

HIPAA Privacy WorkGroups™

The innovative approach to self-implementation

December Double WorkGroups Sessions

**Authorizations “Opt-Out” Uses
and Related Issues and Disclosures**

Verification

Lafayette, Louisiana – December 10, 2001
Baton Rouge, Louisiana – December 12, 2001
Monroe, Louisiana – December 14, 2001

[[Page 82820]]

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and how the product or service relates to the health of the individual.

- (iii) The covered entity must make reasonable efforts to ensure that individuals who decide to opt out of receiving future marketing communications, under paragraph (e)(3)(i)(C) of this section, are not sent such communications.
- (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 § 164.510¹, 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

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such person is not known² to the covered entity; and

¹ Uses and disclosures requiring an opportunity for the individual to agree or object (the "opt-out" situations). See Rules, page 82812.

- (ii) Obtain any documentation, statements, or representations, whether oral or written, from the person requesting the protected health information when such documentation, statement, or representation is a condition of the disclosure under this subpart.
- (2) Implementation specifications: verification³.
- (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)⁴ 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.

² The knowledge of the person may take the form of a known place of business, address, phone or fax number, as well as a known human being. Preamble, page 82546.

³ "The covered entity must establish and use written policies and procedures (which may be standard protocols)..." Preamble, page 82546.

⁴ In the case of "an administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law" the following conditions:

- (1) The information sought is relevant and material to a legitimate law enforcement inquiry;
- (2) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and
- (3) De-identified information could not reasonably be used.

See Rules, page 82815.

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

(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 authority⁵ when the disclosure of protected health information is to a

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public official or a person acting on behalf of the public official⁶:

(A) A written statement of the legal authority under which the information is requested, or, if a written statement would be impracticable, an oral statement of such legal authority;

(B) If a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal is presumed to constitute legal authority.

(iv) Exercise of professional judgment. The verification requirements of this paragraph are met if the covered entity relies on the exercise of professional judgment in making a use or disclosure in accordance with § 164.510 or acts on a good faith belief in making a disclosure in accordance with § 164.512(j).

⁵ “For most disclosures, verifying the authority for the request means taking reasonable steps to verify that the request is lawful under this regulation.” Preamble, page 82547.

⁶ “Under 164.514(h), a covered entity may reasonably rely on the representation of such public officials.” Preamble, page 82541.

Section 164.514(h)--Verification of Identity and Authority of Persons Requesting Protected Health Information***Disclosure of Protected Health Information***

We reorganize the provision regarding verification of identity of individuals requesting protected health information to improve clarity, but we retain the substance of requirements proposed in the NPRM in § 164.518(c), as follows.

The covered entity must establish and use written policies and procedures (which may be standard protocols) that are reasonably designed to verify the identity and authority of the requestor where the covered entity does not know the person requesting the protected health information. The knowledge of the person may take the form of a known place of business, address, phone or fax number, as well as a known human being. Where documentation, statements or representations, whether oral or written, from the person requesting the protected health information is a condition of disclosure under this rule or other law, this verification must involve obtaining such documentation, statement, or representation. In such a case, additional verification is only required where this regulation (or other law) requires additional proof of authority and identity.

The NPRM proposed that covered entities would be permitted to rely on the required documentation of IRB or privacy board approval to constitute sufficient verification that the person making the request was a researcher and that the research is authorized. The final rule retains this provision.

For most disclosures, verifying the authority for the request means taking reasonable steps to verify that the request is lawful under this regulation. Additional proof is required by other provisions of this regulation where the request is made pursuant to § 164.512 for national priority purposes. Where the person requesting the protected health information is a public official, covered entities must verify the identity of the requester by examination of reasonable evidence, such as a written statement of identity on agency letterhead, an identification badge, or similar proof of official status. Similarly, covered entities are required to verify the legal authority supporting the request by examination of reasonable evidence, such as a written request provided on agency letterhead that describes the legal authority for requesting the release. Where § 164.512 explicitly requires written evidence of legal process or other authority before a disclosure may be made, a public official's proof of identity and the official's oral statement that the request is authorized by law are not sufficient to constitute the required reasonable evidence of legal authority; under these provisions, only the required written evidence will suffice.

In some circumstances, a person or entity acting on behalf of a government agency may make a request for disclosure of protected health information under these subsections. For example, public health agencies may contract with a nonprofit agency to collect and analyze certain data. In such cases, the covered entity is required to verify the requestor's identity and authority through examination of reasonable documentation that the requestor is acting on behalf of the government agency. Reasonable evidence includes a written request provided on agency letterhead that describes the legal authority for requesting the release and states that the person or entity is acting under the agency's authority, or other documentation, including a contract, a memorandum of understanding, or purchase order that confirms that the requestor is acting on behalf of the government agency.

In some circumstances, identity or authority will be verified as part of meeting the underlying requirements for disclosure. For example, a disclosure under § 164.512(j)(1)(i) to avert an imminent threat to safety is lawful only if made in the good faith belief that the disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public, and to a person reasonably able to prevent or lessen the threat. If these conditions are met, no further verification is needed. In such emergencies, the covered entity is not required to demand written proof that the person requesting the protected health information is legally authorized. Reasonable reliance on verbal representations are appropriate in such situations.

Similarly, disclosures permitted under § 164.510(a) for facility directories may be made to the general public; the covered entity's policies and procedures do not need to address verifying the identity and authority for these disclosures. In § 164.510(b) we do not require verification of identity for persons assisting in an individual's care or for notification purposes. For disclosures when the individual is not present, such as when a friend is picking up a prescription, we allow the covered entity to use professional judgment and experience with common practice to make reasonable inferences.

Under § 164.524, a covered entity is required to give individuals access to protected health information about them (under most circumstances). Under the general verification requirements of § 164.514(h), the covered entity is required to take reasonable steps to verify the identity of the individual making the request. We do not mandate particular identification requirements (e.g., drivers licence, photo ID), but rather leave this to the discretion of the covered entity. The covered entity must also establish and document procedures for verification of identity and authority of personal representatives, if not known to the entity. For example, a health care provider can require a copy of a power of attorney, or can ask questions to determine that an adult acting for a young child has the requisite relationship to the child.

In Subpart C of Part 160, we require disclosure to the Secretary for purposes of enforcing this regulation. When a covered entity is asked by the Secretary to disclose protected health information for compliance purposes, the covered entity must verify the same information that it is required to verify for any other law enforcement or oversight request for disclosure.

Use of Protected Health Information

The proposed rule's verification requirements applied to any person requesting protected health information, whether for a use or a disclosure. In the final regulation, the verification provisions apply only to disclosures of protected health information. The requirements in § 164.514(d), for implementation of policies and procedures for 'minimum necessary' uses of protected health information, are sufficient to ensure that only appropriate persons within a covered entity will have access to protected health information.