

Summary: HIPAA Privacy Rule to Support Reproductive Health Care Privacy Final Rule

Updated: May 2024

Background

The Biden-Harris Administration, through the US Department of Health and Human Services (HHS) Office for Civil Rights (OCR), released the [HIPAA Privacy Rule to Support Reproductive Health Care Privacy](#) Final Rule on April 22, 2024. The final rule modifies the HIPAA Privacy Rule to strengthen privacy protections for individuals' protected health information (PHI) related to reproductive healthcare. The requirements finalized in this rule were proposed in April 2023 and makes several adjustments to the regulation in response to public comments, including [comments provided by AHIMA](#).

Overview

Modifications to the HIPAA Privacy Rule included in the final rule prohibits a regulated entity from using or disclosing an individual's PHI for the purpose of conducting a criminal, civil, or administrative investigation into or imposing criminal, civil, or administrative liability on any person for the act of seeking, obtaining, providing, or facilitating reproductive healthcare that is lawful under the circumstances in which it is provided. The rule requires regulated healthcare providers, health plans, clearinghouses, and business associates (BAs) to obtain signed attestations from law enforcement agencies that requests for PHI related to reproductive healthcare will not be used against a provider or patient in legal cases related to the provision of reproductive healthcare.

Included in the final rule are also requirements for providers to update their Notice of Privacy Practices. The changes instruct providers to update their NPPs to support both the Reproductive Health Care Privacy final rule and the NPP updates included in the joint Substance Abuse and Mental Health Services Administration (SAMHSA) and OCR final rule on aligning 42 CFR Part 2 and HIPAA finalized earlier this year.

The effective date for the final rule is **June 25, 2024** with a compliance date of **December 22, 2024**. Updates to the provider's NPP are due **February 16, 2026**, giving providers additional time to comply.

Provisions At a Glance

- Finalizes the proposed prohibition that restricts the ability of regulated entities to use or disclose PHI for activities with the purpose of investigating or imposing liability on any person for the act of seeking, obtaining, providing, or facilitating reproductive healthcare that is lawful under the circumstances in which it was provided, or to identify any person for such purposes.
- Regulated entities must follow a new presumption provision that presumes the reproductive healthcare at issue was lawful under the circumstances in which such healthcare was provided when it was provided by a person other than the regulated entity receiving the request. The presumption can be overcome when a regulated entity has either actual knowledge, or factual information supplied by the person requesting the use or disclosure, that demonstrates a substantial factual basis that the reproductive healthcare was not lawful under the specific circumstances in which it was provided.
- Requires regulated entities to obtain a signed and dated written attestation from the person requesting PHI potentially related to reproductive healthcare attesting that the use or disclosure of PHI would not be used to investigate or impose liability on individuals, healthcare providers, or others who seek, obtain, provide, or facilitate reproductive healthcare that is lawful under the circumstances in which such healthcare is provided, or to identify persons for such activities.
- Updates provider notice of privacy practices to incorporate changes included in the SAMHSA/OCR Part 2 final rule finalized in February 2024 and provisions in this final rule related to the disclosure of data related to reproductive healthcare.
- Updates key definitions relating to reproductive care are included in the final rule, as well as a clarification of the definition of a person.

Detailed Overview of Final Rule Provisions

Key Definitions

There are multiple key terms defined in the final rule that are pertinent to understanding how to comply with its provisions. Those definitions include:

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.” OCR clarifies this to mean an individual, child, or victim under the HIPAA rules must be a natural person.

Reproductive Healthcare: Healthcare that affects the health of the individual in all matters relating to the reproductive system and to its functions and processes. The definition should not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive healthcare.

Non-exclusive list of examples of reproductive healthcare provided by OCR in the final rule include: contraception, including emergency contraception; preconception screening and counseling; management of pregnancy and pregnancy-related conditions, including pregnancy screening, prenatal care, miscarriage management, treatment for preeclampsia, hypertension during pregnancy, gestational diabetes, molar or ectopic pregnancy, and pregnancy termination; fertility and infertility diagnosis and treatment, including assisted reproductive technology and its components (e.g., in vitro fertilization (IVF)); diagnosis and treatment of conditions that affect the reproductive system (e.g., perimenopause, menopause, endometriosis, adenomyosis); and other types of care, services and supplies used for the diagnosis and treatment of conditions related to the reproductive system (e.g., mammography, pregnancy-related nutrition services, postpartum care products).

OCR notes that the statement on standards of care should be left broad to mean that either a provider or patient/individual may determine whether received healthcare, such as over-the-counter contraceptives, is reproductive healthcare.

Uses and Disclosures for Which an Attestation is Required

- A regulated entity is required to obtain certain assurances from the person – not necessarily law enforcement – requesting PHI related to reproductive healthcare before the PHI is used or disclosed, in the form of a signed and dated written statement attesting the use of disclosure would not be for the investigation of lawfulness of reproductive healthcare for one of the following purposes:
 - Disclosures for health oversight activities
 - Disclosures for judicial and administrative proceedings

- Disclosures for law enforcement purposes
- Disclosures about decedents to coroners and medical examiners
- The attestation may be collected in written or electronic format; however, a new attestation is required for each use or disclosure request.
- Regulated entities may rely on an attestation provided to them, provided it is objectively reasonable under the circumstances for the regulated entity to believe the statement that the requested disclosure of PHI is not for a prohibited purpose, rather than requiring a regulated entity to investigate the validity of an attestation.
- The use or disclosure of PHI based on a defective attestation does not meet the attestation requirement. Examples of defective attestations include:
 - The expiration date has passed or the expiration event is known by the covered entity to have occurred.
 - The authorization has not been filled out completely.
 - The authorization is known by the covered entity to have been revoked.
 - Any material information in the authorization is known by the covered entity to be false.
- To determine whether an attestation is reasonable to rely on, the regulated entity should consider:
 - Who is requesting the use or disclosure of PHI.
 - The permission upon which the person making the request is relying.
 - The information provided to satisfy other conditions of the relevant permission.
 - The PHI requested and its relationship to the stated purpose of the request.
 - Where the reproductive healthcare was supplied by another person:
 - Actual knowledge that the reproductive healthcare was not lawful under the circumstances it was provided.
 - Factual information supplied by the person requesting the use or disclosure of PHI that would demonstrate to a reasonable regulated entity a substantial factual basis that the reproductive healthcare was not lawful under the specific circumstances it was provided.
- A regulated entity is required to cease use or disclosure of PHI if the regulated entity discovers information reasonably showing that the representations contained within the attestation are materially incorrect.
- The attestation is prohibited from being combined with any other document and must be written in plain language.
- The attestation must include the following information:
 - The name of the individual whose PHI is being requested, or the class of individuals whose PHI is being requested if it is not practicable to provide a name.
 - Confirmation in writing that the use or disclosure is not for a prohibited purpose.
 - A clear statement that the use or disclosure is not for a prohibited purpose or that the reproductive healthcare at issue was not lawful under the circumstances in which it was provided.

- A statement that the attestation is signed with the understanding that a person who knowingly violates the attestation violates HIPAA.
- A regulated entity is permitted to use or disclose PHI in response to the request upon receipt of an attestation where it is reasonable to rely on the representations made in the attestation. It is not reasonable for the regulated entity to rely solely on a statement of the person requesting the use or disclosure of PHI that the reproductive healthcare was unlawful. The requesting entity must provide the regulated entity with information to demonstrate the unlawfulness of the care.

OCR indicated it will publish a model attestation prior to the compliance date of December 22, 2024.

Additions/Clarifications of Prohibited Uses and Disclosures

- Regulated entities that receive a request for PHI are required to make a reasonable determination about the lawfulness of the reproductive healthcare in the circumstances in which such healthcare was provided. A regulated entity receiving the request for PHI must evaluate the facts and circumstances under which reproductive healthcare was provided. The regulated entity cannot rely on assertions from the person making the request and must itself evaluate the facts and circumstances to determine if the disclosure is required by law.
 - The facts and circumstances include, but are not limited to: diagnosis and prognosis, the time the healthcare was provided, the location where the healthcare was provided, and the particular healthcare provider who provided the care.
- OCR clarifies that regulated entities are not expected to conduct research or perform an analysis of an individual's PHI to determine whether prior reproductive healthcare was lawful under the circumstances in which it was provided when such healthcare was provided by someone other than the regulated entity that receives the request for the use or disclosure of PHI.
 - Example: A health plan must presume that the reproductive healthcare was lawful unless the health plan has actual knowledge that the reproductive healthcare was not lawful, or the investigator supplied information that demonstrates a substantial factual basis to believe that the reproductive healthcare was not lawful under these circumstances.
- There is no prohibition against the use or disclosure of PHI where the PHI is sought to investigate or impose liability on a person for submitting a false claim for reproductive healthcare for payment to the government.
- The prohibition from sharing a patient's PHI with a law enforcement entity does not apply when the use or disclosure of PHI is to penalize the provision of reproductive healthcare that is not lawful, as long as the HIPAA Privacy Rule permission applies.
- The prohibition remains against the use or disclosure of PHI for activities conducted for the purpose of investigating or imposing liability on "any person" for the act of seeking,

obtaining, providing, or facilitating lawful reproductive healthcare or for identifying “any person.”

Clarifying Personal Representative Status in the Context of Reproductive Healthcare

- OCR indicates the covered The final rule prevents covered entities from denying an individual personal representative status where the basis of the denial is that the personal representative provided or facilitated reproductive healthcare.entity does not have to determine whether the reproductive healthcare is the “primary” basis for denying a personal presentative status.

Notice of Privacy Practices for Protected Health Information

- A covered entity that creates or maintains Part 2 records must provide notice to individuals of the ways in which it may use and disclose such records, and of the individuals’ rights and the covered entities’ responsibilities with respect to such records. A covered entity that receives or maintains records subject to Part 2 must provide an NPP that is written in plain language and contains the required elements.
- Updates the required content of the NPP to reflect other applicable law that is more stringent than the Privacy Rule, including details on the attestation requirements outlined in this rule.
- The NPP is updated to include a new paragraph, that includes a statement explaining to individuals that PHI disclosed pursuant to the Privacy Rule may be subject to re-disclosure and no longer protected by the Privacy Rule.
- Covered entities must provide individuals with a clear and conspicuous opportunity to elect not to receive any fundraising communications before using Part 2 records for fundraising purposes that benefit the covered entity.
- Clarifies that notices for Part 2 and Privacy Rule requirements may be met with a single notice as long as all of the required elements are included.