

HHS Publishes Final Rule to Support Reproductive Health Care Privacy

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The Supreme Court's 2022 decision in *Dobbs v. Jackson Women's Health Organization* to eliminate the federal constitutional right to abortion continues to alter the legal landscape across the country. On April 26, 2024, the U.S. Department of Health and Human Services ("HHS") Office for Civil Rights ("OCR") published the "HIPAA Privacy Rule to Support Reproductive Health Care Privacy" (the "[Final Rule](#)").

The Final Rule—amending the Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule") under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as well as the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act)—strengthens privacy protections related to the use and disclosure of reproductive health care information. HIPAA's Privacy Rule limits the disclosure of protected health information (PHI) and is part of HHS's efforts to ensure that patients will not be afraid to seek health care from, or share important information with, health care providers.

The Final Rule:

- Prohibits the use or disclosure of PHI when it is sought to investigate or impose liability on individuals, health care providers, or others who seek, obtain, provide, or facilitate reproductive health care that is lawful under the circumstances in which such health care is provided, or to identify persons for such activities.
- Requires covered entities and business associates to obtain a signed attestation that certain requests for PHI potentially related to reproductive health care are not for these prohibited purposes.
- Requires covered entities to modify their NPPs to support reproductive health care privacy.

"Since the fall of *Roe v. Wade*, providers have shared concerns that when patients travel to their

clinics for lawful care, their patients' records will be sought, including when the patient goes home," OCR Director Melanie Fontes Rainer said in a [news release](#). OCR administers the Privacy Rule, which requires most health care providers, health plans, health care clearinghouses ("covered entities") and business associates to safeguard the privacy of PHI.

Commenters to an earlier notice of proposed rulemaking ("[2023 NPRM](#)") raised concerns that PHI related to reproductive health care would be used and disclosed to expose both patients and providers to investigation and liability under state abortion laws, particularly new and revived laws. This Final Rule is intended to prohibit the disclosure of PHI related to *lawful* reproductive health care—a change from the current Privacy Rule where an entity is generally permitted, but not required, to disclose relevant and material information in a legitimate law enforcement inquiry.

Key Takeaways

New Category of Protected Health Information. The Final Rule changes the HIPAA Privacy Rule by defining a new category of protected health information and adds a new "prohibited use and disclosure" under the HIPAA Privacy Rule at 45 CFR 164.502—mandating that a covered entity or business associate may not use or disclose PHI:

- To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating "reproductive health care";
- To impose criminal, civil, or administrative liability on any "person" for the mere act of seeking, obtaining, providing or facilitating "reproductive health care"; and
- To identify any "person" for any of those above described purposes.

Prohibition. Under the Final Rule, HIPAA-covered entities and business associates who receive requests for protected health information must make a reasonable determination that one or more of the following conditions exists:

- The reproductive health care is lawful in the state in which such health care is provided under the circumstances in which it is provided (e.g., if a resident of one state traveled to another state to receive reproductive health care, such as an abortion, that is lawful in the state where such health care was provided).
- The reproductive health care is protected, required, or authorized by federal law, including the U.S. Constitution, regardless of the state in which such health care is provided (e.g., reproductive health care such as contraception is protected by the Constitution).

Presumption. Such care is presumed lawful unless the HIPAA-covered entity or business associate has

- actual knowledge that the reproductive care was not lawful under the circumstances it was provided; or
- factual information supplied by the requester demonstrating a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided.

Attestation Requirement. The Final Rule adds 45 CFR § 164.509(c) to require a covered entity or business associate, when it receives a request for PHI potentially related to reproductive health care, to obtain a signed attestation from the requester. However, obtaining the attestation does not relieve a covered entity or business associate from its responsibility to determine whether the

reproductive health care that may be the subject of the requested information was lawful. An attestation must contain the following elements:

- A description of the information requested that identifies the information in a specific fashion, including one of the following:
 - The name(s) of any individual(s) whose protected health information is sought, if practicable;
 - If that name is not practicable, the name(s) or other specific identification of the person(s) or class of person(s) who are requested to make the use or disclosure;
- 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;
- A clear statement that the use or disclosure is not for a purpose prohibited under 45 CFR § 164.502(a)(5)(iii) (i.e., identifying any person under the newly added prohibition);
- A statement that a person may be subject to criminal penalties if they use or disclose the reproductive health information improperly;
- Must be in plain language and contain the elements set forth in 45 CFR § 164.509(c) (inclusion of other elements not set forth in 45 CFR § 164.509(c) is prohibited); and
- Must be signed by the person requesting the disclosure (which may take an electronic format).

The Final Rule prohibits the attestation from being “combined with” any other document (yet allows additional supporting information or documentation needed for the request to be submitted with the attestation (for example, a clearly labelled subpoena). While covered entities can develop their own attestation form, to reduce the compliance burden, HHS plans to publish a model attestation form prior to the compliance date.

Notices of Policy Practices. With the new processes for using and disclosing reproductive health information, covered entities must update their Notices of Privacy Practices (NPPs) required under [45 CFR § 164.520](#). For purposes of this Final Rule, updates to the NPPs must describe among other things the types and uses of disclosures of PHI that are prohibited under 45 CFR 164.502(a)(5)(iii). The notice should also contain a description of the uses and disclosures for which an attestation is required under the new 45 CFR § 164.509. Further, the Office of Management and Budget’s (OMB’s) Office of Information and Regulatory Affairs determined that this Final Rule meets the criteria in [5 USC § 804\(2\)](#) for being a major rule because it is projected to have an annualized impact of more than \$100,000,000 based on the number of covered entities and business associates that will have to implement these changes.

Practical Implications for HIPAA Covered Entities & Business Associates

Considering the significant changes this Final Rule introduces, there is no time like the present for covered entities and business associates to consider the compliance implications that a new category of PHI will have on existing HIPAA policies and procedures. In addition to developing and/or obtaining new attestation forms, making reasonable determinations of the lawfulness of reproductive health care and updating notices of privacy practices, privacy and security officers will likely need to evaluate the impact these changes will have on the policies that govern data dissemination, and the processes and procedures that may change as well. Covered entities and business associates will also likely want to include these changes into training for employees involved in these activities.

The Final Rule goes into effect on June 25, 2024, with a compliance date of December 23, 2024. The NPP requirements, however, take effect on February 16, 2026—consistent with OCR’s 42 CFR Part 2

Rule of [February 16, 2024](#), so that covered entities regulated under both rules can implement changes to their NPPs at the same time.

HIPAA covered entities and business associates should consider the context and framework of the HIPAA Privacy Rule and these new modifications as they consider third-party requests for any PHI that may include reproductive health information ([the current HIPAA Privacy Rule remains in effect until the new rule takes effect](#)). If the new reproductive health prohibition is not applicable, HIPAA covered entities should still consider the fact that HIPAA otherwise permits, but does not require, them to disclose PHI under most of the HIPAA exceptions contained in 45 CFR § 164.512. Therefore, HIPAA affords covered entities the ability to protect the privacy interests of their patients, especially in the current *post-Dobbs* environment.

Covered entities and business associates now face the challenge of implementing these new requirements and training their workforce members on how to analyze and respond to requests that include reproductive health care information. Questions remain surrounding a covered entity or business associate's burden of determining that the reproductive health care provided to an individual was in fact lawful. For example, if a complaint follows, does a covered entity have to account for the disclosures that are made? While the Final Rule is gender-neutral, what is the likelihood that it would be applied to men—could it? In any case, we will continue to monitor developments, including questions of how HIPAA and other privacy concerns interact with reproductive health care, in the wake of *Dobbs*. For more on the subject, please see our past blog on the 2023 [proposed rule](#).

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