

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, 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 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 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 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;

(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 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 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 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 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 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.

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.

164.310 Physical safeguards.

164.312 Technical safeguards.

164.314 Organizational requirements.

164.316 Policies and 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 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 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 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 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.
 - (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 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 reasonable and appropriate protection of electronic protected health information as described at § 164.316.

§ 164.308 Administrative safeguards.

(a) A covered entity must, in 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 (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 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 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 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 natural disaster) that damages systems that contain electronic protected health information.

(ii) *Implementation specifications:*

(A) *Data backup 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 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 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 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 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 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 backup and storage (Addressable)*. Create a retrievable, exact copy of electronic protected health information, when needed, before movement of equipment.

§ 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 procedures to protect electronic protected health 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 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 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 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 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 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.

§ 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, activity, or assessment.

(2) *Implementation specifications:*

(i) *Time limit (Required).* Retain the documentation required by paragraph (b)(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.

(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 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.

(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 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.

§164.500 [Amended]

6. § In 164.500(b)(1)(iv), remove the words “including the designation of health care components of a covered entity”.

§ 165.501 [Amended]

7. In §164.501, the definitions of the following terms are removed: *Covered functions, Disclosure, Individual, Organized health care arrangement, Plan sponsor Protected health information, Required by law, and Use.*

§ 164.504 [Amended]

8. In §164.504, the following changes are made:

a. The definitions of the following terms are removed: *Common control, Common ownership, Health care component, and Hybrid entity.*

b. Paragraphs (b) through (d) are removed and reserved.

Authority: Sections 1173 and 1175 of the Social Security Act (42 U.S.C. 1329d-2 and 1320-4).

Dated: January 13, 2003.

Tommy G. Thompson,

Secretary.

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Appendix A to Subpart C of Part 164—Security Standards: Matrix

Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable
Administrative Safeguards		
Security Management Process	164.308(a)(1)	Risk Analysis (R) Risk Management (R) Sanction Policy (R) Information System Activity Review (R)
Assigned Security Responsibility	164.308(a)(2)	(R)
Workforce Security	164.308(a)(3)	Authorization and/or Supervision (A) Workforce Clearance Procedure Termination Procedures (A)
Information Access Management	164.308(a)(4)	Isolating Health care Clearinghouse Function (R) Access Authorization (A) Access Establishment and Modification (A)
Security Awareness and Training	164.308(a)(5)	Security Reminders (A) Protection from Malicious Software (A) Log-in Monitoring (A) Password Management (A)
Security Incident Procedures	164.308(a)(6)	Response and Reporting (R)
Contingency Plan	164.308(a)(7)	Data Backup Plan (R) Disaster Recovery Plan (R) Emergency Mode Operation Plan (R) Testing and Revision Procedure (A) Applications and Data Criticality Analysis (A)
Evaluation	164.308(a)(8)	(R)
Business Associate Contracts and Other Arrangement.	164.308(b)(1)	Written Contract or Other Arrangement (R)
Physical Safeguards		
Facility Access Controls	164.310(a)(1)	Contingency Operations (A) Facility Security Plan (A) Access Control and Validation Procedures (A) Maintenance Records (A)
Workstation Use	164.310(b)	(R)
Workstation Security	164.310(c)	(R)
Device and Media Controls	164.310(d)(1)	Disposal (R) Media Re-use (R) Accountability (A) Data Backup and Storage (A)
Technical Safeguards (see § 164.312)		
Access Control	164.312(a)(1)	Unique User Identification (R) Emergency Access Procedure (R) Automatic Logoff (A) Encryption and Decryption (A)
Audit Controls	164.312(b)	(R)
Integrity	164.312(c)(1)	Mechanism to Authenticate Electronic Protected Health Information (A)
Person or Entity Authentication	164.312(d)	(R)
Transmission Security	164.312(e)(1)	Integrity Controls (A) Encryption (A)

Lawrence's Added Table: The other Two "Requirements" Sections

Organizational Requirements		
Business Associate Contracts or Other Arrangements	164.314(a)(1)	(R)
Requirement for Group Health Plans	164.314(b)(1)	(R)
Policies and Procedures and Documentation Requirements		
Policies and Procedures	164.316(a)	
Documentation	164.316(b)(1)	Time Limit (R) Availability (R) Updates (R)

Compliance Roadmap

The Three (3) Safeguards ...

and the Two (2) Requirements.

