

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. Amend § 160.102(b), by removing the phrase “section 201(a)(5) of the Health Insurance Portability Act of 1996, (Pub. L. 104–191)” and adding in its place the phrase “the Social Security Act, 42 U.S.C. § 1320a-7c(a)(5)”.

3. In § 160.103 add the definition of “individually identifiable health information” in alphabetical order to read as follows:

§ 160.103 Definitions.

* * * * *

Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

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4. *revise paragraphs*
Revise §§ 160.202(2) and (4) of the definition of "more stringent" to read as

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follows:

§ 160.202 Definitions.

* * * * *

More stringent means * * *

(2) With respect to the rights of an individual, who is the subject of the individually identifiable health information, regarding access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable.

* * * * *

(4) With respect to the form, substance, or the need for express legal permission from an individual, who is the subject of the individually identifiable health information, for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the express legal permission, as applicable.

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5. Amend § 160.203(b) by adding the words "individually identifiable" before the word "health".

PART 164—SECURITY AND PRIVACY

Subpart E – Privacy of Individually Identifiable Health Information

1. The authority citation for part 164 continues to read as follows:

Authority: 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. Amend § 164.102 by removing the words “implementation standards” and adding in its place the words “implementation specifications.”

3. In § 164.500, remove “consent,” from paragraph (b)(1)(v).

4. Amend § 164.501 as follows:

a. In the definition of “health care operations” remove from the introductory text of the definition “, and any of the following activities of an organized health care arrangement in which the covered entity participates” and revise paragraphs (6)(iv) and (v).

b. Remove the definition of “individually identifiable health information”.

c. Revise the definition of “marketing”.

d. In paragraph (1)(ii) of the definition of “payment,” remove the word “covered”.

e. Revise paragraph (2) of the definition of “protected health information”.

The revisions read as follows:

§ 164.501 Definitions.

* * * * *

Health care operations means * * *

(6) * * *

(iv) The sale, transfer, merger, or consolidation of all or part of a covered entity with another covered entity, or an entity that following such activity will become a

covered entity and due diligence related to such activity; and

(v) Consistent with the applicable requirements of § 164.514, creating de-identified health information and fundraising for the benefit of the covered entity.

* * * * *

Marketing means to make a communication about a product or service to encourage recipients of the communication to purchase or use the product or service.

Marketing excludes a communication made to an individual:

(1) To describe the entities participating in a health care provider network or health plan network, or to describe if, and the extent to which, a product or services (or payment for such product or service) is provided by a covered entity or included in a plan of benefits;

(2) For treatment of that individual; or

(3) For case management or care coordination for that individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to that individual.

* * * * *

Protected health information means * * *

(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.

* * * * *

5. Amend § 164.502 as follows:

a. Revise paragraphs (a)(1)(ii), (iii), and (vi).

b. Revise paragraph (b)(2)(ii).

c. Redesignate paragraphs (b)(2)(iii) through (v) as paragraphs (b)(2)(iv) through (vi).

d. Add a new paragraph (b)(2)(iii).

e. Redesignate paragraphs (g)(3)(i) through (iii) as (g)(3)(i)(A) through (C) and redesignate paragraph (g)(3) as (g)(3)(i).

f. Add new paragraphs (g)(3)(ii) and (iii).

The revisions and additions read as follows:

§ 164.502 Uses and disclosures of protected health information: general rules.

(a) Standard. * * *

(1) Permitted uses and disclosures. * * *

(ii) For treatment, payment, or health care operations, as permitted by and in compliance with § 164.506;

(iii) As incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of § 164.502(b), § 164.514(d), and § 164.530(c) with respect to such otherwise permitted or required uses or disclosures;

* * * * *

(vi) As permitted by and in compliance with this section, § 164.512, or § 164.514(f) and (g).

* * * * *

(b) Standard: Minimum necessary. * * *

(2) Minimum necessary does not apply. * * *

(ii) Uses or disclosures made to the individual, as permitted under paragraph (a)(1)(i) of this section or as required by paragraph (a)(2)(i) of this section;

(iii) Uses or disclosures made pursuant to an authorization under § 164.508;

* * * * *

(g) (1) Standard: Personal representatives. * * *

(3) Implementation specification: unemancipated minors. (i) * * *

(ii) Notwithstanding the provisions of paragraph (g)(3)(i) of this section:

(A) A covered entity may disclose protected health information about an unemancipated minor to a parent, guardian, or other person acting in loco parentis if an applicable provision of State or other law, including applicable case law, permits or requires such disclosure; and

(B) A covered entity may not disclose protected health information about an unemancipated minor to a parent, guardian, or other person acting in loco parentis if an applicable provision of State or other law, including applicable case law, prohibits such disclosure.

(iii) Notwithstanding the provisions of paragraph (g)(3)(i) of this section, a covered entity must, consistent with State or other applicable law, provide a right of

access, as set forth in § 164.524 to either:

(A) A parent, guardian, or other person acting in loco parentis, as the personal representative of the unemancipated minor;

(B) The unemancipated minor; or

(C) Both.

* * * * *

6. Amend § 164.504 as follows:

a. In paragraph (a), revise the definitions of “health care component” and “hybrid entity”.

b. Revise paragraph (c)(1)(ii).

c. Revise paragraph (c)(3)(iii).

d. Revise paragraph (f)(1)(i).

e. Add paragraph (f)(1)(iii).

The revisions and addition read as follows:

§ 164.504 Uses and disclosures: Organizational requirements.

(a) Definitions. * * *

Health care component means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with paragraph (c)(3)(iii) of this section.

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

(2) Consent of an individual under this paragraph shall not be effective to permit a use or disclosure of protected health information that is not otherwise permitted or required by this subpart.

(c) Implementation specifications: Treatment, payment, or health care operations.

(1) A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.

(2) A covered entity may disclose protected health information for treatment activities of another health care provider.

(3) A covered entity may disclose protected health information to another covered entity or health care provider for the payment activities of the entity that receives the information.

(4) A covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if both entities have a relationship with the individual who is the subject of the protected health information being requested, and the disclosure is:

(i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations; or

(ii) For the purpose of health care fraud and abuse detection or compliance.

(5) A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to another covered entity that participates in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

8. Amend § 164.508 as follows:
- a. Remove “consistent with consent requirements in § 164.506” in paragraph (a)(2)(i).
 - b. Add “the” before “originator” in paragraph (a)(2)(i)(A).
 - c. Remove the word “in” after the term “covered entity” and add in its place the words “for its own” in paragraph (a)(2)(i)(B).
 - d. Add the words “itself in” after the word “defend” in paragraph (a)(2)(i)(C).
 - e. Add paragraph (a)(3).
 - f. Revise paragraphs (b)(1)(i).
 - g. Remove the word “be” in paragraph (b)(1)(ii).
 - h. Remove “, (d), (e), or (f)” from paragraph (b)(2)(ii).
 - i. Remove paragraph (b)(2)(iv).
 - j. Redesignate paragraphs (b)(2)(v) and (vi) as paragraphs (b)(2)(iv) and (v).
 - k. Add “or (4)” after “(b)(3)” in redesignated paragraph (b)(2)(iv).
 - l. Revise paragraphs (b)(3)(i).
 - m. Add a comma after the term “psychotherapy notes” in paragraph (b)(3)(iii).
 - n. Remove “under paragraph (f) of” and add in its place “for the use or disclosure of protected health information for such research under” in paragraph (b)(4)(i).
 - o. Add the word “and” at the end of paragraph (b)(4)(ii)(B).
 - p. Remove paragraph (b)(4)(iii).
 - q. Redesignate paragraph (b)(4)(iv) as paragraph (b)(4)(iii).
 - r. Add “or the policy itself” after the word “policy” in paragraph (b)(5)(ii).

s. Remove paragraphs (d), (e), and (f).

t. Revise paragraph (c).

The revisions and addition read as follows:

§ 164.508 Uses and disclosures for which an authorization is required.

(a) Standard: Authorizations for uses and disclosures. * * *

(3) Authorization required: Marketing. (i) Notwithstanding any other provision of this subpart other than § 164.532, a covered entity must obtain an authorization for any use or disclosure of protected health information for marketing, except if the communication is in the form of:

(A) A face-to-face communication made by a covered entity to an individual; or

(B) A promotional gift of nominal value provided by the covered entity.

(ii) If the marketing is expected to result in direct or indirect remuneration to the covered entity from a third party, the authorization must state that such remuneration is expected.

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(b) Implementation specifications: General requirements. * * *

(1) Valid authorizations.

(i) A valid authorization is a document that meets the requirements in paragraphs (c)(1) and (2) of this section.

* * * * *

(3) Compound authorizations. * * *

(i) An authorization for the use or disclosure of protected health information for a

specific research study may be combined with any other type of written permission for the same research study, including another authorization for the use or disclosure of protected health information for such research or a consent to participate in such research;

* * * * *

(c) Implementation specifications: Core elements and requirements. (1) Core elements. A valid authorization under this section must contain at least the following elements:

(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

(iv) A description of each purpose of the requested use or disclosure. The statement “at the request of the individual” is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.

(v) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The following statements meet the requirements for an expiration date or an expiration event if the appropriate conditions apply:

(A) The statement “end of the research study” or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research.

(B) The statement “none” or similar language is sufficient if the authorization is for the covered entity to use or disclose protected health information for the creation and maintenance of a research database or research repository.

(vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative’s authority to act for the individual must also be provided.

(2) Required statements. In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following:

(i) The individual’s right to revoke the authorization in writing, and either:

(A) The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or

(B) To the extent that the information in paragraph (c)(2)(i)(A) of this section is included in the notice required by § 164.520, a reference to the covered entity’s notice.

(ii) The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either:

(A) The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations in paragraph (b)(4) of this section applies; or

(B) The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of this section, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

- d. Add the word “and” after the semicolon at the end of paragraph (b)(1)(v)(C).
- e. Redesignate paragraphs (f)(3)(ii) and (iii) as (f)(3)(i) and (ii).
- f. In the second sentence of paragraph (g)(2) add the word “to” after the word “directors.”
- g. In paragraph (i)(1)(iii)(A) remove the word “is” after the word “disclosure.”
- h. Revise paragraph (i)(2)(ii).

The revisions read as follows:

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. * * *

* * * * *

(b) Standard: uses and disclosures for public health activities.

(1) Permitted disclosures. * * *

(iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:

(A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or

labeling of a product), or biological product deviations;

(B) To track FDA-regulated products;

(C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or

(D) To conduct post marketing surveillance;

* * * * *

(i) Standard: Uses and disclosures for research purposes. * * *

(2) Documentation of waiver approval. * * *

(ii) Waiver criteria. A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

(1) An adequate plan to protect the identifiers from improper use and disclosure;

(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of

protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information.

* * * * *

11. Amend § 164.514 as follows:

- a. Revise paragraph (b)(2)(i)(R).
- b. Revise paragraph (d)(1).
- c. Revise paragraph (d)(4)(iii).
- d. Remove and reserve paragraph (e).

The revisions read as follows:

§ 164.514 Other requirements relating to uses and disclosures of protected health information.

* * * * *

(b) Implementation specifications: Requirements for de-identification of protected health information. * * *

(2) ^(ci) * * *

(f) * * * e

(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and

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(d)(1) Standard: minimum necessary requirements. In order to comply with § 164.502(b) and this section, a covered entity must meet the requirements of paragraphs (d)(2) through (d)(5) of this section with respect to a request for or the use and disclosure of protected health information.

* * * * *

(4) Implementation specifications: Minimum necessary requests for protected health information. * * *

(iii) For all other requests, a covered entity must:

(A) Develop criteria designed to limit the request for protected health information to the information reasonably necessary to accomplish the purpose for which the request is made; and

(B) Review requests for disclosure on an individual basis in accordance with such criteria.

* * * * *

(e) [Removed and Reserved]

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12. Amend § 164.520 as follows:

a. Remove the word “consent or” from paragraph (b)(1)(ii)(B).

b. Revise paragraph (c)(2)(i).

c. Redesignate paragraphs (c)(2)(ii) and (iii) as (c)(2)(iii) and (iv).

d. Add new paragraph (c)(2)(ii).

e. Amend redesignated paragraph (c)(2)(iv) by removing “(c)(2)(ii)” and adding in

its place “(c)(2)(iii)”.

f. Revise paragraph (c)(3)(iii) by adding a sentence at the end.

g. Revise paragraph (e).

The revisions and addition read as follows:

§ 164.520 Notice of privacy practices for protected health information.

* * * * *

(c) Implementation specifications: provision of notice. * * *

(2) Specific requirements for certain covered health care providers. * * *

(i) Provide the notice:

(A) No later than the date of the first service delivery, including service delivered electronically, to such individual after the compliance date for the covered health care provider; or

(B) In an emergency treatment situation, as soon as reasonably practicable after the emergency treatment situation.

(ii) Except in an emergency treatment situation, make a good faith effort to obtain a written acknowledgment of receipt of the notice provided in accordance with paragraph (c)(2)(i) of this section, and if not obtained, document its good faith efforts to obtain such acknowledgment and the reason why the acknowledgment was not obtained;

* * * * *

(3) Specific requirements for electronic notice. * * *

(iii) * * * The requirements in paragraph (c)(2)(ii) of this section apply to electronic notice.

* * * * *

(e) Implementation specifications: Documentation. A covered entity must document compliance with the notice requirements, as required by § 164.530(j), by retaining copies of the notices issued by the covered entity and, if applicable, any written acknowledgments of receipt of the notice or documentation of good faith efforts to obtain such written acknowledgment, in accordance with paragraph (c)(2)(ii) of this section.

13. Amend § 164.522 by removing the reference to “164.502(a)(2)(i)” in paragraph (a)(1)(v), and adding in its place “164.502(a)(2)(ii)”.

14. Amend § 164.528 as follows:

a. In paragraph (a)(1)(i), remove “§ 164.502” and add in its place “§ 164.506”.

b. Redesignate paragraphs (a)(1)(iii) through (vi) as (a)(1)(iv) through (vii).

c. Add paragraph (a)(1)(iii).

d. Revise paragraph (b)(2)(iv) in its entirety.

e. Remove “or pursuant to a single authorization under § 164.508,” from paragraph (b)(3).

The addition and revision read as follows:

§ 164.528 Accounting of disclosures of protected health information.

(a) Standard: Right to an accounting of disclosures of protected health information.

(1) * * *

(iii) Pursuant to an authorization as provided in § 164.508.

* * * * *

(b) Implementation specifications: Content of the accounting. * * *

(2) * * *

(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.

* * * * *

15. Amend § 164.530 as follows:

a. Redesignate paragraph (c)(2) as (c)(2)(i).

b. Add paragraph (c)(2)(ii).

c. Remove the words “the requirements” from paragraph (i)(4)(ii)(A) and add in their place the word “specifications.”

The addition reads as follows:

§ 164.530 Administrative requirements.

* * * * *

(c) Standard: Safeguards. * * *

(2) Implementation specifications: Safeguards. (i) * * *

(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.

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16. Revise § 164.532 to read as follows:

§ 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 permission 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 use or disclose, for a specific research study, 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 that the covered entity has obtained, prior to the applicable compliance date, either:

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

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

(3) A waiver, by an IRB, of informed consent for the research study, 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 study.

(d) Standard: Effect of prior contracts or other arrangements with business associates. Notwithstanding any other provisions of this subpart, a covered entity, other than a small health plan, may disclose protected health information to a business associate and may allow a business associate to create, receive, or use protected health information on its behalf pursuant to a written contract or other written arrangement with such business associate that does not comply with §§ 164.502(e) and 164.504(e) consistent with the requirements, and only for such time, set forth in paragraph (e) of this section.

(e) Implementation specification: Deemed compliance. (1) Qualification. Notwithstanding other sections of this subpart, a covered entity, other than a small health plan, is deemed to be in compliance with the documentation and contract requirements of §§ 164.502(e) and 164.504(e), with respect to a particular business associate relationship, for the time period set forth in paragraph (e)(2) of this section, if:

(i) Prior to the effective date of this provision, such covered entity has entered into

and is operating pursuant to a written contract or other written arrangement with a business associate for such business associate to perform functions or activities or provide services that make the entity a business associate; and

(ii) The contract or other arrangement is not renewed or modified from the effective date of this provision and until the compliance date set forth in § 164.534.

(2) Limited deemed compliance period. A prior contract or other arrangement that meets the qualification requirements in paragraph (e) of this section, shall be deemed compliant until the earlier of:

(i) The date such contract or other arrangement is renewed or modified on or after the compliance date set forth in § 164.534; or

(ii) April 14, 2004.

(3) Covered entity responsibilities. Nothing in this section shall alter the requirements of a covered entity to comply with Part 160, Subpart C of this subchapter and §§ 164.524, 164.526, and 164.528 with respect to protected health information held by a business associate.