

Department of Health and Human Services

§ 164.504

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).

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53267, Aug. 14, 2002]

§ 164.504 Uses and disclosures: Organizational requirements.

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

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.

Summary health information means information, that may be individually identifiable health information, and:

(1) That summarizes the claims history, claims expenses, or type of claims experienced by individuals for whom a plan sponsor has provided health benefits under a group health plan; and

(2) From which the information described at § 164.514(b)(2)(i) has been deleted, except that the geographic information described in § 164.514(b)(2)(i)(B) need only be aggregated to the level of a five digit zip code.

(b)-(d)

(e)(1) *Standard: Business associate contracts.* (i) The contract or other arrangement between the covered entity and the business associate required by § 164.502(e)(2) must meet the requirements of paragraph (e)(2) or (e)(3) of this section, as applicable.

(ii) A covered entity is not in compliance with the standards in § 164.502(e) and paragraph (e) of this section, if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:

(A) Terminated the contract or arrangement, if feasible; or

(B) If termination is not feasible, reported the problem to the Secretary.

(2) *Implementation specifications: Business associate contracts.* A contract between the covered entity and a business associate must:

(i) Establish the permitted and required uses and disclosures of such information by the business associate. The contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity, except that:

(A) The contract may permit the business associate to use and disclose protected health information for the proper management and administration of the business associate, as provided in paragraph (e)(4) of this section; and

information received by the business associate in its capacity as a business associate to the covered entity, if necessary:

(A) For the proper management and administration of the business associate; or

(B) To carry out the legal responsibilities of the business associate.

(ii) The contract or other arrangement between the covered entity and the business associate may permit the business associate to disclose the information received by the business associate in its capacity as a business associate for the purposes described in paragraph (e)(4)(i) of this section, if:

(A) The disclosure is required by law; or

(B)(1) The business associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person; and

(2) The person notifies the business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(f)(i) *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.

(ii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose summary health information to the plan sponsor, if the plan sponsor requests the summary health information for the purpose of:

(A) Obtaining premium bids from health plans for providing health insurance coverage under the group health plan; or

(B) Modifying, amending, or terminating the group health plan.

(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.

(2) *Implementation specifications: Requirements for plan documents.* The plan documents of the group health plan must be amended to incorporate provisions to:

(i) Establish the permitted and required uses and disclosures of such information by the plan sponsor, provided that such permitted and required uses and disclosures may not be inconsistent with this subpart.

(ii) Provide that the group health plan will disclose protected health information to the plan sponsor only upon receipt of a certification by the plan sponsor that the plan documents have been amended to incorporate the following provisions and that the plan sponsor agrees to:

(A) Not use or further disclose the information other than as permitted or required by the plan documents or as required by law;

(B) Ensure that any agents, including a subcontractor, to whom it provides protected health information received from the group health plan agree to the same restrictions and conditions that apply to the plan sponsor with respect to such information;

(C) Not use or disclose the information for employment-related actions and decisions or in connection with any other benefit or employee benefit plan of the plan sponsor;

(D) Report to the group health plan any use or disclosure of the information that is inconsistent with the uses or disclosures provided for of which it becomes aware;

(E) Make available protected health information in accordance with § 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with § 164.526;

(B) For each such person or class of persons, the category or categories of protected health information to which access is needed and any conditions appropriate to such access.

(ii) A covered entity must make reasonable efforts to limit the access of such persons or classes identified in paragraph (d)(2)(i)(A) of this section to protected health information consistent with paragraph (d)(2)(i)(B) of this section.

(3) *Implementation specification: Minimum necessary disclosures of protected health information.* (i) For any type of disclosure that it makes on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information disclosed to the amount reasonably necessary to achieve the purpose of the disclosure.

(ii) For all other disclosures, a covered entity must:

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

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

(iii) A covered entity may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when:

(A) Making disclosures to public officials that are permitted under § 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s);

(B) The information is requested by another covered entity;

(C) The information is requested by a professional who is a member of its workforce or is a business associate of the covered entity for the purpose of providing professional services to the covered entity, if the professional represents that the information requested is the minimum necessary for the stated purpose(s); or

(D) Documentation or representations that comply with the applicable requirements of § 164.512(i) have been

provided by a person requesting the information for research purposes.

(4) *Implementation specifications: Minimum necessary requests for protected health information.* (i) A covered entity must limit any request for protected health information to that which is reasonably necessary to accomplish the purpose for which the request is made, when requesting such information from other covered entities.

(ii) For a request that is made on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information requested to the amount reasonably necessary to accomplish the purpose for which the request is made.

(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.

(5) *Implementation specification: Other content requirement.* For all uses, disclosures, or requests to which the requirements in paragraph (d) of this section apply, a covered entity may not use, disclose or request an entire medical record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the use, disclosure, or request.

(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.

(f)(1) *Standard: Uses and disclosures for fundraising.* A covered entity may use, or disclose to a business associate or to an institutionally related foundation, the following protected health information for the purpose of raising funds

for its own benefit, without an authorization meeting the requirements of § 164.508:

(i) Demographic information relating to an individual; and

(ii) Dates of health care provided to an individual.

(2) *Implementation specifications: Fundraising requirements.* (i) The covered entity may not use or disclose protected health information for fundraising purposes as otherwise permitted by paragraph (f)(1) of this section unless a statement required by § 164.520(b)(1)(iii)(B) is included in the covered entity's notice;

(ii) The covered entity must include in any fundraising materials it sends to an individual under this paragraph a description of how the individual may opt out of receiving any further fundraising communications.

(iii) The covered entity must make reasonable efforts to ensure that individuals who decide to opt out of receiving future fundraising communications are not sent such communications.

(g) *Standard: Uses and disclosures for underwriting and related purposes.* If a health plan receives protected health information for the purpose of underwriting, premium rating, or other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits, and if such health insurance or health benefits are not placed with the health plan, such health plan may not use or disclose such protected health information for any other purpose, except as may be required by law.

(h)(1) *Standard: Verification requirements.* Prior to any disclosure permitted by this subpart, a covered entity must:

(i) Except with respect to disclosures under § 164.510, verify the identity of a person requesting protected health information and the authority of any such person to have access to protected health information under this subpart, if the identity or any such authority of such person is not known to the covered entity; and

(ii) Obtain any documentation, statements, or representations, whether oral or written, from the person requesting the protected health information when such documentation, state-

ment, or representation is a condition of the disclosure under this subpart.

(2) *Implementation specifications: Verification.* (i) *Conditions on disclosures.* If a disclosure is conditioned by this subpart on particular documentation, statements, or representations from the person requesting the protected health information, a covered entity may rely, if such reliance is reasonable under the circumstances, on documentation, statements, or representations that, on their face, meet the applicable requirements.

(A) The conditions in § 164.512(f)(1)(ii)(C) may be satisfied by the administrative subpoena or similar process or by a separate written statement that, on its face, demonstrates that the applicable requirements have been met.

(B) The documentation required by § 164.512(i)(2) may be satisfied by one or more written statements, provided that each is appropriately dated and signed in accordance with § 164.512(i)(2)(i) and (v).

(ii) *Identity of public officials.* A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify identity when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:

(A) If the request is made in person, presentation of an agency identification badge, other official credentials, or other proof of government status;

(B) If the request is in writing, the request is on the appropriate government letterhead; or

(C) If the disclosure is to a person acting on behalf of a public official, a written statement on appropriate government letterhead that the person is acting under the government's authority or other evidence or documentation of agency, such as a contract for services, memorandum of understanding, or purchase order, that establishes that the person is acting on behalf of the public official.

(iii) *Authority of public officials.* A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify authority when the disclosure of protected health information is to a