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(D) The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;

(E) The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and

(F) A statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity.

(ii) If the covered entity provides an accounting for research disclosures, in accordance with paragraph (b)(4) of this section, and if it is reasonably likely that the protected health information of the individual was disclosed for such research protocol or activity, the covered entity shall, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.

(c) *Implementation specifications: Provision of the accounting.* (1) The covered entity must act on the individual's request for an accounting, no later than 60 days after receipt of such a request, as follows.

(i) The covered entity must provide the individual with the accounting requested; or

(ii) If the covered entity is unable to provide the accounting within the time required by paragraph (c)(1) of this section, the covered entity may extend the time to provide the accounting by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (c)(1) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will provide the accounting; and

(B) The covered entity may have only one such extension of time for action on a request for an accounting.

(2) The covered entity must provide the first accounting to an individual in any 12 month period without charge. The covered entity may impose a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12 month period, provided that the covered enti-

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ty informs the individual in advance of the fee and provides the individual with an opportunity to withdraw or modify the request for a subsequent accounting in order to avoid or reduce the fee.

(d) *Implementation specification: Documentation.* A covered entity must document the following and retain the documentation as required by §164.530(j):

(1) The information required to be included in an accounting under paragraph (b) of this section for disclosures of protected health information that are subject to an accounting under paragraph (a) of this section;

(2) The written accounting that is provided to the individual under this section; and

(3) The titles of the persons or offices responsible for receiving and processing requests for an accounting by individuals.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53271, Aug. 14, 2002]

§ 164.530 Administrative requirements.

(a)(1) *Standard: Personnel designations.*

(i) A covered entity must designate a privacy official who is responsible for the development and implementation of the policies and procedures of the entity.

(ii) A covered entity must designate a contact person or office who is responsible for receiving complaints under this section and who is able to provide further information about matters covered by the notice required by §164.520.

(2) *Implementation specification: Personnel designations.* A covered entity must document the personnel designations in paragraph (a)(1) of this section as required by paragraph (j) of this section.

(b)(1) *Standard: Training.* A covered entity must train all members of its workforce on the policies and procedures with respect to protected health information required by this subpart and subpart D of this part, as necessary and appropriate for the members of the workforce to carry out their functions within the covered entity.

(2) *Implementation specifications: Training.* (i) A covered entity must provide training that meets the requirements of paragraph (b)(1) of this section, as follows:

(A) To each member of the covered entity's workforce by no later than the compliance date for the covered entity;

(B) Thereafter, to each new member of the workforce within a reasonable period of time after the person joins the covered entity's workforce; and

(C) To each member of the covered entity's workforce whose functions are affected by a material change in the policies or procedures required by this subpart or subpart D of this part, within a reasonable period of time after the material change becomes effective in accordance with paragraph (i) of this section.

(ii) A covered entity must document that the training as described in paragraph (b)(2)(i) of this section has been provided, as required by paragraph (j) of this section.

(c)(1) *Standard: Safeguards.* A covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information.

(2)(i) *Implementation specification: Safeguards.* A covered entity must reasonably safeguard protected health information from any intentional or unintentional use or disclosure that is in violation of the standards, implementation specifications or other requirements of this subpart.

(ii) A covered entity must reasonably safeguard protected health information to limit incidental uses or disclosures made pursuant to an otherwise permitted or required use or disclosure.

(d)(1) *Standard: Complaints to the covered entity.* A covered entity must provide a process for individuals to make complaints concerning the covered entity's policies and procedures required by this subpart and subpart D of this part or its compliance with such policies and procedures or the requirements of this subpart or subpart D of this part.

(2) *Implementation specification: Documentation of complaints.* As required by paragraph (j) of this section, a covered entity must document all complaints received, and their disposition, if any.

(e)(1) *Standard: Sanctions.* A covered entity must have and apply appropriate sanctions against members of its workforce who fail to comply with the privacy policies and procedures of the covered entity or the requirements of this subpart or subpart D of this part. This standard does not apply to a member of the covered entity's workforce with respect to actions that are covered by and that meet the conditions of §164.502(j) or paragraph (g)(2) of this section.

(2) *Implementation specification: Documentation.* As required by paragraph (j) of this section, a covered entity must document the sanctions that are applied, if any.

(f) *Standard: Mitigation.* A covered entity must mitigate, to the extent practicable, any harmful effect that is known to the covered entity of a use or disclosure of protected health information in violation of its policies and procedures or the requirements of this subpart by the covered entity or its business associate.

(g) *Standard: Refraining from intimidating or retaliatory acts.* A covered entity—

(1) May not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against any individual for the exercise by the individual of any right established, or for participation in any process provided for, by this subpart or subpart D of this part, including the filing of a complaint under this section; and

(2) Must refrain from intimidation and retaliation as provided in §160.316 of this subchapter.

(h) *Standard: Waiver of rights.* A covered entity may not require individuals to waive their rights under §160.306 of this subchapter, this subpart, or subpart D of this part, as a condition of the provision of treatment, payment, enrollment in a health plan, or eligibility for benefits.

(i)(1) *Standard: Policies and procedures.* A covered entity must implement policies and procedures with respect to protected health information that are designed to comply with the standards, implementation specifications, or other requirements of this subpart and subpart D of this part. The policies and

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procedures must be reasonably designed, taking into account the size and the type of activities that relate to protected health information undertaken by a covered entity, to ensure such compliance. This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirement of this subpart.

(2) *Standard: Changes to policies and procedures.* (i) A covered entity must change its policies and procedures as necessary and appropriate to comply with changes in the law, including the standards, requirements, and implementation specifications of this subpart or subpart D of this part.

(ii) When a covered entity changes a privacy practice that is stated in the notice described in §164.520, and makes corresponding changes to its policies and procedures, it may make the changes effective for protected health information that it created or received prior to the effective date of the notice revision, if the covered entity has, in accordance with §164.520(b)(1)(v)(C), included in the notice a statement reserving its right to make such a change in its privacy practices; or

(iii) A covered entity may make any other changes to policies and procedures at any time, provided that the changes are documented and implemented in accordance with paragraph (i)(5) of this section.

(3) *Implementation specification: Changes in law.* Whenever there is a change in law that necessitates a change to the covered entity's policies or procedures, the covered entity must promptly document and implement the revised policy or procedure. If the change in law materially affects the content of the notice required by §164.520, the covered entity must promptly make the appropriate revisions to the notice in accordance with §164.520(b)(3). Nothing in this paragraph may be used by a covered entity to excuse a failure to comply with the law.

(4) *Implementation specifications: Changes to privacy practices stated in the notice.* (i) To implement a change as provided by paragraph (i)(2)(ii) of this section, a covered entity must:

(A) Ensure that the policy or procedure, as revised to reflect a change in the covered entity's privacy practice as stated in its notice, complies with the standards, requirements, and implementation specifications of this subpart;

(B) Document the policy or procedure, as revised, as required by paragraph (j) of this section; and

(C) Revise the notice as required by §164.520(b)(3) to state the changed practice and make the revised notice available as required by §164.520(c). The covered entity may not implement a change to a policy or procedure prior to the effective date of the revised notice.

(ii) If a covered entity has not reserved its right under §164.520(b)(1)(v)(C) to change a privacy practice that is stated in the notice, the covered entity is bound by the privacy practices as stated in the notice with respect to protected health information created or received while such notice is in effect. A covered entity may change a privacy practice that is stated in the notice, and the related policies and procedures, without having reserved the right to do so, provided that:

(A) Such change meets the implementation specifications in paragraphs (i)(4)(i)(A)–(C) of this section; and

(B) Such change is effective only with respect to protected health information created or received after the effective date of the notice.

(5) *Implementation specification: Changes to other policies or procedures.* A covered entity may change, at any time, a policy or procedure that does not materially affect the content of the notice required by §164.520, provided that:

(i) The policy or procedure, as revised, complies with the standards, requirements, and implementation specifications of this subpart; and

(ii) Prior to the effective date of the change, the policy or procedure, as revised, is documented as required by paragraph (j) of this section.

(j)(1) *Standard: Documentation.* A covered entity must:

(i) Maintain the policies and procedures provided for in paragraph (i) of

this section in written or electronic form;

(ii) If a communication is required by this subpart to be in writing, maintain such writing, or an electronic copy, as documentation; and

(iii) If an action, activity, or designation is required by this subpart to be documented, maintain a written or electronic record of such action, activity, or designation.

(iv) Maintain documentation sufficient to meet its burden of proof under § 164.414(b).

(2) *Implementation specification: Retention period.* A covered entity must retain the documentation required by paragraph (j)(1) of this section for six years from the date of its creation or the date when it last was in effect, whichever is later.

(k) *Standard: Group health plans.* (1) A group health plan is not subject to the standards or implementation specifications in paragraphs (a) through (f) and (i) of this section, to the extent that:

(i) The group health plan provides health benefits solely through an insurance contract with a health insurance issuer or an HMO; and

(ii) The group health plan does not create or receive protected health information, except for:

(A) Summary health information as defined in § 164.504(a); or

(B) Information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan.

(2) A group health plan described in paragraph (k)(1) of this section is subject to the standard and implementation specification in paragraph (j) of this section only with respect to plan documents amended in accordance with § 164.504(f).

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53272, Aug. 14, 2002; 71 FR 8433, Feb. 16, 2006; 74 FR 42769, Aug. 24, 2009]

§ 164.532 Transition provisions.

(a) *Standard: Effect of prior authorizations.* Notwithstanding §§ 164.508 and 164.512(i), a covered entity may use or disclose protected health information, consistent with paragraphs (b) and (c) of this section, pursuant to an authorization or other express legal permis-

sion obtained from an individual permitting the use or disclosure of protected health information, informed consent of the individual to participate in research, or a waiver of informed consent by an IRB.

(b) *Implementation specification: Effect of prior authorization for purposes other than research.* Notwithstanding any provisions in § 164.508, a covered entity may use or disclose protected health information that it created or received prior to the applicable compliance date of this subpart pursuant to an authorization or other express legal permission obtained from an individual prior to the applicable compliance date of this subpart, provided that the authorization or other express legal permission specifically permits such use or disclosure and there is no agreed-to restriction in accordance with § 164.522(a).

(c) *Implementation specification: Effect of prior permission for research.* Notwithstanding any provisions in §§ 164.508 and 164.512(i), a covered entity may, to the extent allowed by one of the following permissions, use or disclose, for research, protected health information that it created or received either before or after the applicable compliance date of this subpart, provided that there is no agreed-to restriction in accordance with § 164.522(a), and the covered entity has obtained, prior to the applicable compliance date, either:

(1) An authorization or other express legal permission from an individual to use or disclose protected health information for the research;

(2) The informed consent of the individual to participate in the research; or

(3) A waiver, by an IRB, of informed consent for the research, in accordance with 7 CFR 1c.116(d), 10 CFR 745.116(d), 14 CFR 1230.116(d), 15 CFR 27.116(d), 16 CFR 1028.116(d), 21 CFR 50.24, 22 CFR 225.116(d), 24 CFR 60.116(d), 28 CFR 46.116(d), 32 CFR 219.116(d), 34 CFR 97.116(d), 38 CFR 16.116(d), 40 CFR 26.116(d), 45 CFR 46.116(d), 45 CFR 690.116(d), or 49 CFR 11.116(d), provided that a covered entity must obtain authorization in accordance with § 164.508 if, after the compliance date, informed consent is sought from an individual participating in the research.