

(d) *Implementation specifications: Denial of access.* If the covered entity denies access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) *Making other information accessible.* The covered entity must, to the extent possible, give the individual access to any other protected health information requested, after excluding the protected health information as to which the covered entity has a ground to deny access.

(2) *Denial.* The covered entity must provide a timely, written denial to the individual, in accordance with paragraph (b)(2) of this section. The denial must be in plain language and contain:

(i) The basis for the denial;

(ii) If applicable, a statement of the individual's review rights under paragraph (a)(4) of this section, including a description of how the individual may exercise such review rights; and

(iii) A description of how the individual may complain to the covered entity pursuant to the complaint procedures in § 164.530(d) or to the Secretary pursuant to the procedures in § 160.306. The description must include the name, or title, and telephone number of the contact person or office designated in § 164.530(a)(1)(ii).

(3) *Other responsibility.* If the covered entity does not maintain the protected health information that is the subject of the individual's request for access, and the covered entity knows where the requested information is maintained, the covered entity must inform the individual where to direct the request for access.

(4) *Review of denial requested.* If the individual has requested a review of a denial under paragraph (a)(4) of this section, the covered entity must designate a licensed health care professional, who was not directly involved in the denial to review the decision to deny access. The covered entity must promptly refer a request for review to such designated reviewing official. The designated reviewing official must determine, within a reasonable period of time, whether or not to deny the access requested based on the standards in paragraph (a)(3) of this section. The covered entity must promptly provide written notice to the individual of the determination of the designated reviewing official and take other action as required by this section to carry out the designated reviewing official's determination.

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

(1) The designated record sets that are subject to access by individuals; and

(2) The titles of the persons or offices responsible for receiving and processing requests for access by individuals.

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§ 164.526 Amendment of protected health information.

(a) *Standard: Right to amend.* (1) *Right to amend.* An individual has the right to have a covered entity amend protected health information or a record about the individual in a designated record set for as long as the protected health information is maintained in the designated record set.

(2) *Denial of amendment.* A covered entity may deny an individual's request for amendment, if it determines that the protected health information or record that is the subject of the request:

(i) Was not created by the covered entity, unless the individual provides a reasonable basis to believe that the originator of protected health information is no longer available to act on the requested amendment;

(ii) Is not part of the designated record set;

(iii) Would not be available for inspection under § 164.524; or

(iv) Is accurate and complete.

(b) *Implementation specifications: Requests for amendment and timely action.* (1) *Individual's request for amendment.* The covered entity must permit an individual to request that the covered entity amend the protected health information maintained in the designated record set. The covered entity may require individuals to make requests for amendment in writing and to provide a reason to support a requested amendment, provided that it informs individuals in advance of such requirements.

(2) *Timely action by the covered entity.* (i) The covered entity must act on the individual's request for an amendment no later than 60 days after receipt of such a request, as follows.

(A) If the covered entity grants the requested amendment, in whole or in part, it must take the actions required by paragraphs (c)(1) and (2) of this section.

(B) If the covered entity denies the requested amendment, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d)(1) of this section.

(ii) If the covered entity is unable to act on the amendment within the time required by paragraph (b)(2)(i) of this section, the covered entity may extend the time for such action by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) 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 complete its action on the request; and

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

(c) *Implementation specifications: Accepting the amendment.* If the covered entity accepts the requested amendment, in whole or in part, the covered entity must comply with the following requirements.

(1) *Making the amendment.* The covered entity must make the appropriate amendment to the protected health information or record that is the subject of the request for amendment by, at a minimum, identifying the records in the designated record set that are affected by the amendment and appending or otherwise providing a link to the location of the amendment.

(2) *Informing the individual.* In accordance with paragraph (b) of this section, the covered entity must timely inform the individual that the amendment is accepted and obtain the individual's identification of and agreement to have the covered entity notify the relevant persons with which the amendment needs to be shared in accordance with paragraph (c)(3) of this section.

(3) *Informing others.* The covered entity must make reasonable efforts to inform and provide the amendment within a reasonable time to:

(i) Persons identified by the individual as having received protected health information about the individual and needing the amendment; and

(ii) Persons, including business associates, that the covered entity knows have the protected health information that is the subject of the amendment and that may have relied, or could foreseeably rely, on such information to the detriment of the individual.

(d) *Implementation specifications: Denying the amendment.* If the covered entity denies the requested amendment, in whole or in part, the covered entity must comply with the following requirements.

(1) *Denial.* The covered entity must provide the individual with a timely, written denial, in accordance with paragraph (b)(2) of this section. The denial must use plain language and contain:

(i) The basis for the denial, in accordance with paragraph (a)(2) of this section;

(ii) The individual's right to submit a written statement disagreeing with the denial and how the individual may file such a statement;

(iii) A statement that, if the individual does not submit a statement of disagreement, the individual may request that the covered entity provide the individual's request for amendment and the denial with any future disclosures of the protected health information that is the subject of the amendment; and

(iv) A description of how the individual may complain to the covered entity pursuant to the complaint procedures established in § 164.530(d) or to the Secretary pursuant to the procedures established in § 160.306. The description must include the name, or title, and telephone number of the contact person or office designated in § 164.530(a)(1)(ii).

(2) *Statement of disagreement.* The covered entity must permit the individual to submit to the covered entity a written statement disagreeing with the denial of all or part of a requested amendment and the basis of such disagreement. The covered entity may reasonably limit the length of a statement of disagreement.

(3) *Rebuttal statement.* The covered entity may prepare a written rebuttal to the individual's statement of disagreement. Whenever such a rebuttal is prepared, the covered entity must provide a copy to the individual who submitted the statement of disagreement.

(4) *Recordkeeping.* The covered entity must, as appropriate, identify the record or protected health information in the designated record set that is the subject of the disputed amendment and append or otherwise link the individual's request for an amendment, the covered entity's denial of the request, the individual's statement of disagreement, if any, and the covered entity's rebuttal, if any, to the designated record set.

(5) *Future disclosures.* (i) If a statement of disagreement has been submitted by the individual, the covered entity must include the material appended in accordance with paragraph (d)(4) of this section, or, at the election of the covered entity, an accurate summary of any such information, with any subsequent disclosure of the protected health information to which the disagreement relates.

(ii) If the individual has not submitted a written statement of disagreement, the covered entity must include the individual's request for amendment and its denial, or an accurate summary of such information, with any subsequent disclosure of the protected health information only if the individual has requested such action in accordance with paragraph (d)(1)(iii) of this section.

(iii) When a subsequent disclosure described in paragraph (d)(5)(i) or (ii) of this section is made using a standard transaction under part 162 of this subchapter that does not permit the additional material to be included with the disclosure, the covered entity may separately transmit the material required by paragraph (d)(5)(i) or (ii) of this section, as applicable, to the recipient of the standard transaction.

(e) *Implementation specification: Actions on notices of amendment.* A covered entity that is informed by another covered entity of an amendment to an individual's protected health information, in accordance with paragraph (c)(3) of this section, must amend the protected health information in designated record sets as provided by paragraph (c)(1) of this section.

(f) *Implementation specification: Documentation.* A covered entity must document the titles of the persons or offices responsible for receiving and processing requests for amendments by individuals and retain the documentation as required by § 164.530(j).

§ 164.528 Accounting of disclosures of protected health information.

(a) *Standard: Right to an accounting of disclosures of protected health information.* (1) An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:

(i) To carry out treatment, payment and health care operations as provided in § 164.506;

(ii) To individuals of protected health information about them as provided in § 164.502;

- (iii) Incident to a use or disclosure otherwise permitted or required by this subpart, as provided in § 164.502;
 - (iv) Pursuant to an authorization as provided in § 164.508;
 - (v) For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in § 164.510;
 - (vi) For national security or intelligence purposes as provided in § 164.512(k)(2);
 - (vii) To correctional institutions or law enforcement officials as provided in § 164.512(k)(5);
 - (viii) As part of a limited data set in accordance with § 164.514(e); or
 - (ix) That occurred prior to the compliance date for the covered entity.
- (2)(i) The covered entity must temporarily suspend an individual's right to receive an accounting of disclosures to a health oversight agency or law enforcement official, as provided in § 164.512 (d) or (f), respectively, for the time specified by such agency or official, if such agency or official provides the covered entity with a written statement that such an accounting to the individual would be reasonably likely to impede the agency's activities and specifying the time for which such a suspension is required.
- (ii) If the agency or official statement in paragraph (a)(2)(i) of this section is made orally, the covered entity must:
- (A) Document the statement, including the identity of the agency or official making the statement;
 - (B) Temporarily suspend the individual's right to an accounting of disclosures subject to the statement; and
 - (C) Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to paragraph (a)(2)(i) of this section is submitted during that time.
- (3) An individual may request an accounting of disclosures for a period of time less than six years from the date of the request.
- (b) *Implementation specifications: Content of the accounting.* The covered entity must provide the individual with a written accounting that meets the following requirements.
- (1) Except as otherwise provided by paragraph (a) of this section, the accounting must include disclosures of protected health information that occurred during the six years (or such shorter time period at the request of the individual as provided in paragraph (a)(3) of this section) prior to the date of the request for an accounting, including disclosures to or by business associates of the covered entity.
- (2) Except as otherwise provided by paragraphs (b)(3) or (b)(4) of this section, the accounting must include for each disclosure:
- (i) The date of the disclosure;
 - (ii) The name of the entity or person who received the protected health information and, if known, the address of such entity or person;
 - (iii) A brief description of the protected health information disclosed; and
 - (iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under § 164.502(a)(2)(ii) or § 164.512, if any.
- (3) If, during the period covered by the accounting, the covered entity has made multiple disclosures of protected health information to the same person or entity for a single purpose under § 164.502(a)(2)(ii) or § 164.512, the accounting may, with respect to such multiple disclosures, provide:

(i) The information required by paragraph (b)(2) of this section for the first disclosure during the accounting period;

(ii) The frequency, periodicity, or number of the disclosures made during the accounting period; and

(iii) The date of the last such disclosure during the accounting period.

(4)(i) If, during the period covered by the accounting, the covered entity has made disclosures of protected health information for a particular research purpose in accordance with § 164.512(i) for 50 or more individuals, the accounting may, with respect to such disclosures for which the protected health information about the individual may have been included, provide:

(A) The name of the protocol or other research activity;

(B) A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;

(C) A brief description of the type of protected health information that was disclosed;

(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 entity 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.

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§ 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