

HIPAA Reproductive Health Rule



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(12.24)

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Preliminaries

- Presentation will be recorded and available for free at our website, <https://hhhealthlawblog.com/2024-webinar-recordings/>
- Materials
 - .ppts
 - Stanger, *The New HIPAA Reproductive Health Rule: What You Need to Know*, <https://www.hollandhart.com/the-new-hipaa-reproductive-health-rule-what-you-need-to-know>
 - E-mail CECobbins@HollandHart.com
- Questions?
 - Submit with chat feature or e-mail me at KCStanger@HollandHart.com

Overview

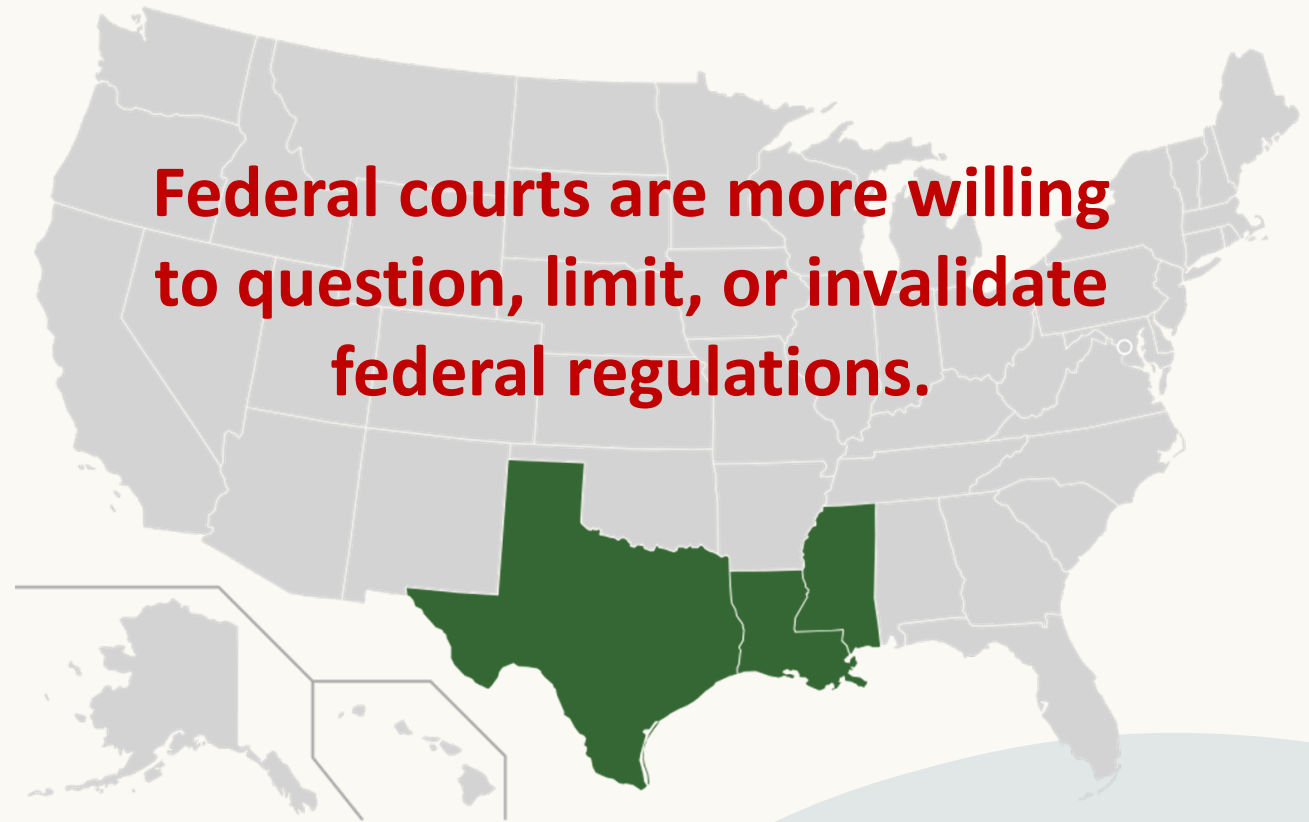
- Background
- Rule requirements
 - Prohibition on disclosure
 - Attestation
 - Notice of Privacy Practices
- Challenges to the Rule
- Resources



CAUTION:
The Rules may change....



Trump administration may change or undermine the Rule.



Federal courts are more willing to question, limit, or invalidate federal regulations.

In the meantime, HHS apparently intends to enforce the Rule.

INFO LIVE

Podcasts

Media Guidelines for HHS Employees

FOR IMMEDIATE RELEASE
November 26, 2024

Contact: HHS Press Office

202-690-6343

media@hhs.gov

- Hospital's disclosure of PHI to patient's employer exceeded patient's authorization.
- Hospital pays \$35,581 and enters corrective action plan.

HHS Office for Civil Rights Settles with Holy Redeemer Hospital Over Disclosure of Patient's Protected Health Information, Including Reproductive Health Information

Settlement emphasizes the need to ensure the privacy of PHI, including reproductive health information

Today, the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR) announced a settlement with Holy Redeemer Family Medicine (Holy Redeemer), a Pennsylvania hospital, concerning an alleged violation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule due to an impermissible disclosure of a female patient's protected health information, including information related to reproductive health care. OCR enforces the [HIPAA Privacy, Security, and Breach Notification Rules](#), which set forth the requirements that covered entities (health plans, health care clearinghouses, and most health care providers) and business associates must follow relating to the privacy and security of protected health information. The HIPAA Privacy Rule establishes national standards to protect individuals' medical records, requires appropriate safeguards to protect the privacy of protected health information and sets limits and conditions on the uses and disclosures that may be made of such information without an individual's authorization, (such as disclosures for health oversight activities or for law enforcement purposes), and gives individuals rights such as the ability to access their own medical records.

OCR is sending a message:

“OCR is committed to ensuring the privacy of lawful reproductive health care....”

Background



HIPAA

- Prohibits use or disclosure of protected health info (PHI) unless:
 - Patient consents to or authorizes use or disclosure, or
 - HIPAA exception applies, e.g.,
 - Treatment, payment or healthcare operations.
 - Avert serious threat of harm.
 - Disclosure required by law.
 - Judicial or administrative proceedings.
 - Law enforcement purposes.
 - Public health activities.
 - Health oversight activities.
 - Others
- **If another law is more restrictive (more protection for PHI), then apply the more restrictive law.**
- *Know state laws...*

Conditions must be satisfied

Background

- 6/24/22: *Dobbs v. Jackson Women's Health Organization* overturns *Roe v. Wade*.
- Abortion prohibitions take effect in many states.

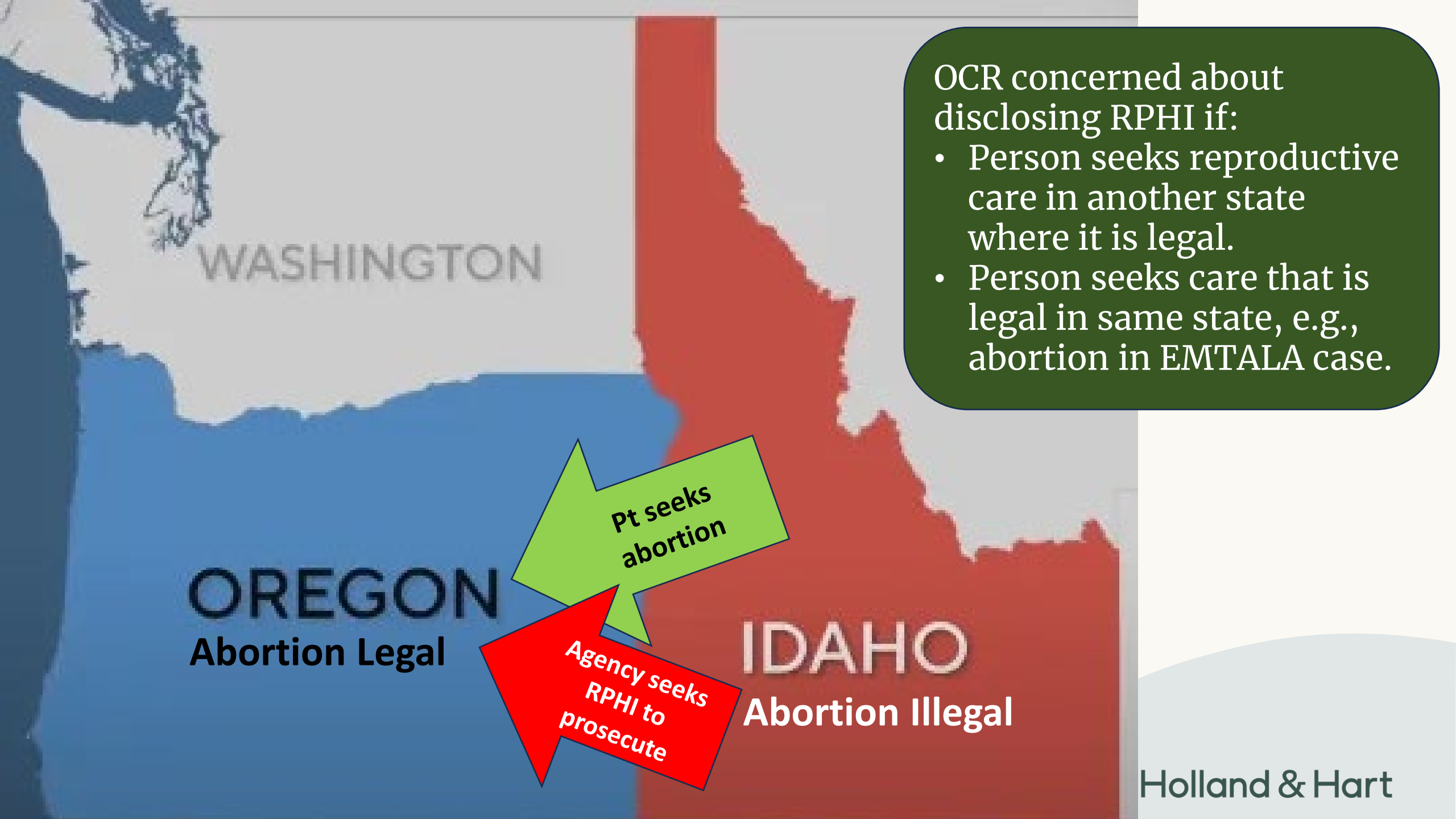
Biden Administration response:

- 6/29/22: *OCR Guidance on HIPAA and Reproductive Rights*
 - HIPAA protects **reproductive health info (RPHI)** as with other PHI.
 - Although HIPAA exceptions permit disclosures, they do not require disclosures; thus, providers may decline to disclose PHI.
 - ***But other law may require disclosure (e.g., state law, subpoena, warrant, order, etc.)***
- 7/8/22: Executive Order 14076
 - Among other things, directs HHS to consider amending HIPAA to protect RPHI.

Background

According to HHS:

- HIPAA was intended to promote high quality care by ensuring confidentiality of health info, thereby promoting patient trust and open communication of health info with provider.
- “[P]atients are increasingly concerned about the confidentiality of information they share with their health care providers out of fear that their information may be used by or shared with law enforcement.” (<https://www.hhs.gov/sites/default/files/social-media-toolkit-hipaa-reproductive-health-care-privacy.pdf>)
- Specifically, Biden administration/HHS concerned about situations in which prosecutors, agencies, or individuals seek RPHI to investigate, prosecute, or sue persons for seeking or obtaining reproductive health care that is **legal** where or under the circumstances in which the care was provided.



WASHINGTON

OREGON
Abortion Legal

IDAHO
Abortion Illegal

Pt seeks abortion

Agency seeks RPHI to prosecute

OCR concerned about disclosing RPHI if:

- Person seeks reproductive care in another state where it is legal.
- Person seeks care that is legal in same state, e.g., abortion in EMTALA case.

HIPAA Reproductive Health Rule

- Published 4/26/24.
 - Prohibits covered entities and business associates to disclose RPHI for purposes of investigating, prosecuting or suing persons who obtain reproductive healthcare that was **legal** where or under the circumstances in which it was rendered.
 - Does not protect RPHI about **illegal** reproductive healthcare.
- Effective Date: 6/25/24.
- Compliance Date:
 - Prohibition on disclosing RPHI: **by 12/23/24.**
 - Notice of Privacy Practices: **by 2/16/26.**

(89 FR 2024)

HIPAA Reproductive Health Rule

- Applies to PHI re “reproductive health care”, i.e., “healthcare that that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes.”
 - Broader than just abortion; extends to any PHI re reproductive healthcare.

(45 CFR 160.103)

- Applies to any provider or business associate who has RPHI, not just the provider who rendered the reproductive healthcare.

(45 CFR 164.502)

- *If you are covered by HIPAA and have RPHI, you need to comply with the Rule by 12/23/24 (unless a court stays enforcement or strikes the rule).*

HIPAA Reproductive Health Rule

- If reproductive healthcare was legal, covered entities and business associates may not use or disclose RPHI for purposes of criminal, civil or administrative liability or investigation.

(45 CFR 164.502(a)(5))

- Must obtain attestation from persons seeking RPHI for purposes of criminal, civil or administrative investigation or liability to confirm purpose and legality.

(45 CFR 164.509)

- ✓ Ability to use or disclose depends on the purpose for which info is sought, not necessarily its status as RPHI.

Reproductive Health Rule: Prohibits Disclosure of RPHI

- Covered entity and 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 healthcare;
 - Impose criminal, civil or administrative liability on any person for the mere act of seeking, obtaining, providing or facilitating reproductive healthcare; or
 - Identify any person for foregoing purposes.
- Covered entity and business associate may use or disclose RPHI for other purposes, e.g.,
 - Treatment, payment or healthcare operations.
 - Investigations or prosecutions that are not for purposes of imposing liability for seeking or obtaining reproductive care.
 - Other permitted purposes.

(45 CFR 164.502(a)(5)(iii))

✓ **But only if reproductive healthcare was legal.**

Reproductive Health Rule: Protection of Reproduction Care PHI

Prohibition on use or disclosure of RPHI only applies if:

- Activity is in connection with a person seeking, obtaining, providing or facilitating reproductive healthcare (i.e., “expressing interest in, using, performing, furnishing, paying for, disseminating info about, arranging, insuring, administering, authorizing, providing coverage for or otherwise taking action to engage in reproductive health care.”), and
- Covered entity or business associate determines one of following exist:
 - The reproductive care is lawful under the state law and circumstances when rendered; or
 - The reproductive care is protected, required or authorized by federal law.
 - Care provided by another is presumed lawful unless the covered entity or business associate:
 - Has actual knowledge that the care was not lawful; or
 - Factual info provided by person requesting use or disclosure of reproductive PHI demonstrates a substantial factual basis that the care was not lawful.

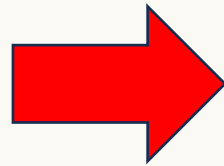
(45 CFR 164.502(a)(5))

✓ *Rule does not protect illegal activity.*

Reproductive Health Rule: Required Attestation

- Covered entity or business associate may not use or disclose reproductive care PHI for **these purposes** without first obtaining a required attestation from the person seeking the PHI.

(45 CFR 164.509)



- Uses or disclosures for health oversight activities. (164.512(d))
 - e.g., govt agencies, licensing, audits, etc.
- Disclosures for judicial and administrative proceedings. (164.512(e))
 - e.g., court orders, subpoenas, warrants, etc.
- Disclosures for law enforcement purposes. (164.512(f))
 - e.g., warrant, police request to locate victim or suspect, report crime on premises, report victim of crime, etc.
- Disclosures to coroners and medical examiners. (164.512(g)(1))

Reproductive Health Rule: Required Attestation

Valid attestation =

- Description of info requested, including name of patient whose info was sought or description of class of such persons.
- Name or description of class of persons requested to make the disclosure.
- Statement that the use or disclosure is not for purpose prohibited by the rule, i.e., criminal, civil or administrative liability.
- Statement that person may be criminally liable under 42 USC 1320d-6 for improperly obtaining or disclosing info in violation of HIPAA.
- Signature of person requesting disclosure.
- Does not contain additional elements.
- Generally, cannot be combined with other documents.

(45 CFR 164.509(b)-(c)).

Reproductive Health Rule: OCR Model Attestation



Model Attestation for a Requested Use or Disclosure of Protected Health Information Potentially Related to Reproductive Health Care

When a HIPAA covered entity¹ or business associate² receives a request for protected health information (PHI)³ potentially related to reproductive health care,⁴ it must obtain a signed attestation that clearly states the requested use or disclosure is not for the prohibited purposes described below, where the request is for PHI for any of the following purposes:

- Health oversight activities⁵
- Judicial or administrative⁶ proceedings
- Law enforcement⁷
- Regarding decedents, disclosures to coroners and medical examiners⁸

Prohibited Purposes. Covered entities and their business associates may not use or disclose PHI for the following purposes:

- (1) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care.
- (2) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care.
- (3) To identify any person for any purpose described in (1) or (2).⁹

The prohibition applies when the reproductive health care at issue (1) is lawful under the law of the state in which such health care is provided under the circumstances in which it is provided, (2) is protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided, or (3) is provided by another person and presumed lawful.¹⁰

Model Instructions

Information for the Person Requesting the PHI

- By signing this attestation, you are verifying that you are not requesting PHI for a prohibited purpose and acknowledging that criminal penalties may apply if untrue.¹¹
- You may not add content that is not required or combine this form with another document except where another document is needed to support your statement that the requested disclosure is not for a prohibited purpose.¹² For example, if the requested PHI is potentially related to reproductive health care that was provided by someone other than the covered entity or business associate from whom you are requesting the PHI, you may submit a document that supplies information that demonstrates a

- Available at <https://www.hhs.gov/sites/default/files/model-attestation.pdf>.

Problems with the Rule



- Forces provider or business associate to make determinations about legality of care that was rendered.
- Forces provider to fight subpoenas, warrants, court orders, etc., seeking RPHI about care that provider or business associate believes was legal.
 - “[T]he prohibition [on the Rule] would preempt state or other laws requiring a regulated entity to use or disclose PHI in response to a court order or other type of legal process for a purpose prohibited under the proposed rule.” (89 FR 33010).
 - “A regulated entity ... would not be prohibited from disclosing an individual’s PHI when subpoenaed by law enforcement for the purpose of investigating such allegations, assuming that law enforcement provided a valid attestation and met the other conditions of the applicable permission.” (89 FR 32995)

Problems with the Rule



“For example, a regulated entity receives an attestation from a Federal law enforcement official, along with a court ordered warrant demanding PHI potentially related to reproductive health care. The law enforcement official represents that the request is about reproductive health care that was not lawful under the circumstances in which such health care was provided, but the official will not divulge more information because they allege that doing so would jeopardize an ongoing criminal investigation. In this example, if the regulated entity itself provided the reproductive health care and, based on the information in its possession, reasonably determines that such health care was lawful under the circumstances in which it was provided, the regulated entity may not disclose the requested PHI.” (89 FR 33032; *see also id.* at 33015)

Problems with the Rule



The new rule “potentially put[s] [providers and business associates] in situations where they need to choose between complying with a court order and impermissibly disclosing PHI....”

“*Response:* ...[A]ny burden the attestation may impose on persons requesting PHI is outweighed by the privacy interests that this final rule is designed to protect.” (89 FR 33033)

Reproductive Health Rule: Additional changes

- *Person* means 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.
 - Fetuses are not protected by HIPAA.
 - Mothers are.
- *Public health* defined to exclude activities to investigate or impose criminal, civil or administrative liability for the mere act of seeking, obtaining, providing or facilitating reproductive care.
 - Exception that would allow disclosures for public health activities does not apply to the extent the activity is intended to investigate or assert claims based on obtaining reproductive health care.

(45 CFR 160.103)

Reproductive Health Rule: Personal Representatives

- Personal representative may generally access patient's PHI.

(45 CFR 164.504(g)(1))

- Notwithstanding any state law to the contrary, a covered entity may elect not to treat person as the personal representative if both the following apply:

- Covered entity has reasonable belief that:

- Patient has been or may be subjected to domestic violence, abuse or neglect by such person, or
- Treating person as the personal rep could endanger the individual; and

- Covered entity decides that it is not in the best interest of the patient to treat the person as the patient's personal representative.

- Not a “reasonable belief” if the basis for belief is that the person is seeking reproductive care for the patient at the patient's request.

(45 CFR 164.504(g)(5))

Enforcement



Civil Penalties (if regulated by HIPAA)

Conduct	Penalty
Did not know and should not have known of violation	<ul style="list-style-type: none">• \$141* to \$71,162* per violation• Up to \$2,067,813* per type per year• No penalty if correct w/in 30 days• OCR may waive or reduce penalty
Violation due to reasonable cause	<ul style="list-style-type: none">• \$1,379* to \$71,162* per violation• Up to \$2,067,813* per type per year• No penalty if correct w/in 30 days• OCR may waive or reduce penalty
Willful neglect, but correct w/in 30 days	<ul style="list-style-type: none">• \$14,232* to \$71,162* per violation• Up to \$2,067,813* per type per year• Penalty is mandatory
Willful neglect, but do not correct w/in 30 days	<ul style="list-style-type: none">• \$71,162 to \$2,134,831* per violation• Up to \$2,134,831* per type per year• Penalty is mandatory

(45 CFR 102.3, 160.404; 85 FR 2879)

OCR Enforcement

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FOR IMMEDIATE RELEASE
November 26, 2024

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202-690-6343

media@hhs.gov

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Criminal Penalties (even if not regulated by HIPAA)

Applies if individuals obtain or disclose PHI from covered entity without authorization, e.g., submit false attestation.

Conduct	Penalty
Knowingly obtain info in violation of the law	\$50,000 fine 1 year in prison
Committed under false pretenses	100,000 fine 5 years in prison
Intent to sell, transfer, or use for commercial gain, personal gain, or malicious harm	\$250,000 fine 10 years in prison

(42 USC 1320d-6(a))

On the other hand...

- If refuse to produce info in response to subpoena, warrant, court order:
 - Potential civil, criminal, or administrative penalties, e.g.,
 - Contempt
 - Obstruction of justice
 - Failure to respond to process
 - Cost of defending against charges or disclosure.
 - No insurance coverage?



Future of the Rule?



Lawsuits Filed in Texas Federal Court

Texas v. HHS (ND Tex. 9/4/24)

- Argues that HIPAA statute doesn't limit how covered entities may share PHI with state govt investigators.

Purl v. HHS (ND Texas 10/21/24)

- Argues no statutory authority for the rule and it is arbitrary and capricious under the APA.

We will likely receive a preliminary decision before the 12/23/24 compliance date. Stay tuned...

Trump Administration



- Not clear how the Trump administration will respond, e.g.,
 - Will it refuse to defend the pending lawsuits?
 - Will it change the rule?
- Again, stay tuned...

HIPAA

Proposed Privacy Rule Changes

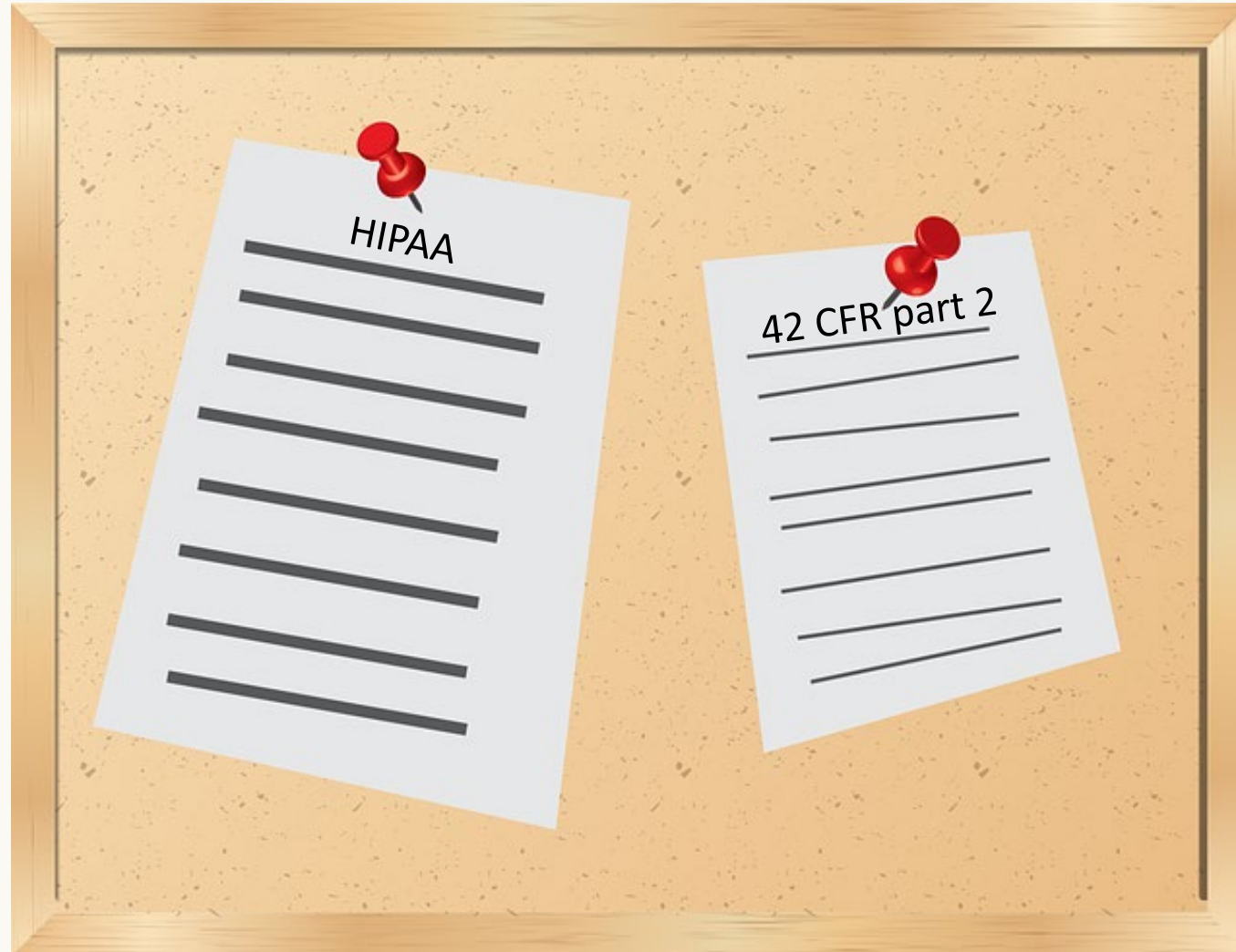
COMING
SOON

Proposed rule published 1/21/21; still waiting...

- Strengthens individual's right of access.
 - Individuals may take notes or use other personal devices to view and capture images of PHI.
 - Must respond to requests to access within 15 days instead of 30 days.
 - Must share info when directed by patient.
 - Additional limits to charges for producing PHI.
- Facilitates individualized care coordination.
- Clarifies the ability to disclose to avert threat of harm.
- Not required to obtain acknowledgment of Notice of Privacy Practices.
- Modifies content of Notice of Privacy Practices.

(86 FR 6446 (1/21/21))

HIPAA: Notice of Privacy Practices



HIPAA: Notice of Privacy Practices

- Reproductive Health Rule modified NPP requirements to accommodate Part 2 changes.
 - Covered entities creating or maintaining SUD records subject to Part 2 must provide the notice to the patient as required by 42 CFR 2.22.
 - Uses and disclosures.
 - Patient rights.
 - Covered entities' duties.
- (45 CFR 164.520(a)(2))
- Other covered entities must update their NPP.
- Must comply by **2/16/26**.
- ✓ *Check applicable regulations when drafting updated NPP.*
- ✓ *Watch for new NPP requirements when final HIPAA revisions are published.*
- ✓ *OCR plans to publish model NPP.*

HIPAA and Administrative Requests



HIPAA

Disclosures per Administrative Requests

- HIPAA allows disclosures for certain law enforcement requests, including but not limited to:
 - “(C) An administrative request for which response is required by law, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:
 - “(1) The information sought is relevant and material to a legitimate law enforcement inquiry;
 - “(2) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and
 - “(3) De-identified information could not reasonably be used.”

(45 CFR 164.512(f)(1)(C))

- ✓ *Clarifies that “administrative request” exception only applies if the response is required by law, not just because the agent requests the info.*

Additional Resources



OCR Education

- Final Rule
- Press Release
- Fact Sheet
- Webinar + Slides
- Model Attestation
- Social Media Resources



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office for Civil Rights

December 5, 2024

Compliance With Most Provisions of the HIPAA Privacy Rule to Support Reproductive Health Care Privacy is Required by December 23, 2024

On April 22, 2024, the U.S. Department of Health and Human Services, Office for Civil Rights announced a final rule, entitled the *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*. The rule strengthens privacy protections for medical records and health information for individuals who are seeking, obtaining, providing, or facilitating lawful reproductive health care.

Health Plans, health care clearinghouses, and most health care providers and business associates are required to be in compliance with most provisions of the final rule by December 23, 2024. In order to ensure the public and regulated entities understand their rights and responsibilities, OCR has posted several documents and videos on its [website](#) and [YouTube channel](#) including:

- [Final Rule](#)
- [Press Release](#)
- [Fact Sheet \(en español\)](#)
- [Director's message on YouTube \(en español\)](#)
- [Webinar](#)
- Social Media Toolkit: [HIPAA Privacy Rule to Support Reproductive Health Care Privacy - PDF | en español - PDF](#)
- [June 20, 2024, Presentation on Final Rule \(Slides\) - PDF](#)
- [Director's message on Attestation Compliance](#)
- For HIPAA Covered Entities or Business Associates: [Model Attestation for a Requested Use or Disclosure of Protected Health Information Potentially Related to Reproductive Health Care - PDF](#)

OCR Resources

<https://www.hhs.gov/hipaa/for-professionals/special-topics/reproductive-health/index.html>

Privacy	+
Security	+
Breach Notification	+
Compliance & Enforcement	+
Special Topics	—
HIPAA and Part 2	
Change Healthcare Cybersecurity Incident FAQs	
HIPAA and COVID-19	
HIPAA and Reproductive Health	—
HIPAA and Final Rule Notice	
HIPAA and Telehealth	
HIPAA and FERPA	
Research	

HIPAA and Reproductive Health

Final Rule HIPAA Privacy Rule to Support Reproductive Health Care Privacy

On April 22, 2024, OCR issued a Final Rule, entitled *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*. The Final Rule strengthens the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule by prohibiting the disclosure of protected health information related to lawful reproductive health care in certain circumstances. HHS issued this Final Rule 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. This Final Rule bolsters patient-provider confidentiality and helps promote trust and open communication between individuals and their health care providers or health plans, which is essential for high-quality health care.

[Press Release](#)

[To read the Fact Sheet \(en español\)](#)

OCR Webinar:

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

HIPAA Privacy Rule to Support Reproductive Health Care Privacy Final Rule 1 / 10 98%

These slides provide a brief educational summary, not an independent interpretation of the HIPAA Privacy Rule to Support Reproductive Health Care Privacy Final Rule.

HIPAA Privacy Rule to Support Reproductive Health Care Privacy Final Rule

Office for Civil Rights (OCR)
U.S. Department of Health and Human Services



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

9:16 AM
12/7/2024

Slides available at:
<https://www.hhs.gov/sites/default/files/hipaa-support-rhc-privacy.pdf>

[HTTPS://WWW.HOLLAND
HART.COM/HEALTHCARE](https://www.hollandhart.com/healthcare)

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The screenshot shows the Holland & Hart website's Healthcare section. At the top, the navigation bar includes the firm's logo, 'People', 'Capabilities', and a search bar. The main header features the word 'Healthcare' in large white text on a dark background. Below this is a secondary navigation bar with 'Overview', 'Expertise', 'People', and 'News and Insights'. The 'Areas of Focus' section contains three icons: a computer monitor for 'WEBINAR RECORDINGS', an open book for 'PUBLICATIONS', and a caduceus for 'IDAHO PATIENT ACT TIMELINE'. To the right, there are two buttons for 'Mergers and Acquisitions' and 'Real Estate'. Further down, there is a section for 'Primary Contacts' featuring a photo of Kim Stanger, a man in a suit and glasses. The footer of the page displays the Holland & Hart logo.

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IDAHO PATIENT ACT TIMELINE

Mergers and Acquisitions

Real Estate

Legal advice.

and highly regulated. In an ultra-competitive market, our attorneys focus on the most critical issues so they can focus on

the Affordable Care Act, HIPAA, and other regulatory changes; mergers, acquisitions, and joint ventures; government investigations and compliance; employee benefits; and other issues that our healthcare clients face that we

Primary Contacts



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Questions?



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