end the violation and terminate this Agreement [and the ___ Agreement/ sections __ of the ___ Agreement] if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity;

(2) Immediately terminate this Agreement [and the ___ Agreement/ sections __ of the ___ Agreement] if Business Associate has breached a material term of this Agreement and cure is not possible; or

(3) If neither termination nor cure are feasible, Covered Entity shall report the violation to the Secretary. [Bracketed language in this provision may be necessary if there is an underlying services agreement. Also, opportunity to cure is permitted, but not required by the Privacy Rule.]

(c) *Effect of Termination.*

(1) Except as provided in paragraph (2) of this section, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.

(2) In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon [Insert negotiated terms] that return or destruction of Protected Health Information is infeasible, Business Associate shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

Miscellaneous

(a) *Regulatory References.* A reference in this Agreement to a section in the Privacy Rule means the section as in effect or as amended.

(b) *Amendment.* The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule and the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104–191.

(c) *Survival.* The respective rights and obligations of Business Associate under Section [Insert Section Number Related to ''Effect of Termination''] of this Agreement shall survive the termination of this Agreement.

(d) *Interpretation.* Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule.

List of Subjects

45 CFR Part 160

Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Medicaid, Medical research, Medicare, Privacy, Reporting and record keeping requirements.

45 CFR Part 164

Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Medicaid, Medical research, Medicare, Privacy, Reporting and record keeping requirements.

Dated: August 6, 2002.

Tommy G. Thompson,

Secretary.

For the reasons set forth in the preamble, the Department amends 45 CFR subtitle A, subchapter C, as follows:

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. No. 104–191, 110 Stat. 2021–2031 and sec. 264 of Pub. L. No. 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. No. 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.

* * * * *

4. In § 160.202 revise paragraphs (2) and (4) of the definition of ''more stringent'' to read as 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.

* * * * *

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. No. 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''.

f. Remove the words ''a covered'' and replace them with ''an'' in the definition of ''required by law''.

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 the 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 or a limited data set, and fundraising for the benefit of the covered entity.

* * * * *

Marketing means:

(1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless the communication is made:

(i) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits.

(ii) For treatment of the individual; or

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

(2) An arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.

* * * * *

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 a new paragraph (g)(3)(ii).

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) 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 use or disclosure;

* * * * *

(vi) As permitted by and in compliance with this section, § 164.512, or § 164.514(e), (f), or (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) If, and to the extent, permitted or required by an applicable provision of State or other law, including applicable case law, a covered entity may disclose, or provide access in accordance with § 164.524 to, protected health information about an unemancipated minor to a parent, guardian, or other person acting *in loco parentis*;

(B) If, and to the extent, prohibited by an applicable provision of State or other law, including applicable case law, a covered entity may not disclose, or provide access in accordance with § 164.524 to, protected health information about an unemancipated minor to a parent, guardian, or other person acting *in loco parentis*; and

(C) Where the parent, guardian, or other person acting *in loco parentis*, is not the personal representative under paragraphs (g)(3)(i)(A), (B), or (C) of this section and where there is no applicable access provision under State or other law, including case law, a covered entity may provide or deny access under § 164.524 to a parent, guardian, or other person acting *in loco parentis,* if such action is consistent with State or other applicable law, provided that such decision must be made by a licensed health care professional, in the exercise of professional judgment.

* * * * *

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)(2)(ii).

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

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

f. 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

(3) That designates health care components in accordance with paragraph (c)(3)(iii) of this section.

* * * * *

(c)(1) *Implementation specification: Application of other provisions.* * * *

(ii) 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; and

* * * * *

(2) *Implementation specifications: Safeguard requirements.* * * *

(ii) A component that is described by paragraph (c)(3)(iii)(B) 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 this subpart; and

* * * * *

(3) *Implementation specifications: Responsibilities of the covered entity.* * * *

(iii) 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 as required by § 164.530(j), 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:

(A) Covered functions; or

(B) Activities that would make such component a business associate of a component that performs covered functions if the two components were separate legal entities.

* * * * *

(f)(1) *Standard: Requirements for group health plans.* (i) Except as provided under paragraph (f)(1)(ii) or (iii) of this section or as otherwise authorized under § 164.508, a group health plan, in order to disclose protected health information to the plan sponsor or to provide for or permit the disclosure of protected health information to the plan sponsor by a health insurance issuer or HMO with respect to the group health plan, must ensure that the plan documents restrict uses and disclosures of such information by the plan sponsor consistent with the requirements of this subpart.

* * * * *

(iii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose to the plan sponsor 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.

* * * * *

7. Revise § 164.506 to read as follows:

§ 164.506 Uses and disclosures to carry out treatment, payment, or health care operations.

(a) *Standard: Permitted uses and disclosures.* Except with respect to uses or disclosures that require an authorization under § 164.508(a)(2) and (3), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

(b) *Standard: Consent for uses and disclosures permitted.* (1) A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.

(2) Consent, under paragraph (b) of this section, shall not be effective to permit a use or disclosure of protected health information when an authorization, under § 164.508, is required or when another condition must be met for such use or disclosure to be permissible under 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 a health care provider.

(3) A covered entity may disclose protected health information to another covered entity or a 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 each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, 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. Revise § 164.508 to read as follows:

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

(a) *Standard: authorizations for uses and disclosures.*—(1) *Authorization required: general rule.* Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.

(2) *Authorization required: psychotherapy notes.* Notwithstanding any provision of this subpart, other than the transition provisions in § 164.532, a covered entity must obtain an authorization for any use or disclosure of psychotherapy notes, except:

(i) To carry out the following treatment, payment, or health care operations:

(A) Use by the originator of the psychotherapy notes for treatment;

(B) Use or disclosure by the covered entity for its own training programs in which students, trainees, or practitioners in mental health learn under supervision to practice or improve their skills in group, joint, family, or individual counseling; or

(C) Use or disclosure by the covered entity to defend itself in a legal action or other proceeding brought by the individual; and

(ii) A use or disclosure that is required by § 164.502(a)(2)(ii) or permitted by § 164.512(a); § 164.512(d) with respect to the oversight of the originator of the psychotherapy notes; § 164.512(g)(1); or § 164.512(j)(1)(i).

(3) *Authorization required: Marketing.* (i) Notwithstanding any provision of this subpart, other than the transition provisions in § 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 involves direct or indirect remuneration to the covered entity from a third party, the authorization must state that such remuneration is involved.

(b) *Implementation specifications: general requirements.*—(1) *Valid authorizations.* (i) A valid authorization is a document that meets the requirements in paragraphs (a)(3)(ii), (c)(1), and (c)(2) of this section, as applicable.

(ii) A valid authorization may contain elements or information in addition to the elements required by this section, provided that such additional elements or information are not inconsistent with the elements required by this section.

(2) *Defective authorizations.* An authorization is not valid, if the document submitted has any of the following defects:

(i) The expiration date has passed or the expiration event is known by the covered entity to have occurred;

(ii) The authorization has not been filled out completely, with respect to an element described by paragraph (c) of this section, if applicable;

(iii) The authorization is known by the covered entity to have been revoked;

(iv) The authorization violates paragraph (b)(3) or (4) of this section, if applicable;

(v) Any material information in the authorization is known by the covered entity to be false.

(3) *Compound authorizations.* An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows:

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

(ii) An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes;

(iii) An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes, may be combined with any other such authorization under this section, except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under paragraph (b)(4) of this section on the provision of one of the authorizations.

(4) *Prohibition on conditioning of authorizations.* A covered entity may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization, except:

(i) A covered health care provider may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of protected health information for such research under this section;

(ii) A health plan may condition enrollment in the health plan or eligibility for benefits on provision of an authorization requested by the health plan prior to an individual's enrollment in the health plan, if:

(A) The authorization sought is for the health plan's eligibility or enrollment determinations relating to the individual or for its underwriting or risk rating determinations; and

(B) The authorization is not for a use or disclosure of psychotherapy notes under paragraph (a)(2) of this section; and

(iii) A covered entity may condition the provision of health care that is solely for the purpose of creating protected health information for disclosure to a third party on provision of an authorization for the disclosure of the protected health information to such third party.

(5) *Revocation of authorizations.* An individual may revoke an authorization provided under this section at any time, provided that the revocation is in writing, except to the extent that:

(i) The covered entity has taken action in reliance thereon; or

(ii) If the authorization was obtained as a condition of obtaining insurance coverage, other law provides the insurer with the right to contest a claim under the policy or the policy itself.

(6) *Documentation.* A covered entity must document and retain any signed authorization under this section as required by § 164.530(j).

(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 statement ''end of the research study,'' ''none,'' or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including 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.

(iii) The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this subpart.

(3) *Plain language requirement.* The authorization must be written in plain language.

(4) *Copy to the individual.* If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.

9. Amend § 164.510 as follows:

a. Revise the first sentence of the introductory text.

b. Remove the word ''for'' from paragraph (b)(3).

The revision reads as follows:

§ 164.510 Uses and disclosures requiring an opportunity for the individual to agree or to object.

A covered entity may use or disclose protected health information, provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the use or disclosure, in accordance with the applicable requirements of this section. * * *

* * * * *

10. Amend § 164.512 as follows:

a. Revise the section heading and the first sentence of the introductory text.

b. Revise paragraph (b)(1)(iii).

c. In paragraph (b)(1)(v)(A) remove the word ''a'' before the word ''health.''

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).

i. In paragraph (i)(2)(iii) remove ''(i)(2)(ii)(D)'' and add in its place ''(i)(2)(ii)(C)''.

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. In paragraph (d)(5), remove the word ''discloses'' and add in its place the word ''disclose''.

e. Revise 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)(i) * * *

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

* * * * *

(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) (1) *Standard: Limited data set.* A covered entity may use or disclose a limited data set that meets the requirements of paragraphs (e)(2) and (e)(3) of this section, if the covered entity enters into a data use agreement with the limited data set recipient, in accordance with paragraph (e)(4) of this section.

(2) *Implementation specification: Limited data set:* A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

(i) Names;

(ii) Postal address information, other than town or city, State, and zip code;

(iii) Telephone numbers;

(iv) Fax numbers;

(v) Electronic mail addresses;
(vi) Social security numbers;
(vii) Medical record numbers;
(viii) Health plan beneficiary numbers;
(ix) Account numbers;
(x) Certificate/license numbers;
(xi) Vehicle identifiers and serial numbers, including license plate numbers;
(xii) Device identifiers and serial numbers;
(xiii) Web Universal Resource Locators (URLs);
(xiv) Internet Protocol (IP) address numbers;
(xv) Biometric identifiers, including finger and voice prints; and
(xvi) Full face photographic images and any comparable images.

(3) *Implementation specification: Permitted purposes for uses and disclosures.* (i) A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only for the purposes of research, public health, or health care operations.

(ii) A covered entity may use protected health information to create a limited data set that meets the requirements of paragraph (e)(2) of this section, or disclose protected health information only to a business associate for such purpose, whether or not the limited data set is to be used by the covered entity.

(4) *Implementation specifications: Data use agreement.*—(i) *Agreement required.* A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only if the covered entity obtains satisfactory assurance, in the form of a data use agreement that meets the requirements of this section, that the limited data set recipient will only use or disclose the protected health information for limited purposes.

(ii) *Contents.* A data use agreement between the covered entity and the limited data set recipient must:

(A) Establish the permitted uses and disclosures of such information by the limited data set recipient, consistent with paragraph (e)(3) of this section. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity;

(B) Establish who is permitted to use or receive the limited data set; and

(C) Provide that the limited data set recipient will:

(*1*) Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;

(*2*) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;

(*3*) Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;

(*4*) Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and

(*5*) Not identify the information or contact the individuals.

(iii) *Compliance.* (A) A covered entity is not in compliance with the standards in paragraph (e) of this section if the covered entity knew of a pattern of activity or practice of the limited data set recipient that constituted a material breach or violation of the data use agreement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:

(1) Discontinued disclosure of protected health information to the recipient; and

(2) Reported the problem to the Secretary.

(B) A covered entity that is a limited data set recipient and violates a data use agreement will be in noncompliance with the standards, implementation specifications, and requirements of paragraph (e) of this section.

* * * * *

12. Amend § 164.520 as follows:

a. Remove the words ''consent or'' from paragraph (b)(1)(ii)(B).

b. In paragraph (c), introductory text, remove ''(c)(4)'' and add in its place ''(c)(3)''.

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

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

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

f. Amend redesignated paragraph (c)(2)(iv) by removing ''(c)(2)(ii)'' and adding in its place ''(c)(2)(iii)''.

g. Amend paragraph (c)(3)(iii) by adding a sentence at the end.

h. 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. Remove the word ''or'' from paragraph (a)(1)(v).

c. Redesignate paragraph (a)(1)(vi) as (a)(1)(ix) and redesignate paragraphs (a)(1)(iii) through (v) as (a)(1)(v) through (vii).

d. Add paragraphs (a)(1)(iii), (iv), and (a)(1)(viii).

e. Revise paragraph (b)(2), introductory text.

f. Revise paragraph (b)(2)(iv).

g. Remove ''or pursuant to a single authorization under § 164.508,'' from paragraph (b)(3), introductory text.

h. Add paragraph (b)(4).

The additions and revisions 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) 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;

* * * * *

(viii) As part of a limited data set in accordance with § 164.514(e); or

* * * * *

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

(2) Except as otherwise provided by paragraphs (b)(3) or (b)(4) of this section, the accounting must include for each disclosure:

* * * * *

(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.

* * * * *

(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.

* * * * *

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.

* * * * *

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, 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.

(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 October 15, 2002, 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

October 15, 2002, 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, 164.528, and 164.530(f) with respect to protected health information held by a business associate.

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