in keeping with the intent of the Act. Still others specifically wanted personal computer-fax transmissions included. One commenter asked for clarification of when we would cover faxes, and another commenter asked why we were excluding them. Several commenters suggested that the other security requirements provide for adequate security of these systems. Response: In light of these comments, we have decided that telephone voice response and "faxback" (that is, a request for information from a computer made via voice or telephone keypad input with the requested information returned as a fax) systems fall under this rule because they are used as input and output devices for computers, not because they have computers in them. Excluding these features would provide a huge loophole in any system concerned with security of the information contained and/or processed therein. It should be noted that employment of

See also 67 FR 53191 through 53193). The scope of information covered in the Privacy Rule is referred to as "protected health information." Based upon the comments we received, we align the requirements of the Security and Privacy Rules with regard to the scope of information covered, in order to eliminate confusion and ease implementation. Thus, this final rule requires protection of the same scope of information as that covered by the Privacy Rule, except that it only covers that information if it is in electronic form. We note that standards for the security of all health information or protected health information in nonelectronic form may be proposed at a later date. a. Comment: One commenter stated that the rule should apply to aggregate information that is not identifiable to an individual. In contrast, another commenter asked that health information used for statistical analysis be exempted if the covered entity may reasonably expect that the removed information cannot be used to re-identify an individual. Response: As a general proposition, any electronic protected health information received, created, maintained, or transmitted by a covered entity is covered by this final rule. We agree with the second commenter that certain information, from which identifiers have been stripped, does not come within the purview of this final rule. Information that is de-identified, as defined in the	individually identifiable, and much eligibility information will also contain health information. If the information is "individually identifiable" and is "health information," (with three very specific exceptions noted in the general discussion above) and it is in electronic form, it is covered by the security standards if maintained or transmitted by a covered entity. c. Comment: Several commenters requested clarification as to whether the standards apply to identifiable health information in paper form. Some commenters believed the rule should be applicable to paper; others argued that it should apply to all confidential, identifiable health information. Response: While we agree that protected health information in paper or other form also should have appropriate security protections, the proposed rule proposing the security standards proposed to apply those standards to health information in electronic form only. We are, accordingly, not extending the scope in this final rule. We may establish standards to secure protected health information in other media in a future rule, in accordance with our statutory authority to do so. See discussion, supra, responding to a comment on the definition of "health information" and "individually identifiable health information." d. Comment: The proposed rule would have excluded "telephone voice response"	telephone voice response and/or faxback systems will generally require security protection by only one of the parties involved, and not the other. Information being transmitted via a telephone (either by voice or a DTMP tone pad) is not in electronic form (as defined in the first paragraph of the definition of "electronic media") before transmission and therefore is not subject to the Security Rule. Information being returned via a telephone voice response system in response to a telephone request is data that is already in electronic form and stored in a computer. This latter transmission does require protection under the Security Rule. Although most recently made electronic devices contain microprocessors (a form of computer) controlled by firmware (an unchangeable form of computer program), we intend the term "computer" to include only software programmable computers, for example, personal computers, minicomputers, and mainframes. Copy machines, fax machines, and telephones, even those that contain memory and can produce multiple copies for multiple people are not intended to be included in the term "computer." Therefore, because "paper-to-paper" faxes, person-to- person telephone calls, video teleconferencing, or messages left on voice-mail were not in electronic form before the transmission, those activities are not covered by this rule. See also the definition of "electronic media" at §

Privacy Rule at § 164.502(d) and § 164.514(a), is not "individually identifiable" within the We note that this guidance differs from the guidance regarding the applicability of the Transactions Rule to faxback and voice response systems. HHS has stated that faxback and voice response systems are not required to follow the standards mandated in the Transactions Rule. This new guidance refers only to this rule. e. Comment: One commenter asked whether there is a need to implement special security practices to address the shipping and receiving of health information and asked that we more fully explain our expectations and solutions in the final rules. Response: If the handling of electronic protected health information involves shipping and receiving, appropriate measures must be taken to protect the information. However, specific solutions are not provided within this rule, as discussed in section **III.A.3 of this final rule. The device and media controls standard under § 164.310(d)(1) addresses this situation.** f. Comment: One commenter wanted the "HTML" statement reworded to eliminate a specific exemption for HTML from the regulation. Response: The Transactions Rule did not adopt the proposed exemption for HTML. The use of HTML or any other electronic protocol is not exempt from the security	and "faxback" systems from the security standards, and we specifically solicited comments on that issue. A number of commenters agreed that telephone voice response and faxback should be excluded from the regulation, suggesting that the privacy standards rather than the security standards should apply. Others wanted access to the information or is authorized to have access. Response: The issue of re-identification is addressed in the Privacy Rule at § 164.502(d) and § 164.514(c). The reader is referred to those sections and the related discussion in the preamble to the Privacy Rule (65 FR 82712) and the preamble to the Privacy Modifications (67 FR 53232 through 53234) for a full discussion of the issues of re-identification. We note that once information in the possession (or constructive possession) of a covered entity is re- identified and meets the definition of electronic protected health information, the security standards apply. 2. Technology-Neutral Standards Comment: Many commenters expressed support for our efforts to develop standards for the security of health information. A number of comments were made in support of the technology-neutral approach of the proposed rule. For example, one commenter stated, "By avoiding prescription of the specific technologies health care entities should use to	160.103. information; and (3) ensuring its availability to those authorized to access the information. The standards do not allow organizations to make their own rules, only their own technology choices. 3. Miscellaneous Comments a. Comment: Some commenters stated that the requirements and implementation features set out in the proposed rule were not specific enough to be considered standards, and that the actual standards are delegated to the discretion of the covered entities, at the expense of medical record privacy. Several commenters stated that it was inappropriate to balance the interests of those seeking to use identifiable medical information without patient consent against the interest of patients. Several other commenters believe that allowing covered entities to make their own decisions about the adequacy and balance of security measures undermined patient confidentiality interests, and stated that the proposed rule did not appear to adequately consider patient concerns and viewpoints. Response: Again, the overwhelming majority of commenters supported our approach. This final rule sets forth requirements with which covered entities must comply and labels those requirements as standards and implementation specifications. Adequate implementation of this final rule by covered entities will ensure that the

standards. Generally, if protected health information is contained in any form of electronic transmission, it must be appropriately safeguarded. g. Comment: One commenter asked to what degree “family history” is considered health information under this rule and what protections apply to family members included in a patient's family history. Response: Any health-related “family history” contained in a patient's record that identifies a patient, including a person other than the patient, is individually identifiable health information and, to the extent it is also electronic protected health information, must be afforded the security protections. h. Comment: Two commenters asked that the rule prohibit re- identification of de-identified data. In contrast, several commenters asked that we identify a minimum list or threshold of specific re-identification data elements (for example, name, city, and ZIP) that would fall under this final rule so that, for example, the rule would not affect numerous systems, for example, network adequacy and population-based clinical analysis databases. One commenter asked that we establish a means to use re-identified information if the entity already has adversely affect a provider's practice environment. Response: The HIPAA statute requires us to promulgate a rule adopting security standards for health information. Resource	meet the law's requirements, you are opening the door for industry to apply innovation. Technologies that don't currently exist or are impractical today could, in the near future, enhance health information security while minimizing the overall cost.” Several other commenters stated that the requirements should be general enough to withstand changes to technology without becoming obsolete. One commenter anticipates no problems with meeting the standards. In contrast, one commenter suggested that whenever possible, specific technology recommendations should provide sufficient detail to promote systems interoperability and decrease the tendency toward adoption of multiple divergent standards. Several commenters stated that by letting each organization determine its own rules, the rules impose procedural burdens without any substantive benefit to security. Response: The overwhelming majority of comments supported our position. We do not believe it is appropriate to make the standards technology-specific because technology is simply moving too fast, for example, the increased use and sophistication of internet-enabled hand held devices. We believe that the implementation of these rules will promote the security of electronic protected health information by (1) providing integrity and confidentiality; (2) allowing only authorized	electronic protected health information in a covered entity's care will be as protected as is feasible for that entity. We disagree that covered entities are given complete discretion to determine their security polices under this rule, resulting in effect, in no standards. While cost is one factor a covered identity may consider in determining whether to implement a particular implementation specification, there is nonetheless a clear requirement that adequate security measures be implemented, see 45 CFR 164.306(b). Cost is not meant to free covered entities from this responsibility. b. Comment: Several commenters requested we withdraw the regulations, citing resource shortages due to Y2K preparation, upcoming privacy legislation, and/or the “excessive micro-management” contained in the rules. One commenter stated that, to insurers, these rules were onerous, not necessary, and not justified as cost-effective, as they already have effective practices for computer security and are subject to rigorous State laws for the safeguarding of health information. Another commenter stated that these rules would health plans, clearinghouses, vendors, and government programs participated actively. The NCVHS developed recommendations to the Secretary, which were relied upon as we developed the proposed rule. Finally, we note

concerns due to Y2K should no longer be an issue. Covered entities will have 2 years (or, in the case of small health plans, 3 years) from the adoption of this final rule in which to comply. Concerns relative to effective and compliance dates and the Privacy Rule are discussed under § 164.318, Compliance dates for initial implementation, below and at 65 FR 82751 through 82752. We disagree that these standards will adversely affect a provider's practice environment. The scalability of the standards allows each covered entity to implement security protections that are appropriate to its specific needs, risks, and environments. These protections are necessary to maintain the confidentiality, integrity, and availability of patient data. A covered entity that lacks adequate protections risks inadvertent disclosure of patient data, with resulting loss of public trust, and potential legal action. For example, a covered entity with poor facility access controls and procedures would be susceptible to hacking of its databases. A provider with appropriate security protections already in place would only need to ensure that the protections are documented and are reassessed periodically to ensure that they continue to be appropriate and are actually being implemented. Our decision to classify many implementation specifications as addressable, rather than mandatory, provides even more flexibility to covered	individuals access to that consulted extensively with experts in the field of security throughout the health care industry. The standards are consistent with generally accepted security principles and practices that are already in widespread use. Data back-up need not result in increased access to that data. Backups should be stored in a secure location with controlled access. The appropriate secure location and access control will vary, based upon the security needs of the covered entity. For example, a procedure as simple as locking back-up diskettes in a safe place and restricting who has access to the key may be suitable for one entity, whereas another may need to store backed-up information off-site in a secure computer facility. The information provided in security awareness training heightens awareness of security anomalies and helps to prevent security incidents. d. Comment: Several commenters suggested that the proposed rule appears to reflect the Medicare program's perspective on security risks and solutions, and that it should be noted that not all industry segments share all the same risks as Medicare. One commenter stated that as future proposed rules are drafted, we should solicit input from those most significantly affected, for example, providers, plans, and clearinghouses. Others stated that Medicaid agencies were not sufficiently	that the opportunity to comment was available to all during the public comment period. e. Comment: One commenter stated that there is a need to ensure the confidentiality of risk analysis information that may contain sensitive information. Response: The information included in a risk analysis would not be subject to the security standards if it does not include electronic protected health information. We agree that risk analysis data could contain sensitive information, just as other business information can be sensitive. Covered entities may wish to develop their own business rules regarding access to and protections for risk analysis data. f. Comment: One commenter expressed concern over the statement in the preamble of the proposed rule (63 FR 43250) that read: “No one item is considered to be more important than another.” The commenter suggested that security management should be viewed as most critical and perhaps what forms the foundation for all other security actions. Response: The majority of comments received on this subject requested that we prioritize the standards. In response, we have regrouped the standards and implementation specifications in what we believe is a logical order within each of three categories: “Administrative safeguards,” “Physical safeguards,” and “Technical

entities to develop cost-effective solutions. We believe that insurers who already have effective security programs in place will have met many of the requirements of this regulation. c. Comment: One commenter believes the rule is arbitrary and capricious in its requirements without any justification that they will significantly improve the security of medical records and with the likelihood that their implementation may actually increase the vulnerability of the data. The commenter noted that the data back-up requirements increase access to data and that security awareness training provides more information to employees. Response: The standards are based on generally accepted security procedures, existing industry standards and guidelines, and recommendations contained in the National Research Council's 1997 report For The Record: Protecting Electronic Health Information, Chapter 6. We also Response: We agree. Section 164.308 of this final rule describes administrative safeguards that address these topics. Section 164.308 requires covered entities to implement standards and required implementation specifications, as well as consider and implement, when appropriate and reasonable, addressable implementation specifications. For example, the security management process standard requires implementation of a risk	involved in the discussions and debate. Still another stated that States would be unable to perform some basic business functions if all the standards are not designed to meet their needs. Response: We believe that the standards are consistent with common industry practices and equitable, and that there has been adequate consultation with interested parties in the development of the standards. These standards are the result of an intensive process of public consultation. We consulted with the National Uniform Billing Committee, the National Uniform Claim Committee, the American Dental Association, and the Workgroup for Electronic Data Interchange, in the course of developing the proposed rule. Those organizations were specifically named in the Act to advise the Secretary, and their membership is drawn from the full spectrum of industry segments. In addition, the National Committee on Vital and Health Statistics (NCVHS), an independent advisory group to the Secretary, held numerous public hearings to obtain the views of interested parties. Again, many segments of the health care industry, including provider groups, j. Comment: One commenter suggested we include a revised preamble in the final publication. Another questioned how clarification of points in the preamble will be handled if the preamble is not part of the final regulation. Response: Preambles to	safeguards." In this final rule, we order the standards in such a way that the "Security management process" is listed first under the "Administrative safeguards" section, as we believe this forms the foundation on which all of the other standards depend. The determination of the specific security measures to be implemented to comply with the standards will, in large part, be dependent upon completion of the implementation specifications within the security management process standard (see § 164.308(a)(1)). We emphasize, however, that an entity implementing these standards may choose to implement them in any order, as long as the standards are met. g. Comment: One commenter stated that there is a need for requirements concerning organizational practices (for example, education, training, and security and confidentiality policies), as well as technical practices and procedures. "standards" must have been developed by ANSI-recognized Standards Development Organizations (SDOs). Response: In general, HHS is required to adopt standards developed by ANSI-accredited SDOs when such standards exist. The currently existing security standards developed by ANSI-recognized SDOs are targeted to specific technologies and/or activities. No existing security standard, or group of standards, is

analysis, risk management, a sanction policy, and an information system activity review. The information access management standard requires consideration, and implementation where appropriate and reasonable, of access authorization and access establishment and modification policies and procedures. Other areas addressed are assigned security responsibility, workforce security, security awareness and training, security incident procedures, contingency planning, business associate contracts, and evaluation. h. Comment: One commenter stated that internal and external security requirements should be separated and dealt with independently. Response: The presentation of the standards within this final rule could have been structured in numerous ways, including by addressing separate internal and external security standards. We chose the current structure as we considered it a logical breakout for purposes of display within this final rule. Under our structure a covered entity may apply a given standard to internal activities and to external activities. Had we displayed separately the standards for internal security and the standards for external security, we would have needed to describe a number of the standards twice, as many apply to both internal and external security. However, a given entity may address the standards in whatever order it chooses, as	proposed rules are not republished in the final rule. The preamble in this final rule contains summaries of the information presented in the preamble of the proposed rule, summaries of the comments received during the public comment period, and responses to questions and concerns raised in those comments and a summary of changes made. Additional clarification will be provided by HHS on an ongoing basis through written documents and postings on HHS's websites. k. Comment: One commenter asked that we clarify that no third party can require implementation of more security features than are required in the final rule, for example, a third party could not require encryption but may choose to accept it if the other party so desires. Response: The security standards establish a minimum level of security to be met by covered entities. It is not our intent to limit the level of security that may be agreed to between trading partners or others above this floor. l. Comment: One commenter asked how privacy legislation would affect these rules. The commenter inquired whether covered entities will have to reassess and revise actions already taken in the spirit of compliance with the security regulations. Response: We cannot predict if or how future legislation may affect the rules below. At present, the privacy standards at subpart E of 42 CFR part	technology-neutral, scaleable to the extent required by HIPAA, and broad enough to be adopted in this final rule. Therefore, this final rule adopts standards under section 1172(c)(2)(B) of the Act, which permits us to develop standards when no industry standards exist. o. Comment: One commenter stated that this regulation goes beyond the scope of the law, unjustifiably extending into business practices, employee policies, and facility security. Response: We do not believe that this regulation goes beyond the scope of the law. The law requires HHS to adopt standards for reasonable and appropriate security safeguards concerning such matters as compliance by the officers and employees of covered entities, protection against reasonably anticipated unauthorized uses and disclosures of health information, and so on. Such standards will inevitably address the areas the commenter pointed to. The intent of this regulation is to provide standards for the protection of electronic protected health information in accordance with the Act. In order to do this, covered entities are required to implement administrative, physical, and technical safeguards. Those entities must ensure that data are protected, to the extent feasible, from inappropriate access, modification, dissemination, and destruction. As noted above, however, this final rule has been modified to increase

long as the standards are met.

i. Comment: Two commenters stated that the standards identified in Addendum 3 of the proposed rule may not all have matured to implementation readiness.

Response: Addendum 3 of the proposed rule cross-referred individual requirements on the matrix to existing industry standards of varying levels of maturity. Addendum 3 was intended to show what we evaluated in searching for existing industry standards that could be adopted on a national level. No one standard was found to be comprehensive enough to be adopted, and none were proposed as the standards to be met under the Security Rule.

However, we have relocated material that relates to both security and privacy (including definitions) to the general section of part 164.

q. Comment: One commenter asked that data retention be addressed more specifically, since this will become a significant issue over time. It is recommended that a national work group be convened to address this issue.

Response: The commenter's concern is noted. While the documentation relating to Security Rule implementation must be retained for a period of 6 years (see § 164.316(b)(2)), it is not within the scope of this final rule to address data retention time frames for administrative or clinical records.

r. Comment: One commenter stated that requiring provider

164 have been adopted, and this final rule is compatible with them.

m. Comment: One commenter stated that a data classification policy, that is a method of assigning sensitivity ratings to specific pieces of data, should be part of the final regulations.

Response: We did not adopt such a policy because this final rule requires a floor of protection of all electronic protected health information. A covered entity has the option to exceed this floor. The sensitivity of information, the risks to and vulnerabilities of electronic protected health information and the means that should be employed to protect it are business determinations and decisions to be made by each covered entity.

n. Comment: One commenter stated that this proposed rule conflicts with previously stated rules that acceptable

information in its keeping, we intend that a covered entity take steps, to the best of its ability, to protect that information. This will involve establishing a balance between the information's identifiable risks and vulnerabilities, and the cost of various protective measures, and will also be dependent upon the size, complexity, and capabilities of the covered entity, as provided in § 164.306(b).

E. Administrative Safeguards (§ 164.308)

We proposed that measures taken to comply with the rule

flexibility as to how this protection is accomplished.

p. Comment: One commenter stated that all sections regarding confidentiality and privacy should be removed, since they do not belong in this regulation.

Response: As the discussion in section III.A above of this final rule makes clear, the privacy and security standards are very closely related. Section 1173(d)(2) of the Act specifically mentions "confidentiality" and authorizes uses and disclosures of information as part of what security safeguards must address. Thus, we cannot omit all references to confidentiality and privacy in discussions of the security standards.

system activity (for example, logins, file accesses, and security incidents) maintained by an entity.

In this final rule, risk analysis, risk management, and sanction policy are adopted as required implementation specifications although some of the details are changed, and the proposed internal audit requirement has been renamed as "information system activity review" and incorporated here as an additional implementation specification.

a. Comment: Three commenters asked that this requirement be deleted. Two commenters cited this requirement as a possible burden. Several commenters asked that the implementation features be made optional.

Response: This standard and its component implementation

practices to develop policies, procedures, and training programs and to implement record keeping and documentation systems would be tremendously resource-intensive and increase the costs of health care. Response: We expect that many of the standards of this final rule are already being met in one form or another by covered entities. For example, as part of normal business operations, health care providers already take measures to protect the health information in their keeping. Health care providers already keep records, train their employees, and require employees to follow office policies and procedures. Similarly, health plans are already frequently required by State law to keep information confidential. While revisions to a practice's or plan's current activities may be necessary, the development of entirely new systems or procedures may not be necessary. s. Comment: One commenter stated that there is no system for which risk has been eliminated and expressed concern over phrases such as covered entities must "assure that electronic health information pertaining to an individual remains secure." Response: We agree with the commenter that there is no such thing as a totally secure system that carries no risks to security. Furthermore, we believe the Congress' intent in the use of the word "ensure" in section 1173(d) of the Act was to set an exceptionally high goal for the security of	be appropriate to protect the health information in a covered entity's care. Most importantly, we proposed to require that both the measures taken and documentation of those measures be kept current, that is, reviewed and updated periodically to continue appropriately to protect the health information in the care of covered entities. We would have required the documentation to be made available to those individuals responsible for implementing the procedure. We proposed a number of administrative requirements and supporting implementation features, and required documentation for those administrative requirements and implementation features. In this final rule, we have placed these administrative standards in §164.308. We have reordered them, deleted much of the detail of the proposed requirements, as discussed below, and omitted two of the proposed sets of requirements (system configuration requirements and a requirement for a formal mechanism for processing records) as discussed in paragraph 10 of the discussion of §164.308 of section III.E. of this preamble. Otherwise, the basic elements of the administrative safeguards are adopted in this final rule as proposed. 1. Security Management Process (§164.308(a)(1)(i)) We proposed the establishment of a formal security management process to involve the creation,	specifications form the foundation upon which an entity's necessary security activities are built. See NIST SP 800-30, "Risk Management Guide for Information Technology Systems," chapters 3 and 4, January 2002. An entity must identify the risks to and vulnerabilities of the information in its care before it can take effective steps to eliminate or minimize those risks and vulnerabilities. Some form of sanction or punishment activity must be instituted for noncompliance. Indeed, we question how the statutory requirement for safeguards "to ensure compliance * * * by a [covered entity's] officers and employees" could be met without a requirement for a sanction policy. See section 1176(d)(2)(C) of the Act. Accordingly, implementation of these specifications remains mandatory. However, it is important to note that covered entities have the flexibility to implement the standard in a manner consistent with numerous factors, including such things as, but not limited to, their size, degree of risk, and environment. We have deleted the implementation specification calling for an organizational security policy, as it duplicated requirements of the security management and training standard. We note that the implementation specification for a risk analysis at § 164.308(a)(1)(ii)(A) does not specifically require that a covered entity perform a risk analysis often enough to ensure that its security measures are adequate to

electronic protected health information. However, we note that the Congress also recognized that some trade-offs would be necessary, and that "ensuring" protection did not mean providing protection, no matter how expensive. See section 1173(d)(1)(A)(ii) of the Act. Therefore, when we state that a covered entity must ensure the safety of the in general that must be periodically reassessed and updated as needed. The risk analysis implementation specification contains other terms that merit explanation. Under §164.308(a)(1)(ii)(A), the risk analysis must look at risks to the covered entity's electronic protected health information. A thorough and accurate risk analysis would consider "all relevant losses" that would be expected if the security measures were not in place. "Relevant losses" would include losses caused by unauthorized uses and disclosures and loss of data integrity that would be expected to occur absent the security measures. b. Comment: Relative to the development of an entity's sanction policy, one commenter asked that we describe the sanction penalties for breach of security. Another suggested establishment of a standard to which one's conduct could be held and adoption of mitigating circumstances so that the fact that a person acted in good faith would be a factor that could be used to reduce or otherwise minimize any sanction imposed. Another	administration, and oversight of policies to address the full range of security issues and to ensure the prevention, detection, containment, and correction of security violations. This process would include implementation features consisting of a risk analysis, risk management, and sanction and security policies. We also proposed, in a separate requirement under administrative procedures, an internal audit, which would be an in-house review of the records of suggest that the smaller amount of data would be considered more sensitive. Response: All electronic protected health information must be protected at least to the degree provided by these standards. If an entity desires to protect the information to a greater degree than the risk analysis would indicate, it is free to do so. e. Comment: One commenter asked that we add "threat assessment" to this requirement. Response: We have not done this because we view threat assessment as an inherent part of a risk analysis; adding it would be redundant. f. Comment: We proposed a requirement for internal audit, the in- house review of the records of system activity (for example, logins, file accesses, and security incidents) maintained by an entity. Several commenters wanted this requirement deleted. One suggested the audit trail requirement should not be	provide the level of security required by §164.306(a). In the proposed rule, an assurance of adequate security was framed as a requirement to keep security measures "current." We continue to believe that security measures must remain current, and have added regulatory language in §164.306(e) as a more precise way of communicating that security measures be renamed for clarity and that it should actually be an implementation specification of the security management process rather than an independent standard. We accordingly remove "internal audit" as a separate requirement and add "information system activity review" under the security management process standard as a mandatory implementation specification. 2. Assigned Security Responsibility (§ 164.308(a)(2)) We proposed that the responsibility for security be assigned to a specific individual or organization to provide an organizational focus and importance to security, and that the assignment be documented. Responsibilities would include the management and supervision of (1) the use of security measures to protect data, and (2) the conduct of personnel in relation to the protection of data. In this final rule, we clarify that the final responsibility for a covered entity's security must be assigned to one

commenter suggested sanction activities not be implemented before the full implementation and testing of all electronic transaction standards. Response: The sanction policy is a required implementation specification because--(1) the statute requires covered entities to have safeguards to ensure compliance by officers and employees; (2) a negative consequence to noncompliance enhances the likelihood of compliance; and (3) sanction policies are recognized as a usual and necessary component of an adequate security program. The type and severity of sanctions imposed, and for what causes, must be determined by each covered entity based upon its security policy and the relative severity of the violation. c. Comment: Commenters requested the definitions of "risk analysis" and "breach." Response: "Risk analysis" is defined and described in the specification of the security management process standard, and is discussed in the preamble discussion of § 164.308(a)(1)(ii)(A) of this final rule. The term breach is no longer used and is, therefore, not defined. d. Comment: One commenter asked whether all health information is considered equally "sensitive," the thought being that, in determining risk, an entity may consider the loss of a smaller amount of extraordinarily sensitive data to be more significant than the loss of a	mandatory, while another stated that internal audits would be unnecessary if physical security requirements are implemented. A number of commenters asked that we clarify the nature and scope of what an internal audit covers and what the audit time frame should be. Several commenters offered further detail concerning what should and should not be required in an internal audit for security purposes. One commenter stated that ongoing intrusion detection should be included in this requirement. Another wanted us to specify the retention times for archived audit logs. Several commenters had difficulty with the term "audit" and suggested we change the title of the requirement to "logging and violation monitoring." A number of commenters stated this requirement could result in an undue burden and would be economically unfeasible. Response: Our intent for this requirement was to promote the periodic review of an entity's internal security controls, for example, logs, access reports, and incident tracking. The extent, frequency, and nature of the reviews would be determined by the covered entity's security environment. The term "internal audit" apparently, based on the comments received, has certain rigid formal connotations we did not intend. We agree that the implementation of formal internal audits could prove	official. The requirement for documentation is retained, but is made part of §164.316 below. This policy is consistent with the analogous policy in the Privacy Rule, at 45 CFR 164.530(a), and the same considerations apply. See 65 FR 82744 through 87445. The same person could fill the role for both security and privacy. a. Comment: Commenters were concerned that delegation of assigned security responsibility, especially in large organizations, needs to be to more than a single individual. Commenters believe that a large health organization's security concerns would likely cross many departmental boundaries requiring group responsibility. Response: The assigned security responsibility standard adopted in this final rule specifies that final security responsibility must rest with one individual to ensure accountability within each covered entity. More than one individual may be given specific security responsibilities, especially within a large organization, but a single individual must be designated as having the overall final responsibility for the security of the entity's electronic protected health information. This decision also aligns this rule with the final Privacy Rule provisions concerning the Privacy Official. b. Comment: One commenter disagreed with placing assigned security responsibility as part of physical safeguards. The commenter suggested that

larger amount of routinely collected data. The commenter stated that common reasoning would Response: Upon review of the matrix and regulations text, we agree with the commenter, because this requirement involves an administrative decision at the highest levels of who should be responsible for ensuring security measures are implemented and maintained. Assigned security responsibility has been removed from "Physical safeguards" and is now located under "Administrative safeguards" at § 164.308. 3. Workforce Security (§164.308(a)(3)(i)) We proposed implementation of a number of features for personnel security, including ensuring that maintenance personnel are supervised by a knowledgeable person, maintaining a record of access authorizations, ensuring that operating and maintenance personnel have proper access authorization, establishing personnel clearance procedures, establishing and maintaining personnel security policies and procedures, and ensuring that system users have proper training. In this final rule, to provide clarification and reduce duplication, we have combined the "Assure supervision of maintenance personnel by authorized, knowledgeable person" implementation feature and the "Operating, and in some cases, maintenance personnel have proper access authorization" feature into one addressable	burdensome or even unfeasible, to some covered entities due to the cost and effort involved. However, we do not want to overlook the value of internal reviews. Based on our review of the comments and the text to which they refer, it is clear that this requirement should assurance that all personnel with access to electronic protected health information have the required access authority as well as appropriate clearances. a. Comment: The majority of comments concerned the supervision of maintenance personnel by an authorized knowledgeable person. Commenters stated this would not be feasible in smaller settings. For example, the availability of technically knowledgeable persons to ensure this supervision would be an issue. We were asked to either reword this implementation feature or delete it. Response: We agree that a "knowledgeable" person may not be available to supervise maintenance personnel. We have accordingly modified this implementation specification so that, in this final rule, we are adopting an addressable implementation specification titled, "Authorization and/or supervision," requiring that workforce members, for example, operations and maintenance personnel, must either be supervised or have authorization when working with electronic protected health information or in locations where it resides (see § 164.308(a)(3)(ii)(A)). Entities	assigned security responsibility should be included under the Administrative Procedures. performed by the covered entity. So long as the standard is met and the underlying standard of § 164.306(a) is met, covered entities have choices in how they meet these standards. To clarify the intent of this provision, we retitle the implementation specification "Workforce clearance procedure." c. Comment: One commenter asked that we expand the implementation features to include the identification of the restrictions that should be placed on members of the workforce and others. Response: We have not adopted this comment in the interest of maintaining flexibility as discussed in § 164.306. Restrictions would be dependent upon job responsibilities, the amount and type of supervision required and other factors. We note that a covered entity should consider in this regard the applicable requirements of the Privacy Rule (see, for example, § 164.514(d)(2) (relating to minimum necessary requirements), and §164.530(c) (relating to safeguards). d. Comment: One commenter believes that the proposed "Personnel security" requirement was reasonable, since an administrative determination of trustworthiness is needed before allowing access to sensitive information. Two commenters asked that we

implementation specification titled “Authorization and/or supervision.” In a related, but separate, requirement entitled “Termination procedures,” we proposed implementation features for the ending of an employee's employment or an internal or external user's access. These features would include things such as changing combination locks, removal from access lists, removal of user account(s), and the turning in of keys, tokens, or cards that allow access. In this final rule, “Termination procedures” has been made an addressable implementation specification under “Workforce security.” This is addressable because in certain circumstances, for example, a solo physician practice whose staff consists only of the physician's spouse, formal procedures may not be necessary. The proposed “Personnel security policy/procedure” and “record of access authorizations” implementation features have been removed from this final rule, as they have been determined to be redundant. Implementation of the balance of the “Workforce security” implementation specifications and the other standards contained within this final rule will result in Was too detailed and some of the requirements excessive. Response: Based upon the comments received, we agree that termination procedures should not be a separate standard; however,	can decide on the feasibility of meeting this specification based on their risk analysis. b. Comment: The second largest group of comments requested assurance that, with regard to the proposed “Personnel clearance procedure” implementation feature, having appropriate clearances does not mean performing background checks on everyone. We were asked to delete references to “clearance” and use the term “authorization” in its place. Response: We agree with the commenters concerning background checks. This feature was not intended to be interpreted as an absolute requirement for background checks. We retain the use of the term “clearance,” however, because we believe that it more accurately conveys the screening process intended than does the term “authorization.” We have attempted to clarify our intent in the language of § 164.308(a)(3)(ii)(B), which now reads, “Implement procedures to determine that the access of a workforce member to electronic protected health information is appropriate.” The need for and extent of a screening process is normally based on an assessment of risk, cost, benefit, and feasibility as well as other protective measures in place. Effective personnel screening processes may be applied in a way to allow a range of implementation, from minimal procedures to more stringent procedures based on the risk analysis a. Comment: One commenter	delete the requirement entirely. A number of commenters requested that we delete the implementation features. Another commenter stated that all the implementation features may not be applicable or even appropriate to a given entity and should be so qualified. Response: While we do not believe this requirement should be eliminated, we agree that all the implementation specifications may not be applicable or even appropriate to a given entity. For example, a personal clearance may not be reasonable or appropriate for a small provider whose only assistant is his or her spouse. The implementation specifications are not mandatory, but must be addressed. This final rule has been changed to reflect this approach (see § 164.308(a)(3)(ii)(B)). e. Comment: The majority of commenters on the “Termination procedures” requirement asked that it be made optional, stating that it may not be applicable or even appropriate in all circumstances and should be so qualified or posed as guidelines. A number of commenters stated that the requirement should be deleted. One commenter stated that much of the material covered under the “Termination procedures” requirement is already covered in “Information access control.” A number of commenters stated that this requirement caused considerable concern among commenters, as it was

consideration of termination procedures remains relevant for any covered entity with employees, because of the risks associated with the potential for unauthorized acts by former employees, such as acts of retribution or use of proprietary information for personal gain. We further agree with the reasoning of the commenters who asked that these procedures be made optional; therefore, "Termination procedures" is now reflected in this final rule as an addressable implementation specification. We also removed reference to all specific termination activities, for example, changing locks, because, although the activities may be considered appropriate for some covered entities, they may not be reasonable for others. f. Comment: One commenter asked whether human resource employee termination policies and procedures must be documented to show the types of security breaches that would result in termination. Response: Policies and procedures implemented to adhere to this standard must be documented (see § 164.316 below). The purpose of termination procedure documentation under this implementation specification is not to detail when or under which circumstances an employee should be terminated. This information would more appropriately be part of the entity's sanction policy. The purpose of termination procedure	asked that the requirement be deleted, expressing the opinion that this requirement goes beyond "reasonable boundaries" into regulating common business practices. In contrast, another asked that we expand this requirement to identify participating parties and access privileges relative to specific data elements. Response: We disagree that this requirement improperly imposes upon business functions. Restricting access to those persons and entities with a need for access is a basic tenet of security. By this mechanism, the risk of inappropriate disclosure, alteration, or destruction of information is minimized. We cannot, however, specifically identify participating parties and access privileges relative to data elements within this regulation. These will vary depending upon the entity, the needs within the user community, the system in which the data resides, and the specific data being accessed. This standard is consistent with § 164.514(d) in the Privacy Rule (minimum necessary requirements for use and disclosure of protected health information), and is, therefore, being retained. b. Comment: Several commenters asked that we not mandate the implementation features, but leave them as optional, a suggested means of compliance. The commenters noted that this might make the rules more scalable and flexible, since this approach would allow providers to implement	thought "formal" carried the connotation of a rigidly defined structure similar to what might be found in the Department of Defense instructions. As used in the proposed rule, this word was not intended to convey such a strict structure. Rather, it was meant to convey that documentation should be an official organizational statement as opposed to word-of-mouth or cryptic notes scratched on a notepad. While documentation is still required (see § 164.316), to alleviate confusion, the word "formal" has been deleted. d. Comment: One commenter asked that we clarify that this requirement relates to both the establishment of policies for the access control function and to access control (the implementation of those policies). Response: "Information access management" does address both the establishment of access control policies and their implementation. We use the term "implement" to clarify that the procedures must be in use, and we believe that the requirement to implement policies and procedures requires, as an antecedent condition, the establishment or adaptation of those policies and procedures. 5. Security Awareness and Training (§ 164.308(a)(5)(i)) We proposed, under the requirement "Training," that security training be required for all staff, including management. Training would include awareness training for all personnel, periodic security

documentation is to ensure that termination procedures include security-unique actions to be followed, for example, revoking passwords and retrieving keys when a termination occurs. 4. Information Access Management (§ 164.308(a)(4)) We proposed an "information access control" requirement for establishment and maintenance of formal, documented policies and procedures defining levels of access for all personnel authorized to access health information, and how access is granted and modified. In § 164.308(a)(4)(ii)(B) and (C) below, the proposed implementation features are made addressable specifications. We have added in § 164.308(a)(4)(ii)(A), a required implementation specification to isolate health care clearinghouse functions to address the provisions of section 1173(d)(1)(B) of the Act which related to this area. system users would be too difficult to do in a large organization. Response: We disagree with the commenter. Security awareness training is a critical activity, regardless of an organization's size. This feature would typically become part of an entity's overall training program (which would include privacy and other information technology items as well). For example, the Government Information Systems Reform ACT (GISRA) of 2000 requires security awareness training as part of	safeguards that best addressed their needs. Along this line, one commenter expressed the belief that each organization should implement features deemed necessary based on its own risk assessment. Response: While the information access management standard in this final rule must be met, we agree that the implementation specifications at § 164.308(a)(4)(ii)(B) and (C) should not be mandated but posed as a suggested means of compliance, which must be addressed. These specifications may not be applicable to all entities based on their size and degree of automation. A fully automated covered entity spanning multiple locations and involving hundreds of employees may determine it has a need to adopt a formal policy for access authorization, while a small provider may decide that a desktop standard operating procedure will meet the specifications. The final rule has been revised accordingly. c. Comment: Clarification was requested concerning the meaning of "formal." Response: The word "formal" has safeguards" as well as "Administrative safeguards." Others questioned the appropriateness of security awareness training under "Physical safeguards." Response: We reviewed the definitions of the proposed "Awareness training for all personnel" ("Administrative	reminders, user education concerning virus protection, user education in the importance of monitoring login success/failure, and how to report discrepancies, and user education in password management. In this final rule, we adopt this proposed requirement in modified form. For the standard "Security awareness and training," in § 164.308(a)(5), we require training of the workforce as reasonable and appropriate to carry out their functions in the facility. All proposed training features have been combined as implementation specifications under this standard. Specific implementation specifications relative to content are addressable. The "Virus protection" implementation feature has been renamed "protection from malicious software," because we did not intend by the nomenclature to exclude coverage of malicious acts that might not come within the prior term, such as worms. a. Comment: One commenter believes that security awareness training for all 6. Security Incident Procedures (§164.308(a)(6)) We proposed a requirement for implementation of accurate and current security incident procedures: formal, documented report and response procedures so that security violations would be reported and handled promptly. We adopt this standard in the final rule, along with an implementation

Federal agencies' information security programs, including Federal covered entities, such as the Medicare program. In addition, National Institute of Standards and Technology (NIST) SP 800-16, Information Technology Security Training Requirements, A role and performance base model, April 1998, provides an excellent source of information and guidance on this subject and is targeted at industry as well as government activities. We also note that covered entities must have discretion in how they implement the requirement, so they can incorporate this training in other existing activities. One approach would be to require this training as part of employee orientation. b. Comment: A number of commenters asked that this requirement be made optional or used as a guideline only. Several commenters stated that this requirement is too specific and is burdensome. Several asked that the implementation features be removed. Several others stated that this requirement is not appropriate for agents or contractors. One commenter asked how to apply this requirement to outsiders having access to data. Another asked if this requirement included all subcontractor staff. Others stated that contracts, signed by entities such as consultants, that address training should be sufficient. Response: Security training remains a requirement because of its criticality; however, we have revised the implementation specifications	safeguards") implementation feature and the proposed "Security awareness training" ("Physical safeguards") requirement. We agree that, to avoid confusion and eliminate redundancy, security awareness and training should appear in only one place. We believe the appropriate location for it is under "Administrative safeguards," as such training is essentially an administrative function. d. Comment: Several commenters objected to the blanket requirement for security awareness training of individuals who may be on site for a limited time period (for example, a single day). Response: Each individual who has access to electronic protected health information must be aware of the appropriate security measures to reduce the risk of improper access, uses, and disclosures. This requirement does not mean lengthy training is appropriate in every instance; there are alternative methods to inform individuals of security responsibilities (for example, provisions of pamphlets or copies of security policies, and procedures). e. Comment: One commenter asked that "training" be changed to "orientation." Response: We believe the term "training," as presented within this rule is the more appropriate term. The rule does not contemplate a one-time type of activity as connoted by "orientation," but rather an on-going, evolving process as an entity's security needs and procedures	specification for response and reporting, since documenting and reporting incidents, as well as responding to incidents are an integral part of a security program. a. Comment: Several commenters asked that we further define the scope of a breach of security. Along this same line, another commenter stated that the proposed security incident procedures were too vague as stated. We were asked to specify what a security incident would be, what the internal chain for reporting procedures would be, and what should be included in the documentation (for example, hardware/ software, personnel responses). Response: We define a security incident in § 164.304. Whether a specific action would be considered a security incident, the specific process of documenting incidents, what information should be contained in the documentation, and what the appropriate response should be will be dependent upon an entity's environment and the information involved. An entity should be able to rely upon the information gathered in complying with the other security standards, for example, its risk assessment and risk management procedures and the privacy standards, to determine what constitutes a security incident in the context of its business operations. b. Comment: One commenter asked what types of incidents must be reported to outside entities. Another commented

to indicate that the amount and type of training needed will be dependent upon an entity's configuration and security risks. Business associates must be made aware of security policies and procedures, whether through contract language or other means. Covered entities are not required to provide training to business associates or anyone else that is not a member of their workforce. c. Comment: Several commenters questioned why security awareness training appeared in two places, under "Physical d. Comment: One commenter stated that this requirement should address suspected misuse also. Response: We agree that security incidents include misuse of data; therefore, this requirement is addressed. e. Comment: Several commenters asked that this requirement be deleted. One commenter asked that we delete the implementation features. Response: As indicated above, we have adopted the proposed standard and combined the implementation specifications. 7. Contingency Plan (§ 164.308(a)(7)(i)) We proposed that a contingency plan must be in effect for responding to system emergencies. The plan would include an applications and data criticality analysis, a data back-up plan, a disaster recovery plan, an emergency mode operation plan, and	change. f. Comment: Several commenters asked how often training should be conducted and asked for a definition of "periodic," as it appears in the proposed implementation feature "Periodic security reminders." One asked if the training should be tailored to job need. Response: Amount and timing of training should be determined by each covered entity; training should be an on-going, evolving process in response to environmental and operational changes affecting the security of electronic protected health information. While initial training must be carried out by the compliance date, we provide flexibility for covered entities to construct training programs. Training can be tailored to job need if the covered entity so desires. must be met, we agree that the proposed testing and revision implementation feature should be an addressable implementation specification in this final rule. Dependent upon the size, configuration, and environment of a given covered entity, the entity should decide if testing and revision of all parts of a contingency plan should be done or if there are more reasonable alternatives. The same is true for the proposed applications and data criticality analysis implementation feature. We have revised the final rule to reflect this approach. b. Comment: One commenter	that we clarify that incident reporting is internal. Response: Internal reporting is an inherent part of security incident procedures. This regulation does not specifically require any incident reporting to outside entities. External incident reporting is dependent upon business and legal considerations. c. Comment: One commenter stated that network activity should be included here. Response: We see no reason to exclude network activity under this requirement. Improper network activity should be treated as a security incident, because, by definition, it represents an improper instance of access to or use of information. show that it only involves those critical business processes that must occur to protect the security of electronic protected health information during and immediately after a crisis situation. 8. Evaluation (§ 164.308(a)(8)) We proposed that certification would be required and could be performed internally or by an external accrediting agency. We solicited input on appropriate mechanisms to permit an independent assessment of compliance. We were particularly interested in input from those engaging in health care electronic data interchange (EDI), as well as independent certification and auditing organizations addressing issues of documentary evidence of steps taken for compliance; need for, or desirability of,

testing and revision procedures. In this final rule, we make the implementation specifications for testing and revision procedures and an applications and data criticality analysis addressable, but otherwise require that the contingency features proposed be met. a. Comment: Several commenters suggested the contingency plan requirement be deleted. Several thought that this aspect of the proposed regulation went beyond its intended scope. Another believed that more discussion and development is needed before developing regulatory guidance on contingency plans. Others wanted this to be an optional requirement. In contrast, one commenter requested more guidance concerning contingency planning. Still others wanted to require that a contingency plan be in place but stated that we should not regulate its contents. One comment stated that data back-up, disaster recovery, and emergency mode operation should not be part of this requirement. Response: A contingency plan is the only way to protect the availability, integrity, and security of data during unexpected negative events. Data are often most exposed in these events, since the usual security measures may be disabled, ignored, or not observed. Each entity needs to determine its own risk in the event of an emergency that	believed that adhering to this requirement could prove burdensome. Another stated that testing of certain parts of a contingency plan would be burdensome, and even infeasible, for smaller entities. Response: Without contingency planning, a covered entity has no assurance that its critical data could survive an emergency situation. Recent events, such as September 11, 2001, illustrate the importance of such planning. Contingency planning will be scalable based upon, among other factors, office configuration, and risk assessment. However, in response to the scalability issue raised by the commenter, we have made the testing and revision implementation specification addressable (see § 164.308(a)(7)(ii)). c. Comment: Two commenters considered a 2-year implementation time frame for this requirement inadequate for large health plans. Another commenter stated that implementation of measures against natural disaster would be too big an issue for this regulation. Response: The statute sets forth the compliance dates for the initial standards. The statute requires that compliance with initial standards is not later than 2 years after adoption of the standards for all covered entities except small health plans for which the compliance date is not later than 3 years after adoption. The final rule calls for covered entities to consider how natural disasters	independent verification, validation, and testing of system changes; and certifications required for off-the-shelf products used to meet the requirements of this regulation. We also solicited comments on the extent to which obtaining external certification would create an undue burden on small or rural providers. In this final rule, we require covered entities to periodically conduct an evaluation of their security safeguards to demonstrate and document their compliance with the entity's security policy and the requirements of this subpart. Covered entities must assess the need for a new evaluation based on changes to their security environment since their last evaluation, for example, new technology adopted or responses to newly recognized risks to the security of their information. a. Comment: We received several comments that certification should be performed externally. A larger group of commenters preferred self- certification. The majority of the comments, however, were to the effect that external certification should be encouraged but not mandated. A number of commenters thought that mandating external certification would create an undue financial burden, regardless of the size of the entity being certified. One commenter stated that external certification would not place an undue burden on a small or rural provider. Response: Evaluation by an

would result in a loss of operations. A contingency plan may involve highly complex processes in one processing site, or simple manual processes in another. The contents of any given contingency plan will depend upon the nature and configuration of the entity devising it. While the contingency plan standard b. Comment: Several commenters stated that the certification should cover all components of the proposed rule, not just the information systems. Response: We agree. We have revised this section to reflect that evaluation would be both technical and nontechnical components of security. c. Comment: A number of commenters expressed a desire for the creation of certification guides or models to complement the rule. Response: We agree that creation of compliance guidelines or models for different business environments would help in the implementation and evaluation of HIPAA security requirements and we encourage professional associations and others to do so. We may develop technical assistance materials, but do not intend to create certification criteria because we do not have the resources to address the large number of different business environments. d. Comment: Some commenters asked how	could damage systems that contain electronic protected health information and develop policies and procedures for responding to such situations. We consider this to be a reasonable precautionary step to take since in many cases the risk would be deemed to be low. d. Comment: A commenter requested clarification of the term “Emergency mode” with regard to the proposed “Emergency mode operation plan” implementation feature. Response: We have clarified the “Emergency mode operations plan” to certifying services to ensure security compliance.” Response: In view of the enormous number and variety of covered entities, we believe that evaluation can best be handled through the marketplace, which can develop more usable and targeted evaluation instruments and processes. 8. Business Associate Contracts or Other Arrangements (§ 164.308(b)(1)) In the proposed rule § 142.308(a)(2) “Chain of trust” requirement, we proposed that covered entities be required to enter into a chain of trust partner agreement with their business partners, in which the partners would agree to electronically exchange data and protect the integrity, confidentiality, and availability of the data exchanged. This standard has been modified from the proposed requirement to reflect, in § 164.308(b)(1) “Business associate contracts	external entity is a business decision to be left to each covered entity. Evaluation is required under § 164.308(a)(8), but a covered entity may comply with this standard either by using its own workforce or an external accreditation agency, which would be acting as a business associate. External evaluation may be too costly an option for small entities. A number of commenters requested that security testing be deleted because this implementation feature is too detailed, unreasonable, impractical, and beyond the scope of the legislation. Others stated that the testing would be very complex and expensive. Others wanted more clarification of what we intend by security testing, and how much would be enough. A number of commenters asked that all of the implementation features be deleted. Others asked that the implementation features be made optional. Several commenters wanted to know the scope of organizational integration required. Several others asked if what we meant by Security Configuration Management was change or version control. Response: Upon review, this requirement appears unnecessary because it is redundant of other requirements we are adopting in this rule. A covered entity will have addressed the activities described by the features under this proposed requirement by virtue of having implemented the risk analysis, risk management measures, sanction policies, and

certification is possible without specifying the level of risk that is permissible. Response: The level of risk that is permissible is specified by § 164.306(a). How such risk is managed will be determined by a covered entity through its security risk analysis and the risk mitigation activities it implements in order to ensure that the level of security required by § 164.306 is provided. e. Comment: Several commenters requested creation of a list of Federally "certified" security software and off-the-shelf products. Several others stated that this request was not feasible. Regarding certification of off-the-shelf products, one commenter thought this should be encouraged, but not mandated; several thought this would be an impractical endeavor. Response: While we will not assume the task of certifying software and off-the-shelf products for the reason described above, we have noted with interest that other Government agencies such as the National Institute of Standards and Technology (NIST) are working towards that end. The health care industry is encouraged to monitor the activity of NIST and provide comments and suggestions when requested (see http://www.niap.nist.gov.). f. Comment: One commenter stated, "With HCFA's publishing of these HIPAA standards, and their desire to retain the final responsibility for determining violations and	and other arrangements," the business associate structure put in place by the Privacy Rule. In this final rule, covered entities must enter into a contract or other arrangement with persons that meet the definition of business associate in § 160.103. The covered entity must obtain satisfactory assurances from the business associate that it will appropriately safeguard the information in accordance with these standards (see § 164.314(a)(1)). The comments received on the proposed chain of trust partner agreements are discussed in section 2 "Business associate contracts and other arrangements" of the discussion of § 164.314 below. 9. Proposed Requirements Not Adopted in This Final Rule a. Security Configuration Management We proposed that an organization would be required to implement measures, practices, and procedures regarding security configuration management. They would be coordinated and integrated with other system configuration management practices for the security of information systems. These would include documentation, hardware and/or software installation and maintenance review and testing for security features, inventory procedures, security testing, and virus checking. Comment: Several commenters asked that the entire requirement be deleted. Several others asked that the	information systems criticality review called for under the security management process. The proposed documentation implementation feature has been made a separate standard (see § 164.316). As a result, the Security Configuration Management requirement is not adopted in this final rule. b. Formal Mechanism for Processing Records The proposed rule proposed requiring a formal mechanism for processing records, and documented policies and procedures for the routine and nonroutine receipt, manipulation, storage, dissemination, transmission, and/or disposal of health information. This requirement has not been adopted in the final rule. Comment: Several commenters thought this requirement concerned the regulation of formal procedures for how an entity does business and stated that such procedures should not be regulated. Others asked for additional clarification of what is meant by this requirement. One commenter thought the requirement too ambiguous and asked for clarification as to whether we meant such things as "the proper handling of storage media, databases, transmissions," or "the clinical realm of processes." Two commenters asked how extensive this requirement would be and whether systems' user manuals and policies and procedures for handling health information would suffice and what level of

imposing penalties of the statute, it also seems appropriate for HCFA to also provide Several thought this requirement could result in a significant resource and monetary burden to develop and maintain formal procedures. Two asked for an explanation of the benefit to be derived from this requirement. One asked that covered entities be required to document processes that create a security risk only and suggested that a risk assessment would determine the need for this documentation. Response: We agree with the commenters that the standard is ambiguous, and upon review, is unnecessary because the remaining standards, for example, device and media controls, provide adequate safeguards. Accordingly, this requirement is not adopted in this final rule. **F. Physical Safeguards (§ 164.310)** We proposed requirements and implementation features for documented physical safeguards to guard data integrity, confidentiality, and availability. We proposed to require safeguards in the following areas: Assigned security responsibility; media controls; physical access controls; policies and guidelines on workstation use; a secure workstation location; and security awareness training. A number of specific implementation features were proposed under the media controls and physical access	inventory and virus checking implementation features be removed as they believe those features are not germane to security configuration management. 2. Facility Access Controls (§ 164.310(a)(1)) We proposed, under the "Physical access controls" requirement, formal, documented policies and procedures for limiting physical access to an entity while ensuring that properly authorized access is allowed. These controls would include the following implementation features: disaster recovery, emergency mode operation, equipment control (into and out of site), a facility security plan, procedures for verifying access authorizations before physical access, maintenance records, need-to-know procedures for personnel access, sign-in for visitors and escort, if appropriate, and testing and revision. In § 164.310(a)(2) below, we combine and restate these as addressable implementation specifications. These are contingency operations, facility security plan, access control and validation procedures, and maintenance records. a. Comment: Many commenters were concerned because the proposed language would require implementation of all physical access control features. Other commenters were concerned that the language did not allow entities to use the results of their risk assessment and risk management process to arrive	detail would be expected. c. Comment: Several commenters questioned whether "Physical Access Controls" was a descriptive phrase to describe a technology to be used, or whether the phrase referred to a facility. Response: We agree that the term "Physical" may be misleading; to remove any confusion, the requirement is reflected in this final rule as a standard titled "Facility access controls." We believe this is a more precise term to describe that the standard, and its associated implementation specifications, is applicable to an entity's business location or locations. d. Comment: Several commenters requested that the disaster recovery and emergency mode operations features be moved to "Administrative safeguards." Other commenters recommended that disaster recovery and emergency mode operations should be replaced by, and included in, a "Contingency Operations" implementation feature. Response: The "Administrative safeguards" section addresses the contingency planning that must be done to contend with emergency situations. The placement of the disaster recovery and emergency mode operations implementation specifications in the "Physical safeguards" section is also appropriate, however, because "Physical safeguards" defines the physical operations (processes) that provide

controls requirements. In § 164.310 of this final rule, most of the proposed implementation features are adopted as addressable implementation specifications. The proposed requirements for the assigned security responsibility and security awareness training requirements are relocated in § 164.308. 1. General Comments a. Comment: Several commenters made suggestions to modify the language to more clearly describe “Physical safeguards.” Response: In response to comments, we have revised the definition of “Physical safeguards” to read as follows: “Physical safeguards are security measures to protect a covered entity's electronic information systems and related buildings and equipment, from natural and environmental hazards, and unauthorized intrusion.” b. Comment: One commenter was concerned that electronic security systems could not be used in lieu of physical security systems. Response: This final rule does not preclude the use of electronic security systems in lieu of, or in combination with, physical security systems to meet a “Physical safeguard” standard. 3. Workstation Use (§ 164.310(b)) We proposed policy and guidelines on workstation use that included documented instructions/procedures	at the appropriate solutions for them. Response: We agree that implementation of all implementation specifications may not be appropriate in all situations. While the facility access controls standard must be met, we agree that the implementation specifications should not be required in all circumstances, but should be addressable. In this final rule, all four implementation specifications are addressable. We have also determined, based on “level of detail” comments requesting consolidation of the list of implementation features, that the proposed implementation feature “Equipment control (into and out of site)” was redundant. “Equipment control” is already covered under the “Device and media controls” standard at § 164.310(d)(1). Accordingly, we have eliminated it as a separate implementation specification. b. Comment: One commenter raised the issue of a potential conflict of authority between those having access to the data and those responsible for checking and maintaining access controls. Response: Any potential conflicts should be identified, addressed, and resolved in the policies and procedures developed according to the standards under § 164.308. “Disposal.” In this final rule, we adopt most of these provisions as addressable implementation specifications and add a specification for media re-use.	access to the facility to implement the associated plans, developed under §164.308. We agree, however, that the term “contingency operations” better describes, and would include, disaster recovery and emergency mode operations, and have modified the regulation text accordingly (see § 164.310(a)(1)). e. Comment: Commenters were concerned about having to address in their facility security plan the exterior/interior security of a building when they are one of many occupants rather than the sole occupant. Additional commenters were concerned that the responsibility for physical security of the building could not be delegated to a third party when the covered entity shares the building with other offices. Response: The facility security plan is an addressable implementation specification. However, the covered entity retains responsibility for considering facility security even where it shares space within a building with other organizations. Facility security measures taken by a third party must be considered and documented in the covered entity's facility security plan, when appropriate. implementation specification as implementation specification as addressable to provide more flexibility in meeting the standard. e. Comment: One commenter was concerned about the

delineating the proper functions to be performed and the manner in which those functions are to be performed (for example, logging off before leaving a workstation unattended) to maximize the security of health information. In this final rule, we adopt this standard. Comment: One commenter was concerned most people may be misled by the use of "terminal" as an example in the definition of workstation. The concern was that the standard only addresses "fixed location devices," while in many instances the workstation has become a laptop computer. Response: For clarity, we have added the definition of "workstation" to § 164.304 and deleted the word "terminal" from the description of workstation use in § 164.310(b). 4. Workstation Security (§ 164.310(c)) We proposed that each organization would be required to put in place physical safeguards to restrict access to information. In this final rule, we retain the general requirement for a secure workstation. Comment: Comments were directed toward the example profiled in the definition of a secure workstation location. It was believed that what constitutes a secure workstation location must be dependent upon the entity's risk management process. Response: We agree that what constitutes an appropriate solution to a covered entity's workstation	We change the name from "Media controls" to "Device and media controls" to more clearly reflect that this standard concerns hardware as well as electronic media. The proposed "Access control" implementation feature has been removed, as it is addressed as part of other standards (see section **III.C.12.c of this preamble).** a. Comment: One commenter was concerned about the exclusion of removable media devices from examples of physical types of hardware and/or software. Response: The media examples used were not intended to represent all possible physical types of hardware and/or software. Removable media devices, although not specifically listed, are not intended to be excluded. b. Comment: Comments were made that the issue of equipment re-use or recycling of media containing mass storage was not addressed in "Media controls." Response: We agree that equipment re-use or recycling should be addressed, since this equipment may contain electronic protected health information. The "Device and media controls" standard is accordingly expanded to include a required implementation specification that addresses the re-use of media (see § 164.310(d)(2)(ii)). c. Comment: Several commenters asked for a definition of the term "facility," as used in the proposed	accountability impact of audit trails on system resources and the pace of system services. Response: The proposed audit trail implementation feature appears as the addressable "Accountability" implementation specification. The name change better reflects the purpose and intended scope of the implementation specification. This implementation specification does not address audit trails within systems and/or software. Rather it requires a record of the actions of a person relative to the receipt and removal of hardware and/or software into and out of a facility that are traceable to that person. The impact of maintaining accountability on system resources and services will depend upon the complexity of the mechanism to establish accountability. For example, the appropriate mechanism for a given entity may be manual, such as receipt and removal restricted to specific persons, with logs kept. Maintaining accountability in such a fashion should have a minimal, if any, effect on system resources and services. f. Comment: A commenter was concerned about the resource expenditure (system and fiscal) for total e-mail back-up and wanted a clarification of the extensiveness of data back-up. Response: The data an entity needs to back-up, and which operations should be used to carry out the back-up, should be determined by the entity's risk analysis and risk management process. The

security issues is dependent on the entity's risk analysis and risk management process. Because many commenters incorrectly interpreted the examples as the required and only solution for securing the workstation location, we have modified the regulations text description to generalize the requirement (see § 164.310(c)). Also, for clarity, the title "Secure workstation location" has been changed to "Workstation security" (see also the definition of "Workstation" at § 164.304). 5. Device and Media Controls (§ 164.310(d)(1)) We proposed that covered entities have media controls in the form of formal, documented policies and procedures that govern the receipt and removal of hardware and/or software (for example, diskettes and tapes) into and out of a facility. Implementation features would have included "Access control," "Accountability" (tracking mechanism), "Data back-up," "Data storage," and Encryption; Alarm; Audit trails; Entity authentication; and Event reporting. In this final rule, we consolidate these provisions into § 164.312. That section now includes standards regarding access controls, audit controls, integrity (previously titled data authentication), person or entity authentication, and transmission security. As discussed below, while certain implementation specifications are required, many of the proposed security	"Media controls" requirement description. Commenters were unclear whether we were talking about a corporate entity or the physical plant. Response: The term "facility" refers to the physical premises and the interior and exterior of a building(s). We have added this definition to § 164.304. d. Comment: Several commenters believe the "Media controls" implementation features are too onerous and should be deleted. Response: While the "Device and media controls" standard must be met, we believe, based upon further review, that implementation of all specifications would not be necessary in every situation, and might even be counter-productive in some situations. For example, small providers would be unlikely to be involved in large-scale moves of equipment that would require systematic tracking, unlike, for example, large health care providers or health plans. We have, therefore, reclassified the "Accountability and data back-up" of inactivity lockout, and that this type of feature be made optional, based more on the particular configuration in use and a risk assessment/analysis. Response: We agree with the comments that mandating an automatic logoff is too specific. This final rule has been written to clarify that the proposed implementation feature of automatic logoff now appears as an addressable access control implementation	data back-up plan, which is part of the required contingency plan (see § 164.308(a)(7)(ii)(A)), should define exactly what information is needed to be retrievable to allow the entity to continue business "as usual" in the face of damage or destruction of data, hardware, or software. The extent to which e-mail back-up would be needed would be determined through that analysis. **G. Technical Safeguards (§ 164.312)** We proposed five technical security services requirements with supporting implementation features: Access control; Audit controls; Authorization control; Data authentication; and Entity authentication. We also proposed specific technical security mechanisms for data transmitted over a communications network, Communications/network controls with supporting implementation features; Integrity controls; Message authentication; Access controls; "Accountability" in this final rule because it is not descriptive of the requirement, which is to have the capability to record and examine system activity. We believe that it is appropriate to specify audit controls as a type of technical safeguard. Entities have flexibility to implement the standard in a manner appropriate to their needs as deemed necessary by their own risk analyses. For example, see NIST Special Publication 800-14, Generally

implementation features are now addressable implementation specifications. The function of authorization control has been incorporated into the information access management standard under § 164.308, Administrative safeguards. 1. Access Control (§ 164.312(a)(1)) In the proposed rule, we proposed to require that the access controls requirement include features for emergency access procedures and provisions for context-based, role-based, and/or user-based access; we also proposed the optional use of encryption as a means of providing access control. In this final rule, we require unique user identification and provision for emergency access procedures, and retain encryption as an addressable implementation specification. We also make "Automatic logoff" an addressable implementation specification. "Automatic logoff" and "Unique user identification" were formerly implementation features under the proposed "Entity authentication" (see § 164.312(d)). a. Comment: Some commenters believe that in specifying "Context," "Role," and "User" based controls, use of other controls would effectively be excluded, for example, "Partition rule-based access controls," and the development of new access control technology. Response: We agree with the commenters that other types of access controls should be	specification and also permits the use of an equivalent measure. c. Comment: We received comments asking that encryption be deleted as an implementation feature and stating that encryption is not required for "data at rest." Response: The use of file encryption is an acceptable method of denying access to information in that file. Encryption provides confidentiality, which is a form of control. The use of encryption, for the purpose of access control of data at rest, should be based upon an entity's risk analysis. Therefore, encryption has been adopted as an addressable implementation specification in this final rule. d. Comment: We received one comment stating that the proposed implementation feature "Procedure for emergency access," is not access control and recommending that emergency access be made a separate requirement. Response: We believe that emergency access is a necessary part of access controls and, therefore, is properly a required implementation specification of the "Access controls" standard. Access controls will still be necessary under emergency conditions, although they may be very different from those used in normal operational circumstances. For example, in a situation when normal environmental systems, including electrical power,	Accepted Principles and Practices for Securing Information Technology Systems and NIST Special Publication 800-33, Underlying Technical Models for Information Technology Security. b. Comment: One commenter recommended that this final rule state that audit control mechanisms should be implemented based on the findings of an entity's risk assessment and risk analysis. The commenter asserted that audit control mechanisms should be utilized only when appropriate and necessary and should not adversely affect system performance. Response: We support the use of a risk assessment and risk analysis to determine how intensive any audit control function should be. We believe that the audit control requirement should remain mandatory, however, since it provides a means to assess activities regarding the electronic protected health information in an entity's care. c. Comment: One commenter was concerned about the interplay of State and Federal requirements for auditing of privacy data and requested additional guidance on the interplay of privacy rights, laws, and the expectation for audits under the rule. Response: In general, the security standards will supercede any contrary provision of State law. Security standards in this final rule establish a minimum level of security that covered entities

allowed. There was no intent to limit the implementation features to the named technologies and this final rule has been reworded to make it clear that use of any appropriate access control mechanism is allowed. Proposed implementation features titled “Context-based access,” “Role-based access,” and “User-based access” have been deleted and the access control standard at § 164.312(a)(1) states the general requirement. b. Comment: A large number of comments were received objecting to the identification of “Automatic logoff” as a mandatory implementation feature. Generally the comments asked that we not be so specific and allow other forms individual upon request. There has been a tendency to assume that this Privacy Rule requirement would be satisfied via some sort of process involving audit trails. We caution against assuming that the Security Rule's requirement for an audit capability will satisfy the Privacy Rule's requirement regarding accounting for disclosures of protected health information. The two rules cover overlapping, but not identical information. Further, audit trails are typically used to record uses within an electronic information system, while the Privacy Rule requirement for accounting applies to certain disclosures outside of the covered entity (for example, to public health authorities). 3. Integrity (§ 164.312(c)(1))	have been severely damaged or rendered inoperative due to a natural or man-made disaster, procedures should be established beforehand to provide guidance on possible ways to gain access to needed electronic protected health information. 2. Audit Controls (§ 164.312(b)) We proposed that audit control mechanisms be put in place to record and examine system activity. We adopt this requirement in this final rule. a. Comment: We received a comment stating that “Audit controls” should be an implementation feature rather than the standard, and suggesting that we change the title of the standard to “Accountability,” and provide additional detail to the audit control implementation feature. Response: We do not adopt the term the different situations faced by the various health care entities implementing this regulation. Further, we believe that this standard will not prove difficult to implement, since there are numerous techniques available, such as processes that employ digital signature or check sum technology to accomplish the task. b. Comment: We received numerous comments suggesting that “Double keying” be deleted as a viable “Data authentication” mechanism, since this practice was generally associated with the use of punched cards. Response: We agree that the	must meet. We note that covered entities may be required by other Federal law to adhere to additional, or more stringent security measures. Section 1178(a)(2) of the statute provides several exceptions to this general rule. With regard to protected health information, the preemption of State laws and the relationship of the Privacy Rule to other Federal laws is discussed in the Privacy Rule beginning at 65 FR 82480; the preemption provisions of the rule are set out at 45 CFR part 160, subpart B. It should be noted that although the Privacy Rule does not incorporate a requirement for an “audit trail” function, it does call for providing an accounting of certain disclosures of protected health information to an “Automatic logoff” has also been moved from this standard to the “Access control” standard and is now an addressable implementation specification. 5. Transmission Security (§ 164.312(e)(1)) Under “Technical Security Mechanisms to Guard Against Unauthorized Access to Data that is Transmitted Over a Communications Network,” we proposed that “Communications/network controls” be required to protect the security of health information when being transmitted electronically from one point to another over open networks, along with a combination of mandatory and optional implementation

We proposed under the "Data authentication" requirement, that each organization be required to corroborate that data in its possession have not been altered or destroyed in an unauthorized manner and provided examples of mechanisms that could be used to accomplish this task. We adopt the proposed requirement for data authentication in the final rule as an addressable implementation specification "Mechanism to authenticate data," under the "Integrity" standard. a. Comment: We received a large number of comments requesting clarification of the "Data authentication" requirement. Many of these comments suggested that the requirement be called "Data integrity" instead of "Data authentication." Others asked for guidance regarding just what "data" must be authenticated. A significant number of commenters indicated that this requirement would put an extraordinary burden on large segments of the health care industry, particularly when legacy systems are in use. Requests were received to make this an "optional" requirement, based on an entity's risk assessment and analysis. Response: We adopt the suggested "integrity" terminology because it more clearly describes the intent of the standard. We retain the meaning of the term "Data authentication" under the addressable implementation specification "Mechanism to authenticate data," and	process of "Double keying" is outdated. This final rule omits any reference to "Double keying." 4. Person or Entity Authentication (§ 164.312(d)) We proposed that an organization implement the requirement for "Entity authentication", the corroboration that an entity is who it claims to be. "Automatic logoff" and "Unique user identification" were specified as mandatory features, and were to be coupled with at least one of the following features: (1) A "biometric" identification system; (2) a "password" system; (3) a "personal identification number"; and (4) "telephone callback," or a "token" system that uses a physical device for user identification. In this final rule, we provide a general requirement for person or entity authentication without the specifics of the proposed rule. Comment: We received comments from a number of organizations requesting that the implementation features for entity authentication be either deleted in their entirety or at least be made optional. On the other hand, comments were received requesting that the use of digital signatures and soft tokens be added to the list of implementation features. Response: We agree with the commenters that many different mechanisms may be used to authenticate entities, and this final rule now reflects this fact by not incorporating a list of implementation	features. We proposed that some form of encryption must be employed on "open" networks such as the Internet or dial-up lines. In this final rule, we adopt integrity controls and encryption, as addressable implementation specifications. a. Comment: We received a number of comments asking for overall clarification as well as a definition of terms used in this section. A definition for the term "open networks" was the most requested action, but there was a general expression of dislike for the manner in which we approached this section, with some comments suggesting that the entire section be rewritten. A significant number of comments were received on the question of encryption requirements when dial-up lines were to be employed as a means of connectivity. The overwhelming majority strongly urged that encryption not be mandatory when using any transmission media other than the Internet, but rather be considered optional based on individual entity risk assessment/analysis. Many comments noted that there are very few known breaches of security over dial-up lines and that nonjudicious use of encryption can adversely affect processing times and become both financially and technically burdensome. Only one commenter suggested that "most" external traffic should be encrypted. Response: In general, we agree with the commenters who asked for clarification and revision. This final rule has

provide an example of a potential means to achieve data integrity. Error-correcting memory and magnetic disc storage are examples of the built-in data authentication mechanisms that are ubiquitous in hardware and operating systems today. The risk analysis process will address what data must be authenticated and should provide answers appropriate to We agree with the commenters that switched, point-to-point connections, for example, dial-up lines, have a very small probability of interception. Thus, we agree that encryption should not be a mandatory requirement for transmission over dial-up lines. We also agree with commenters who mentioned the financial and technical burdens associated with the employment of encryption tools. Particularly when considering situations faced by small and rural providers, it became clear that there is not yet available a simple and interoperable solution to encrypting e-mail communications with patients. As a result, we decided to make the use of encryption in the transmission process an addressable implementation specification. Covered entities are encouraged, however, to consider use of encryption technology for transmitting electronic protected health information, particularly over the internet. As business practices and	specifications, in order to allow covered entities to use whatever is reasonable and appropriate. "Digital signatures" and "soft tokens" may be used, as well as many other mechanisms, to implement this standard. The proposed mandatory implementation feature, "Unique user identification," has been moved from this standard and is now a required implementation specification under "Access control" at § 164.312(a)(1). consideration of the use of encryption will satisfy the intent of this feature. We retain as addressable implementation specifications two features: (1) "Integrity controls" and "encryption". "Message authentication" has been deleted as an implementation feature because the use of data authentication codes (called for in the "integrity controls" implementation specification) satisfies the intent of "Message authentication." c. Comment: A number of comments were received asking that this final rule establish a specific (or at least a minimum) cryptographic algorithm strength. Others recommended that the rule not specify an encryption strength since technology is changing so rapidly. Several commenters requested guidelines and minimum encryption standards for the Internet. Another stated that, since an example was included (small or rural providers for example), the government should feel free to name a specific encryption	been significantly revised to reflect a much simpler and more direct requirement. The term "Communications/network controls" has been replaced with "Transmission security" to better reflect the requirement that, when electronic protected health information is transmitted from one point to another, it must be protected in a manner commensurate with the associated risk. modified without detection (see § 164.312(c)(1)). e. Comment: Three commenters asked for clarification and guidance regarding the unsolicited electronic receipt of health information in an unsecured manner, for example, when the information was submitted by a patient via e-mail over the Internet. Commenters asked for guidance as to what was their obligation to protect data received in this manner. Response: The manner in which electronic protected health information is received by a covered entity does not affect the requirement that security protection must subsequently be afforded to that information by the covered entity once that information is in possession of the covered entity. 6. Proposed Requirements Not Adopted in This Final Rule a. Authorization Control We proposed, under "Technical Security Services to Guard Data Integrity, Confidentiality, and Availability," that a mechanism be required for obtaining consent for the use and

technology change, there may arise situations where electronic protected health information being transmitted from a covered entity would be at significant risk of being accessed by unauthorized entities. Where risk analysis showed such risk to be significant, we would expect covered entities to encrypt those transmissions, if appropriate, under the addressable implementation specification for encryption. We do not use the term "open network" in this final rule because its meaning is too broad. We include as an addressable implementation specification the requirement that transmissions be encrypted when appropriate based on the entity's risk analysis. b. Comment: We received comments requesting that the implementation features be deleted or made optional. Three commenters asked that the requirement for an alarm be deleted. Response: This final rule has been revised to reflect deletion of the following implementation features: (1) The alarm capability; (2) audit trail; (3) entity authentication; and (4) event reporting. These features were associated with a proposed requirement for "Communications/network controls" and have been deleted since they are normally incorporated by telecommunications providers as part of network management and control functions that are included with the provision of network services. A health care entity	package. One commenter stated that the requirement for encryption on the Internet should reference the "CMS Internet Security Policy." Response: We remain committed to the principle of technology neutrality and agree with the comment that rapidly changing technology makes it impractical and inappropriate to name a specific technology. Consistent with this principle, specification of an algorithm strength or specific products would be inappropriate. Moreover, rapid advances in the success of "brute force" cryptanalysis techniques suggest that any minimum specification would soon be outmoded. We maintain that it is much more appropriate for this final rule to state a general requirement for encryption protection when necessary and depend on covered entities to specify technical details, such as algorithm types and strength. Because "CMS Internet Security Policy" is the policy of a single organization and applies only to information sent to CMS, and not between all covered entities, we have not referred to it here. d. Comment: The proposed definition of "Integrity controls" generated comments that asked that the word "validity" be changed to "Integrity." Commenters were concerned about the ability of an entity to ensure that information was "valid." Response: We agree with the commenters about the meaning of the word "validity" in the context of the proposed definition of "Integrity controls."	disclosure of health information using either "Role-based access" or "User-based access" controls. In this final rule, we do not adopt this requirement. Comment: We received a large number of comments regarding use of the word "consent." It was pointed out that this could be construed to mean patient consent to the use or disclosure of patient information, which would make this a privacy issue, rather than one of security. Other comments suggested deletion of the requirement in its entirety. We received a comment asking for clarification about the distinction between "Access control" and "Authorizations." Response: These requirements were intended to address authorization of workforce members and others for the use and disclosure of health information, not patient consent. Upon reviewing the differences between "Access control" and "Authorization control," we found it to be unnecessary to retain "Authorization control" as a separate requirement. Both the access control and the authorization control proposed requirements involved implementation of types of automated access controls, that is, role-based access and user-based access. It can be argued that the process of managing access involves allowing and restricting access to those individuals that have been authorized to access the data. The intent of the proposed authorization control

would not expect to be responsible for these technical telecommunications features. "Access controls" has also been deleted from the implementation features since the feature is now incorporated in the access authorization implementation specification under the information access management standard in § 164.308(a)(4). Under the information access management standard, a covered entity must implement, if appropriate and reasonable to its situation, policies and procedures first to authorize a person to access electronic protected health information and then to actually establish such access. These policies and procedures will enable entities to follow the Privacy Rule minimum necessary requirements, which provide when persons should have access to information. **H. Organizational Requirements (§ 164.314)** We proposed that each health care clearinghouse must comply with the security standards to ensure all health information and activities are protected from unauthorized access. If the clearinghouse is part of a larger organization, then unauthorized access by the larger organization must be prevented. We also proposed that parties processing data through a third party would be required to enter into a chain of trust partner agreement, a contract in which the parties agree to electronically exchange data	We have named "integrity controls" as an implementation specification in this final rule to require mechanisms to ensure that electronically transmitted information is not improperly of a health care clearinghouse is not inappropriately accessed by the larger organization of which it is a part, this final rule implements the statutory language through the information access management provision of § 164.308(a)(4)(ii)(A). The final rule, at § 164.105, makes the health care component and affiliated entity standards of the Privacy Rule applicable to the security standards. Therefore, we have not changed those standards substantively. In pertaining to the Privacy Rule, we have simply moved them to a new location in part 164. Any differences between § 164.105 and § 164.504(a) through (d) reflects the addition of requirements specific to the security standards. The health care component approach was developed in response to extensive comment received principally on the Privacy Rule. See 65 FR 82502 through 82503 and 82637 through 82640 for a discussion of the policy concerns underlying the health care component approach. Since the security standards are intended to support the protection of electronic information protected by the Privacy Rule, it makes sense to incorporate organizational requirements that parallel those required of covered entities by the Privacy Rule. This policy will also minimize	implementation which the health care clearinghouse is one. External communication must be protected as sent by the clearinghouse, but need not be protected once received. b. Comment: One commenter asked that the first sentence in § 142.306(b) of the proposed rule, "If a health care clearinghouse is part of a larger organization, it must assure all health information is protected from unauthorized access by the larger organization" be expanded to read, "If a health care clearinghouse or any other health care entity is part of a larger organization . . ." Response: The Act specifically provides, at section 1173(d)(1)(B), that the Secretary must adopt standards to ensure that a health care clearinghouse, if part of a larger organization, has policies and security procedures to protect information from unauthorized access by the larger organization. Health care providers and health plans are often part of larger organizations that are not themselves health care providers or health plans. The security measures implemented by health plans and covered health care providers should protect electronic protected health information in circumstances such as the one identified by the commenter. Therefore, we agree with the comment that the requirement should be expanded as suggested by the commenter. In this final rule,

and to protect the transmitted data in accordance with the security standards. In this final rule, we have adopted the concepts of hybrid and affiliated entities, as previously defined in § 164.504, and now defined in § 164.103, and business associates as defined in § 160.103, to be consistent with the Privacy Rule. General organizational requirements related to affiliated covered entities and hybrid entities are now contained in a new § 164.105. The proposed chain of trust partner agreement has been replaced by the standards for business associate contracts or other arrangements and the standards for group health plans. Consistent with the statute and the policy of the Privacy Rule, this final rule does not require noncovered entities to comply with the security standards. 1. Health Care Clearinghouses The proposed rule proposed that if a health care clearinghouse were part of a larger organization, it would be required to ensure that all health information pertaining to an individual is protected from unauthorized access by the larger organization; this statement closely tracked the statutory language in section 1173(d)(1)(B) of the Act. Since the point of the statutory language is to ensure that health care information in the possession receives, maintains, or transmits on behalf of the covered entity; (2) ensure that	the burden of complying with both rules. a. Comment: Relative to the following preamble statement (63 FR 43258): "If the clearinghouse is part of a larger organization, then security must be imposed to prevent unauthorized access by the larger organization." One commenter asked what is considered to be "the larger organization." For example, if a clearinghouse function occurs in a department of a larger business entity, will the regulation cover all internal electronic communication, such as e-mail, within the larger business and all external electronic communication, such as e-mail with its owners? Response: The "larger organization" is the overall business entity that a clearinghouse would be part of. Under the Security Rule, the larger organization must assure that the health care clearinghouse function has instituted measures to ensure only that electronic protected health information that it processes is not improperly accessed by unauthorized persons or other entities, including the larger organization. Internal electronic communication within the larger organization will not be covered by the rule if it does not involve the clearinghouse, assuming that it has designated health care components, of required by the above described business associate contract and documents the attempt and the reasons that these assurances cannot be	those components of a hybrid entity that are designated as health care components must comply with the security standards and protect against unauthorized access with respect to the other components of the larger entity in the same way as they must deal with separate entities. 1. Business Associate Contracts and Other Arrangements We proposed that parties processing data through a third party would be required to enter into a chain of trust partner agreement, a contract in which the parties agree to electronically exchange data and to protect the transmitted data. This final rule narrows the scope of agreements required. It essentially tracks the provisions in § 164.502(e) and § 164.504(e) of the Privacy Rule, although appropriate modifications have been made in this rule to the required elements of the contract. In this final rule, a contract between a covered entity and a business associate must provide that the business associate must--(1) implement safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, this subpart. a. Comment: Several commenters expressed confusion concerning the applicability of proposed § 142.104 to security. Response: The proposed preamble included language

any agent, including a subcontractor, to whom it provides this information agrees to implement reasonable and appropriate safeguards; (3) report to the covered entity any security incident of which it becomes aware; (4) make its policies and procedures, and documentation required by this subpart relating to such safeguards, available to the Secretary for purposes of determining the covered entity's compliance with this subpart; and (5) authorize termination of the contract by the covered entity if the covered entity determines that the business associate has violated a material term of the contract. When a covered entity and its business associate are both governmental entities, an "other arrangement" is sufficient. The covered entity is in compliance with this standard if it enters into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of the above-described business associate contract. However, the covered entity may omit from this memorandum the termination authorization required by the business associate contract provisions if this authorization is inconsistent with the statutory obligations of the covered entity or its business associate. If other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that	obtained. We have added a standard for group health plans that parallels the provisions of the Privacy Rule. It became apparent during the course of the security and privacy rulemaking that our original chain of trust approach was both overly broad in scope and failed to address appropriately the circumstances of certain covered entities, particularly the ERISA group health plans. These latter considerations and the solutions arrived at in the Privacy Rule are described in detail in the Privacy Rule at 65 FR 82507 through 82509. Because the purpose of the security standards is in part to reinforce privacy protections, it makes sense to align the organizational policies of the two rules. This decision should also make compliance less burdensome for covered entities than would a decision to have different organizational requirements for the two sets of rules. Thus, we have added at § 164.314(b) a standard for group health plan that tracks the standard at § 164.504(f) very closely. The purpose of these provisions is to ensure that, except when the electronic protected health information disclosed to a plan sponsor is summary health information or enrollment or disenrollment information as provided for by § 164.504(f), group health plan documents provide that the plan sponsor will reasonably and appropriately safeguard electronic protected health information created, received, maintained or transmitted to or	generally applicable to most of the proposed standards under HIPAA. Proposed § 142.104 concerned general requirements for health plans relative to processing transactions. We proposed that plans could not refuse to conduct a transaction as a standard transaction, or delay or otherwise adversely affect a transaction on the grounds that it was a standard transaction; health information transmitted and received in connection with a transaction must be in the form of standard data elements; and plans conducting transactions through an agent must ensure that the agent met all the requirements that applied to the health plan. Except for the statement that a plan's agent ("business associate" in the final rule) must meet the requirements (which would include security) that apply to the health plan, this proposed section did not pertain to the security standards and was addressed in the Transaction Rule. b. Comment: The majority of comments concerned proposed rule language stating "the same level of security will be maintained at all links in the chain * * *" Commenters believed the current language will have an adverse impact on one of the security standard's basic premises, which is scalability. It was requested that the language be changed to indicate that, while appropriate security must be maintained, all partners do not need to maintain the same level of security.

accomplish the objectives of the above- described business associate contract, a contract or agreement is not required. If a covered entity enters into other arrangements with another governmental entity that is a business associate, such arrangements may omit provisions equivalent to the termination authorization required by the business associate contract, if inconsistent with the statutory obligation of the covered entity or its business associate. If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of business associate in § 160.103 of this subchapter to a covered entity, the covered entity may permit the business associate to receive, create, maintain, or transmit electronic protected health information on its behalf to the extent necessary to comply with the legal mandate without meeting the requirements of the above-described business associate contract, provided that the covered entity attempts in good faith to obtain satisfactory assurances as requirements, a “chain of trust” agreement does not add to overall security. Compliance with the regulation should be sufficient. Response: We believe the commenters are correct that the rule as proposed would--(1) not allow for scalability; and (2) would lead an entity to believe it is responsible, and liable, for making sure all entities down the line maintain	by the plan sponsor on behalf of the group health plan. The plan documents of the group health plan must be amended to incorporate provisions to require the plan sponsor to implement reasonable and appropriate safeguards to protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of the group health plan; ensure that the adequate separation required by § 164.504(f)(2)(iii) is supported by reasonable and appropriate security measures; ensure that any agents, including a subcontractor, to whom it provides this information agrees to implement reasonable and appropriate safeguards to protect the information; report to the group health plan any security incident of which it becomes aware; and make its policies and procedures and documentation relating to these safeguards available to the Secretary for purposes of determining the group health plan's compliance with of the Privacy Rule should facilitate the implementation and coordination of security and privacy policies and procedures by covered entities. In contrast, when another entity is not acting as a business associate for the covered entity, but rather is acting in the capacity of some other sort of trading partner, we do not require the covered entity to require the other entity to adopt particular	A number of commenters expressed some confusion concerning their responsibility for the security of information once it has passed from their control to their trading partner's control, and so on down the trading partner chain. Requests were made that we clarify that chain of trust partner agreements were really between two parties, and that, if a trading partner agreement has been entered into, any given partner would not be responsible, or liable, for the security of data once it is out of his or her control. In line with this concern, several commenters were concerned that they would have some responsibility to ensure the level of security maintained by their trading partner. Several commenters believe a chain of trust partner agreement should not be a security requirement. One commenter stated that because covered entities must already conform to the regulation upon by both parties in order to successfully complete the transmission. However, the determination of the specific transmission mechanisms and the specific security features to be implemented remains a business decision. d. Comment: Several commenters asked whether existing contracts could be used to meet the requirement for a trading partner agreement, or does the rule require entry into a new contract specific to this purpose. Also, the

the same level of security. The confusion here seems to come from the phrase “same level of security.” Our intention was that each trading partner would maintain reasonable and appropriate safeguards to protect the information. We did not mean that partners would need to implement the same security technology or measures and procedures. We have replaced the proposed “Chain of trust” standard with a standard for “Business associate contracts and other arrangements.” When another entity is acting as a business associate of a covered entity, we require the covered entity to require the other entity to protect the electronic protected health information that it creates, receives, maintains or transmits on the covered entity's behalf. The level of security afforded particular electronic protected health information should not decrease just because the covered entity has made the business decision to entrust a business associate with using or disclosing that information in connection with the performance of certain functions instead of doing those functions itself. Thus, the rule below requires covered entities to require their business associates to implement certain safeguards and take other measures to ensure that the information is safeguarded (see § 164.308(b)(1) and §164.314(a)(1)). The specific requirements of § 164.314(a)(1) are drawn from the analogous requirements at	security measures, as previously proposed. This policy is likewise consistent with the general approach of the Privacy Rule (see the discussion in the Privacy Rule at 65 FR 82476). The covered entity is free to negotiate security arrangements with its non-business associate trading partners, but this rule does not require it to do so. A similar approach underlies § 164.314(b) below. These provisions are likewise drawn from, and intended to support, the analogous privacy protections provided for by 45 CFR 164.504(f) (see the discussion of § 164.504(f) of the Privacy Rule at 65 FR 82507 through 82509, and 82646 through 82648). As with the business associate contract provisions, however, they are imported and adapted only to the extent they make sense in the security context. Thus, for example, the requirement at § 164.504(f)(2)(ii)(C) prohibits the plan documents from permitting disclosure of protected health information to the plan sponsor for employment-related purposes. As this prohibition goes entirely to the permissibility of a particular type of disclosure, it has no analog in § 164.314(b). c. Comment: Several commenters stated that if security features are determined by agreements established between “trading partners,” as stated in the proposed regulations, there should be some guidelines or boundaries for those agreements so that extreme or	commenters want to know about those whose working agreements do not involve written contractual agreement: Do they now need to set up formal agreements and incur the additional expense that would entail? Response: This final rule requires written agreements between covered entities and business associates. New contracts do not have to be entered into specifically for this purpose, if existing written contracts adequately address the applicable requirements (or can be amended to do so). e. Comment: Several commenters asked whether covered entities are responsible for the security of all individual health information sent to them, or only information sent by chain of trust partners. They also asked if they can refuse to process standard transactions sent to them in an unsecured fashion. In addition, they inquired if they can refuse to send secured information in standard transactions to entities not required by law to secure the information. One commenter asked if there is a formula for understanding in any particular set of relationships where the ultimate responsibility for compliance with the standards would lie. Response: Pursuant to the Transactions Rule, if a health plan receives an unsecured standard transaction, it may not refuse to process that transaction simply because it was sent in an unsecured manner. The health plan is not responsible under this rule, for

45 CFR 164.504(e) of the Privacy Rule, although they have been adapted to reflect the objectives and context of the security standards. Compare, in particular, 45 CFR 164.504(e)(2)(ii) with § 164.314(a)(1). We have not imported all of the requirements of 45 CFR 164.504(e), however, as many have no clear analog in the security context (see, for example, 45 CFR 164.504(e)(2)(i) regarding permitted and required uses and disclosures made by a business associate). HHS had previously committed to reconciling its security and privacy policies regarding business associates (see 65 FR 82643). The close relationship of many of the organizational requirements in section 164.314 with the analogous requirements covered entity to obtain written assurance from a business associate receiving the transmission that it will provide an adequate level of protection to the information. For the business associate provisions, see § 164.308(b) and § 164.314(a) of this final rule. f. Comment: One commenter asked what security standards a vendor having access to a covered entity's health information during development, testing, and repair must meet and wanted to know whether the rule anticipates having a double layer of security compliance (one at the user level and one at the vendor level). If so, the commenter believes this will cause duplication of work.	unusual provisions are not permitted. Response: This final rule sets a baseline, or minimum level, of security measures that must be taken by a covered entity and stipulates that a business associate must also implement reasonable and appropriate safeguards. This final rule does not, however, prohibit a covered entity from employing more stringent security measures or from requiring a business associate to employ more stringent security measures. A covered entity may determine that, in order to do business with it, a business associate must also employ equivalent measures. This would be a business decision and would not be governed by the provisions of this rule. Security mechanisms relative to the transmission of electronic protected health information between entities may need to be agreed documents and implements the changes in accordance with the applicable requirements. Covered entities must also document designations, for example, of affiliation between covered entities (see § 164.105(b)), and other actions, as required by other provisions of the subpart. 1. Comment: One commenter wanted development of written policies regarding such things as confidentiality and privacy rights for access to medical records, and approval of research by a review board when appropriate. Response: These issues are covered in the Privacy Rule	how the transaction was sent to it (unless the transmission was made by a business associate, in which case different considerations apply); however, once electronic protected health information is in the possession of a covered entity, the covered entity is responsible for the security of the electronic protected health information received. The covered entity must implement technical security mechanisms to guard against unauthorized access to electronic protected health information that is transmitted over an electronic communication network. In addition, the rule requires the transmitting and update will vary dependent upon a given entity's size, configuration, environment, operational changes, and the security measures implemented. **J. Compliance Dates for Initial Implementation (§ 164.318)** We proposed that how the security standard would be implemented by each covered entity would be dependent upon industry trading partner agreements for electronic transmissions. Covered entities would be able to adapt the security matrix to meet business needs. We suggested that requirements of the security standard may be implemented earlier than the compliance date. However, we would require implementation to be complete by the applicable compliance date, which is 24 months after adoption of the standard, and 36 months after adoption of

Response: In the situation described, the vendor would be acting as a business associate. The covered entity must require the business associate to implement reasonable and appropriate security protections of electronic protected health information. This requirement, however, does not impose detailed requirements for how that level of protection must be achieved. The resulting flexibility should permit entities and their business associates to adapt their security safeguards in ways that make sense in their particular environments. g. Comment: A number of commenters requested sample contract language or models of contracts. We also received one comment that suggested that we should not dictate the contents of contracted agreements. Response: We will consider developing sample contract language as part of our guideline development. I. Policies and Procedures and Documentation Requirements (§ 164.316) We proposed requiring documented policies and procedures for the routine and nonroutine receipt, manipulation, storage, dissemination, transmission, and/or disposal of health information. We proposed that the documentation be reviewed and updated periodically. We have emphasized throughout this final rule the scalability allowed by the security standards. This final	(65 FR 82462) (see, in particular, § 164.512(i), § 164.524, and § 164.530(i)). 2. Comment: One commenter asked if standards will override agreements that require others to maintain hardcopy documentation (for example, signature on file) and no longer require submitters to maintain hardcopy documentation. Response: The security standards will require a minimum level of documentation of security practices. Any agreements between trading partners for the exchange of electronic protected health information that impose additional documentation requirements will not be overridden by this final rule. 3. Comment: One commenter stated that there should be a requirement to document only applications deemed necessary by an applications and data criticality assessment. Response: Electronic protected health information must be afforded security protection under this rule regardless of what application it resides in. The measures taken to protect that information must be documented. 4. Comment: One commenter asked how detailed the documentation must be. Another commenter asked what “kept current” meant. Response: Documentation must be detailed enough to communicate the security measures taken and to facilitate periodic evaluations	the standard for small health plans, as provided by the Act. In the proposed rule, we suggested that an entity choosing to convert from paper to standard EDI transactions, before the effective date of the security standard, consider implementing the security standard at the same time. In this final rule the dates by which entities must be in compliance with the standards are called “compliance dates,” consistent with our practice in the Transactions, Privacy, and Employer Identifier Rules. Section 164.318 in this final rule is also organized consistent with the format of those rules. The substantive requirements, which are statutory, remain unchanged. Many of the comments received concerning effective dates and compliance dates, including the compliance dates for modifications of standards, were addressed in the Transactions Rule. Those that were not addressed in that publication are presented below. 1. Comment: A number of commenters expressed support for the effective dates of the rules and stated that they should not be delayed. In contrast, one commenter stated that we should delay this rule to allow for an open consensus building debate to occur concerning security. One commenter asked that the rule be delayed until after implementation of the ICD-CM changes. A number of comments were received expressing the

rule requires covered entities to implement policies and procedures that are reasonably designed, taking into account the size and type of activities of the covered entity that relate to electronic protected health information, and requires that the policies and procedures must be documented in written form, which may be in electronic form. This final rule also provides that a covered entity may change its policies and procedures at any time, provided that it ourselves in the difficult position of reacting to proposed rules setting the standards for how information should be physically and electronically protected, without having reached agreement on the larger issues of consent for and disclosure of individual medical information." Response: The effective date of the final rule is 60 days after this final rule is published in the Federal Register. The statute sets forth the compliance dates for the standards. Covered entities must comply with this final rule no later than 24 months (36 months for small plans) after the effective date. The final Privacy Rule has already been published. We note that numerous comments concerning the timing of the adoption of privacy and security standards were also received in the privacy rulemaking and are discussed in the Privacy Rule at 65 FR 82752. 2. Comment: One commenter	pursuant to § 164.308(a)(8). While the term "current" is not in the final rule, this concept has been adopted in the requirement that documentation must be updated as needed to reflect security measures currently in effect. 5. Comment: We received one comment concerning review and updating of implementing documentation suggesting that "periodically" be changed to "at least annually." Response: We believe that the requirement should remain as written, in order to allow individual entities to establish review and update cycles as deemed necessary. The need for review 4. Comment: One commenter asked us to establish a research site or test laboratory for a trial implementation. Response: The concept of a "trial implementation" that would have widespread relevance is inconsistent with our basic principles of flexibility, scalability, and technology-neutrality. 5. Comment: One commenter stated that the 2-year time frame for implementation of a contingency plan is too short for health plans that serve multiple regions of the country. Response: The Congress mandated that entities must be in compliance 2 years from the initial standard's adoption date (3 years for small plans). **K. Appendix** The proposed rule contained three addenda. Addendum 1 set out in matrix form the proposed requirements and	opinion that the security regulation should not be published until either the Congress has enacted legislation governing standards with respect to the privacy of individually identifiable health information, or the Secretary of HHS has promulgated final regulations containing these standards. One commenter stated, "we find section of the final rule. One commenter stated that the glossary should not be part of this final rule. Response: The terms defined in the glossary in Addendum 2 of the proposed rule are found throughout this final rule, either as part of the text of § 164.306 through § 164.312 or under § 164.304, as appropriate. We included only terms relevant to the particular standards and implementation specifications being adopted. 3. Comment: Several commenters requested that the mapped matrix located in Addendum 3 of the proposed rule be included in this final rule, either as part of the rule or as an addendum, while others stated that it should not be part of this final rule. Several commenters cited items to be added to the mapped matrix. Response: The mapped matrix was merely a snapshot of current standards and guidelines that the implementation team was able to obtain for review during the development of the security and electronic signature requirements and was provided in the proposed rule

asked that proposed § 142.312 be rewritten to separate the effective dates for the Security Rule and the Transactions Rule.

Response: The proposed rule incorporated general language applicable to all the proposed Administrative Simplification standards. Language concerning standards other than Security is not included in § 164.318. Because this final rule is adopted after the Transactions Rule was adopted, the compliance dates for the security standards differ from those for the transactions standards. Comments concerning general effective dates were addressed in the Transactions Rule. Comments specific to the security standards are addressed here.

3. Comment: Several commenters suggested that we not allow early implementation of the Security Rules. A number of others asked that we allow, but not require, early implementation by willing trading partners. Another commenter suggested that early implementation by willing trading partners be allowed as long as the data content transmitted is equal to that required by statute. Another commenter requested that it be stipulated that entities cannot implement less than 1 year from the date of this final rule and then only after successful testing, and that a "start testing by" date be defined.

Response: Whether or not to implement before the compliance date is a business decision that each covered

related implementation features of the proposed rule. Addendum 2 set out in list form a glossary of terms with citations to the sources of those terms. Addendum 3 identified and mapped areas of overlap in the proposed security standard and implementation features.

This final rule retains only the first proposed addendum, the matrix, as an appendix, that is modified to reflect the changes in the administrative, physical, and technical safeguard portions of the rule below. Numerous terms in the glossary now appear in the rule below, typically (but not always) as definitions.

1. Comment: Over two-thirds of the comments received on this topic asked that the matrix be incorporated into the final rule. One commenter asked that a simplified version be made part of the final rule. Six commenters wanted it kept in this final rule as an addendum. One commenter stated that it should be in an appendix to the rule, while others stated that it should not be included in this final rule.

Response: Since a significant majority of commenters requested retention of the matrix, it has been incorporated into this final rule as an appendix. The matrix displays, in tabular form, the administrative, physical, and technical safeguard standards and relating implementation specifications described in this final rule in § 164.308, § 164.310, and § 164.312. It should be noted that the requirements of § 164.105, § 164.314, and § 164.316 are

as background material. Since this matrix has not been fully populated or kept up-to-date, it is not being published as part of this final rule. Where relevant, we do reference various standards and guidelines indicated in the matrix in this preamble.

L. Miscellaneous Issues

1. Preemption

The statute requires generally that the security standards supersede contrary provisions of State law including State law requiring medical or health plan records to be maintained or transmitted in written rather than electronic formats. The statute provides certain exceptions to the general rule; section 1178(a)(2) of the Act identifies conditions under which an exception applies. The proposed rule did not provide for a process for making exception determinations; rather, a process was proposed in the privacy rulemaking and was adopted with the Privacy Rule (see part 160, subpart B). This process applies to exception determinations for all of the Administrative Simplification rules, including this rule.

a. Comment: Several commenters stated that the proposed rule does not include substantive protections for the privacy rights of patients' electronic medical records, while the rule attempts to preempt State privacy laws with respect to these records. Comments stated that, by omitting a clarification of State privacy law applicability, the proposed rule creates confusion. They believe that

entity must make. Moreover, the vast majority of the standards address internal policies and procedures that can be implemented at any time without any impact on trading partners. express and specific exemptions of State laws with respect to medical privacy. Response: The Privacy Rule establishes standards for the rights of patients in regard to the privacy of their medical records and for the allowable uses and disclosures of protected health information. The identified concerns were discussed in the Privacy Rule (see 65 FR 82587 through 82588). The security standards do not specifically address privacy but will safeguard electronic protected health information against unauthorized access or modification. b. Comment: One commenter asked how these regulations relate to confidentiality laws, which vary from State to State. Response: It is difficult to respond to this question in the abstract without the benefit of reference to a specific State statute. However, in general, these security standards will preempt contrary State laws. Per section 1178(a)(2) of the Act, this general rule would not hold if the Secretary determines that a contrary provision of State law is necessary for certain identified purposes to prevent fraud and abuse; to ensure appropriate State regulation of insurance and health plans; for State reporting on health care delivery costs; or if it	not presented in the matrix. 2. Comment: A large majority of commenters stated that the glossary located in Addendum 2 of the proposed rule should be included as part of the final rule. Several commenters asked that it be incorporated into the definitions security standards in this final rule supersede contrary State law. Only where the Secretary has granted an exception under section 1178(a)(2)(A) of the Act, or in situations under section 1178(b) or (c) of the Act, will the general rule not hold true. Covered entities may be required to adhere to stricter State-imposed security measures that are not contrary to this final rule. 2. Enforcement . The proposed rule did not contain specific enforcement provisions. This final rule likewise does not contain specific enforcement provisions; it is expected that enforcement provisions applicable to all Administrative Simplification rules will be proposed in a future rulemaking. a. Comment: One commenter voiced support for the proposed rule's approach. Another stated that the process is poorly defined. One commenter stated that fines should be eliminated, or the scope of activity subject to fines should be more narrowly defined. While a number of commenters were of the opinion that HHS must retain enforcement responsibility, stating that it would be unconstitutional to give it to a private entity, several others	the rule must contain 3. Comment Period The comment period on the proposed rule was 60 days. Comment: We received comments suggesting that significant changes to the standards could occur in the final rule as a result of changes made in response to comments. The commenter believes such changes could adversely affect payers and providers, and suggested that the rule should be republished as a proposed rule with a new comment period to allow additional comments concerning any changes. A “work-in- progress” approach was also suggested, to give all stakeholders time to read, analyze, and comment upon evolving versions of a particular proposed rule. Response: We have not accepted these suggestions. The numerous comments received were thoughtful, analytical, detailed, and addressed every area of the proposed rule. This response to the proposed rule indicates that the public had ample time to read, analyze, and comment upon the proposed rule. If we were to treat the rule as a “work-in- progress” and issue evolving versions, allowing for comments to each version, we would never implement the statute and achieve administrative simplification as directed by the Congress. **M. Proposed Impact Analysis** The preamble to the Transactions Rule contains comments and responses on

addresses controlled substances. See 45 CFR part 160 subpart B. In such case, the contrary provision of State law would preempt a Federal provision of these security standards. State laws that are related but not contrary to this final rule, will not be affected. Section 1178 of the Act also limits the preemptive effect of the Federal requirements on certain State laws other than where the Secretary makes certain determinations. Section 1178(b) of the Act provides that State laws for reporting of disease and other conditions and for public health surveillance, investigation, or intervention are not invalidated or limited by the Administrative Simplification rules. Section 1178(c) of the Act provides that the Federal requirements do not limit States' abilities to require that health plans report or provide access to certain information. c. Comment: Several commenters stated that allowing State law to establish additional security restrictions conflicts with the purpose of the Federal rule and/or would make implementation very difficult. One commenter asked for clarification as to whether additional requirements tighter than the requirements outlined in the proposed rule may be imposed. Response: The general rule is that the HHS cost estimates should be publicized for comparison purposes. Still another commenter stated	stated that it may not be practical for HHS to retain the responsibility for determining violations and imposing penalties specified by the statute. A concern was voiced over HHS's ability to fairly and consistently apply the rules due to budget constraints. Several commenters support industry solutions to enforcement with some level of government involvement. One commenter recommended a single audit process using accrediting bodies already in place. Another stated that entities providing accreditation services should not be involved in enforcement as this would result in a conflict of interest. Clarification was requested, including the use of examples, concerning what constitutes a violation, and how a penalty applies to a “person.” Commenters asked if the term “person” referred to the people responsible for the system and how penalties would apply to corporations and other entities. Response: It is expected that enforcement of HIPAA standards will be addressed in regulations to be issued at a later date. b. Comment: Several commenters stated that enforcement of the security standards will be arbitrarily delegated to private businesses that compete with physicians and with each other. Response: These comments are premature for the reasons stated above.	the impact of all the administrative simplification standards in general except privacy. Comments and responses specific to the relative impact of implementing this final rule are presented below. a. Comment: Several commenters stated that the proposed security standards are complex, costly, administratively burdensome, and could result in decreased use of EDI. One commenter stated that this rule runs counter to the explicit intent of Administrative Simplification that requires, “any standard adopted under this part shall be consistent with the objective of reducing the administrative costs of providing and paying for health care.” Several commenters expressed concern that there was no cost benefit analysis provided for these proposed regulations, stating that, faced with increasingly limited resources, it is essential that a security standards cost/benefit analysis for all health care trading partners be provided. Another said an independent cost estimate by the General Accounting Office (GAO) should be performed on these rules and are significant issues regarding the funding and implementation of HIPAA by Medicaid State agencies, and intends to address them through normal channels of communication with States. d. Comment: One commenter stated that the proposed rule does not establish how the

that HHS must provide accurate public sector implementation cost figures and provide funds to offset the cost burden. One commenter asked for cost benefit evaluations to understand the relationship between competing technologies, levels of security and potential threats to be guarded against. These would demonstrate the costs and the benefits to be gained for both large and small organizations and would provide an understanding of how the levels of security vary by organization size and what the inducements and support available to facilitate adoption are. One commenter suggested that we establish a workgroup to more fully assess the costs and provide Federal funds to offset implementation costs. One commenter noted a seeming disconnect between two statements in the preamble. Section A, Security standards, states, "no individual small entity is expected to experience direct costs that exceed benefits as a result of this rule." In contrast, section E, Factors in establishing the security standards reads, "We cannot estimate the per-entity cost of implementation because there is no information available regarding the extent to which providers', plans', and clearinghouses' current security practices are deficient." Response: We are unable to estimate, of the nation's 2 million-plus health plans and 1 million-plus providers that	significant changes to this final rule, reducing the number of required implementation features and providing for greater flexibility in satisfaction of the requirements. In other words, we have focused more on what needs to be done and less on how it should be accomplished. We have removed the statement regarding the extent of costs versus benefits for small entities. b. Comment: One commenter stated that on page 43262 of the proposed rule, it indicate that complexity of conversion to the security standards would be affected by the choice to use a clearinghouse. The commenter stated that this choice would have little effect on implementation of security standards. Another commenter stated that the complexity (and cost) of the conversion to meet the security standards is affected by far more than just the "volume of claims health plans process electronically and the desire to transmit the claims or to use the services of a VAN or clearinghouse" as is stated on page 43262. Because the security standards apply to internal systems as well as to transactions between entities, a number of additional factors must be considered, for example, modification of existing security mechanisms, legacy systems, architecture, and culture. Response: We agree. We have modified the Regulatory Impact Analysis section to take into account that there are other factors involved, such as the architecture and	security standards will contribute to reduced cost for providers. One commenter expected the unintended result of this regulation will be impediment of EDI growth and perhaps even a decline in EDI use by providers. Another stated that the proposed rule actively discourages physician EDI participation by suggesting a fallback to paper processing for those unable to meet the cost of highly complex security compliance. Response: Ensuring the integrity of an electronic message, its delivery to the correct person, and its confidentiality must be an integral part of conducting electronic commerce. We believe that the consistent application of the measures provided in this rule will actually encourage use of EDI because it will provide increased confidence in the reliability and confidentiality of health information to all parties involved. Also, the implementation of these security requirements will reduce the potential overall cost of risk to a greater extent than additional security controls will increase costs. Put another way, the potential cost of not reasonably addressing security risks could substantially exceed the cost of compliance. e. Comment: One commenter stated that the implementation impact of the technical safeguards is clearly understated for physicians who use digitally-based equipment that has been in place for some time. The commenter believes that the

conduct electronic transactions, the number of entities that would require new or modified security safeguards and procedures beyond what they currently have in place. Nor are we able to estimate the number of entities that neither conduct electronic transactions nor maintain individually identifiable electronic health information but may become covered entities at some future time. As we are unable to estimate the number of entities and what measures are or are not already in place, or what specific implementation will be chosen to meet the requirements of the regulation, we are also unable to estimate the cost to those entities. However, the use of electronic technology to maintain or transmit health information results in many new and potentially large risks. These risks represent expected costs, both monetary and social. Leaving risk assessment up to individual entities will minimize the impact and ensure that security effort is proportional to security risk. As discussed earlier, the security requirements are both scalable and technically flexible. We have made a new regulatory mandate, HIPAA costs must be factored into any base year calculations for the proposed prospective payment system. Without an adjustment, this will be another regulatory mandate that comes at the cost of patient care. Response: Costs included in	technology limitations of existing systems. c. Comment: One commenter stated that States will need 90 percent funding of development and implementation, without the burden of an advanced planning documents requirement, from us for this costly process to succeed. Any new operational obligation should be 100 percent funded. Also human resource obligations will be significant. Some States believe they will have difficulty obtaining the budget funds for the State share of the costs. State Medicaid agencies, as purchasers, may also face paying the implementation costs of health care providers, clearinghouses, and health plans in the form of higher rates. Response: The statute does not authorize any new or special funding for implementation of the regulations. Medicaid system changes, simply because they are “HIPAA related” do not automatically qualify for 90 percent Federal funding participation. As with any systems request, the usual rules will be applied to determine funding eligibility for State HIPAA initiatives. Nevertheless, HHS recognizes that there 1. Response: We agree. The health care industry is striving to do this. HHS is also considering provider outreach and education activities. 2. IV. Provisions of the Final Regulation ▪ We have made the	rule will likely have greatest impact on the installed base of digital systems, including imaging modalities and other medical devices that store or transmit patient information because software for legacy systems will likely require retrofitting or replacement to come into compliance. The commenter believes that this is a negative impact and would outweigh any benefits derived from the potential risk of security breaches. The commenter recommended compliance for digital imaging devices be extended by an additional 3 years to allow time to upgrade systems and defray the associated costs. Response: Compliance dates for the initial implementation of the initial standards are statutorily prescribed; therefore, we are unable to allow additional time outside of the statutory timeframes for compliance. f. Comment: A commenter stated that, as 1. specification,” since this information is covered in the “Standards for Electronic Transactions” final rule (65 FR 50312). ▪ Moved proposed § 142.302 to § 164.302. Changed the section heading from “Applicability and scope” to “Applicability.” Modified language to state that covered entities must comply with the security standards. ▪ Moved proposed § 142.304 to § 164.304. Modified language to remove definitions of words and concepts not used in this final rule: “Access control,”

the prospective payment system are legislatively mandated. The Congress did not direct the inclusion of HIPAA costs into the system, so they are not included. However, the Department believes that the HIPAA standards will provide savings to the provider community over the next 10 years. g. Comment: One commenter suggested that we include requirements for how a compliant business could dually operate--(1) in a HIPAA compliant manner; and (2) in their former noncompliant manner in order to accommodate doing business with other organizations that are not yet compliant. Response: The statute imposes a 2-year implementation period between the adoption of the initial standards and the date by which covered entities (except small health plans) must be in compliance. An entity may come into compliance at any point in time during the 2 years. Therefore, the rule does not require a covered entity to comply before the established compliance date. Those entities that come into compliance before the 2-year deadline should decide how best to deal with entities that are not yet compliant. Further, we note that, generally speaking, compliance by a covered entity with these Security Rules will not hinge on compliance by other entities. h. Comment: One commenter stated that privacy legislation could impose significant	following changes to the provisions of the August 12, 1998 proposed rule. Specifically, we have— ▪ Changed the CFR part from 142 to 164. ▪ Removed information throughout the document pertaining to electronic signature standards. Electronic signature standards will be published in a separate final rule. ▪ Replaced the word "requirement," when referring to a standard, with "standard." Replaced "Implementation feature" with "Implementation specification." ▪ Made minor modifications to the text throughout the document for purposes of clarity. ▪ Modified numerous implementation features so that they are now addressable rather than mandatory. ▪ Removed the word "formal" when referring to documentation. ▪ Revised the phrase "health information pertaining to an individual" to "electronic protected health information." ▪ Added the following definitions to § 160.103: "Disclosure," "Electronic protected health information," "Electronic media," "Organized health care arrangement," and "Use." ▪ Removed proposed § 142.101 as this information is conveyed in § 160.101 and §160.102 of the Privacy Rule (65 FR 82798). Removed proposed § 142.102 as it is redundant.	"Contingency plan," "Participant," "Role-based access control," "Token," and "User-based access." ▪ Moved proposed § 142.304 to § 164.304. Modified language to add definitions requested by commenters; previously published in Addendum 2 but not in the draft regulation itself; or necessitated by the change of scope to electronic protected health information and alignment with the Privacy Rule to include: "Administrative safeguards," "Availability," "Confidentiality," "Data," "Data authentication Code," "Integrity," "Electronic protected health information," "Facility," "Information System," "Security or security measures," "Security incident," "Technical safeguards," "User," and "Workstation." ▪ Moved definitions related to privacy from § 164.504 to new § 164.103: "Common control," "Common ownership," "Health care component," "Hybrid entity." ▪ Moved proposed § 142.306, "Rules for the security Standard," to § 164.306. Modified language to more clearly state the general requirements of the final rule relative to the standards and implementation specifications contained therein. Retitled the section as "Security standards: General Rules." ▪ Moved proposed § 142.308 to § 164.308. Where this section was proposed to contain all of the security standards in paragraphs (a) through (d), it now encompasses the

changes to written policies and procedures on authorization, access to health information, and how sensitive information is disclosed to others. The commenter believes these changes could mean the imposition of security requirements different from those contained in the proposed rule, and money spent complying with the security provisions could be ill spent if significant new requirements result from the privacy legislation. Response: The privacy standards at subpart E of 42 CFR part 164 are now in effect, and this final rule is compatible with them. If, in the future, the Congress passes a law whose provisions differ from these standards, the standards would have to be modified. i. Comment: One commenter stated that the private sector should develop educational tools or models in order to assist physicians, other providers, and health plans to comply with the security regulations. ▪ Moved proposed § 142.308(a)(3), "Contingency plan," to §164.308(a)(7)(i). Modified language to state that two implementation specifications, "Applications and data criticality analysis" and "Testing and revision procedures," are addressable. ▪ Removed "Formal mechanism for processing records" (proposed § 142.308(a)(4)) since this requirement was determined to be in part intrusive into	▪ Removed the following definitions from proposed § 142.103 since they are pertinent to other administrative simplification regulations and are defined elsewhere: code set, health care clearinghouse, health care provider, health information, health plan, medical care, small health plan, standard, and transaction. ▪ Moved the following definitions from § 164.501 to § 164.103 (proposed § 142.103): " "Plan sponsor" and "Protected health information." Added definitions of "Covered functions" and "Required by law." ▪ Removed proposed § 142.104, "General requirements for health plans," and proposed § 142.105, "Compliance using a health care clearinghouse," since these sections are not pertinent to the security standards. ▪ Removed proposed § 142.106, "Effective dates of a modification to a standard or implementation "Documentation" (hardware and/or software installation, Inventory, Security testing, and Virus checking), since this requirement was determined to be redundant. "Documentation" has been made a discrete standard at § 164.316. ▪ Moved proposed § 142.308(a)(9), "Security incident procedures," to § 164.308(a)(6)(i) and reworded for clarity. Combined "Report procedures" and "Response procedures" features into a	Administrative safeguards. ▪ Moved and reorganized proposed § 142.308 (a) through (d) requirements to § 164.308, § 164.310, and § 164.312. ▪ Moved proposed §142.308(a)(1), "Certification," to § 164.308(a)(8). Modified language to indicate both technical and nontechnical evaluation is involved and renamed "Evaluation". ▪ Moved proposed § 142.308(a)(2), "Chain of trust," to §164.308(b)(1), renamed to "Business associate contracts and other arrangements," and revised language to redefine who must enter into a contract under this rule for the protection of electronic protected health information. □ implementation specification at § 164.310(d)(2)(ii). ▪ Removed proposed § 142.308(b)(2)(i), "Access control," implementation feature as it was determined to be redundant. ▪ Moved proposed § 142.308(b)(2)(ii), "Accountability" implementation feature to §164.310(d)(2)(iii), and made it an addressable implementation specification. ▪ Combined proposed §142.308(b)(2)(iii), "Data back-up," implementation feature with proposed § 142.308(b)(2)(iv), "Data storage" implementation feature, renamed as "Data back-up and storage", moved to § 164.310(d)(2)(iv), and made it an addressable implementation specification.

business functions and in part redundant. ▪ Moved proposed § 142.308(a)(5), "Information access control," to § 164.308(a)(4)(i) and renamed as "Information access management." removed the word "formal" from description. Modified language to state that two implementation specifications ("Access Authorization" and Access Establishment and Modification") are addressable. ▪ Moved proposed § 142.308(a)(6), "Internal audit," to § 164.308(a)(1)(ii)(D) as an implementation specification under the "Security management process" standard since this was determined to be a more logical placement of this item. Retitled, for clarity, "Information system activity review." ▪ Moved proposed § 142.308(a)(7), "Personnel security," to § 164.308(a)(3)(i) and retitled "Workforce security." Modified language to state that implementation specifications are addressable. ▪ Combined proposed § 142.308(a)(7)(i), and § 142.308(a)(7)(iii) ("Assuring supervision of maintenance personnel by an authorized, knowledgeable person" and "Assuring that operations and maintenance personnel have proper access authorization,") under § 164.308(a)(3)(ii)(A) and renamed to "Authorization and/or supervision." Modified description for clarity. ▪ Moved proposed §	single required implementation specification, named "Response and Reporting" at § 164.308(a)(6)(ii). ▪ Moved proposed § 142.308(a)(10), "Security management process," to § 164.308(a)(1 ▪ Moved proposed § 142.308(a)(10)(i), "Risk analysis," to § 164.308(a)(1)(ii)(A). ▪ Moved proposed § 142.308(a)(10)(ii), "Risk management," to § 164.308(a)(1)(ii)(B). ▪ Moved proposed § 142.308(a)(10)(iii), "Sanction policy," to § 164.308(a)(1)(ii)(C). ▪ Removed proposed § 142.308(a)(10)(iv), "Security policy," since this requirement was determined to be redundant. ▪ Moved proposed § 142.308(a)(11), "Termination," to § 164.308(a)(3)(ii)(C) as an addressable implementation specification under the "Workforce security" standard, and renamed as "Termination procedures". Removed "Termination" implementation features (changing locks, removal from access lists, removal of user accounts, turning in of keys, tokens, or cards) since these were determined to be too specific. ▪ Moved proposed § 142.308(a)(12), "Training," to § 164.308(a)(5)(i) and renamed as "Security awareness and training." Language modified to incorporate all training information under this one standard. Revised and made addressable all	▪ Moved proposed § 142.308(b)(2)(v), "Data disposal," implementation feature to § 164.310(d)(2)(i) and made it a required implementation specification. ▪ Moved proposed §142.308(b)(3),"Physical access controls," to § 164.310(a)(1) and renamed as "Facility access controls." Removed word "formal." ▪ Moved proposed §142.308(b)(3)(i), "Disaster recovery," implementation feature to §164.310(a)(2)(i). It is now part of the "Contingency operations" implementation specification. ▪ Moved proposed §142.308(b)(3)(ii), "Emergency mode operations," implementation feature to §164.310(a)(2)(i). It is now part of the "Contingency operations" implementation specification. ▪ Removed proposed §142.308(b)(3)(iii), "Equipment control (into and out of site)," as this information is now covered under § 164.310(d)(1), "Device and media controls." ▪ Moved proposed § 142.308(b)(3)(iv), "A facility security plan," to § 164.310(a)(2)(ii). ▪ Moved proposed § 142.308(b)(3)(v), "Procedure for verifying access authorizations," to § 164.310(a)(2)(iii) and renamed as "Access control and validation procedures." Removed the word "formal" from text. ▪ Moved proposed §142.308(b)(3)(vi),

142.308(a)(7)(iv), "Personnel clearance procedure," to § 164.308(a)(3)(ii)(B), renamed to "Workforce clearance procedure," and modified description for clarity. ▪ Removed proposed § 142.308(a)(7)(v), "Personnel security policies and procedures," as this feature was determined to require redundant effort. ▪ Removed proposed § 142.308(a)(7)(vi), "Security awareness training." Information concerning this subject has been incorporated under § 164.308(a)(5)(i), "Security awareness and training." ▪ Removed proposed § 142.308(a)(8), "Security configuration management," and all implementation features, except in visitors and provide escort, if appropriate," to § 164.310(a)(2)(iii) and renamed as "Access control and validation procedures." ▪ Moved proposed § 142.308(b)(3)(ix), "Testing and revision," to § 164.310(a)(2)(iii) and renamed as "Access control and validation procedures." ▪ Moved proposed §142.308(b)(4), "Policy and guidelines on workstation use," to §164.310(b) and renamed as "Workstation use." ▪ Moved proposed §142.308(b)(5), "Secure work station location," to § 164.310(c) and renamed as "Workstation security." ▪ Removed proposed § 142.308(b)(6), "Security awareness training," as a	implementation specifications under this standard. ▪ Moved proposed § 142.308(b), "Physical safeguards to guard data integrity, confidentiality and availability," to § 164.310 and renamed as "Physical safeguards." Removed specific reference to locks and keys. ▪ Moved proposed §142.308(b)(1), "Assigned security responsibility requirement," to §164.308(a)(2) since this has been determined to be an administrative procedure. Modified language to clarify that responsibility could be assigned to more than one individual. ▪ Moved proposed § 142.308(b)(2), "Media controls," to § 164.310(d)(1) and renamed as "Device and media controls." Removed the word "formal." Added "Media re-use" as a required implementation specification. Removed reference to double keying. ▪ Moved proposed §. 142.308(c)(1)(v), "Entity authentication," to § 164.312(d) and retitled as "Person or entity authentication." ▪ Moved proposed § 142.308(c)(1)(v)(A), "Automatic logoff," to § 164.312(a)(2)(iii). ▪ Moved proposed § 142.308(c)(1)(v)(B), "Unique user identification," to § 164.312(a)(2)(i). ▪ Removed proposed § 142.308(c)(1)(v)(C) since text is no longer pertinent. ▪ Removed proposed §	"Maintenance records," to §164.310(a)(2)(iv). ▪ Moved proposed § 142.308(b)(3)(vii), "Need to know procedures for personnel access," to § 164.310(a)(2)(iii) and renamed as "Access control and validation procedures." ▪ Moved proposed §142.308(b)(3)(viii), "Procedures to sign the "Physical safeguards." ▪ Moved proposed § 142.312, "Effective date of the implementation of the security and electronic signature standards," to § 164.318 and retitled as "Compliance dates for the initial implementation of the security standards." Reworded and retitled subsections. ▪ Added § 164.105, "Organizational requirements," with two standards, "Health care component and "Affiliated covered entities" with related implementation specifications. ▪ Added §164.310(d)(2)(ii), "Media re-use procedures," implementation specification. ▪ Added § 164.312, "Technical safeguards," encompassing the combined technical services and technical mechanisms standards (proposed § 142.308(c) and (d)). ▪ Added § 164.314, "Organizational requirements." ▪ Added §164.314(a)(1), "Business associate contracts or other arrangements" standard and related implementation specifications. ▪ Added § 164.314(b)(1), "Requirements for group

separate requirement. This requirement has been incorporated under §164.308(a)(5)(i), "Security awareness and training." ▪ Combined and moved proposed §. 142.308(c) and §142.308(d), "Technical security services to guard data integrity, confidentiality and availability" and "Technical security mechanisms," to § 164.312 and renamed as "Technical safeguards." ▪ Removed proposed § 142.308(c)(1) since it is no longer pertinent. ▪ Moved proposed §. 142.308(c)(1)(i), "Access control," to §. 164.312(a)(1). ▪ Moved proposed §142.308(c)(1)(i)(A), "Procedure for emergency access," to §164.312(a)(2)(ii), and renamed as "Emergency access procedures." ▪ Removed proposed § 142.308(c)(1)(i)(B). ▪ Removed proposed §142.308(c)(1)(i)(B)(1), "Context- based access," §142.308(c)(1)(i)(B)(2), "Role-based access," and § 142.308(c)(1)(i)(B)(3), "User-based access," since these features were deemed too specific and were perceived as the only options permissible. ▪ Moved proposed § 142.308(c)(1)(i)(C), "Optional use of encryption," to § 164.312(a)(2)(iv) and retitled "Encryption and decryption." ▪ Moved proposed § 142.308(c)(1)(ii), "Audit controls," to § 164.312(b). ▪ Removed proposed § 142.308(c)(1)(iii), "Authorization control," and all	142.308(c)(1)(v)(C)(2), "Password," as too specific. ▪ Removed proposed § 142.308(c)(1)(v)(C)(3), "PIN," as too specific. ▪ Removed proposed § 142.308(c)(1)(v)(C)(4), "Telephone callback," as too specific. ▪ Removed proposed § 142.308(c)(1)(v)(C)(5), "Token," as too specific. ▪ Removed proposed § 142.308(c)(2), as no longer relevant. ▪ Moved proposed § 142.308(d)(1), "Communications or network controls," to § 164.312(e)(1) and renamed as "Transmission security." ▪ Removed proposed § 142.308(d)(1)(i), since it is no longer pertinent. ▪ Moved proposed § 142.308(d)(1)(i)(A), "Integrity controls," to § 164.312(e)(2)(i) and reworded for clarity. ▪ Removed proposed § 142.308(d)(1)(i)(B), "Message authentication," since this subject is now covered under § 164.312(e)(2)(i), "Integrity controls." ▪ Removed proposed § 142.308(d)(1)(ii) text since it is no longer pertinent. ▪ Removed proposed § 142.308(d)(1)(ii)(A), "Access controls." ▪ Moved proposed § 142.308(d)(1)(ii)(B), "Encryption," to § 164.312(e)(2)(ii) and reworded to enhance flexibility and scalability. ▪ Removed proposed § 142.308(d)(2) text regarding:	health plans" standard and related implementation specifications. ▪ Added § 164.316, "Policies and procedures and documentation requirements." ▪ Added § 164.316(a), "Policies and procedures" standard. ▪ Added § 164.316(b)(1), "Documentation" standard and related implementation specifications. ▪ Added § 164.318, "Compliance dates for the initial implementation of the security standards." ▪ Renamed Addendum 1 as Appendix A. ▪ Removed Addendum 2. Definitions of terms used in this final rule are now incorporated into § 164.103 and § 164.304, or within the rule itself. ▪ Removed Addendum 3. V. Collection of Information Requirements Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues: ▪ The need for the information collection and its usefulness in carrying out the

implementation features (Role-based access, User- based access) since this function has been incorporated into §164.308(a)(4), "Information access management." ▪ Moved proposed § 142.308(c)(1)(iv), "Data Reworded part of description and placed in § 164.312(c)(2), "Mechanism to authenticate data," a new, addressable ▪ The accuracy of our estimate of the information collection burden. ▪ The quality, utility, and clarity of the information to be collected. ▪ Recommendations to minimize the information collection burden on the affected public, including automated collection techniques. As discussed below, we are soliciting comment on the recordkeeping requirements, as referenced in § 164.306, § 164.308, § 164.310, § 164.314, and § 164.316 of this document. Section 164.306 Security Standards: General Rules Under paragraph (d), a covered entity must, if implementing the implementation specification is not reasonable and appropriate, document why it would not be reasonable and appropriate to implement the implementation specification. We estimate that 75,000 entities will be affected by this requirement and that they will have to create documentation 3 times for this requirement. We estimate each instance of	"Network controls," and all implementation features ("Alarm," "Audio trail," "Entity authentication," "Event reporting"). ▪ Removed proposed § 142.310, "Electronic signature," and all subheadings. This section will be issued as a separate future regulation. ▪ Moved proposed § 142.310 "Electronic signature Standard," to § 164.310. Where this section was proposed to contain the electronic signature standard, it now encompasses Section 164.310 Physical Safeguards This section requires that a covered entity implement policies and procedures to document repairs and modifications to the physical components of a facility that are related to security (for example, hardware, walls, doors, and locks). We believe that 15,500 entities will have to repair or modify physical components, most of which will need to be done in the first year of implementation. In the following years, we estimate that 500 entities will need to make repairs or modifications. We estimate that it will take 10 minutes to document each repair or modification for a burden of 2,583 hours the first year and 83 hours annually subsequently. This section requires that a covered entity create a retrievable, exact copy of electronic protected health	proper functions of our agency. satisfactory assurances as required by paragraph (a)(2)(ii)(A) of this section, and documents the attempt and the reasons that these assurances cannot be obtained. We believe that this situation will affect 20 entities and that it will take 60 minutes to document attempts to obtain assurances and the reasons they cannot be obtained for an annual burden of 20 hours. This section further requires that business associate contracts or other arrangements and group health plans must require the business entity and plan sponsor, respectively, to report to the covered entity any security incident of which it becomes aware. We believe that the burden associated with this requirement is not subject to the PRA. It is good business practice for entities to document their agreements via written contracts, and as such is usual and customary among the entities subject to them. A burden associated with a requirement conducted in the normal course of business is exempt from the PRA as defined in 5 CFR 1320.3(b)(2). Section 164.316 Policies and Procedures and Documentation Requirements Paragraph (b)(1), Standard: Documentation, of this section requires a covered entity to— (i) Maintain the policies and

documentation will take .25 hours, for a one-time total burden of 56,250 hours. Section 164.308 Administrative Safeguards Under this section, a covered entity must document known security incidents and their outcomes. We estimate that there will be 50 known incidents annually and that it will take 8 hours to document this requirement, for an annual burden of 400 hours. This section further requires that each entity have a contingency plan, with specified components. We estimate that there will be 60,000 entities affected by this requirement and that it will take each entity 8 hours to comply, for a total one-time burden of 480,000 hours. This section also requires that the written contract or other arrangement with a business associate document the satisfactory assurances that the business associate will appropriately safeguard the information through a written contract or other arrangement with the business associate that meets the applicable requirements of §164.314(a). 1. We believe that the burden associated with this requirement is not subject to the PRA. It is good business practice for entities to document their arrangements via written contracts and as such is usual and customary among the entities subject to them. A burden associated with a requirement conducted in the normal course of business is exempt from the PRA as defined in 5 CFR	information, where needed, before movement of equipment. We believe that the burden associated with this requirement is not subject to the PRA. It is good business practice for entities to back-up their data files, and as such is usual and customary among the entities subject to them. A burden associated with a requirement conducted in the normal course of business is exempt from the PRA as defined in 5 CFR 1320.3(b)(2). Section 164.314 Organizational Requirements This section requires that a covered entity report to the Secretary problems with a business associate's pattern of an activity or practice of the business associate that constitute a material breach or violation of the business associate's obligation under the contract or other arrangement if it is not feasible to terminate the contract or arrangement. We believe that 10 entities will need to comply with this reporting requirement and that it will take them 60 minutes to comply with this requirement for an annual burden of 10 hours. This section also requires that a covered entity may, if a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of business associate as specified in §160.103 of this subchapter to a covered entity, permit the business associate to create, receive, maintain, or	procedures implemented to comply with this subpart in written (which may be electronic) form; and (ii) If an action, activity, assessment, or designation is required by this subpart to be documented, maintain a written (which may be electronic) record of the action, activity, assessment, or designation. We estimate that it will take the 4,000,000 entities covered by this final rule 16 hours to document their policies and procedures, for a total one-time burden of 64,000,000 hours. The total annual burden of the information collection requirements contained in this final rule is 64,539,264 hours. These information collection requirements will be submitted to OMB for review under the PRA and will not become effective until approved by OMB. If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following: Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: Reports The required risk analysis is also a tool to allow flexibility for entities in meeting the requirements of this final rule. The risk analysis requirement is designed to allow entities to look at their own operations and determine the security risks involved. The degree of

1320.3(b)(2). Clearance Officer, 7500 Security Boulevard, Baltimore, MD 21244-1850, Attn: Julie Brown, CMS-0049-F; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer. **IV. Regulatory Impact Analysis** **A. Overall Impact** We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132. Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Although we cannot determine	transmit electronic protected health information on its behalf to the extent necessary to comply with the legal mandate without meeting the requirements of paragraph (a)(2)(i) of this section, provided that the covered entity attempts in good faith to obtain businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. While each standard may not have a significant impact on a substantial number of small entities, the combined effects of all the standards are likely to have a significant effect on a substantial number of small entities. Although we have certified this rule as having a significant impact, we have previously discussed the impact of small entities in the RFA published as part of the August 17, 2000 final regulation for the Standards for Electronic Transactions (65 FR 50312), on pages 50359 through 50360. That analysis included the impact of the set of HIPAA standards regulations (transactions and code sets, identifiers, and security). Although we discussed the impact on small entities in the previous analysis, we would like to discuss how this final rule has been structured to minimize the impact on small entities, compared to the proposed rule. The proposed rule mandated	response is determined by the risks identified. We assume that smaller entities, who deal with smaller amounts of information would have smaller physical facilities, smaller work forces, and therefore, would assume less risk. The smaller amount of risk involved means that the response to that risk can be developed on a smaller scale than that for larger organizations. Individuals and States are not included in the definition of a small entity. However, the security standards will affect small entities, such as providers and health plans, and vendors in much the same way as they affect any larger entities. Small providers who conduct electronic transactions and small health plans must meet the provisions of this regulation and implement the security standards. A more detailed analysis of the impact on small entities is part of the impact analysis published on August 17, 2000 (65 FR 50312), which provided the impact for all of the HIPAA standards, except privacy. As we discussed above, the scalability factor of the standards means that the requirements placed upon small providers and plans would be consistent with the complexity of their operations. Therefore, small providers and plans with appropriate security processes in place would need to do relatively little in order to comply with the standards. Moreover, small plans will have an additional year to come into compliance. In addition, section 1102(b) of

the specific economic impact of the standards in this final rule (and individually each standard may not have a significant impact), the overall impact analysis makes clear that, collectively, all the standards will have a significant impact of over $100 million on the economy. Because this rule affects over 2 million entities, a requirement as low as $50 per entity would render this rule economically significant. This rule requires each of these entities to engage in, for example, at least some risk assessment activity; thus, this rule is almost certainly economically significant even though we do not have an estimate of the marginal impact of the additional security standards. However, the standards adopted in this rule are considerably more flexible than those anticipated in the overall impact analysis. Therefore, their implementation costs should be lower than those assumed in the impact analysis. The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We estimate that implementation of all the standards will require the expenditure of more than $110 million by the private	69 implementation features for all entities. A large number of commenters indicated that mandating such a large number would be burdensome for all entities. As a result, we have restructured this final rule to permit greater flexibility. While all standards must be met, we are now only requiring 13 implementation specifications. The remainder of the implementation specifications is “addressable.” For addressable specifications, an entity decides whether each specification is a reasonable and appropriate security measure to apply within its particular security framework. This decision is based on a variety of factors, for example, the entity's risk analysis, what measures are already in place, the particular interest to small entities, and the cost of implementation. Based on the decision, an entity can--(1) implement the specification if reasonable and appropriate; (2) implement an alternative security measure to accomplish the purposes of the standard; or (3) not implement anything if the specification is not reasonable and appropriate and the standard can still be met. This approach will provide flexibility for all entities, and especially small entities that would be most concerned about the cost and complexity of the security standards. Small entities can look at the addressable implementation specifications and tailor their compliance based on their risks and capabilities of addressing those risks.	the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. While this rule may have a significant impact on small rural hospitals, the impact should be minimized by the scalability factors of the standards, as discussed above in the impact on all small entities. In addition, we have previously discussed the impact of small entities in the RIA published as part of the August 17, 2000 final regulation for the Standards for Electronic Transactions. Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 Standards for Electronic Transactions cost estimate (45 CFR parts 160 and 162), which was published in the Federal Register on August 17, 2000 (65 FR 50312). This analysis showed that the combined impact of the Administrative Simplification standards is expected to save the industry $29.9 billion over 10 years. We are including in each subsequent rule an impact analysis that is specific to the standard or standards in that rule, but the impact analysis will assess only the incremental cost of implementing a given standard over another. Thus, the

sector. Therefore, the rule establishes a Federal private sector mandate and is a significant regulatory action within the meaning of section 202 of UMRA (2 U.S.C. 1532). We have included the statements to address the anticipated effects of these rules under section 202.

These standards also apply to State and local governments in their roles as health plans or health care providers. Because these entities, in their roles as health plans or providers, must implement the requirements in these rules, the rules impose unfunded mandates on them. Further discussion of this issue can be found in the previously published impact analysis for all standards (65 FR 50360 through 50361).

The anticipated benefits and costs of the security standards, and other issues raised in section 202 of the UMRA, are addressed in the analysis below, and in the combined impact analysis. In addition, as required under section 205 of the UMRA (2 U.S.C. 1535), having considered a reasonable number of alternatives as outlined in the preamble to this rule, HHS has concluded that this final rule is the most cost-effective alternative for implementation of HHS's statutory objective of administrative simplification.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct cost of implementing security features as implementation needs will vary dependent upon a risk assessment and upon what is already in place. However, the previously referenced impact analysis in the August 17, 2000 final rule (65 FR 50312) showed that Administrative Simplification costs will be offset by future savings.

In complying with the requirements of part C of title XI, the Secretary established interdepartmental implementation teams who consulted with appropriate State and Federal agencies and private organizations. These external groups consisted of the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards and Security, the Workgroup for Electronic Data Interchange (WEDI), the National Uniform Claim Committee (NUCC), the National Uniform Billing Committee (NUBC), and the American Dental Association (ADA). The teams also received comments on the proposed regulation from a variety of organizations, including State Medicaid agencies and other Federal agencies.

B. Anticipated Effects

The analysis in the August 2000, Transaction Rule included the expected costs and benefits of the administrative simplification regulations related to electronic systems for 10 years. Although only the electronic transaction following discussion contains the impact analysis for the marginal costs of the security standards in this final rule.

The following describes the specific impacts that relate to the security standards. The security of electronic protected health information is, and has been for some time, a basic business requirement that health care entities ignore at their peril. Instances of “hacking” and other security violations may be widely publicized, and can seriously damage an institution's community standing. Appropriate security protections are crucial for encouraging the growth and use of electronic data interchange. The synergistic effect of the employment of the security standards will enhance all aspects of HIPAA's Administrative Simplification requirements. In addition, it is important to recognize that security is not a one-time project, but rather an on-going, dynamic process.

C. Changes From the 1998 Impact Analysis

The overall impact analysis for Administrative Simplification was first published on May 7, 1998 (63 FR 25320) in the proposed rule for the National Provider Identifier standard (45 CFR part 142), the first of the proposed Administrative Simplification rules. That impact analysis was based on the industry situation at that time, used statistics which were current at that time, and assumed that all of the HIPAA standards would be implemented at roughly the

requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. The proposed rule was published before the enactment of Executive Order 13132 of August 4, 1999, Federalism (published in the Federal Register on August 10, 1999 (64 FR 43255)), which required meaningful and timely input by State and local officials in the development of rules that have Federalism implications). However, we received and considered comments on the proposed rule from State agencies and from entities who conduct transactions with State agencies. Several of the comments referred to the costs that will result from implementation of the HIPAA standards. As we stated in the impact analysis, we are unable to estimate the information have been developed over the past several years. As a result, HHS has consulted with the Gartner Group, a leading technology assessment organization, regarding what impact these changes in the industry might have on the expected impact of this regulation. The Gartner analysis indicated that the cost of meeting the requirements of a reasonable interpretation of the Security Rule in 2002 is probably less than 10 percent higher in 2002 than it was in 1998. This increase is mainly driven by more active threats and increased personnel costs offsetting decreases in technology costs over the past 4 years. However, spending by companies who have	standards were promulgated in the transaction rule, HHS expected affected parties to make systems compliance investments collectively because the regulations are so integrated. Moreover, the data available to us were also based on the collective requirements of this regulation. It is not feasible to identify the incremental technological and computer costs for each regulation. Although HHS is issuing rules under HIPAA sequentially, affected entities and vendors are bundling services, that is, they have been anticipating the various needs and are designing relatively comprehensive systems as they develop hardware and software. For example, a vendor developing a system for electronic billing would also anticipate and include security features, even in the absence of any regulation. Moreover, a draft of the Security Rule was first published in 1998. Even though the final is different (and less burdensome), vendors had a reasonable indication of the direction policy would go. Thus, in preparing the electronic transaction rule, we recognized and included costs that might theoretically be associated with security or other HIPPA rules. Hence, some of the “costs” of security have already been accounted for in the standards parallel those for privacy, and can easily be satisfied using the solutions for privacy. Administrative requirements like the need for written policies, responsible officers, and business	same time, which would permit software changes to be made less expensively. While the original impact analysis represented our best information at that time, we realize that the state of the industry, and of security technology, has changed since 1998. We discuss several of those changes and how they affect the impact of this regulation. 1. Changes in Technology The state of technology for health care security has changed since 1998. New technologies to protect respondents to the survey (hospitals, payers, vendors, and clearinghouses) have moderately to greatly increased their attention on overall security. If these organizations have already made investments in security that meet some of the requirements of this rule, it will reduce their added costs of compliance. However, HHS can make no clear statement of the impact of this attention. **D. Guiding Principles for Standard Selection** The implementation teams charged with designating standards under the statute have defined, with significant input from the health care industry, a set of common criteria for evaluating potential standards. These criteria are based on direct specifications in the HIPAA, the purpose of the law, and principles that support the regulatory philosophy set forth in the E.O. 12866 of September 30, 1993, and the Paperwork Reduction Act of 1995. In order to be

anticipated the Security Rule or who have independently made business decisions to implement security policies and procedures as good business practice(s) has already occurred, and probably will cancel out the increased costs of implementation. Therefore, Gartner expects the cost of complying with the HIPAA security standards to be about the same now as it was in 1998. 2. Synchronizing Standards The timelines for the implementation of the initial HIPAA standards (transactions, identifiers, and security) are no longer closely synchronized. However, we do not believe that this lack of synchronization will have a significant impact on the cost of implementing security. The analysis provided by the Gartner group indicated that implementing security standards is being viewed by entities as a separate task from implementing the transaction standards, and that this is not having a significant impact on costs. As with other HIPAA standards, most current entities will have a 2-year implementation period before compliance with the standards is required. Covered entities will develop their own implementation schedules, and may phase in various security measures over that time period. 3. Relationship to Privacy Standards The publication of the final Privacy Rules (45 CFR parts 160 and 164) on December	associate agreements that are already required by the Privacy Rule can also serve to meet the security standards without significant additional cost. The analysis of data flows and data uses that covered entities are doing so as to comply with the Privacy Rule should also serve as the starting point for parallel analysis required by this final rule. Second, it is likely that covered entities will meet a number of the requirements in the security standards through the implementation of the privacy requirements. For example, in order to comply with the Privacy Rule requirements to make reasonable efforts to limit the access of members of the work force to specified categories of protected health information, covered entities may implement some of the administrative, physical, and technical safeguards that the entity's risk analysis and assessment would require under the Security Rule. E-mail authentication procedures put into place for privacy protection may also meet the security standards, thereby eliminating the need for additional investments to meet these standards. As a result, covered entities that have moved forward in implementing the privacy standards are also implementing security measures at the same time. Since the proposed security standards proposed rule represents the most authoritative guidance now available on the nature of these standards, some entities have been using them to	designated as such, a standard should do the following: ▪ Improve the efficiency and effectiveness of the health care system by leading to cost reductions for or improvements in benefits from electronic health care transactions. This principle supports the regulatory goals of cost-effectiveness and avoidance of burden. ▪ Meet the needs of the health data standards user community, particularly health care providers, health plans, and health care clearinghouses. This principle supports the regulatory goal of cost- effectiveness. ▪ Be consistent and uniform with the other HIPAA standards (that is, their data element definitions and codes, and their privacy and security requirements) and, secondarily, with other private and public sector health data standards. This principle supports the regulatory goals of consistency and avoidance of incompatibility, and it establishes a performance objective for the standard. ▪ Have low additional development and implementation costs relative to the benefits of using the standard. This principle supports the regulatory goals of cost-effectiveness and avoidance of burden. ▪ Be supported by an ANSI-accredited standards developing organization or other private or public organization that would ensure continuity and efficient updating of the standard over

28, 2000 in the Federal Register (65 FR 82462) and on August 14, 2002 (67 FR 53182) has affected the impact of this regulation significantly. Covered entities must implement the privacy standards by April 14, 2003 (April 14, 2004 for small health plans). The implementation of privacy standards reduces the cost of implementing the security standards in two significant areas. First, we have made substantial efforts to ensure that the many requirements in the security principle establishes a performance objective for the standard. ▪ Be technologically independent of the computer platforms and transmission protocols used in health transactions, except when they are explicitly part of the standard. This principle establishes a performance objective for the standard and supports the regulatory goal of flexibility. ▪ Be precise and unambiguous but as simple as possible. This principle supports the regulatory goals of predictability and simplicity. ▪ Keep data collection and paperwork burdens on users as low as is feasible. This principle supports the regulatory goals of cost-effectiveness and avoidance of duplication and burden. ▪ Incorporate flexibility to adapt more easily to changes in the health care infrastructure (for example, new services, organizations, and provider types) and	develop their security measures. Those entities should face minimal incremental costs in implementing the final version of these standards. We are unable to quantify these overlaps, but we believe they may reduce the cost of implementing these security standards. The analysis provided to the HHS by the Gartner Group also stated that compliance with the Privacy Rule will have a moderate effect on the cost of compliance with the Security Rule, reducing it slightly. 4. Sensitivity to Security Concerns as a Result of September 11, 2001 In our discussions with the Gartner Group, they indicated that they saw little evidence of increased security awareness in health care organizations as a result of the events of September 11, 2001. However, a survey conducted by Phoenix Health Systems in the winter of 2002 showed that 65 percent of the modify their systems to meet the security standards. This conversion would have a one-time cost impact on Federal, State, and private plans alike. We recognize that this conversion process has the potential to cause business disruption of some health plans. However, health plans would be able to schedule their implementation of the security standards and other standards in a way that best fits their needs, as long as they meet the deadlines specified in the HIPAA law and regulations. Moreover, small	time. This principle supports the regulatory goal of predictability. ▪ Have timely development, testing, implementation, and updating procedures to achieve administrative simplification benefits faster. This an assessment of how their current security measures conform to the new standards. However, we assume that most, if not all, covered entities already have at least some rudimentary security measures in place. Covered entities that identify gaps in their current measures would need to establish or revise their security precautions. It is also important to note that the standards specify what goals are to be achieved, but give the covered entity some flexibility to determine how to meet those goals. This is different from the transaction standards, where all covered entities must use the exact same implementation guide. With respect to security, covered entities will be able to blend security processes now in place with new processes. This should significantly reduce compliance costs. Based on our analysis and comments received, the security standards adopted in this rule do not impose a greater burden on the industry than the options we did not select, and they present significant advantages in terms of universality and flexibility. We understand that some large health plans, health care providers, and health care clearinghouses that currently

information technology. This principle supports the regulatory goals of flexibility and encouragement of innovation.

We assessed a wide variety of security standards and guidelines against the principles listed above, with the overall goal of achieving the maximum benefit for the least cost. As we stated in the proposed rule, we found that no single standard for security exists that encompasses all the requirements that were listed in the law. However, we believe that the standards we are adopting in this final rule collectively accomplish these goals.

E. Affected Entities

1. Health Care Providers

Covered health care providers may incur implementation costs for establishing or updating their security systems. The majority of costs to implement the security standard (purchase and installation of appropriate computer hardware and software, and physical safeguards) would generally be incurred in the initial implementation period for the specific requirements of the security standard. Health care providers that do not conduct electronic transactions for which standards have been adopted are not affected by these regulations.

2. Health Plans

All health plans, as the term is defined in regulation at 45 CFR 160.103, must comply with these security standards. In addition, health plans that

plans (many of which are employer- sponsored) will have an additional year in which to achieve compliance. Small health plans are defined at 45 CFR 160.103 as health plans with annual receipts of $5 million or less.

3. Clearinghouses

All health care clearinghouses must meet the requirements of this regulation. Health care clearinghouses would face effects similar to those experienced by health care providers and health plans. However, because clearinghouses represent one way in which providers and plans can achieve compliance, the clearinghouses' costs of complying with these standards would probably be passed along to those entities, to be shared over the entire customer base.

4. System Vendors

Systems vendors that provide computer software applications to health care providers and other billers of health care services would likely be affected. These vendors would have to develop software solutions that would allow health plans, providers, and other users of electronic transactions to protect these transactions and the information in their databases from unauthorized access to their systems. Their costs would also probably be passed along to their customer bases.

F. Factors in Establishing the Security Standard

1. General Effect

In assessing the impact of

exchange health information among trading partners may already have security systems and procedures in place to protect the information from unauthorized access. These entities may not incur significant costs to meet the security standards. Large entities that have sophisticated security systems in place may only need minor revisions or updates to their systems to meet the security standards, or indeed, may not need to make any changes in their systems.

While small providers are not likely to have implemented sophisticated security measures, they are also not as likely to need them as larger covered entities. The scalability principle allows providers to adopt measures that are appropriate to their own circumstances.

2. Complexity of Conversion

The complexity of the conversion to the security standards could be significantly affected by the volume of transactions that covered entities transmit and process electronically and the desire to transmit directly or to use the services of a Value Added Network (VAN) or a clearinghouse. If a VAN or clearinghouse is used, some of the conversion activities would be carried out by that organization, rather than by the covered entity. This would simplify conversion for the covered entity, but makes the covered entity dependent on the success of its business associate. The architecture, and specific technology

of certain requirements,

engage in electronic health care transactions may have to modify their systems to meet the security standards. Health plans that maintain electronic health information may also have to limitations of existing systems could also affect the complexity of the conversion (for example, certain practice management software that does not contain password protection will require a greater conversion effort than software that has a password protection option already built into it). 3. Cost of Conversion Virtually all providers, health plans, and clearinghouses that transmit or store data electronically have already implemented some security measures and will need to assess existing security, identify areas of risk, and implement additional measures in order to come into compliance with the standards adopted in this rule. We cannot estimate the per-entity cost of implementation because there is no information available regarding the extent to which providers', plans', and clearinghouses' current security practices are deficient. Moreover, some security solutions are almost cost-free to implement (for example, reminding employees not to post passwords on their monitors), while others are not. Affected entities will have many choices regarding how they will implement security. Some may choose to assess security using in-house staff,	these standards, it is first necessary to focus on the general nature of the standards, their scalability, and the fact that they are not dependent upon specific technologies. These factors will make it possible for covered entities to implement them with the least possible impact on resources. Because there is no national security standard in widespread use throughout the industry, adopting any of the candidate standards would require most health care providers, health plans, and health care clearinghouses to at least conduct today but may choose to do so at some future time (these would be entities that send and receive paper transactions and maintain paper records and thus would not be affected). We believe that the security standards represent the minimum necessary for adequate protection of health information in an electronic format and as such should be implemented by all covered entities. As discussed earlier in this preamble, the security requirements are both scalable and technically flexible; and while the law requires each health plan that is not a small plan to comply with the security and electronic signature requirements no later than 24 months after the effective date of the final rule, small plans will be allowed an additional 12 months to comply. Since we are unable to estimate the number of entities that may need to make changes to meet the security	duplication and ambiguity of some requirements, and the overall complexity of the approach. Based on those comments, it was clear that revisions had to be made. In addition, the proposed rule was developed before the Privacy Rule requirements were developed. Thus, it did not allow for any alignment of requirements between the Privacy and Security standards. As a result, the Department determined that an approach that modified the proposed rule and aligned the requirements with the Privacy standards was the preferred alternative. **V. Federalism** Executive Order 13132 of August 4, 1999, Federalism, published in the Federal Register on August 10, 1999 (64 FR 43255), requires us to ensure meaningful and timely input by State and local officials in the development of rules that have Federalism implications. Although the proposed rule for security standards was published before the enactment of this Executive Order, the Department consulted with State and local officials as part of an outreach program in the process of developing the proposed regulation. The Department received comments on the proposed rule from State agencies and from entities that conduct transactions with State agencies. Many of these comments were concerned with the burden that the proposed security standards would place on their

while others will use consultants. Practice management software vendors may also provide security consultation services to their customers. Entities may also choose to implement security measures that require hardware and/or software purchases at the time they do routine equipment upgrades. The security standards we adopt in this rule were developed with considerable input from the health care industry, including providers, health plans, clearinghouses, vendors, and standards organizations. Industry members strongly advocated the flexible approach we adopt in this rule, which permits each affected entity to develop cost-effective security measures appropriate to their particular needs. We believe that this approach will yield the lowest implementation cost to industry while ensuring that electronic protected health information is safeguarded. All of the nation's health plans (over 2 million) and providers (over 600,000) will need to conduct some level of gap analysis to assess current procedures against the standards. However, we cannot estimate the number of covered entities that would have to implement additional security systems and procedures to meet the adopted standards. Also, we are not able to estimate the number of providers that do not conduct electronic transactions records, Medicaid, Medical research, Medicare, Privacy, Reporting and record keeping	standards, we are also unable to estimate the cost for those entities. However, we believe that the cost of establishing security systems and procedures is a portion of the costs associated with converting to the administrative simplification standards that are required under HIPAA, which are estimated in the previously referenced impact analysis. This discussion on conversion costs relates only to health plans, health care providers, and health care clearinghouses that are required to implement the security standards. The cost of implementing security systems and procedures for entities that do not transmit, receive, or maintain health information electronically is not a cost imposed by the rule, and thus, is not included in our estimates. G. Alternatives Considered In developing this final rule, the Department considered some alternatives. One alternative was to not issue a final rule. However, this would not meet the Department's obligations under the HIPAA statute. It would also leave the health industry without a set of standards for protecting the security of health information. The vast majority of commenters supported our efforts in developing a set of standards. Thus, we concluded that not publishing a final rule was not in the best interests of the industry and not in the best interests of persons whose medical information will be protected by these measures.	organizations. In response to those comments, we have modified the security standards to make them more flexible and less burdensome. In complying with the requirements of part C of Title XI, the Secretary established an interdepartmental team who consulted with appropriate State and Federal agencies and private organizations. These external groups included the NCVHS Workgroup on Standards and Security, the Workgroup for Electronic Data Interchange, the National Uniform Claim Committee, and the National Uniform Billing Committee. Most of these groups have State officials as members. We also received comments on the proposed regulation from these organizations. In accordance with the provisions of Executive Order 12866, this rule has been reviewed by the Office of Management and Budget. List of Subjects 45 CFR Part 160 Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health respect to such group health plans, but only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans. Protected health information means individually identifiable health information:

requirements. 45 CFR Part 162 Administrative practice and procedure, Health facilities, Health insurance, Hospitals, Medicaid, Medicare, report and recordkeeping requirement. 45 CFR Part 164 Administrative practice and procedure, Health facilities, Health insurance, Hospitals, Medicaid, Medicare, Electronic Information System, Security, Report and recordkeeping requirement. For the reasons set forth in the preamble, the Department of Health and Human Services amends title 45, subtitle A, subchapter C, parts 160, 162, and 164 as set forth below: **PART 160--GENERAL ADMINISTRATIVE REQUIREMENTS** 1. The authority citation for part 160 continues to read as follows: Authority: Sec. 1171 through 1179 of the Social Security Act, (42 U.S.C. 1320d-1329d-8) as added by sec. 262 of Pub. L. 104-191, 110 Stat. 2021-2031 and sec. 264 of Pub. L. 104-191 (42 U.S.C. 1320d-2(note)). 2. In § 160.103, the definitions of “disclosure”, “electronic media”, “electronic protected health information,” “individual,” “organized health care arrangement”, “protected health information,” and “use” are added in alphabetical order to read as follows:	A second alternative was to publish the final rule basically unchanged from the proposed rule. Although most commenters supported the approach of the proposed rule, there were significant objections to the number of required specifications, concerns about the scope paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission. Electronic protected health information means information that comes within paragraphs (1)(i) or (1)(ii) of the definition of protected health information as specified in this section. * * * * * Individual means the person who is the subject of protected health information. * * * * * Organized health care arrangement means: (1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider; (2) An organized system of health care in which more than one covered entity participates and in which the participating covered entities: (i) Hold themselves out to the public as participating in a joint arrangement; and (ii) Participate in joint activities that include at least one of the following: (A) Utilization review, in which	(1) Except as provided in paragraph (2) of this definition, that is: (i) Transmitted by electronic media; (ii) Maintained in electronic media; or (iii) Transmitted or maintained in any other form or medium. (2) Protected health information excludes individually identifiable health information in: (i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g; (ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and (iii) Employment records held by a covered entity in its role as employer. * * * * * Use means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information. * * * * * **PART 162--ADMINISTRATIVE REQUIREMENTS** 1. The authority citation for part 162 is revised to read as follows: Authority: Secs. 1171 through 1179 of the Social Security Act (42 U.S.C. 1320d-1320d-8), as added by sec. 262 of Pub. L. 104-191, 110 Stat. 2021-2031, and sec. 264 of Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2 (note)).

§ 160.103 Definitions. * * * * * Disclosure means the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information. * * * * * Electronic media means: (1) Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic" tape or disk, optical disk, or digital memory card; or (2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/ transportable electronic storage media. Certain transmissions, including of significantly to influence or direct the actions or policies of another entity. Common ownership exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity. Covered functions means those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care	health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf; (B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or (C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk. (3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan; (4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or (5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with	§162.103 [Amended] 2. In § 162.103, the definition of "electronic media" is removed. **PART 164--SECURITY AND PRIVACY** 1. The authority citation for part 164 is revised to read as follows: Authority: Secs. 1171 through 1179 of the Social Security Act (42 U.S.C. 1320d-1320d-8), as added by sec. 262 of Pub. L. 104-191, 110 Stat. 2021-2031, and 42 U.S.C. 1320d-2 and 1320d-4, sec. 264 of Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2 (note)). 2. A new § 164.103 is added to read as follows: § 164.103 Definitions. As used in this part, the following terms have the following meanings: Common control exists if an entity has the power, directly or indirectly, with respect to another component of the covered entity to the same extent that it would be required under subpart C of this part to protect such information if the health care component and the other component were separate and distinct legal entities; (C) A component that is described by paragraph (a)(2)(iii)(C)(2) of this section does not use or disclose protected health information that it creates or receives from or on behalf of the health care component in a way prohibited by subpart E of this part; (D) A component that is

clearinghouse. Health care component means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with § 164.105(a)(2)(iii)(C). Hybrid entity means a single legal entity: (1) That is a covered entity; (2) Whose business activities include both covered and non-covered functions; and (3) That designates health care components in accordance with paragraph § 164.105(a)(2)(iii)(C). Plan sponsor is defined as defined at section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B). Required by law means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public	a business associate of a covered entity, the clearinghouse must comply with § 164.105 relating to organizational requirements for covered entities, including the designation of health care components of a covered entity. 4. A new §164.105 is added to read as follows: § 164.105 Organizational requirements. (a)(1) Standard: Health care component. If a covered entity is a hybrid entity, the requirements of subparts C and E of this part, other than the requirements of this section, §164.314, and §. 164.504, apply only to the health care component(s) of the entity, as specified in this section. (2) Implementation specifications: (i) Application of other provisions. In applying a provision of subparts C and E of this part, other than the requirements of this section, §164.314, and §164.504, to a hybrid entity: (A) A reference in such provision to a “covered entity” refers to a health care component of the covered entity; (B) A reference in such provision to a “health plan,” “covered health care provider,” or “health care clearinghouse,” refers to a health care component of the covered entity if such health care component performs the functions of a health plan, health care provider, or health care clearinghouse, as applicable;	described by paragraph (a)(2)(iii)(C)(2) of this section that creates, receives, maintains, or transmits electronic protected health information on behalf of the health care component is in compliance with subpart C of this part; and (E) If a person performs duties for both the health care component in the capacity of a member of the workforce of such component and for another component of the entity in the same capacity with respect to that component, such workforce member must not use or disclose protected health information created or received in the course of or incident to the member's work for the health care component in a way prohibited by subpart E of this part. (iii) Responsibilities of the covered entity. A covered entity that is a hybrid entity has the following responsibilities: (A) For purposes of subpart C of part 160 of this subchapter, pertaining to compliance and enforcement, the covered entity has the responsibility of complying with subpart E of this part. (B) The covered entity is responsible for complying with § 164.316(a) and § 164.530(i), pertaining to the implementation of policies and procedures to ensure compliance with applicable requirements of this section and subparts C and E of this part, including the safeguard requirements in paragraph (a)(2)(ii) of this section. (C) The covered entity is

benefits. 3. Section 164.104 is revised to read as follows: §164.104 Applicability. (a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this part apply to the following entities: (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter. (b) When a health care clearinghouse creates or receives protected health information as a business associate of another covered entity, or other than as component that performs covered functions if the two components were separate legal entities. (b)(1) Standard: Affiliated covered entities. Legally separate covered entities that are affiliated may designate themselves as a single covered entity for purposes of subparts C and E of this part. (1) Implementation specifications: (i) Requirements for designation of an affiliated covered entity. (A) Legally separate covered entities may designate themselves (including any health care component of such covered entity) as a single affiliated covered entity, for purposes of subparts C and E	(C) A reference in such provision to "protected health information" refers to protected health information that is created or received by or on behalf of the health care component of the covered entity; and (D) A reference in such provision to "electronic protected health information" refers to electronic protected health information that is created, received, maintained, or transmitted by or on behalf of the health care component of the covered entity. (ii) Safeguard requirements. The covered entity that is a hybrid entity must ensure that a health care component of the entity complies with the applicable requirements of this section and subparts C and E of this part. In particular, and without limiting this requirement, such covered entity must ensure that: (A) Its health care component does not disclose protected health information to another component of the covered entity in circumstances in which subpart E of this part would prohibit such disclosure if the health care component and the other component were separate and distinct legal entities; (B) Its health care component protects electronic protected health information 164.310 Physical safeguards. 164.312 Technical safeguards. 164.314 Organizational requirements. 164.316 Policies and	responsible for designating the components that are part of one or more health care components of the covered entity and documenting the designation in accordance with paragraph (c) of this section, provided that, if the covered entity designates a health care component or components, it must include any component that would meet the definition of covered entity if it were a separate legal entity. Health care component(s) also may include a component only to the extent that it performs: (1) Covered functions; or (2) Activities that would make such component a business associate of a destroyed in an unauthorized manner. Malicious software means software, for example, a virus, designed to damage or disrupt a system. Password means confidential authentication information composed of a string of characters. Physical safeguards are physical measures, policies, and procedures to protect a covered entity's electronic information systems and related buildings and equipment, from natural and environmental hazards, and unauthorized intrusion. Security or Security measures encompass all of the administrative, physical, and technical safeguards in an information system. Security incident means the attempted or successful unauthorized access, use, disclosure, modification, or

of this part, if all of the covered entities designated are under common ownership or control. (B) The designation of an affiliated covered entity must be documented and the documentation maintained as required by paragraph (c) of this section. (ii) Safeguard requirements. An affiliated covered entity must ensure that: (A) The affiliated covered entity's creation, receipt, maintenance, or transmission of electronic protected health information complies with the applicable requirements of subpart C of this part; (B) The affiliated covered entity's use and disclosure of protected health information comply with the applicable requirements of subpart E of this part; and (C) If the affiliated covered entity combines the functions of a health plan, health care provider, or health care clearinghouse, the affiliated covered entity complies with §164.308(a)(4)(ii)(A) and § 164.504(g), as applicable. (c)(1) Standard: Documentation. A covered entity must maintain a written or electronic record of a designation as required by paragraphs (a) or (b) of this section. (2) Implementation specification: Retention period. A covered entity must retain the documentation as required by paragraph (c)(1) of this section for 6 years from the date of its creation or the date when it last was in effect, whichever is later.	procedures and documentation requirements. 164.318 Compliance dates for the initial implementation of the security standards. Appendix A to Subpart C of Part 164--Security Standards: Matrix Authority: 42 U.S.C. 1320d-2 and 1320d-4. §164.302 Applicability. A covered entity must comply with the applicable standards, implementation specifications, and requirements of this subpart with respect to electronic protected health information. §164.304 Definitions. As used in this subpart, the following terms have the following meanings: Access means the ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any system resource. (This definition applies to “access” as used in this subpart, not as used in subpart E of this part.) Administrative safeguards are administrative actions, and policies and procedures, to manage the selection, development, implementation, and maintenance of security measures to protect electronic protected health information and to manage the conduct of the covered entity's workforce in relation to the protection of that information. Authentication means the corroboration that a person is the one claimed. Availability means the property that data or information is accessible and useable upon demand by	destruction of information or interference with system operations in an information system. Technical safeguards means the technology and the policy and procedures for its use that protect electronic protected health information and control access to it. User means a person or entity with authorized access. Workstation means an electronic computing device, for example, a laptop or desktop computer, or any other device that performs similar functions, and electronic media stored in its immediate environment. § 164.306 Security standards: General rules. (a) General requirements. Covered entities must do the following: (1) Ensure the confidentiality, integrity, and availability of all electronic protected health information the covered entity creates, receives, maintains, or transmits. (2) Protect against any reasonably anticipated threats or hazards to the security or integrity of such information. (3) Protect against any reasonably anticipated uses or disclosures of such information that are not permitted or required under subpart E of this part. (4) Ensure compliance with this subpart by its workforce. (b) Flexibility of approach. (1) Covered entities may use any security measures that allow the covered entity to reasonably and appropriately

5. A new subpart C is added to part 164 to read as follows: Subpart C--Security Standards for the Protection of Electronic Protected Health Information Sec. 164.302 Applicability. 164.304 Definitions. 164.306 Security standards: General rules. 164.308 Administrative safeguards. (ii) The covered entity's technical infrastructure, hardware, and software security capabilities. (iii) The costs of security measures. (iv) The probability and criticality of potential risks to electronic protected health information. (c) Standards. A covered entity must comply with the standards as provided in this section and in §164.308, §164.310, §164.312, §164.314, and § 164.316 with respect to all electronic protected health information. (d) Implementation specifications. In this subpart: (1) Implementation specifications are required or addressable. If an implementation specification is required, the word “Required” appears in parentheses after the title of the implementation specification. If an implementation specification is addressable, the word “Addressable” appears in parentheses after the title of the implementation	an authorized person. Confidentiality means the property that data or information is not made available or disclosed to unauthorized persons or processes. Encryption means the use of an algorithmic process to transform data into a form in which there is a low probability of assigning meaning without use of a confidential process or key. Facility means the physical premises and the interior and exterior of a building(s). Information system means an interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware, software, information, data, applications, communications, and people. Integrity means the property that data or information have not been altered or accordance with §164.306: (1)(i) Standard: Security management process. Implement policies and procedures to prevent, detect, contain, and correct security violations. (ii) Implementation specifications: (A) Risk analysis (Required). Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity. (B) Risk management	implement the standards and implementation specifications as specified in this subpart. (2) In deciding which security measures to use, a covered entity must take into account the following factors: (i) The size, complexity, and capabilities of the covered entity. electronic protected health information that are consistent with the applicable requirements of subpart E of this part. (ii) Implementation specifications: (A) Isolating health care clearinghouse functions (Required). If a health care clearinghouse is part of a larger organization, the clearinghouse must implement policies and procedures that protect the electronic protected health information of the clearinghouse from unauthorized access by the larger organization. (B) Access authorization (Addressable). Implement policies and procedures for granting access to electronic protected health information, for example, through access to a workstation, transaction, program, process, or other mechanism. (C) Access establishment and modification (Addressable). Implement policies and procedures that, based upon the entity's access authorization policies, establish, document, review, and modify a user's right of access to a workstation, transaction, program, or

specification. (2) When a standard adopted in §. 164.308, §164.310, §164.312, §164.314, or §164.316 includes required implementation specifications, a covered entity must implement the implementation specifications. (1) When a standard adopted in §. 164.308, § 164.310, § 164.312, §164.314, or § 164.316 includes addressable implementation specifications, a covered entity must— (i) Assess whether each implementation specification is a reasonable and appropriate safeguard in its environment, when analyzed with reference to the likely contribution to protecting the entity's electronic protected health information; and (ii) As applicable to the entity— (A) Implement the implementation specification if reasonable and appropriate; or (B) If implementing the implementation specification is not reasonable and appropriate— (1) Document why it would not be reasonable and appropriate to implement the implementation specification; and (2) Implement an equivalent alternative measure if reasonable and appropriate. (e) Maintenance. Security measures implemented to comply with standards and implementation specifications adopted under §164.105 and this subpart must be reviewed and modified as needed to continue provision of	(Required). Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with §164.306(a). (C) Sanction policy (Required). Apply appropriate sanctions against workforce members who fail to comply with the security policies and procedures of the covered entity. (D) Information system activity review (Required). Implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports. (2) Standard: Assigned security responsibility. Identify the security official who is responsible for the development and implementation of the policies and procedures required by this subpart for the entity. (3)(i) Standard: Workforce security. Implement policies and procedures to ensure that all members of its workforce have appropriate access to electronic protected health information, as provided under paragraph (a)(4) of this section, and to prevent those workforce members who do not have access under paragraph (a)(4) of this section from obtaining access to electronic protected health information. (ii) Implementation specifications: (A) Authorization and/or supervision (Addressable). Implement procedures for the authorization and/or supervision of workforce	process. (5)(i) Standard: Security awareness and training. Implement a security awareness and training program for all members of its workforce (including management). (ii) Implementation specifications. Implement: (A) Security reminders (Addressable). Periodic security updates. (B) Protection from malicious software (Addressable). Procedures for guarding against, detecting, and reporting malicious software. (C) Log-in monitoring (Addressable). Procedures for monitoring log- in attempts and reporting discrepancies. (D) Password management (Addressable). Procedures for creating, changing, and safeguarding passwords. (6)(i) Standard: Security incident procedures. Implement policies and procedures to address security incidents. (ii) Implementation specification: Response and Reporting (Required). Identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity; and document security incidents and their outcomes. (7)(i) Standard: Contingency plan. Establish (and implement as needed) policies and procedures for responding to an emergency or other occurrence (for example, fire, vandalism, system failure, and

reasonable and appropriate protection of electronic protected health information as described at §164.316. §164.308 Administrative safeguards. (a) A covered entity must, in (A) Data back-up plan (Required). Establish and implement procedures to create and maintain retrievable exact copies of electronic protected health information. (B) Disaster recovery plan (Required). Establish (and implement as needed) procedures to restore any loss of data. (C) Emergency mode operation plan (Required). Establish (and implement as needed) procedures to enable continuation of critical business processes for protection of the security of electronic protected health information while operating in emergency mode. (D) Testing and revision procedures (Addressable). Implement procedures for periodic testing and revision of contingency plans. (E) Applications and data criticality analysis (Addressable). Assess the relative criticality of specific applications and data in support of other contingency plan components. (8) Standard: Evaluation. Perform a periodic technical and nontechnical evaluation, based initially upon the standards implemented under this rule and subsequently, in response to environmental or operational changes affecting	members who work with electronic protected health information or in locations where it might be accessed. (B) Workforce clearance procedure (Addressable). Implement procedures to determine that the access of a workforce member to electronic protected health information is appropriate. (C) Termination procedures (Addressable). Implement procedures for terminating access to electronic protected health information when the employment of a workforce member ends or as required by determinations made as specified in paragraph (a)(3)(ii)(B) of this section. (4)(i) Standard: Information access management. Implement policies and procedures for authorizing access to government program providing public benefits, if the requirements of §164.502(e)(1)(ii)(C) are met. (3) A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and §164.314(a). (4) Implementation specifications: Written contract or other arrangement (Required). Document the satisfactory assurances required by paragraph (b)(1) of this section through a written contract or other arrangement	natural disaster) that damages systems that contain electronic protected health information. (ii) Implementation specifications: protected health information, to restrict access to authorized users. (d)(1) Standard: Device and media controls. Implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain electronic protected health information into and out of a facility, and the movement of these items within the facility. (2) Implementation specifications: (i) Disposal (Required). Implement policies and procedures to address the final disposition of electronic protected health information, and/or the hardware or electronic media on which it is stored. (ii) Media re-use (Required). Implement procedures for removal of electronic protected health information from electronic media before the media are made available for re-use. (iii) Accountability (Addressable). Maintain a record of the movements of hardware and electronic media and any person responsible therefore. (iv) Data back-up and storage (Addressable). Create a retrievable, exact copy of electronic protected health information, when needed, before movement of equipment.

the security of electronic protected health information, that establishes the extent to which an entity's security policies and procedures meet the requirements of this subpart. (b)(1) Standard: Business associate contracts and other arrangements. A covered entity, in accordance with § 164.306, may permit a business associate to create, receive, maintain, or transmit electronic protected health information on the covered entity's behalf only if the covered entity obtains satisfactory assurances, in accordance with § 164.314(a) that the business associate will appropriately safeguard the information. (2) This standard does not apply with respect to— (i) The transmission by a covered entity of electronic protected health information to a health care provider concerning the treatment of an individual. (ii) The transmission of electronic protected health information by a group health plan or an HMO or health insurance issuer on behalf of a group health plan to a plan sponsor, to the extent that the requirements of §164.314(b) and §164.504(f) apply and are met; or (iii) The transmission of electronic protected health information from or to other agencies providing the services at §164.502(e)(1)(ii)(C), when the covered entity is a health plan that is a electronic protected health	with the business associate that meets the applicable requirements of §164.314(a). §164.310 Physical safeguards. A covered entity must, in accordance with § 164.306: (a)(1) Standard: Facility access controls. Implement policies and procedures to limit physical access to its electronic information systems and the facility or facilities in which they are housed, while ensuring that properly authorized access is allowed. (2) Implementation specifications: (i) Contingency operations (Addressable). Establish (and implement as needed) procedures that allow facility access in support of restoration of lost data under the disaster recovery plan and emergency mode operations plan in the event of an emergency. (ii) Facility security plan (Addressable). Implement policies and procedures to safeguard the facility and the equipment therein from unauthorized physical access, tampering, and theft. (iii) Access control and validation procedures (Addressable). Implement procedures to control and validate a person's access to facilities based on their role or function, including visitor control, and control of access to software programs for testing and revision. (iv) Maintenance records (Addressable). Implement policies and procedures to document repairs and modifications to the physical	§ 164.312 Technical safeguards. A covered entity must, in accordance with § 164.306: (a)(1) Standard: Access control. Implement technical policies and procedures for electronic information systems that maintain electronic protected health information to allow access only to those persons or software programs that have been granted access rights as specified in § 164.308(a)(4). (2) Implementation specifications: (i) Unique user identification (Required). Assign a unique name and/or number for identifying and tracking user identity. (ii) Emergency access procedure (Required). Establish (and implement as needed) procedures for obtaining necessary electronic protected health information during an emergency. (iii) Automatic logoff (Addressable). Implement electronic procedures that terminate an electronic session after a predetermined time of inactivity. (iv) Encryption and decryption (Addressable). Implement a mechanism to encrypt and decrypt electronic protected health information. (b) Standard: Audit controls. Implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information. (c)(1) Standard: Integrity. Implement policies and

information from improper alteration or destruction. (2) Implementation specification: Mechanism to authenticate electronic protected health information (Addressable). Implement electronic mechanisms to corroborate that electronic protected health information has not been altered or destroyed in an unauthorized manner. (d) Standard: Person or entity authentication. Implement procedures to verify that a person or entity seeking access to electronic protected health information is the one claimed. (e)(1) Standard: Transmission security. Implement technical security measures to guard against unauthorized access to electronic protected health information that is being transmitted over an electronic communications network. (2) Implementation specifications: (i) Integrity controls (Addressable). Implement security measures to ensure that electronically transmitted electronic protected health information is not improperly modified without detection until disposed of. (ii) Encryption (Addressable). Implement a mechanism to encrypt electronic protected health information whenever deemed appropriate. §164.314 Organizational requirements. (a)(1) Standard: Business associate contracts or other arrangements. (i) The contract or other	components of a facility which are related to security (for example, hardware, walls, doors, and locks). (b) Standard: Workstation use. Implement policies and procedures that specify the proper functions to be performed, the manner in which those functions are to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstation that can access electronic protected health information. (c) Standard: Workstation security. Implement physical safeguards for all workstations that access electronic confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of the covered entity as required by this subpart; (B) Ensure that any agent, including a subcontractor, to whom it provides such information agrees to implement reasonable and appropriate safeguards to protect it; (C) Report to the covered entity any security incident of which it becomes aware; (D) Authorize termination of the contract by the covered entity, if the covered entity determines that the business associate has violated a material term of the contract. (ii) Other arrangements. (A) When a covered entity and its business associate are both governmental entities, the	procedures to protect disclosed pursuant to §164.504(f)(1)(ii) or (iii), or as authorized under § 164.508, a group health plan must ensure that its plan documents provide that the plan sponsor will reasonably and appropriately safeguard electronic protected health information created, received, maintained, or transmitted to or by the plan sponsor on behalf of the group health plan. (2) Implementation specifications (Required). The plan documents of the group health plan must be amended to incorporate provisions to require the plan sponsor to— (i) Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of the group health plan; (ii) Ensure that the adequate separation required by § 164.504(f)(2)(iii) is supported by reasonable and appropriate security measures; (iii) Ensure that any agent, including a subcontractor, to whom it provides this information agrees to implement reasonable and appropriate security measures to protect the information; and (iv) Report to the group health plan any security incident of which it becomes aware.

arrangement between the covered entity and its business associate required by §164.308(b) must meet the requirements of paragraph (a)(2)(i) or (a)(2)(ii) of this section, as applicable. (ii) A covered entity is not in compliance with the standards in §164.502(e) and paragraph (a) of this section if the covered entity knew of a pattern of an activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful— (A) Terminated the contract or arrangement, if feasible; or (B) If termination is not feasible, reported the problem to the Secretary. (2) Implementation specifications (Required). (i) Business associate contracts. The contract between a covered entity and a business associate must provide that the business associate will— (A) Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the activity, or assessment. (2) Implementation specifications: (i) Time limit (Required). Retain the documentation required by paragraph (b)(1) of	covered entity is in compliance with paragraph (a)(1) of this section, if— (1) It enters into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (a)(2)(i) of this section; or (2) Other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (a)(2)(i) of this section. (B) If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of business associate as specified in § 160.103 of this subchapter to a covered entity, the covered entity may permit the business associate to create, receive, maintain, or transmit electronic protected health information on its behalf to the extent necessary to comply with the legal mandate without meeting the requirements of paragraph (a)(2)(i) of this section, provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by paragraph (a)(2)(ii)(A) of this section, and documents the attempt and the reasons that these assurances cannot be obtained. (C) The covered entity may omit from its other arrangements authorization of the termination of the contract	§164.316 Policies and procedures and documentation requirements. A covered entity must, in accordance with §164.306: (a) Standard: Policies and procedures. Implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications, or other requirements of this subpart, taking into account those factors specified in §164.306(b)(2)(i), (ii), (iii), and (iv). This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirements of this subpart. A covered entity may change its policies and procedures at any time, provided that the changes are documented and are implemented in accordance with this subpart. (b)(1) Standard: Documentation. (i) Maintain the policies and procedures implemented to comply with this subpart in written (which may be electronic) form; and (ii) If an action, activity or assessment is required by this subpart to be documented, maintain a written (which may be electronic) record of the action, (2) A small health plan must comply with the applicable requirements of this subpart no later than April 20, 2006. (b) Health care clearinghouse. A health care clearinghouse must comply with the

this section for 6 years from the date of its creation or the date when it last was in effect, whichever is later. (ii) Availability (Required). Make documentation available to those persons responsible for implementing the procedures to which the documentation pertains. (iii) Updates (Required). Review documentation periodically, and update	by the covered entity, as required by paragraph (a)(2)(i)(D) of this section if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate. (b)(1) Standard: Requirements for group health plans. Except when the only electronic protected health information disclosed to a plan sponsor is as needed, in response to environmental or operational changes affecting the security of the electronic protected health information. § 164.318 Compliance dates for the initial implementation of the security standards. (a) Health plan. (1) A health plan that is not a small health plan must comply with the applicable requirements of this subpart no later than April 20, 2005.	applicable requirements of this subpart no later than April 20, 2005. (c) Health care provider. A covered health care provider must comply with the applicable requirements of this subpart no later than April 20, 2005.

VII

Glossary

Access	The ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any system resource.
Access Authorization (addressable)	Implement policies and procedures for granting access to electronic protected health information.
Access Control	Implement technical policies and procedures for electronic information systems that maintain electronic protected health information to allow access only to those persons or software programs that have been granted access rights as specified in Section 164.308(a)(4).
Access Control and Validation Procedures (addressable)	Implement procedures to control and validate a person's access to facilities based on their role or function, including visitor control, and control of access to software programs for testing and revision.
Access Establishment and Modification (addressable)	Implement policies and procedures that, based upon the entity's access authorization policies, establish, document, review, and modify a user's right of access to a workstation, transaction, program, or process.
Accountability (addressable)	Maintain a record of the movements of hardware and electronic media and any person responsible therefore.

Administrative Safeguards	These are administrative actions, and policies and procedures, to manage the selection, development, implementation, and maintenance of security measures to protect electronic protected health information and to manage the conduct of the covered entity's workforce in relation to the protection of that information.
Applications and Data Criticality Analysis (addressable)	Assess the relative criticality of specific applications and data in support of other contingency plan components.
Assigned Security Responsibility	Identify the security official who is responsible for the development and implementation of the policies and procedures required b this subpart for the entity.
Audit Controls (required)	Implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information.
Authentication	The corroboration that a person is the one claimed.
Authorization and/or Supervision (addressable)	Implement procedures for the authorization and/or supervision of workforce members who work with electronic protected health information or in locations where it might be accessed.
Automatic Logoff (addressable)	Implement electronic procedures that terminate an electronic session after a predetermined time of inactivity.
Availability	The property that data or information is accessible and useable upon demand by an authorized person.
Business Associate Contracts and Other Arrangements	A covered entity, in accordance with Section 164.306, may permit a business associate to create, receive, maintain, or transmit electronic protected health information on the covered entity's behalf only if the covered entity obtains satisfactory assurances, in accordance with Section 164.314(a) that the business associate will appropriately safeguard the information.

Common Control	Exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity.
Common Ownership	Exists if an entity or entities possess an ownership or equity interest of 5% or more in another entity.
Confidentiality	The property that data or information is not made available or disclosed to unauthorized persons or processes.
Contingency Operations (addressable)	Establish (and implement as needed) procedures that allow facility access in support of restoration of lost data under the disaster recovery plan and emergency mode operations plan in the event of an emergency.
Contingency Plan	Establish (and implement as needed) policies and procedures for responding to an emergency or other occurrence (for example, fire, vandalism, system failure, and natural disaster) that damages systems that contain electronic protected health information.
Covered Functions	Those functions of a covered entity the performance of which makes the entity a health plan, health care provider or health care clearinghouse.
Custodians	Custodians are in physical or logical possession of either ADPH information or information that has been entrusted to ADPH. Whenever information is maintained only on a personal computer, the User is also the Custodian. Each type of production application information must have one or more designated Custodians. Custodians are responsible for safeguarding the information, including implementing access control systems to prevent

	inappropriate disclosure, and making back-ups so that critical information will not be lost. Custodians are also required to implement, operate, and maintain the security measures defined by information Owners. CSC is the custodian for all department-wide systems.
Data Back Plan (required)	Establish and implement procedures to create and maintain retrievable exact copies of electronic protected health information.
Data Backup and Storage (addressable)	Create a retrievable, exact copy of electronic protected health information, when needed, before movement of equipment.
DLCI	Data link connection identifier. The DLCI values make up the logical connections between different frame-relay users.
Device and Media Controls	Implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain electronic protected health information into and out of a facility, and the movement of these items within the facility.
Disaster Recovery Plan (required)	Establish (and implement as needed0 procedures to restore any loss of data.
Disposal (required)	Implement policies and procedures to address the final disposition of electronic protected health information, and/or the hardware or electronic media on which it is stored.
e-PHI Repository	May be a database, spreadsheet, folder, storage device, document or other form of electronic information.
Electronic Funds Transfer	A system of transferring money from one bank account directly to another without any paper money changing hands. One of the most widely used EFT programs is Direct Deposit, in which payroll is

	deposited straight into an employee's bank account, although EFT refers to any transfer of funds initiated through an electronic terminal, including credit card, ATM, Fedwire and point-of-sale (POS) transactions. It is used for both credit transfers such as payroll payments, and for debit transfers, such as mortgage payments.
Emergency Access Procedure (required)	Establish (and implement as needed) procedures for obtaining necessary electronic protected health information during an emergency.
Emergency Mode Operation Plan (required)	Establish (and implement as needed) procedures to enable continuation of critical business processes for protection of the security of electronic protected health information while operating in emergency mode.
Encryption (addressable)	The use of an algorithmic process to transform data into a form, which there is a low probability of assigning meaning without use of a confidential process or key.
Encryption and Decryption (addressable)	The conversion of data into a form, called a cipher text, which cannot be easily understood by unauthorized people. Decryption is the process of converting encrypted data back into its original form, so it can be understood.
Evaluation	Perform a periodic technical and non-technical evaluation, based initially upon the standards implemented under this rule and subsequently, in response to environmental or operational changes affecting the security of electronic protected health information that

	establishes the extent to which an entity's security policies and procedures meet the requirements of this section.
Extranet	An extranet is a computer network that allows controlled access from the outside for specific business or educational purposes. Extranets are extensions to, or segments of, private intranet networks that have been built in many corporations for information sharing and ecommerce.
Facility	The physical premises and the interior and exterior of a building(s).
Facility Access Controls	Implement policies and procedures to limit physical access to its electronic information systems and the facility or facilities in which they are housed, while ensuring that properly authorized access is allowed.
Facility Security Plan (addressable)	Implement policies and procedures to safeguard the facility and the equipment therein from unauthorized physical access, tampering, and theft.
File Transfer Protocol	A standard Internet protocol is the simplest way to exchange files between computers on the Internet. Like the Hypertext Transfer Protocol (HTTP), which transfers displayable Web pages and related files and the Simple Mail Transfer Protocol (SMTP), which transfer e-mail, FTP is an application protocol that uses the Internet's TCP/IP protocols. FTP is commonly used to transfer Web page files from their creator to the computer that acts as their server for everyone on the Internet. It is also commonly used to download programs and other files to your computer from other servers.

Firewall	A firewall, working closely with a router program, examines each network packet to determine whether to forward it toward its destination. A firewall also includes or works with a proxy sever that makes network requires on behalf of workstation users. A firewall is often installed in a specially designated computer separate from the rest of the network so that no incoming request can get directly at private network resources.
Health Care Component	A component or combination of components of a hybrid entity designated by the hybrid entity in accordance with Section 164.105 (a) (2) (iii) (C).
Hybrid Entity	A single legal entity: (1) that is a covered entity; (2)whose business activities include both covered and non-covered functions; and (3) that designates health care components in accordance with paragraph Section 164.105 (a) (2) (iii) (C).
Information Access Management	Implement policies and procedures for authorizing access to electronic protected health information.
Information System	An interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware, software, information, data, applications, communications, and people.
Information System Activity Review (required)	Implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports.
Integrity	The property that data or information have not been altered or destroyed in an unauthorized manner.

Internet	The Internet is the largest interconnected system of computer networks in the world. It is a three level hierarchy composed of backbone networks, mid-level networks, and stub networks. These include commercial (.com or .co), university (.ac or .edu) and other research networks (.org, .net) and military (.mil) networks and span many different physical networks around the world with various protocols, mainly the Internet Protocols.
Intranet	An intranet is the private, internal network that manages company information –24 hours a day, seven days a week – for employees only.
Isolating health care clearinghouse functions (required)	If a health care clearinghouse is part of a larger organization, the clearinghouse must implement policies and procedures that protect the electronic protected health information of the clearinghouse from unauthorized access by the larger organization
Log-in Monitoring (addressable)	Procedures for monitoring login attempts and reporting discrepancies.
Maintenance Records (addressable)	Implement policies and procedures to document repairs and modifications to the physical components of a facility that are related to security.
Malicious Software	Software, for example, a virus, designed to damage or disrupt a system.
Mechanism to authenticate electronic protected health information (addressable)	Implement electronic mechanism to corroborate that electronic protected health information has not been altered or destroyed in an unauthorized manner.
Media Re-use (required)	Implement procedures for removal of electronic protected health information from electronic media before the media are made available for re-use.
Operational group	Computer Systems Center Technical Support Division
Owner	Owners are the bureau or office directors or their delegates within ADPH who bear

	responsibility for the acquisition, development, and maintenance of production applications which process ADPH information. Production applications are periodically-executed computer programs which support ADPH programs and activities. All production application system information must have a designated Owner. For each type of information, Owners designate whether it is confidential, designate its criticality, define which users will be permitted to access it, and define its authorized uses.
Password	Confidential authentication information composed of a string of characters.
Password Management (addressable)	Procedures for creating, changing, and safeguarding passwords.
Person or Entity Authentication (required)	Implement procedures to verify that a person or entity seeking access to electronic protected health information is the one claimed.
Physical Safeguards	Physical measures, policies, and procedures to protect a covered entity's electronic information systems and related buildings and equipment, from natural and environmental hazards, and unauthorized intrusion.
Plan Sponsor	Defined as Section 3(16) (B) of ERISA, 29 U.S.C. 1002 (16) (B).
Protection from Malicious Software (addressable)	Procedures for guarding against, detecting, and reporting malicious software.
Required by Law	A mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions

	of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.
Response and Reporting (required)	Identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity; and document security incidents and their outcomes.
Risk Analysis (required)	Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity.
Risk Management (required)	Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with Section 164.306(a).
Sanction Policy (required)	Apply appropriate sanctions against workforce members who fail to comply with the security policies and procedures of the covered entity.
Secure Sockets Layer (SSL)	The SSL is a commonly used protocol for managing the security of a message transmission on the Internet. SSL has recently been succeeded by Transport Layer Security (TLS), which is based on SSL. SSL uses a program layer located between the Internet's Hypertext Transfer Protocol (HTTP) and Transport Control Protocol (TCP) layers. SSL is included as part of both the Microsoft and Netscape browsers and most Web server products. SSL uses the public-and-private key

	encryption system from RSA, which also includes the use of a digital certificate.
Security Awareness and Training	Implement a security awareness and training program for all members of its workforce (including management).
Security Incident	The attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.
Security Incident Procedures	Implement policies and procedures to address security incidents.
Security Management Process	Implement policies and procedures to prevent, detect, contain, and correct security violations.
Security or Security Measures	Encompasses all of the administrative, physical, and technical safeguards in an information system.
Security Reminders (addressable)	Periodic security updates.
Technical Safeguards	The technology and the policy procedures for its use that protect electronic protected health information and control access to it. User means a person or entity with authorized access. Workstation means an electronic computing device, for example, a laptop or desktop computer, or any other device that performs similar functions, and electronic media stored in its immediate environment.
Termination Procedures (addressable)	Implement procedures for terminating access to electronic protected health information when the employment of a workforce member ends or as required by determinations made as specified in paragraph (a)(3)(ii)(B) of this section.
Testing and Revision Procedure (addressable)	Implement procedures for periodic testing and revision of contingency plans.
Transmission Security	Implement technical security measures to guard against unauthorized access to electronic protected health information that

	is being transmitted over an electronic communications network.
Unique Users Identification (required)	Assign a unique name and/or number for identifying and tracking user identity.
Users	Users are responsible for familiarizing themselves with and complying with all ADPH policies, procedures, and standards dealing with information security. Questions about the appropriate handling of a specific type of information should be directed to either the Custodian or the Owner of the involved information.
VPN (Virtual Private Network)	A network that is constructed by using public wires to connect nodes. For example, there are a number of systems that enable you to create networks using the Internet as the medium for transporting data. These systems use encryption and other security mechanisms to ensure that only authorized users can access the network and that the data cannot be intercepted.
Workforce Clearance Procedure	Implement procedures to determine that the access of a workforce member to electronic protected health information is appropriate.
Workforce Security	Implement policies and procedures to ensure that all members of its workforce have appropriate access to electronic protected health information, as provided under paragraph (a)(4) of this section, and to prevent those workforce members who do not have access under paragraph (a)(4) of this section from obtaining access to electronic protected health information.
Workstation	A general-purpose computer designed to be used by one person at a time. The usual workstation configuration is comprised of a display terminal, a system unit that includes a disk drive, a keyboard, and a mouse. Optionally a workstation can have additional devices such as CD drives and diskette drives. A typical workstation has installed on it operating system software as

	well as business and office application software.
Workstation Security (required)	Implement physical safeguards for all workstation that access electronic protected health information, to restrict access to authorized users.
Workstation Use (required)	Implement policies and procedures that specify the proper functions to be performed, the manner in which those functions are to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstation that can access electronic protected health information.
Written Contract and Other Arrangement (required)	Document the satisfactory assurance required by paragraph (b)(1) of this section through a written contract or other arrangement with the business associate that meets the applicable requirements of Section 164.314(a)

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VIII

Appendices

Special Note: All forms contained within this document are for sample purposes only. Official up-to-date forms can be obtained from the Document Library.

B

APPENDIX A

D

Appendix A

Security Official Job Description

Objectives

Establish accountability for security of Electronic Protected Health Information (e-PHI) for the Plan as a HIPAA Covered Entity. The Security Official oversees all ongoing activities related to the development, implementation, maintenance of, and adherence to the organization's policies and procedures covering the security of, and Access to, e-PHI in compliance with federal and state laws and the health care organization's information privacy practices.

Responsibilities:

- Accountable for developing and implementing security policies and procedures for the Plan for all members of the workforce that come in contact with e-PHI.
- Provide development guidance and assist in the identification, implementation, and maintenance of information security policies and procedures in coordination with organization management.
- Accountable for ensuring that each bureau, office, area, and county has an appointed Security Coordinator and an alternate Security Coordinator.

Responsibilities of Security Coordinators:

- Assist employees with obtaining User IDs.
- Assist employees with changing passwords.
- Request changes through the CSC Support Desk to employee's access rights.
- Make efforts to locate workstations in areas where public access is restricted and not accessible to the public.
- Assist in other security matters that may develop.
- Request access for employees when an employee assumes new duties, changes duties, or terminates employment.
- Report access problems to the CSC Support Desk.

Work with the Privacy Official:

- Electronic security training and orientation to all personnel, volunteers, contractors, and other appropriate third parties with Access to e-PHI.
- Mitigate the affects of all disclosures that are not HIPAA compliant or contrary to the plan's security goals.
- Cooperate with the Office of Civil Rights, other legal entities, and organization officers in any compliance review or investigation.
- Establish and administer a process for receiving, documenting, tracking, investigating, and taking action on all complaints concerning the organization's security policies and procedures.

- Work with organization administration to represent the organization's information security interest with external parties (government bodies) who undertake to adopt or amend security legislation, regulation, or standard.
- Initiate, facilitate, and promote activities to foster information security awareness within the organization.
- Conduct continuous risk assessment and analysis. As significant threats are discovered, management support for additional initiatives and countermeasures will be sought and implemented.
- Conduct related ongoing compliance monitoring activities in coordination with the organization's other compliance and operational assessment functions.
- Responsible for the security infrastructure of the organization.
- Identify key security initiatives and standards, (e.g., virus protection, security monitoring, intrusion detection, local and remote access control policies, and other technical security services and mechanisms).
- Establish mechanisms to track access to e-PHI as required by law to allow qualified individuals to review or receive a report on such activity.
- Review all system-related information security plans throughout the organization's network to ensure alignment between security and privacy practices.
- Maintain current knowledge of technical security services and mechanisms and monitors advancements in information security technologies to ensure organizational adaptation and compliance

APPENDIX B

H

EMPLOYEE RELATIONS CHECKLIST (APDH-PER-48 (08/03)

Date of Recommendation:	Bureau/Office/Area/Co.:	Co. Fund No.
Contact Person:	Telephone No.:	

PART I: BACKGROUND INFORMATION

Name:	SSAN:		
Address:			
Class Title/Code:			
Date Employed with ADPH:	Last Two Performance Appraisal Scores:		

Dates of Previous Discipline:	Warning: *(attach letter)*	Reprimand: *(attach letter)*	Suspension: *(attach letter)*

PART II: CURRENT INFRACTION

Date:	Policy/Procedure(s) Violated:
Evidence:	
Summary of Actions:	
Date Discussed with Employee:	
Employee's Explanation/Response:	
Name(s) of Witnesses (attach statements):	
Supervisor's Recommendation: Suspension_____ Demotion_____ Termination_____	

PART III: DOCUMENTATION

Orientation/Training Provided (Include Copies of Verification):
Copies of Records/Procedures:

PART IV: APPROVAL SIGNATURES

Immediate Supervisor:	*Date*
Division/County Supervisor:	*Date*
Bureau/Area Administrator:	*Date*

APPENDIX C

COMPUTER SYSTEMS ACCESS REMOVAL FORM

This form must be completed by the Computer Systems Center for all employees separating from the Alabama Department of Public Health. The original will be maintained in the Computer Systems Center files, and a copy will be sent to the initiating office.

Name of Separating Employee: _____ **SS#:** _____
Preferred name, if different than above: _____
Work Location: _____ **Classification:** _____
Network ID: _____ **RACF/3270/MSIQ ID:** _____
Phone Number: _____ **Voice Mail? (Yes or No):** _____
Phone Card? (Yes or No): _____ **Phone Card Number:** _____
Is this person transferring within the Health Department? (Yes or No): _____
If transferring, where are they transferring? _____
Effective Date: _____ **Date Received:** _____

Description	**Initials/Date**
1. Remove system privileges from mainframe and RACF	
2. Remove system privileges from AS/400	
3. Remove system privileges from Lotus Notes	
4. Remove system privileges from Network	
5. Remove system privileges from Oracle	
6. Remove from ASPEN	
7. Ensure return of hardware and software belonging to state inventory	
8. Remove all personal files from computer and file server	
9. Provide all system documentation, procedures, and files to supervisor	
10. Remove all passwords from personal computer and voice mail	
11. Remove name from state directory	

Signature: _____ **Date**: _____
CSC Security Officer

APPENDIX D

P

Computer Systems Access Form

This form should be completed for all computer access needs by the unit security coordinator.

ADD: **CHANGE:** **DELETE:**

Employee Name: **SSN:**
County/Clinic#/Area: **Bureau/Division:**
Physical Location:
Complete Computer Number (Counties Only):
Working Title: **Duties:**
Effective Date: **Date Received:**

NETWORK ID: **NOTES ID:** **RACF/3270 ID:**
PHALCON ID: **ASPEN ID:**

Network Access:

LOTUS Notes Access
- Notes (Desktop)
  - Include in e-mail groups:
  - Notes (Web Access)

3270 Access
- Finance (AFNS)
- Financial Reports
- Personnel (GHRS)
- Personnel (PDD0)
- Medicaid (MSIQ)
- MSIQ Special
- ROSCOE

5250 Access (RSA Tower Only)
- Home Health
- Vital Records

Health Prov Std
- ASPEN

Lab Information System

PHALCON Access
- Level of Access:
  - Clinic:
    - County Viewer
    - County WIC Clerk
    - County Administrator
    - County Clerk
    - State WIC Maint
  - State Level:
    - Vendor Management
    - Vendor Survey Maint
    - Vendor Mgmt Clerk
    - Vendor Data Entry
    - State Bill Clerk
    - Special Formula Clerk
    - State Formula Admin
    - PHALCON Developer
    - State Production

Home Health
- HORIZON

Bureaus:

ADPH Warehouse Operations
BHPI - AL Statewide Cancer Registry
BHPI - Arthritis Branch
BHPI - Bioterrorism
BHPI - Cancer Prevention
BHPI - Chronic Disease Prevention
BHPI - Communications Design
BHPI - Diabetes
BHPI - Director
BHPI - Hypertension
BHPI - Injury Prevention
BHPI - Public Information
BHPI - Risk Surveillance
BHPI - Tobacco Prevention & Control
BHPI - Video Communications
BHPI - Worksite Wellness
CHIP - Admin
CHIP - Enrollment
CHIP - Secretarial
CHS - Admin
CHS - Quality Assurance and Registration
CHS - Record Services
CHS - Special Services
CHS - Statistical Analysis
Clinical Lab
CSC - Admin
CSC - AS400 & Notes Development
CSC - County Support
CSC - Data Entry
CSC - Data Management
CSC - Data Operations
CSC - EMS Support
CSC - Financial Support - ACT
CSC - Financial Support - PGM
CSC - Help Desk
CSC - HPS Support
CSC - IT Research & Acquisition
CSC - Network Engineering
CSC - Notes Admin
CSC - PHALCON
CSC - Security
CSC - Systems Development
CSC - TB Support
Facilities Management Administration
Facilities Management Technical Srvs
FHS - Administration
FHS - Community Development
FHS - Oral Health
FHS - WIC Training Center
FHS - Women's & Children's Health
FHS - Women Infants & Children (WIC)
Finance - Acct Sys & Reports
Finance - Administration
Finance - Budget
Finance - Grants & Contracts
Finance - Payroll & Travel
Finance - Procurement
HCS - Bureau Director
HCS - Community Services
HCS - Deputy Director
HCS - Development & Accreditation
HCS - Enterprise
HCS - Information Systems
HCS - Program Support
HCS - PS Accounting Clerks
BHPI - AL Statewide Cancer Registry
BHPI - Arthritis Branch
BHPI - Cancer Prevention
BHPI - Chronic Disease Prevention
BHPI - Communications Design
BHPI - Diabetes
BHPI - Director's Office
BHPI - Hypertension
BHPI - Injury Prevention
BHPI - Public Information
BHPI - Risk Surveillance
BHPI - Tobacco Compliance
BHPI - Tobacco Prevention & Control
BHPI - Video Communications
BHPI - Worksite Wellness
HPS - Administration
HPS - ALF
HPS - CLIA
HPS - Complaints
HPS - Emergency Medical Services
HPS - Legal

CSC - Technical Support
CSC - Telecommunications
CSC - Virus Team
DC - Communicable Disease Administration
DC - Epidemiology
DC - HIV-AIDS
DC - Immunization
DC - Infection Control
DC - Sexually Transmitted Diseases
DC - Tuberculosis
ENV - Administration
ENV - Community Env Protection
ENV - Food Milk & Lodging
ENV - Receptionist
HPS - Long Term Care
HPS - Managed Care
HPS - Medicare Other
HPS - Nurse Registry
HPS - Provider Services
HPS - Support
Personnel
Primary Care & Rural Health
Professional & Support Services
Program Integrity
Radiation control

Clinic Codes:

Autauga	011	Prattville	Macon	441	Tuskegee
Baldwin	021	Bay Minette	Madison	450	WIC - Max Luther
Baldwin	025	Robertsdale	Madison	451	Eustis Hlth Dep-No WIC
Barbour	031	Clayton	Madison	452	Calvery Hill-No WIC
Barbour	032	Eufaula	Madison	453	WIC - Women's Clinic
Barbour	034	Clio	Madison	454	WIC - Baby Unit
Bibb	041	Centreville	Madison	455	Redstone Arsenal
Blount	051	Oneonta	Madison	457	UAH(PCC) - Inactive
Bullock	061	Bullock Co Hlth Dept	Marengo	460	Linden
Butler	071	Greenville	Marengo	462	River City (PCC)
Butler	072	Georgiana	Marion	471	Hamilton
Calhoun	081	Calhoun Co Hlth Dept	Marion	472	Winfield
Calhoun	082	Jacksonville(PCC)	Marshall	482	Guntersville
Chambers	092	Valley	Mobile	493	Keeler
Cherokee	101	Centre	Mobile	491	Franklin Memorial
Chilton	111	Clanton	Mobile	492	MCHD/Women's Ctr
Choctaw	121	Butler	Mobile	494	Bayou La Batre
Clarke	131	Grove Hill	Mobile	495	Mt. Vernon/Citronelle
Clay	141	Clay	Mobile	496	Wilmer
Cleburne	151	Heflin	Mobile	499	Eight Mile Clinic
Coffee	161	Coffee Co Hlth Dept	Monroe	501	Monroeville
Colbert	171	Tuscumbia	Montgomery	511	Montgomery
Conecuh	181	Evergreen	Montgomery	512	Children's Rehab Srv
Coosa	191	Rockford	Montgomery	514	Training Clinic
Covington	201	Andalusia	Montgomery	513	Gunter AFB WIC Cl
Covington	202	Opp	Montgomery	517	Lister Hill (PCC)
Crenshaw	211	Luverne	Montgomery	518	ListerHill RamerPCC
Cullman	221	Cullman	Montgomery	519	Chishlom FamHlthCtr
Dale	231	Ozark	Montgomery	991	Compliance Buy

Dallas	241	Selma	Morgan	521	Decatur
DeKalb	251	DeKalb Co Hlth Dept	Morgan	522	SRHCC(Decatur)
Elmore	261	Wetumpka	Perry	531	Marion
Escambia	271	Brewton	Perry	532	Uniontown
Escambia	272	Atmore	Perry	535	Uniontown (PCC)
Escambia	273	Poarch Crk Indians WIC	Pickens	541	Carrollton
Etowah	281	Gadsden	Pike	551	Troy
Etowah	286	J.W. Stewart (PCC)	Pike	553	Charles Hend(PCC)
Fayette	291	Fayette	Randolph	561	Roanoke
Franklin	301	Russellville	Randolph	562	Wedowee
Geneva	311	Geneva	Russell	571	Phenix City
Greene	321	Eutaw	St. Claire	581	Ashville
Hale	331	Greensboro	St. Claire	582	Pell City
Henry	341	Abbeville	Shelby	592	Pelham
Henry	342	Headland	Shelby	591	Columbiana
Houston	351	Dothan	Sumter	601	Livingston
Jackson	360	Scottsboro	Sumter	602	York
Jackson	364	Sand Mt.(PCC)	Sumter	605	Livingston (PCC)
Jefferson	370	Birmingham	Talladega	611	Talladega
Jefferson	371	Central	Talladega	613	Munford
Jefferson	372	Bessemer	Talladega	612	Sylacauga
Jefferson	373	Western	Tallapoosa	621	Dadeville
Jefferson	374	Chris McNair Health Ctr	Tallapoosa	622	Alexander City
Jefferson	375	Eastern	Tuscaloosa	631	Tuscaloosa
Jefferson	376	Northern	Tuscaloosa	632	WIC Annex
Jefferson	377	Morris	Tuscaloosa	633	Family Resource Ctr
Jefferson	378	Leeds	Tuscaloosa	635	Head Start
Jefferson	379	Leeds	Walker	641	Jasper
Jefferson	37A	Ensley HS	Walker	642	Sipsey Medical (PCC)
Jefferson	37B	Jess Lanier High	Washington	650	Chatom
Lamar	381	Vernon	Washington	651	Mobile Unit
Lauderdale	391	Florence	Washington	655	McIntosh
Lawrence	401	Moulton	Wilcox	661	Camden
Lawrence	402	SRHCC(Town Creek)	Wilcox	665	Pineapple (PCC)
Lee	411	Opelika	Wilcox	666	Vrendenburg (PCC)
Lee	419	Lee County Head Start	Wilcox	667	Yellow Bluff (PCC)
Limestone	421	Athens	Wilcox	668	Alberta HlthCtr(PCC)
Lowndes	433	Health Dept	Winston	671	Double Springs
Lowndes	431	Hayneville(PCC)	Winston	672	Haleyville

APPENDIX E

COMPUTER INCIDENT REPORTING SHORT FORM

Use this form to report incidents to the Alabama Department of Public Health Information Security Officer. Counties/Areas/Bureaus should contact the ADPH CSC Support Desk at 334-206-5268. The support desk will complete this form and send an electronic copy to Cheryl Perez. This form also outlines the basic information that law enforcement needs on a first call.

STATUS

☐ Site Under Attack ☐ New Incident ☐ Past Incident ☐ Repeated Incidents, unresolved

CONTACT INFORMATION

Name_____Title_____

Organization_____

Direct-Dial Phone_____E-mail_____

Legal Contact Name_____Phone_____

Location/Site(s) Involved_____

Street Address_____

City_____State_____ZIP_____

Main Telephone_____Fax_____

ISP Contact Information_____

INCIDENT DESCRIPTION

☐ Denial of Service

☐ Distributed Denial of Service

☐ Intrusion/Hack

☐ Malicious Code (virus, worm)

☐ Misuse of Systems (internal or external) (Includes inappropriate use by employees)

☐ Probe/Scan

☐ Unauthorized Electronic Monitoring (sniffers)

☐ Website Defacement

☐ Other (specify)_____

DATE/TIME OF INCIDENT DISCOVERY

Date_____Time_____

Duration of Attack_____

IMPACT OF ATTACK

☐ Loss/Compromise of Data

☐ Damage to Systems

☐ System Downtime

☐ Other Organizations' Systems Affected

☐ Financial Loss (estimated amount: $_____)

☐ Damage to the Integrity or Delivery of Critical Goods, Services or Information

SEVERITY OF ATTACK, INCLUDING FINANCIAL LOSS OR INFRASTRUCTURE

☐ High ☐ Medium ☐ Low ☐ Unknown

SENSITIVITY OF DATA

☐ High ☐ Medium ☐ Low ☐ Unknown

How did you detect This?_____

Have you contacted law enforcement about this incident before? Who & when?_____

Has the incident been resolved? Explain_____

Alabama Department of Public Health
Information Systems Administrator's Incident Reporting Form

A. Point of Contact Information

Name	
Title	
Telephone/Fax Numbers	
Email	
Agency	

B. Incident Information

1. Background Information:	
a. Agency (if same as above, enter "SAME":	
b. Physical Location(s) of affected computer system/network (be specific):	
c. Date/time of the incident:	
d. Duration of the incident:	
e. Is the affected system/network critical to the agency's mission? (Yes/No)	

2. Nature of Problem (check all that apply):	
a. Intrusion	
b. System impairment/denial of access	
c. Unauthorized root access	
d. Web site defacement	
e. Compromise of system integrity	
f. Hoax	
g. Theft	
h. Damage	
i. Unknown	
j. Other (provide details in remarks)	
k. REMARKS:	

3. Has your agency experienced this problem before? (Yes/No; If yes, please explain in the remarks section.)
a. REMARKS:

4. Suspected method of intrusion/attack:	
a. Virus (provide name, if known)	
b. Vulnerable exploited (explain)	
c. Denial of Service	
d. Trojan Horse	
e. Distributed Denial of Service	
f. Trapdoor	
g. Unknown	
h. Other (Provide details in remarks)	
i. REMARKS:	

5. Suspected perpetrator(s) or possible motivation(s) of the attack:	
a. Insider/Disgruntled Employee	
b. Former employee	
c. Other (Explain remarks)	
d. Unknown	
e. REMARKS:	

6. The apparent source (IP address) of the intrusion/attack:

7. Evidence of spoofing (Yes/No/Unknown)

8. What computers/systems (hardware and software) were affected (Operating system, version):	
a. Windows 9x	
b. Windows NT	

c. Windows 2000	
d. Windows XP	
e. Windows Server 2003	
f. Other (Please specify in remarks)	
g. REMARKS:	

9. Security Infrastructure in place. (Check all that apply)	
a. Incident/Emergency Response Team	
b. Encryption	
c. Firewall	
d. Secure Remote Access/Authorization Tools	
e. Intrusion Detection System	
f. Security Auditing Tools	
g. Banners	
h. Packet filtering	
i. Access Control Lists	
j. REMARKS:	

10. Did intrusion/attack result in a loss/compromise of sensitive or information classified as private?	
a. Yes (provide details in remarks)	
b. No	
c. Unknown	
d. REMARKS:	

11. Did the intrusion/attack result in damage to system(s) or data?	
a. Yes (provide details in remarks)	
b. No	
c. Unknown	
d. REMARKS:	

12. What actions and technical mitigation have been taken?	
a. System(s) disconnected from the network?	
b. Backup of affected system(s)?	
c. Log files examined?	
d. Other (Please provide details in remarks)	
e. No action(s) taken	
f. REMARKS:	

13. Has ADPH General Counsel or law enforcement been notified? (Check all that apply.)	
a. Yes-ADPH General Counsel	
b. Yes-local law enforcement/State Capitol Police/Alabama State Troopers	
c. Yes-FBI field office/ABI	
d. Not	
e. REMARKS:	

14. Has another agency/organization been informed as assisted with the response?	
a. Yes-ISD	
b. Yes-Other (provide details in remarks)	
c. No	
d. REMARKS:	

15. Additional Remarks:

If the reported incident is a criminal matter, you may be contacted by law enforcement for additional information.

C. Closure Information (Optional, Except 9 & 10)

1. (Optional) Did your detection and response process and procedures work as intended? If not, where did they not work? Why did they not work?
REMARKS:

2. (Optional) Methods of discovery and monitoring procedures that would have improved your ability to detect an intrusion.
REMARKS**:**

3. (Optional) Improvements to procedures and tools that would have aided you in the response process. For example, consider using updated router and firewall filters, placement of firewalls, moving the compromised system to a new name or IP address, or moving the compromised machine's function to a more secure area of your network.
REMARKS**:**

4. (Optional) Improvements that would have enhanced your ability to contain an intrusion.
REMARKS**:**

5. (Optional) Correction procedures that would have improved your effectiveness in recovering your systems.

REMARKS**:**

6. (Optional) Updates to policies and procedures that would have allowed the response and recovery processes to operate more smoothly.
REMARKS**:**

7. (Optional) Topics for improving user and system administrator preparedness.
REMARKS**:**

8. (Optional) Areas for improving communication throughout the detecting and response processes.
REMARKS**:**

9. (Required) A description of the costs associated with an intrusion, including a monetary estimate if possible. (Salaries + Cost of affected equipment)
REMARKS**:**

10. (Required) Summary of post mortem efforts.
REMARKS**:**

EE

FF

APPENDIX F

HH

Mission Criticality

System	Criticality	Impact if Lost
Vital Records	Essential	Alabama residents would have to use alternate means to prove their birth, death, marriages, divorce…etc.
Clinic Systems (PHALCON)	Critical	Medical and Nutritional Services to over 100,000 citizens of Alabama would eventually cease.
Financial System	Fatal	A loss of services would cause complete failure of ADPH to provide service to the citizens as well as to the employees
Personnel System	Fatal	A loss of services would cause complete failure of ADPH to provide services to the citizens as well as to the employees
Home Health (CBW and HCIS)	Critical	This program provides major revenue for Public Health; however, its loss would not stop services.
Billing	Critical	This system is critical to the financial stability of the Department because 80% of ADPH funding is derived from Billing
SIIS (Immunization)	Essential	SIIS is considered low risk to the Department since its failure will not prevent continuation of the disease control functions.
Statewide Network	Essential	If the statewide network goes down, all communications with the Internet, clinics, area offices, labs, etc. will be terminated. The Department will be able to continue to provide services.
Lotus Notes	Essential	If Lotus Notes goes down, communications with the Internet, clinics, area offices, labs, etc. will be terminated. The Department will be able to continue to provide services.

APPENDIX G

LL

Violation Tracking Form

List Violation	Date of Violation	Time Violation Occurred	Corrective Measure(s)	Comments

MM

NN

APPENDIX H

PP

STANDARD CLAUSES REQUIRED FOR PROFESSIONAL SERVICES CONTRACTS

EFFECTIVE JULY 2002

MAXIMUM AMOUNT CLAUSE

Under no circumstances shall the maximum amount payable under this contract /grant exceed $_____ for the contract /grant period.

DEBT OF STATE CLAUSE

It is agreed that the terms and commitments contained herein shall not be constituted as a debt of the State of Alabama in violation of Article 11, Section 213 of the Constitution of Alabama of 1901, as amended by Amendment Number 26. It is further agreed that if any provision of this contract /grant shall contravene any statute or Constitutional provision or amendment, either now in effect or which may, during the course of this contract /grant, be enacted, then that conflicting provision in the contract /grant shall be deemed null and void. The Contractor's (grantee's) sole remedy for the settlement of any and all disputes arising under the terms of this contract /grant shall be limited to the filing of a claim with the Board of Adjustment for the State of Alabama.

For any and all disputes arising under the terms of this contract /grant, the parties hereto agree, in compliance with the recommendations of the Governor and Attorney General, when considering settlement of such disputes, to utilize appropriate forms of non-binding alternative dispute resolution including, but not limited to, mediation by and through the Attorney General's Office of Administrative Hearings or where appropriate, private mediators.

DISCRIMINATION CLAUSE

Contractor /grantee will comply with Titles IV, VI, and VII of the Civil Rights Act of 1964, the Federal Age Discrimination in Employment Act, Section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, and all applicable federal and state laws, rules and regulations implementing the foregoing statutes with respect to nondiscrimination on the basis of race, creed, color, religion, national origin, age, sex or disability, as defined in the above laws and regulations. Contractor /grantee shall not discriminate against any otherwise qualified disabled applicant for, or recipient of aid, benefits, or services or any employee or person on the basis of physical or mental disability in accordance with the Rehabilitation Act of 1973 or the Americans With Disabilities Act of 1990.

HIPAA CLAUSE (This clause is to be used if Department will disclose individually identifiable health information to the other party or if the other party will create or receive individually identifiable health information. Where the instrument is a Grant Agreement or an MOU, use language consistent with the rest of the instrument to identify the Department and the other party.)

Federal Requirement. This Clause is necessitated by the application of the Health Insurance Portability and Accountability Act, being 42 U.S.C. §§ 1320d-1329d-8 as amended by § 262 of P.L.104-191, 110 Stat. 2020-2031 and § 264 of P.L.104-191 (42 U.S.C. § 1320d-2 as amended) and regulations promulgated thereunder. References in this clause are to the Code of Federal Regulations, hereinafter "CFR."

1. Definitions. Terms used, but not otherwise defined, in this Clause shall have the same meaning as those terms in 45 CFR §§ 160.103 and 164.501.

a. "Contractor." The Contractor herein. The Contractor is within the definition of a "Business Associate" under the Privacy Rule.

b. "Department." The Department herein. Department is within the definition of a "Covered Entity" under the Privacy Rule.

c. "Individual" shall have the same meaning as the term "individual" in 45 CFR. § 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR § 164.502(g).

d. "Privacy Rule." Privacy Rule shall mean the Standards for Privacy of Individually Identifiable Health Information found at 45 CFR. Part 160 and Part 164, Subparts A and E.

e. "Protected Health Information" shall have the same meaning as the term "protected health information" in 45 CFR § 164.501, limited to the information created or received by Contractor from or on behalf of Department.

f. "Required By Law" shall have the same meaning as the term "required by law' in 45 CFR § 164.501.

g. "Secretary." The Secretary of the United States Department of Health and Human Services or his designee.

h. "Designated Record Set." A discrete set, file or gathering of protected information obtained from the Department or obtained as a result of this Contract. This is distinguished from integrated records of the Contractor kept in the normal course of business.

2. Obligations and Activities of Contractor

a. Contractor agrees not to use or further disclose Protected Health Information other than as permitted or required by the Contract or as Required By Law.

b. Contractor agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Contract.

c. Contractor agrees to report to Department any use or disclosure of the Protected Health Information not provided for by this Contract.

d. Contractor agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Contractor on behalf of Department agrees to the same restrictions and conditions that apply through this Contract to Contractor with respect to such information.

e. If Contractor maintains a Designated Record Set, Contractor agrees to provide access, at the request of Department, and in the time and manner designated by Department, to Protected Health Information in a Designated Record Set, to Department or, as directed by Department, to an Individual in order to meet the requirements under 45 CFR §164.524.

f. If Contractor maintains a Designated Record Set, Contractor agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the Department directs or agrees to pursuant to 45 CFR § 164.526 at the request of Department or an Individual, and in the time and manner designated by Department.

g. If Contractor maintains a Designated Record Set, Contractor agrees to make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by Contractor on behalf of Department available to the Department, or at the request of the Department to the Secretary, in a time and manner designated by the Department or the Secretary, for purposes of the Secretary determining Department's compliance with the Privacy Rule.

h. Contractor agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for Department to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR § 164.528.

i. Contractor agrees to provide to Department or an Individual, at a time and in a manner designated by Department, information collected by and in the possession of Contractor because of this Contract in order to permit Department to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR § 164.528.

3. Permitted Uses and Disclosures by Contractor.

a. Except as otherwise limited in this Contract, Contractor may use or disclose Protected Health Information on behalf of Department, or to perform functions, activities, or provide services to, Department or patients or clients of Department for the purposes of providing health care to patients and clients in accordance with Department's Confidentiality Policy, if such use or disclosure of Protected Health Information would not otherwise violate the Privacy Rule if such disclosure is made by Department.

b. Except as otherwise limited in this Contract, Contractor may use Protected Health Information for the proper management and administration of the Contractor or to carry out the legal responsibilities of the Contractor.

c. Except as otherwise limited in this Contract, Contractor may disclose Protected Health Information for the proper management and administration of the Contractor, provided that disclosures are required by law, or Contractor obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and will be used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Contractor of any instances of which it is aware in which the confidentiality of the information has been breached.

d. Except as otherwise limited in this Contract, Contractor may use Protected Health Information to provide Data Aggregation services to Department as permitted by 42 CFR § 164.504(e)(2)(i)(B).

4. Obligations of Department.

a. Department shall provide Contractor with Department's Privacy Notice which Department produces in accordance with 45 CFR § 164.520, as well as any changes to such notice.

b. Department shall provide Contractor with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect Contractor's permitted or required uses and disclosures.

c. Department shall notify Contractor of any restriction to the use or disclosure of Protected Health Information that Department has agreed to in accordance with 45 CFR § 164.522.

5. Permissible Requests by Department. Department shall not request Contractor to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Department except that if the Contractor will use or disclose protected health information for data aggregation or management and administrative activities of Contractor, such information may be requested.

6. Return of Information and Survival of the terms of this Clause. The provisions of this paragraph shall survive the termination of this Contract and may constitute a continuing duty in perpetuity

a. Except as otherwise provided , upon termination of this Contract for any reason, Contractor shall delete, return or destroy all Protected Health Information maintained in a designated record set received from Department, or created or received by Contractor on behalf of Department or as a result of this Contract. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Contractor. Where such information is deleted or destroyed, Contractor shall provide Department with an assurance of the deletion or destruction of such.

b. Except in accordance with normal business practices, Contractor shall retain no copies of the Protected Health Information.

c. In the event that Contractor determines that returning or destroying the Protected Health Information is infeasible, Contractor shall provide to Department notification of the conditions that make return or destruction infeasible. Upon mutual Contract of the Parties that return or destruction of Protected Health Information is infeasible, Contractor shall extend the protections of this Contract to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Contractor maintains such Protected Health Information.

7. Administrative Provisions.

a. A reference in this Contract to a section of the Privacy Rule shall mean that section as it is most recently amended.

b. The parties hereto agree to take necessary action as is necessary to amend this Contract from time to time to maintain compliance with the Privacy Rule.

c. Interpretation. Any ambiguity in this Contract regarding the application of the Privacy Rule shall be resolved in favor of a meaning which permits the parties hereto to comply with the Privacy Rule.

<u>DO NOT WORK CLAUSE</u>

Contractor /grantee acknowledges and understands that this contract /grant is not effective until it has received all requisite state government approvals and Contractor

/grantee shall not begin performing work under this contract /grant until notified to do so by the contracting state department. Contractor /grantee is entitled to no compensation for work performed prior to the effective date of this contract /grant.

GOVERNOR'S PRORATION CLAUSE
It is agreed that Department may terminate this contract /grant by giving 30 days written notice to Contractor /grantee should the Governor of Alabama declare proration of the fund from which payment under this contract /grant is to be made. This termination for cause is supplemental to other rights Department may have under this contract /grant or otherwise to terminate such contract.

HOLD HARMLESS CLAUSE
Contractor /grantee hereby holds harmless the State of Alabama and the Department and their officers, agents, servants and employees from any and all claims arising out of acts or omissions committed by the Contractor /grantee or any agent, servant or employee of Contractor while in performance hereunder.

MERIT SYSTEM CLAUSE
Contractor /grantee shall not be entitled to receive any benefits under this contract /grant that merit system employees receive by virtue of their status or employment, nor may Contractor nor any of its officers, agents, servants or employees be employed as a merit system employee during the term of this contract /grant. Any such employment automatically voids this contract /grant.

PROPERTY CLAUSE (When Applicable)
Grantee /contractor hereby acknowledges that any items of tangible personal property that have come or may come into the hands of the grantee /contractor by virtue of this grant (contract) shall be secured and maintained by grantee /contractor and grantee /contractor hereby receives such tangible personal property in bailment from the Department. Grantee /contractor acknowledges that grantee /contractor may be called to account for such tangible personal property and when so called upon, shall present same to the Department in the same condition as issued, normal wear and tear excluded, in completion of the bailment herein created or shall account to Department for the value of same as determined by the appropriate agency of the State of Alabama or government of the United States as the case may be. Grantee /contractor hereby holds harmless the State of Alabama, the Department and their officers, agents, servants, and employees from any loss suffered because of failure or refusal of grantee /contractor to account for said property or the value thereof.

TERMINATION CLAUSE
This contract /grant may be terminated by either party by giving 30 days written notice to the other party.

FUND APPROPRIATION CLAUSE
(Applicable only to contracts for longer than one year)

It is agreed that Department may terminate this contract /grant by giving 30 days written notice to contractor /grantee should the Legislature of Alabama fail to appropriate funds for the continued payment of this contract. This termination for cause is supplemental to any other rights Department may have under this contract /grant or otherwise to terminate such contract.

APPENDIX I

ZZ

ALABAMA DEPARTMENT OF PUBLIC HEALTH
PROPERTY HISTORY CARD

PROPERTY NUMBER:_____ PROPERTY UNIT:_____

SCAN NUMBER:_____ BUILDING NUMBER:_____

DESCRIPTION:_____ OFFICE/TELEPHONE EXT.:_____

MODEL NUMBER:_____ P.O. NUMBER:_____

MANUFACTURER:_____ COST:_____

SERIAL NUMBER:_____ DATE RECEIVED:_____

CERTIFICATION

I, THE LAST UNDERSIGNED, ACKNOWLEDGE RECEIPT OF THE ABOVE DESCRIBED PROPERT
THE STATE OF ALABAMA. EFFECTIVE ON THE DATE SHOWN BY THE SIGNATURE, THIS PRO
CUSTODY AND I ACKNOWLEDGE RESPONSIBILITY FOR THIS PROPERTY PURSUANT TO THE
ALABAMA 1975, SECTION 36-16-8. I WILL BE HELD STRICTLY ACCOUNTABLE FOR THIS PROP
EVENT OF ANY SHORTAGES.

CUSTODIAN

NAME	SIGNATURE	OFFICE/ROOM	LOC

DISPOSITION/TRANSFER

RELEASED BY:

_____
NAME

_____
TITLE

_____
SIGNATURE

_____ ____
PROPERTY UNIT LOC CODE

_____
DATE

RECEIVED BY:

_____
NAME

_____
TITLE

_____
SIGNATURE

_____
PROPERTY UNIT

_____
DATE

BBB

APPENDIX J

DDD

Insert samples of audit logs here.

FFF

APPENDIX K

HHH

Insert Disaster Recovery Plan here.

JJJ

APPENDIX L

LLL

I, the undersigned, acknowledge receipt of a personal identification number ("PIN") for use exclusively with the Alabama Department of Public Health's Automated System ("System"). I further acknowledge that I have been given and understand clear instructions on the use of the PIN and the consequences of such use.

I acknowledge that the PIN has continuing effect on all documents within the System which requires my signature and that such effect is continuing until I withdraw this acknowledgement.

I acknowledge that I have been given clear instructions in the use of the System and the hardware and software requirements of the system.

I hereby acknowledge that the use of the PIN in the System is the legal equivalent to my customary and usual handwritten signature and that my divulging the PIN to any other person allows such person to use the PIN in my place and stead and that by so divulging such PIN, I ratify and affirm any action taken using such PIN as though the action were taken by me personally.

Acknowledged on this the _____ day of _____, 2005

_____

Signature

NNN