

# HIPAA REPRODUCTIVE HEALTH PRIVACY RULE

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# Final Rule

Background

Reproductive Health Care

Applicability and Presumption

Prohibited Purpose

New Attestation Requirement

Key Compliance Dates

Legal Challenges

# HIPAA Privacy Rule To Support Reproductive Health Care Privacy – Published April 26, 2024

Strengthens privacy protections for protected health information (PHI) related to reproductive health care

- In response to changing legal landscape: *Dobbs v. Jackson Women's Health Organization*
- Advances purposes of HIPAA
- Balances interests of society with interests of individuals
- Effective June 25, 2024

# 2022 Survey on Patient Privacy

According to an American Medical Association 2022 survey:

Of **1,000 patients** surveyed:

- **Nearly 75%** - Concern about protecting privacy of their own personal health data
- **59%** - Concern about health data being used to discriminate against them or loved ones

# What is Reproductive Health Care?

Means “health care...that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes.”

- Does not define standard of care or what constitutes clinically appropriate reproductive health care
- Adds definition to §160.103

# Reproductive Health Care

Preamble provides non-exhaustive list which includes:

- Contraception;
- Pre-conception screening and counseling;
- Pregnancy-related health care;
- Fertility and infertility related health care
- Diagnosis and treatment of conditions that affect reproductive system; and
- Other types of care, services, or supplies used for the diagnosis and treatment of conditions related to the reproductive system

# Public Health

“Public health surveillance”, “public health investigation” and “public health intervention” means population level activities to prevent disease in and promote the health of populations.

- Includes identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population
- Such activities are not for a prohibited purpose
- Adds definition to §160.103

# Applicability and Presumption

**Applies** only when the reproductive health care is **lawful**

## **Lawful**

- under the state law in which such health care is provided under the circumstances in which it is provided, or
- if protected, required or authorized by federal law under the circumstances in which such health care is provided, regardless of the state in which it is provided



# Applicability and Presumption

Lawful **presumption**  
applies when provided  
by person other than  
covered entity or  
business associate

## Unless Rebutted - Covered Entity or Business Associate

- Actual knowledge that the reproductive health care was not lawful under the circumstances in which it was provided, or
- Factual information supplied by the requestor demonstrates a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided

## Prohibits Use and Disclosure for Prohibited Purpose

Prohibits covered entities or business associates from using and disclosing PHI related to **lawful** reproductive health care to investigate, impose liability and for identification

-Non-health care purposes

**Preempts** state or other laws to use and disclose for prohibited purpose

# Covered Entity or Business Associate May Not Use or Disclose Reproductive Health Care PHI For Certain Activities

“(1) To conduct a criminal, civil, or administrative **investigation** into any **person** for the **mere act** of **seeking, obtaining, providing, or facilitating reproductive health care**.

(2) To impose criminal, civil, or administrative **liability** on any **person** for the **mere act** of **seeking, obtaining, providing, or facilitating reproductive health care**.

(3) To **identify any person** for any purpose described...” above.

§164.502(a)(5)(iii)

# Definition of “person” & “seeking, obtaining, providing, or facilitating reproductive health care”

**“Person”** definition is revised

-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

**“Seeking, obtaining, providing, or facilitating reproductive health care”** is broadly defined

-Final rule provides a list

# New Attestation Requirement

Effective December 23, 2024, attestation is required when a covered entity or business associate receive a request for PHI potentially related to reproductive health care.

Adds §164.509

# Reviewing a Request for PHI Potentially Related to Reproductive Health Care

**Is the disclosure  
for any of these  
reasons?**

1. Health oversight activities (45 CFR 164.512(d))
2. Judicial or administrative proceedings, including subpoenas (45 CFR 164.512(e))
3. Law enforcement purposes (45 CFR 164.512(f))
4. Coroners and medical examiners about decedents (45 CFR 164.512(g)(i))

**Attestation is required**



# Covered Entities and Business Associate Must Obtain a Valid Attestation

- ✓ Must be written in plain language
- ✓ New attestation required for each specific use and disclosure
- ✓ May be completed electronically
- ✓ HHS released a **model attestation**, can't be combined with any other document
- ✓ Applies to covered entities and business associates

# Requirements for Valid Attestation

- ✓ Description of information requested, including name of individual whose PHI/class of individuals requested
- ✓ To whom the covered entity/business associate is to make the requested use or disclosure
- ✓ Must clearly state it is not for a “prohibited purpose”
- ✓ Statement that the request may be subject to criminal penalties pursuant to 42 U.S.C. 1320d-6
- ✓ Sign and dated by requestor

- Reproductive Health Care is **lawful**



# Defective Attestation

- Lacks a required element or statement
- Contains other content not required
- “Compound attestation” – combined with another document
- Know the material information in attestation is false

Test: Reasonable covered entity or business associate standard

- If it is discovered a facially valid attestation is false, covered entity or business associate **must cease** such use or disclosure

# Key Compliance Dates

- December 23, 2024
- February 1, 2026

## **December 23, 2024**

- Update HIPAA policies and procedures
- Educate and train employees
- Draft attestation form
- Review business associate agreements

**December 23, 2024 Compliance Date**

## **February 16, 2026**

- Update and issue revised notice of privacy practices
- Note: Must reflect new reproductive health care rules along with 42 CFR part 2 rules (substance use disorder patient records)

## **Updates to Privacy notice include**

- Description/at least one example of type of use and disclosure of PHI related to reproductive health care (1) that is prohibited and (2) for which attestation is required
- Statement about redisclosure
- Substance use disorder records/testimony will not be used or disclosed in proceedings against the individual absent consent or court order

**February 16, 2026 Compliance Date**

# Legal Challenges

***State of Texas v. Department of Health and Human Services*** (N. D. Tex 2024)

- Filed on September 4, 2024
- Plaintiff, who is seeking to vacate and set aside the privacy rules from 2000 and 2024 and permanently enjoin HHS from enforcing the privacy rules, claims that there is violation of the Administrative Procedures Act and that HHS exceeded its statutory authority for 2000 Privacy Rule and 2024 Privacy Rule

THANK YOU