

April 2023 Proposed Amendments to HIPAA Privacy Rule (Comparison Document)

§ 160.103 Definitions.

Except as otherwise provided, the following definitions apply to this subchapter:

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Person means a natural person (meaning a human being who is born alive), trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

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Public health, as used in the terms “public health surveillance,” “public health investigation,” and “public health intervention,” means population-level activities to prevent disease and promote health of populations. Such activities do not include uses and disclosures for the criminal, civil, or administrative investigation into or proceeding against a person in connection with obtaining, providing, or facilitating reproductive health care, or for the identification of any person in connection with a criminal, civil, or administrative investigation into or proceeding against a person in connection with obtaining, providing, or facilitating reproductive health care.

Reproductive health care means care, services, or supplies related to the reproductive health of the individual.

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

(a) *Standard*. A covered entity or business associate 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) *Covered entities: Permitted uses and disclosures*. A covered entity is permitted to use or disclose protected health information as follows:

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(iv) Except for uses and disclosures prohibited under § 164.502 paragraph (a)(5)(i) or (iii) of this section, 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 any of the following—this section, § 164.512, § 164.514(e), (f), or (g):

(A) This section.

(B) Section 164.512 and, where applicable, § 164.509.

(C) Section 164.514(e).

(D) Section 164.514(f).

(E) Section 164.514(g).

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(5) Prohibited uses and disclosures.

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(iii) Reproductive health care—(A) Prohibition. Subject to paragraphs (a)(5)(iii)(C) and (D) of this section, a covered entity or business associate may not use or disclose protected health information for either of the following purposes.

(1) Where the use or disclosure is for a criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care.

(2) To identify any person for the purpose of initiating an activity described at paragraph (a)(5)(iii)(A)(1) of this section.

(B) Scope of prohibition. For the purposes of this subpart, seeking, obtaining, providing, or facilitating reproductive health care includes, but is not limited to, any of the following: expressing interest in, inducing, using, performing, furnishing, paying for, disseminating information about, arranging, insuring, assisting, or otherwise taking action to engage in reproductive health care; or attempting any of the same.

(C) Rule of applicability. The prohibition at paragraph (a)(5)(iii) of this section applies where one or more of the following conditions exists.

(1) The relevant criminal, civil, or administrative investigation or proceeding is in connection with any person seeking, obtaining, providing, or facilitating reproductive health care outside of the state where the investigation or proceeding is authorized and where such health care is lawful in the state in which it is provided.

(2) The relevant criminal, civil, or administrative investigation or proceeding is in connection with any person seeking, obtaining, providing, or facilitating reproductive health care that is protected, required, or authorized by Federal law, regardless of the state in which such health care is provided.

(3) The relevant criminal, civil, or administrative investigation or proceeding is in connection with any person seeking, obtaining, providing, or facilitating reproductive health care that is provided in the state in which the investigation or proceeding is authorized and that is permitted by the law of that state.

(D) Rule of construction. Nothing in this section shall be construed to prohibit a use or disclosure of protected health information otherwise permitted by this subpart unless such use or disclosure is primarily for the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

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(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.

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(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.

(iii) Paragraph (g)(5) of this section does not apply where the primary basis for the covered entity's belief is the facilitation or provision of reproductive health care by such person for and at the request of the individual.

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§ 164.509 Uses and disclosures for which an attestation is required.

(a) Standard: Attestations for certain uses and disclosures of protected health information to persons other than covered entities. A covered entity may not use or disclose protected health information potentially related to reproductive health care for purposes specified in § 164.512(d), (e), (f), or (g)(1), without obtaining an attestation that is valid under this section from the person requesting the use or disclosure.

(b) Implementation specifications: General requirements—(1) Valid attestations. (i) A valid attestation is a document that meets the requirements of paragraph (c)(1) of this section.

(ii) A valid attestation verifies that the use or disclosure is not otherwise prohibited by § 164.502(a)(5)(iii).

(iii) A valid attestation may be electronic, provided that it meets the requirements in paragraph (c)(1) of this section, as applicable.

(2) Defective attestations. An attestation is not valid if the document submitted has any of the following defects:

(i) The attestation lacks an element or statement required by paragraph (c) of this section.

(ii) The attestation contains an element or statement not required by paragraph (c) of this section.

(iii) The attestation violates paragraph (b)(3) of this section.

(iv) The covered entity has actual knowledge that material information in the attestation is false.

(v) It is objectively unreasonable for the covered entity to believe that the attestation is true with respect to the requirement at paragraph (c)(1)(iv) of this section.

(3) Compound attestation. An attestation may not be combined with any other document.

(c) Implementation specifications: Content requirements and other obligations—(1)

Required elements. A valid attestation under this section must contain the following elements:

(i) A description of the information requested that identifies the information in a specific fashion, including one of the following:

(A) The name of any individual(s) whose protected health information is sought, if practicable.

(B) If including the name(s) of any individual(s) whose protected health information is sought is not practicable, a description of the class of individuals whose protected health information is sought.

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

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

(iv) A clear statement that the use or disclosure is not for a purpose prohibited under § 164.502(a)(5)(iii).

(v) Signature of the person requesting the protected health information, which may be an electronic signature, and date. If the attestation is signed by a representative of the person

requesting the information, a description of such representative's authority to act for the person must also be provided.

(2) Plain language requirement. The attestation must be written in plain language.

(d) Material misrepresentations. If, during the course of using or disclosing protected health information in reasonable reliance on a facially valid attestation, a covered entity discovers information reasonably showing that the representations in the attestation were materially false, leading to uses or disclosures for a prohibited purpose, the covered entity must cease such use or disclosure.

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

Except as provided by § 164.502(a)(5)(iii), 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 and § 164.509. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given ~~orally~~ verbally.

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(c) Standard: Disclosures about victims of abuse, neglect or domestic violence —(1) Permitted disclosures. Except for reports of child abuse or neglect permitted by paragraph (b)(1)(ii) of this section, a covered entity may disclose protected health information about an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence:

(i) To the extent the disclosure is required by law and the disclosure complies with and is limited to the relevant requirements of such law;

(ii) If the individual agrees to the disclosure; or

(iii) To the extent the disclosure is expressly authorized by statute or regulation and:

(A) The covered entity, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; or

(B) If the individual is unable to agree because of incapacity, a law enforcement or other public official authorized to receive the report represents that the protected health information for which disclosure is sought is not intended to be used against the individual and that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.

(2) *Informing the individual.* A covered entity that makes a disclosure permitted by paragraph (c)(1) of this section must promptly inform the individual that such a report has been or will be made, except if:

(i) The covered entity, in the exercise of professional judgment, believes informing the individual would place the individual at risk of serious harm; or

(ii) The covered entity would be informing a personal representative, and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

(3) Rule of construction. Nothing in this section shall be construed to permit disclosures prohibited by § 164.502(a)(5)(iii) when the report of abuse, neglect, or domestic violence is based primarily on the provision of reproductive health care.

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(f) *Standard: Disclosures for law enforcement purposes.* A covered entity may disclose protected health information for a law enforcement purpose to a law enforcement official if the conditions in paragraphs (f)(1) through (f)(6) of this section are met, as applicable.

(1) *Permitted disclosures: Pursuant to process and as otherwise required by law.* A covered entity may disclose protected health information:

(i) As required by law including laws that require the reporting of certain types of wounds or other physical injuries, except for laws subject to paragraph (b)(1)(ii) or (c)(1)(i) of this section; or

(ii) In compliance with and as limited by the relevant requirements of:

(A) A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;

(B) A grand jury subpoena; or

(C) An administrative request for which response is required by law, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:

(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.

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§ 164.520 Notice of privacy practices for protected health information.

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(b) *Implementation specifications*: Content of notice —(1) Required elements. The covered entity must provide a notice that is written in plain language and that contains the elements required by this paragraph.

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(ii) *Uses and disclosures*. The notice must contain:

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(F) A description, including at least one example, of the types of uses and disclosures prohibited under § 164.502(a)(5)(iii) in sufficient detail for an individual to understand the prohibition.

(G) A description, including at least one example, of the types of uses and disclosures for which an attestation is required under § 164.509.