

HIPAA Privacy Rule to Support Reproductive Health Care Privacy AMA Drafted Summary of Regulatory Changes in Final Rule Published April 26, 2024; Compliance Required by December 23, 2024

Revisions to regulatory text:

1. New definitions:

person: 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.

public health as used in the terms "public health surveillance," "public health investigation," and "public health intervention": population-level activities to prevent disease and promote the health of populations, such as monitoring, preventing, or mitigating threats to the health or safety of a population. **Does not include** civil/criminal investigations or imposing civil/criminal liability for merely seeking, obtaining, providing or facilitating reproductive health care, and further does not include identifying any person for civil/criminal investigations or to impose liability.

reproductive health care: health care, as defined in this <u>section</u>, that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes. This definition shall not be construed to set a standard of care for or regulate what constitutes clinically appropriate reproductive health care.

- 2. Regulations for Use and disclosure of protected health information (PHI):
- 2.1. <u>Prohibition of Uses and Disclosures of Reproductive Health Care PHI</u>. A covered entity (CE) or business associate (BA) may not use or disclose PHI in connection with any person seeking, obtaining, providing, or facilitating reproductive health care (RHC) that was <u>lawfully provided</u>, when the purpose of the disclosure is:
 - To investigate or to impose civil/criminal liability on any person
 - To identify any person for merely seeking, obtaining, providing or facilitating reproductive health care

A CE or BA can rely on a valid attestation, described below, to disclose RHC PHI to persons that are not CEs or BAs.

Note that this protection for RHC PHI—the protection that allows a CE not to disclose it unless a valid attestation is provided—only applies to lawfully provided reproductive health care. RHC is considered lawful only if:

- It was lawful under the law of the state in which it was provided and under the circumstances in which it was provided, or
- When the RHC was protected by Federal law, regardless of the state in which it was provided.

2.2. Presumption that Care Provided by Another was Lawful. When a CE or BA receives a request for PHI that reflects RHC provided by another person, they can assume that the care was provided lawfully, and therefore the PHI is protected and barred from disclosure when the purpose is to investigate/impose civil/criminal liability, or to identify any person for those purposes.

The CE or BA <u>cannot</u> assume that health care provided by another was lawful, if they had actual knowledge or were provided factual information by the requester that demonstrates the RHC was not lawfully provided.

- **2.3.** Abuse, Neglect, or Endangerment. When existing regulations would otherwise allow a CE or BA to treat someone who requests the records of another person (such as a family member) as the personal representative of that person and to access their medical records, **the CE or BA may choose not to give the requester access to the records if:**
 - The CE or BA decides, in their professional judgment, that it is not in the best interests of the person to treat the requester as the person's personal representative; or
 - The CE or BA <u>reasonably believes</u> that treating the requester as a personal representative could endanger the person, or that the requester has subjected the person to domestic violence, abuse or neglect this will not be deemed a <u>reasonable belief</u> if it is based on the requester having facilitated access to RHC for, and at the request of, the individual. [This means that if the requester of another person's PHI had previously helped that person get RHC, then that does not allow the requester to be disqualified as a personal representative; this is necessary because some states consider gender affirming care to be child abuse.]
- **2.4(a).** Attestation Required for Some Uses and Disclosures. An attestation is not required for uses and disclosures by CEs or BAs. [This allows the overwhelming majority of PHI uses and disclosures to continue as they have been.]

Unless they have received a valid attestation, described below, a CE or BA may not use or disclose PHI potentially related to RHC for purposes of:

- Health oversight
- Judicial or administrative proceedings
- Law enforcement
- Coroner or medical examiner activities

A CE or BA who does not obtain a valid attestation in these instances is not in compliance with these regulations.

- **2.4(b).** <u>Valid Attestations</u>. A valid attestation may be electronic, provided that it is written in plain language, includes a description of the requested information, and includes each of the six required elements, described below.
 - A specific description of the information requested with the name of the individual(s) whose PHI is sought or, if that is not possible, a description of the class of individuals whose PHI is sought.
 - The **name** or other specific identification of the person(s), or class of persons, who are requested to make the use or disclosure.
 - The **name** or specific identification of the person(s), or class of persons, to whom the CE is to make the requested disclosure.
 - A clear statement that the use or disclosure is not for a prohibited purpose (the PHI will not be
 used to investigate or to impose civil/criminal liability on any person or to identify any person for
 merely seeking, obtaining, providing or facilitating RHC).
 - A statement that criminal penalties under HIPAA apply to a person who knowingly obtains
 individually identifiable health information relating to an individual or discloses that information
 to another person.

• The **signature**, which may be an electronic signature, of the person requesting the PHI, and the date. If the attestation is signed by a representative of the person requesting the information, a description of their authority to act for the person must also be provided.

[Implementation note: The six required elements sound complicated, but I think of it as 3-2-1; three names, two statements, and a signature.]

2.5. <u>Material Misrepresentations and Defective Attestations</u>. If a CE or BA relies on an attestation that appeared valid, but then discovers that any part of it is materially false, they must cease the use or disclosure.

<u>Defective attestations</u>. An attestation is not valid if:

- It lacks one of the required elements, listed above.
- It contains an element or statement not required by these regulations.
- It is a compound attestation (combined with another document), which is prohibited. A valid attestation is <u>not</u> combined with any other document except when that document is needed to show that the requested use or disclosure is not for a <u>prohibited purpose</u> (that it will not be used to investigate or to impose civil/criminal liability on any person or to identify any person for merely giving, receiving, or facilitating RHC).
- A reasonable CE or BA in the same position would not believe that the requested use or disclosure is not for a <u>prohibited purpose</u>.
- The CE or BA has actual knowledge that material information in the attestation is false.
- **2.6.** Uses and disclosures that do not require authorization or opportunity to agree or object. [This amends 45 CFR §164.512; the following paragraph is a paraphrase of the new introductory paragraph for that section of the regulations.]

Except for the prohibition on RHC PHI uses and disclosures described in this Final Rule, a CE may use or disclose PHI without the written authorization of the individual, and without giving the individual the opportunity to agree or object to a use or disclosure, in the situations covered by current HIPAA regulations that govern <u>uses and disclosures for which an authorization or opportunity to agree or object is not required</u> (45 CFR §164.512), subject to those §164.512 requirements as well as the provisions of this Final Rule that describe the attestation requirements.

When the §164.512 requirements (linked above – they describe circumstances in which a CE is/is not required to give an individual an opportunity to agree or object to a use or disclosure) require the CE to inform the individual of, or when the individual may agree to, a use or disclosure permitted by that regulation (45 CFR §164.512), then the CE's information and the individual's agreement may be given verbally.

2.7. Disclosures about victims of abuse, neglect, or domestic violence. Nothing in the HIPAA regulations that govern uses and disclosures for which an authorization or opportunity to agree or object is not required (45 CFR §164.512), will be construed to permit disclosures that are prohibited by the provisions of this Final Rule that describe the attestation requirements, when the sole basis of the report of abuse, neglect, or domestic violence is the provision or facilitation of reproductive health care.

A CE may disclose PHI to a law enforcement official, for law enforcement purposes, subject to requirements in current HIPAA regulations with the only change being that under the Final Rule, when the disclosure is pursuant to an administrative request, a response to that request must be required by law; such requests include an administrative subpoena or summons, a civil or an authorized investigative demand, or similar legal process, subject to the current requirements of 45 CFR §164.512(f)(C).

Please note that additional regulations regarding the Notice of Privacy Practices, which are the same length in themselves as all the regs summarized above, combined, were also finalized in this Rule. The compliance date for those NPP requirements is February 16, 2026.

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