



## HEALTHCARE REGULATORY ROUND-UP EPISODE #80

# Are Your Ducks in a Row? HIPAA Rule Supporting Reproductive Privacy, New Anti-Discrimination Requirements

**October 9, 2024**

# Introductions

---



**Martie Ross, JD**  
[mross@pyapc.com](mailto:mross@pyapc.com)



**Karin Anderson, JD**  
[kanderson@pyapc.com](mailto:kanderson@pyapc.com)



pyapc.com  
800.270.9629

ATLANTA | CHARLOTTE | KANSAS CITY | KNOXVILLE | NASHVILLE | TAMPA

# Today's Agenda

1. HIPAA Rule Supporting Reproductive Privacy
2. Section 1557 of the Affordable Care Act
3. Accessible Medical Diagnostic Equipment (MDE)
4. Section 504 of the Rehabilitation Act of 1973

The background of the slide is a photograph of a desk. It features a white calendar with a pencil resting on it. The calendar shows days of the week (SUN, MON, Tue, Wed, Thu, Fri, Sat) and numbers (1, 2, 3, 4, 5, 6, 7, 8, 13, 14, 15, 16, 17, 22, 24, 25). A blue spiral notebook is partially visible on the left. A dark blue horizontal band is overlaid across the middle of the image, containing the section header text.

# 1. HIPAA Rule Supporting Reproductive Privacy

# President's Executive Order to HHS

**“[S]trengthen the protection of sensitive information related to reproductive healthcare services and bolster patient-provider confidentiality.”**

# Final Rule – HIPAA Privacy Rule to Support Reproductive Health Care Privacy, effective June 26, 2024



Strengthens privacy protections for medical records and health information for women, their family members, and doctors who are seeking, obtaining, providing, or facilitating lawful reproductive health care.



Bolsters patient-provider confidentiality and helps promote trust and open communication between individuals and their health care providers or health plans – essential components for high-quality health care.



HHS issued after hearing from communities that changes were needed to better protect patient confidentiality and prevent medical records from being used against people for providing or obtaining lawful reproductive health care.

# Final Rule – When does it apply?

- Applies to any Covered Entity that maintains PHI which include reproductive healthcare information whether it was created by the CE or not.
- The Rule is APPLICABLE when the reproductive health care is lawful under the law of the state in which such health care is provided under the circumstances in which it is provided (State Law)
- 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
  - Federal Law (e.g., EMTALA's patient right to receive emergency services)
  - Constitutional Law (e.g., individual's right to birth control, contraceptives)

# Definition of Reproductive Healthcare Information

- PHI that includes healthcare "that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes."
- Goal is that definition be "interpreted broadly"
  - During all life stages
  - A range of care, services, medications, supplies, and equipment
  - Examples
    - Contraception - medications and devices (over the counter or prescription)
    - Pregnancy Related care (prenatal care, miscarriage management, procedures, medication, diagnoses and treatment of conditions (diabetes, HTN, preeclampsia), pregnancy termination).
    - Fertility and infertility, includes assisted reproductive technology and in vitro fertilization
    - Conditions affecting the reproductive system (menopause (peri and post), endometriosis, post partum care, related nutrition, mammography)
    - Counseling/Patient Education related to these issues



# Prohibits Disclosure of Reproductive Health Care Information for Specified Purposes



- Prohibits use or disclosure of protected health information by covered health care provider, health plan, or health care clearinghouse – or their business associate – for either of the following activities:
  - To conduct a criminal, civil, or administrative investigation into or impose criminal, civil or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care, where such health care is lawful under the circumstances in which it is provided
  - The identification of any person for the purpose of conducting such investigation or imposing such liability
- See HHS Guidance - <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/phi-reproductive-health/index.html>

# HIPAA Reproductive Health Care Information Rule Changes - December 23, 2024



- **Privacy policy with “purpose based” disclosure prohibition**
  - If purpose of use or disclosure is for patient’s healthcare, it is permitted
  - If purpose is for Prohibited Purpose (e.g., to investigate or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care and to identify any person for that purpose), it is not permitted without patient’s authorization

# HIPAA Reproductive Health Care Information Rule Changes - December 23, 2024



- Privacy procedures for medical records and requests
  - Determine if Reproductive Healthcare Information is requested
  - How to segment medical record (EMR system flags, HIM reviews)
  - Determine if requestor must sign “Attestation” requirement - certain types of requestors seeking reproductive health information must attest that information sought is for HIPAA-compliant purpose (not for prohibited purpose)
- **Training:** Providers, HIM, Compliance, Legal

# HIPAA Reproductive Health Information Rule NPP changes - February 16, 2026



**Notice of Privacy Practices** – Incorporate reproductive health care information permitted and prohibited uses/disclosures

## Example of NPP for Reproductive Healthcare

**Respond to lawsuits and legal actions.**

**We can disclose information about you in response to a court or administrative order, or in response to a subpoena.**

**We can disclose health information to courts, attorneys, and court employees in the course of conservatorship, and certain other judicial or administrative proceedings.**

**NOTE: This does not include Reproductive Health Care Services. This kind of information will not be shared without your authorization.**

# Final Rule - Presumption

- Final Rule includes presumption that reproductive health care provided was lawful if provided by person other than the covered health care provider, health plan, or clearinghouse (or business associates) receiving request (CE did not provide care, but receives request – presume care is “lawful”)
- Reproductive health care is presumed to be lawful **unless covered entity or business associate:**
  - **Has actual knowledge** that reproductive health care was not lawful under circumstances in which it was provided
  - **Receives factual information** from person making the request for the use or disclosure of **PHI that demonstrates substantial factual basis** that reproductive health care was not lawful under circumstances in which provided

# Final Rule - Attestation

Upon medical record request potentially for reproductive health care, requestor must complete and sign an “attestation” stating that use or disclosure is not for Prohibited Purpose

Model Attestation language available at <https://www.hhs.gov/sites/default/files/model-attestation.pdf>

Attestation required for each specific use or disclosure request



# Final Rule – Disclosures to Law Enforcement



- Covered entities (and business associates), including workforce members, are only permitted to disclose PHI for law enforcement purposes where they suspect individual of obtaining reproductive health care (lawful or otherwise) if covered entity or business associate **is required to do so and all applicable conditions are met:**
  - Disclosure is not subject to prohibition
  - Disclosure is Required by Law
  - Disclosure meets all applicable conditions of Privacy Rule permission to use or disclose PHI as Required by Law

# Changes to Requests for Medical Records/Information

## RHI Consent

- General patient authorization – not permitted to be used for RHI
- RHI requires authorization unless attestation applies

## RHI Release

- Attestation required
  - Health oversight activities (payer audits)
  - Judicial and Administrative Proceedings (court order, subpoena, or government regulatory investigation)
  - Law enforcement
  - Coroners/Medical Examiners



# Enforcement

---

## Preamble to Final Rule by OCR



### Criminal Liability

- A person, including a HIPAA-regulated entity or a person requesting PHI, who **knowingly obtains or discloses** individually identifiable health information in violation of the HIPAA regulations could be subject to criminal liability, which would include a person who falsifies an attestation.



### Civil Liability

- Covered entities and business associates that disclose PHI **without obtaining a valid attestation when one is required** could result in the imposition of civil penalties.

# Tips

- Teams that should be involved:
  - Compliance
  - Privacy
  - Legal
  - HIM
- NPP: SUD deadline is also February 16, 2026, so address proposals made in Notice of Proposed Rulemaking for Confidentiality of Substance Use Disorder Patient Records as required by or consistent with the CARES Act of 2020 (HIPAA Part 2)
- Business Associate Agreement: If not already in BAA, clarify that Business Associate will send PHI requests to CE so CE can respond to any RHI requests and that BA will not make any disclosures of RHI (to ensure CE's policies are followed regarding RHI)

# OCR Briefing and Resources

---

OCR Briefing - June 20, 2024, Webinar - HIPAA Privacy Rule to Support Reproductive Health Care Privacy

OCR leadership's overview of the rule and answers to common questions



<https://www.youtube.com/watch?v=L6O0jnqoA78>

OCR Resources:

Final Rule Reproductive Healthcare: <https://www.federalregister.gov/documents/2024/04/26/2024-08503/hipaa-privacy-rule-to-support-reproductive-health-care-privacy>

Fact Sheet Reproductive Healthcare: <https://www.hhs.gov/hipaa/for-professionals/special-topics/reproductive-health/final-rule-fact-sheet/index.html>

# Legal Challenge

- On September 4, 2024, Attorney General of Texas filed lawsuit in federal district court challenging new rule as beyond scope of HIPAA statute
  - Obstructs states' abilities to enforce their own laws
  - Also challenges provision in effect since 2000 limiting when provider can provide PHI in response to government investigation
- Will court enter preliminary injunction prior to effective date? If yes, will it be limited to Texas? Will HHS immediately appeal?

The background of the slide is a photograph of a desk with a calendar, a pencil, and a spiral notebook. The calendar is the central focus, showing days of the week and dates. A pencil lies diagonally across the bottom right of the calendar. A blue banner is overlaid across the middle of the image, containing the section header text.

## 2. Section 1557 of the Affordable Care Act

## 42 USC § 18116 - Nondiscrimination

- “[A]n individual shall not..., on the ground of [race, color, or national origin; sex; age; or disability], be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance....”
- Applies to Medicare/Medicaid participating providers, Medicare Advantage plans, Medicare Part D plans, state Medicaid agencies, Medicaid managed care plans, qualified health plans (non-exclusive list)

# Implementing Regulations

- HHS Office of Civil Rights published Final Rule in April 2024 effective July 5, 2024
  - 2016 Final Rule superseded by 2020 Final Rule which is now superseded by April 2024 Final Rule
- Revisions to 42 CFR Part 92
  - Prohibition on specified forms of discrimination
  - Administrative requirements to ensure organizational compliance

# Key Provisions – Prohibition on Discrimination

- Defines discrimination *on the basis of sex* to include discrimination based on sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes
  - “[P]roviders do not have an affirmative obligation to offer any health care, including gender-affirming care, that they do not think is clinically appropriate or if religious freedom and conscience protections apply.”
- Replaces blanket abortion and religious freedom exemptions with new religious freedom and conscience protections exemptions process
  - Submission of letter to OCR specifying scope and basis for objections as specified in 42 CFR 92.3, 92.302
- Extends non-discrimination requirements to telehealth services and patient care decision support tools (artificial intelligence)
  - Make reasonable efforts to identify tools that employ input variables/factors measuring race, color, national origin, sex, age, or disability and make reasonable efforts to mitigate risk of discrimination



# Preliminary Injunctions – Gender Identity

- *Tennessee v. Becerra* (S.D. Miss)
  - Attorneys General in 15 states challenging gender identity provisions
  - July 3 nationwide preliminary injunction of provisions prohibiting discrimination based on gender identity
    - Includes 42 C.F.R. §§ 438.3, 438.206, 440.262, 460.98, and 460.112; 45 C.F.R. §§ 92.5, 92.6, 92.7, 92.8, 92.9, 92.10, 92.101, 92.206-211, 92.301, 92.303, and 92.304 “in so far as these regulations are intended to extend discrimination on the basis of sex to include discrimination on the basis of gender identity.”
- *Florida vs. HHS* (M.D. Florida)
  - July 3 Florida-only preliminary injunction of provisions prohibiting discrimination based on gender identity (but shorter list of impacted regulatory provisions)
- *Texas v. Becerra* (E.D. Tex.)
  - July 3 preliminary injunction of all portions of Final Rule “as to Texas and Montana and all covered entities in those States until further order of the Court”
  - Court refused to limit injunction to gender identity provisions

# Key Provisions – Administrative Requirements

- By Nov. 2, 2024, designate Section 1557 Coordinator (if 15 or more employees)
  - Specific responsibilities listed in 42 CFR 92.7
- By July 5, 2025, implement specified policies and procedures
  - Address language access procedures for LEP patients and companions + reasonable modification procedures for individuals with disabilities (42 CFR 92.201-204)
  - Address civil rights grievance procedures (if 15 or more employees)
  - Sample policies available at <https://www.hhs.gov/civil-rights/for-providers/resources-covered-entities/index.html>
- By May 1, 2025, train employees training on policies and procedures
- Comply with notice requirements
  - By Nov. 2, 2024 - Notice of Nondiscrimination
  - By May 1, 2025 - Notice of Availability of Language Assistance Services and Auxiliary Aids

# Notice of Nondiscrimination – 42 CFR 92.10

- Sample notice incorporating all required content available at <https://www.hhs.gov/sites/default/files/notice-non-discrimination-english.pdf>
- Provision of notice (compliance by Nov. 2, 2024)
  - On an annual basis to participants, beneficiaries, enrollees (including late and special enrollees), and applicants of its health program or activity
  - Upon request
  - Posted at conspicuous location on provider's website
  - Posted in clear and prominent physical locations, in no smaller than 20-point sans serif font, where reasonable to expect individuals to be able to read or hear the notice

# Notice of Availability of Language Assistance Services and Auxiliary Aids – 42 CFR 92.11



- Written notice that provider furnishes language assistance services and appropriate auxiliary aids and services free of charge to patients
  - Must be provided in English and at least the 15 languages most commonly spoken by individuals with LEP in state(s) in which provider operates + alternate formats for individuals with disabilities who require auxiliary aids and services
  - Sample notices in multiple languages available at <https://www.hhs.gov/civil-rights/for-providers/resources-covered-entities/index.html>
- Provision of notice (compliance by May 1, 2025)
  - Same as Notice of Nondiscrimination + must be incorporated into specified electronic and written communications by provider
    - Notice of Nondiscrimination; Notice of Privacy Practices; consent forms and instructions for medical procedures, medical power of attorney, or living will; communications related to the cost and payment of care; complaint forms

The background image shows a close-up of a calendar page with a pencil resting on it. The calendar is white with blue and green accents. The pencil is yellow and lies horizontally across the bottom right. The calendar shows days of the week (SUN, MON, Tue, Wed, Thu, Fri, Sat) and numbers (1, 2, 3, 4, 5, 6, 7, 8, 13, 14, 15, 16, 17, 22, 24, 25). A blue banner is overlaid across the middle of the image.

# 3. Accessible Medical Diagnostic Equipment

Image Source: Shutterstock

# Medical Diagnostic Equipment (MDE)

- Equipment used in, or in conjunction with, medical setting by healthcare providers for diagnostic purposes
- Examples
  - Medical examination tables
  - Examination chairs (e.g., chairs used for eye or dental exams)
  - Weight scales
  - Mammography machines
  - Imaging devices (e.g., x-ray, MRI, CT)
- Does not include –
  - Personal devices (e.g., blood glucose monitors)
  - Positioning aids (e.g., wedges)
  - Medical and surgical implements (stethoscopes, forceps, scaples)

# Regulating MDE Accessibility

- ACA added new Section 510 to Rehabilitation Act of 1973 requiring U.S. Access Board to develop/maintain minimum technical criteria for accessible MDE
- U.S. Access Board published standards in 2017
- HHS Office of Civil Rights published regulations under Section 504 of the Rehabilitation Act on May 1, 2024 (applies to same entities as Section 1557)
- Department of Justice published regulations under Title II of the Americans With Disabilities Act on August 9, 2024 (applies to hospitals and clinics operated by state or local governments)

# Compliance with MDE Standards

- All MDE acquired after July 8, 2024, must meet accessibility standards published in 36 CFR Part 1195 (MDE Standards) until scoping requirements satisfied
  - At least 10% of total number of units (but at least 1 unit) of each type of MDE must meet MDE Standards; 20% (but at least 1 unit) for facilities/programs specializing in treatment of conditions affecting mobility subject
  - If use exam tables/weight scales, must acquire at least one accessible unit by July 8, 2026
  - Hospitals/large clinics must disperse accessible MDE proportionately to departments, clinics, or specialties using MDE
- Ensure staff appropriately trained on use of accessible MDE
- In addition to acquisition requirements, cannot deny services to patient with disability that otherwise would be provided due to lack of accessible MDE
  - E.g., provide services at another location, perform home visit



The background of the slide is a photograph of a desk. It features a spiral-bound calendar with a pencil resting on it. The calendar shows days of the week (SUN, MON, Tue, Wed, Thu, Fri, Sat) and numbers (1, 2, 3, 4, 5, 6, 7, 8, 13, 14, 15, 16, 17, 22, 24, 25). A blue horizontal band is overlaid across the middle of the image, containing the section header text.

## 4. Other Provisions of Section 504 Final Rule

# Discrimination Based on Disability

- Cannot deny/limit clinically appropriate treatment to individual with disability based on bias/stereotype, belief that individual will be a burden on others, or belief that life of individual with disability has lesser value
- Ensure web content and mobile apps comply with Web Content Accessibility Guidelines 2.1 levels A and AA (WCAG 2.1 AA) (with specific exceptions)
  - May 11, 2026, for recipients with  $\geq 15$  employees and May 10, 2027, for recipients with  $< 15$  employees
  - Note: Present industry standard = WCAG 2.2
- Ensure individuals with disabilities not denied benefits of any program/activity furnished through self-service kiosks



# Our Next Healthcare Regulatory Round-Ups

**October 23** – 340B Update

**November 13** – 2025 OPPS Final Rule

**November 20, December 4 and 11** – 2025 MPFS Final Rule

## Thank you for attending!

PYA's subject matter experts discuss the latest industry developments in our popular Healthcare Regulatory Roundup webinar series twice each month.

For on-demand recordings of this and all previous HCRR webinars, and information on upcoming topics and dates, please follow the link below.

<https://www.pyapc.com/healthcare-regulatory-roundup-webinars/>



pyapc.com | 800.270.9629

ATLANTA | CHARLOTTE | KANSAS CITY | KNOXVILLE | NASHVILLE | TAMPA



A national healthcare advisory services firm  
providing consulting, audit, and tax services