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.

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)