

- (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.

\* \* \* \* \*

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

(a) *Standard.* A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

(1) *Permitted uses and disclosures.* A covered entity is permitted to use or disclose protected health information as follows:

- (i) To the individual;
- (ii) Pursuant to and in compliance with a consent that complies with §164.506, to carry out treatment, payment, or health care operations;
- (iii) Without consent, if consent is not required under §164.506(a) and has not been sought under §164.506(a)(4), to carry out treatment, payment, or health care operations, except with respect to psychotherapy notes;
- (iv) Pursuant to and in compliance with a valid authorization under §164.508;
- (v) Pursuant to an agreement under, or as otherwise permitted by, §164.510; and
- (vi) As permitted by and in compliance with this section, §164.512, or §164.514(e), (f), and (g).

(2) *Required disclosures.* A covered entity is required to disclose protected health information:

- (i) To an individual, when requested under, and required by §164.524 or §164.528; and
- (ii) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the covered entity's compliance with this subpart.

(b) *Standard: Minimum necessary.* (1) *Minimum necessary applies.* When using or disclosing protected health information or when requesting protected health information from another covered entity, a covered entity must make reasonable efforts to limit pro-

TECTED health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

(2) *Minimum necessary does not apply.* This requirement does not apply to:

- (i) Disclosures to or requests by a health care provider for treatment;
- (ii) Uses or disclosures made to the individual, as permitted under paragraph (a)(1)(i) of this section, as required by paragraph (a)(2)(i) of this section, or pursuant to an authorization under §164.508, except for authorizations requested by the covered entity under §164.508(d), (e), or (f);
- (iii) Disclosures made to the Secretary in accordance with subpart C of part 160 of this subchapter;
- (iv) Uses or disclosures that are required by law, as described by §164.512(a); and
- (v) Uses or disclosures that are required for compliance with applicable requirements of this subchapter.

(c) *Standard: Uses and disclosures of protected health information subject to an agreed upon restriction.* A covered entity that has agreed to a restriction pursuant to §164.522(a)(1) may not use or disclose the protected health information covered by the restriction in violation of such restriction, except as otherwise provided in §164.522(a).

(d) *Standard: Uses and disclosures of de-identified protected health information.* (1) *Uses and disclosures to create de-identified information.* A covered entity may use protected health information to create information that is not individually identifiable health information or disclose protected health information only to a business associate for such purpose, whether or not the de-identified information is to be used by the covered entity.

(2) *Uses and disclosures of de-identified information.* Health information that meets the standard and implementation specifications for de-identification under §164.514(a) and (b) is considered not to be individually identifiable health information, *i.e.*, de-identified. The requirements of this subpart do not apply to information that has been de-identified in accordance with the applicable requirements of §164.514, provided that:

(2) *Uses and disclosures of de-identified information.* Health information that meets the standard and implementation specifications for de-identification under §164.514(a) and (b) is considered not to be individually identifiable health information, *i.e.*, de-identified. The requirements of this subpart do not apply to information that has been de-identified in accordance with the applicable requirements of §164.514, provided that:

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(i) Disclosure of a code or other means of record identification designed to enable coded or otherwise de-identified information to be re-identified constitutes disclosure of protected health information; and

(ii) If de-identified information is re-identified, a covered entity may use or disclose such re-identified information only as permitted or required by this subpart.

(e)(1) *Standard: Disclosures to business associates.* (i) A covered entity may disclose protected health information to a business associate and may allow a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information.

(ii) This standard does not apply:

(A) With respect to disclosures by a covered entity to a health care provider concerning the treatment of the individual;

(B) With respect to disclosures by a group health plan or a health insurance issuer or HMO with respect to a group health plan to the plan sponsor, to the extent that the requirements of §164.504(f) apply and are met; or

(C) With respect to uses or disclosures by a health plan that is a government program providing public benefits, if eligibility for, or enrollment in, the health plan is determined by an agency other than the agency administering the health plan, or if the protected health information used to determine enrollment or eligibility in the health plan is collected by an agency other than the agency administering the health plan, and such activity is authorized by law, with respect to the collection and sharing of individually identifiable health information for the performance of such functions by the health plan and the agency other than the agency administering the health plan.

(iii) A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and §164.504(e).

(2) *Implementation specification: documentation.* A covered entity must document the satisfactory assurances required by paragraph (e)(1) of this section through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of §164.504(e).

(f) *Standard: Deceased individuals.* A covered entity must comply with the requirements of this subpart with respect to the protected health information of a deceased individual.

(g)(1) *Standard: Personal representatives.* As specified in this paragraph, a covered entity must, except as provided in paragraphs (g)(3) and (g)(5) of this section, treat a personal representative as the individual for purposes of this subchapter.

(2) *Implementation specification: adults and emancipated minors.* If under applicable law a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(3) *Implementation specification: unemancipated minors.* If under applicable law a parent, guardian, or other person acting *in loco parentis* has authority to act on behalf of an individual who is an unemancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation, except that such person may not be a personal representative of an unemancipated minor, and the minor has the authority to act as an individual, with respect to protected health information pertaining to a health care service, if:

(i) The minor consents to such health care service; no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained; and the minor has not requested that such person be treated as the personal representative;

(ii) The minor may lawfully obtain such health care service without the consent of a parent, guardian, or other person acting *in loco parentis*, and the minor, a court, or another person authorized by law consents to such health care service; or

(iii) A parent, guardian, or other person acting *in loco parentis* assents to an agreement of confidentiality between a covered health care provider and the minor with respect to such health care service.

(4) *Implementation specification: Deceased individuals.* If under applicable law an executor, administrator, or other person has authority to act on behalf of a deceased individual or of the individual's estate, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(5) *Implementation specification: Abuse, neglect, endangerment situations.* Notwithstanding a State law or any requirement of this paragraph to the contrary, a covered entity may elect not to treat a person as the personal representative of an individual if:

(i) The covered entity has a reasonable belief that:

(A) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person; or

(B) Treating such person as the personal representative could endanger the individual; and

(ii) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual's personal representative.

(h) *Standard: Confidential communications.* A covered health care provider or health plan must comply with the applicable requirements of §164.522(b) in communicating protected health information.

(i) *Standard: Uses and disclosures consistent with notice.* A covered entity that is required by §164.520 to have a notice may not use or disclose protected health information in a manner inconsistent with such notice. A covered entity that is required by §164.520(b)(1)(iii) to include a specific statement in its notice if it intends to

engage in an activity listed in §164.520(b)(1)(iii)(A)–(C), may not use or disclose protected health information for such activities, unless the required statement is included in the notice.

(j) *Standard: Disclosures by whistleblowers and workforce member crime victims.* (1) *Disclosures by whistleblowers.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce or a business associate discloses protected health information, provided that:

(i) The workforce member or business associate believes in good faith that the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards, or that the care, services, or conditions provided by the covered entity potentially endangers one or more patients, workers, or the public; and

(ii) The disclosure is to:

(A) A health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity or to an appropriate health care accreditation organization for the purpose of reporting the allegation of failure to meet professional standards or misconduct by the covered entity; or

(B) An attorney retained by or on behalf of the workforce member or business associate for the purpose of determining the legal options of the workforce member or business associate with regard to the conduct described in paragraph (j)(1)(i) of this section.

(2) *Disclosures by workforce members who are victims of a crime.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce who is the victim of a criminal act discloses protected health information to a law enforcement official, provided that:

(i) The protected health information disclosed is about the suspected perpetrator of the criminal act; and

(ii) The protected health information disclosed is limited to the information listed in §164.512(f)(2)(i).

EFFECTIVE DATE NOTE: At 67 FR 53267, Aug. 14, 2002, §164.502 was amended by revising paragraphs (a)(1)(ii), (iii), and (vi) and (b)(2)(ii); redesignating paragraphs (b)(2)(iii) through (v) as paragraphs (b)(2)(iv) through

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(vi); adding a new paragraph (b)(2)(iii); redesignating paragraphs (g)(3)(i) through (iii) as (g)(3)(i)(A) through (C) and redesignate paragraph (g)(3) as (g)(3)(i); and by adding a new paragraph (g)(3)(ii). For the convenience of the user, the added and revised text is set forth 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 per-

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sonal 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.

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§ 164.504 Uses and disclosures: Organizational requirements.

- (a) Definitions. As used in this section:

Common control exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity.

Common ownership exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity.

Health care component has the following meaning:

(1) Components of a covered entity that perform covered functions are part of the health care component.

(2) Another component of the covered entity is part of the entity's health care component to the extent that:

- (i) It performs, with respect to a component that performs covered functions, activities that would make such other component a business associate of the component that performs covered functions if the two components were separate legal entities; and

(ii) The activities involve the use or disclosure of protected health information that such other component creates or receives from or on behalf of the component that performs covered functions.

Hybrid entity means a single legal entity that is a covered entity and whose covered functions are not its primary functions.

Plan administration functions means administration functions performed by the plan sponsor of a group health plan on behalf of the group health plan and excludes functions performed by the plan sponsor in connection with any other benefit or benefit plan of the plan sponsor.