



HHS Rulemaking: Reproductive Health Care

FPF Health & Wellness Policy Brief

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Summary

In April 2023, the Department of Health and Human Services Office of Civil Rights (HHS OCR) initiated a [Notice of Proposed Rulemaking](#) (NPRM) “To Support Reproductive Health Care Privacy” and “modify existing standards by prohibiting uses and disclosures of [Protected Health Information (PHI)] for criminal, civil, or administrative investigations or proceedings against individuals, covered entities or their business associates (collectively, “regulated entities”), or other persons for seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided.”

The NPRM emphasized that “developments in the legal environment” - with a focus on the Supreme Court’s decision in [Dobbs](#) - “are eroding individuals’ trust in the health care system,” indicating that the *Dobbs* decision “makes it more likely than before that individuals’ PHI may be disclosed in ways that cause harm to the interests that HIPAA seeks to protect.”

HHS OCR released a preliminary version of the updated rule on April 22, 2024, [and the final rule was published on April 26, 2024](#). The final rule will take effect on June 25, 2024.

Key Elements of the New Rule

- HHS is establishing a “purpose-based prohibition” against disclosures of reproductive health care information where the purpose of the disclosure is “investigating or imposing liability for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.”
- “Reproductive health care” is defined broadly as health care “that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes.”
- The updated rule clarifies that the definition of “person” does not include “a fertilized egg, embryo, or fetus,” to “reflect long standing statutory language” in the [Born-Alive Infants Protection Act](#).
- Within the text, HHS has added a Rule of Applicability and Presumption, which addresses that the rule “requires that a regulated entity that receives a request for PHI make a reasonable determination about the lawfulness of the reproductive health care in the circumstances in which such health care was provided,” and is intended to facilitate efficient evaluation of requests in contexts where the provider may not be equipped to exercise legal judgment.

- The Rule of Applicability provides that the rule applies only where “the relevant activity is in connection with any person seeking, obtaining, providing, or facilitating reproductive health care, and the regulated entity or business associate that received the request for protected health information has reasonably determined that...the reproductive health care is lawful...[and] protected, required, or authorized under federal law...under the circumstances in which such health care is provided.”
- The rule will also provide that the entity receiving a request must presume the reproductive health care was attained or given under lawful circumstances. The presumption assumes regulated entities that provide reproductive health care will do so with the knowledge of its lawfulness, and therefore the Rule would not typically apply to the original provider.
- This presumption may only be overcome where “actual knowledge that the reproductive health care was not lawful under the circumstances in which it was provided” or “factual information supplied by the person requesting the use or disclosure of protected health information that demonstrates a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided.” This applies where reproductive health care is legal under state *or federal* law.
- The updated rule adds a requirement for regulated entities to receive an attestation from requestors of reproductive health care information which must include a clear statement that “the use or disclosure is not for a purpose prohibited” under the rule.
 - Valid attestations will include a selection of attributes including plain language and a clear statement that “the use or disclosure is not for a purpose prohibited” under the rule.
 - Business Associates (BAs) will be “directly liable for compliance with the attestation requirement” in the context of reproductive health information regardless of whether the inclusion or exclusion of such compliance is explicitly included in a BA Agreement (BAA) under the new rule.
 - The rule prohibits compound attestations or combining the attestation with other documentation, except where additional documentation serves to satisfy requirements of the attestation (e.g., actual or factual information pertaining to the lawfulness of the reproductive health that is the subject of the information request).
 - HHS also offers guidance that it may not be reasonable to rely solely on an attestation and that regulated entities “must consider the totality of the

circumstances surrounding the attestation and whether it is reasonable to rely on the attestation in those circumstances.”

Additional Takeaways

- The rule also adopts new definitions of “public health” surveillance, investigation, or intervention to mean “population-level activities to prevent disease and promote health of populations” addressing concerns that the new rule will impede public health reporting or management programs that may require access to reproductive health information and noting there is “widely recognized distinction between public health activities, which primarily focus on improving the health of populations, and criminal investigations,”
- The rule modifies personal representative status by adding a new paragraph and stating “it is not reasonable to elect not to treat a person as an individual’s personal representative because the person provides or facilitates reproductive health care for and at the request of the individual.”

FPF Observations

- A key change for regulated entities (who are not direct care providers) is the attestation requirement. As BAs typically do not provide direct care, responses to requests are more likely to be transferred or directed by the covered entity for whom the BA provides services. In the preamble to the updated rule, HHS addresses cloud service providers directly, noting that typically information managed by the cloud service BA would be encrypted, making the requests impossible for the BA to respond to. Therefore, the rule may not apply to BAs except in specific circumstances. An exception may be pharmacies, where the lawfulness of some contraception is currently being [challenged](#).
- The rule extends protections specifically to information pertaining to reproductive health care given or received “under lawful circumstances,” which provides protections for those who have traveled to receive abortion care even outside the jurisdictions in which the care was provided. Covered entities will need to make intentional decisions regarding patient education on applicable rights and impacts of data transfers between providers, partners, and auxiliary healthcare entities that may not share similar organizational values.
- While HHS OCR does not directly address the [Emergency Medical Treatment and Labor Act](#) (EMTALA), the rule emphasized a presumption of lawfulness potentially covering information about abortions necessary to stabilize patients in emergency circumstances even within abortion-restrictive jurisdictions. Current litigation (*Texas v. Becerra*, 2022) challenging emergency care may alter or remove this argument in the future increasing jurisdictional tensions around reproductive health care.

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- A flexible and adaptive definition of “reproductive health care” gives providers broad discretion to be inclusive in applying the definitions to many forms of transgender and cisgender-affirming care.
- HHS’ new definition of “person” is contrary to [recent court rulings](#) regarding embryos and likely preempts certain language that bans abortion in HIPAA contexts.

Did we miss anything? Contact Jordan Wrigley, Data and Policy Analyst at jwrigley@fpf.org, or email to inquire about joining the FPF Health & Wellness Working Group.

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