

Preparing to Comply with the HIPAA Privacy Rule to Support Reproductive Health Care Privacy

November 14, 2024

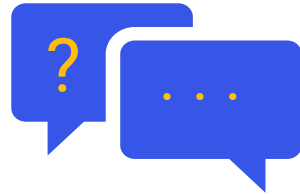


Meeting Logistics



Microphones

All attendees are on mute.



Questions

Type your questions in the Q&A chat box.



Materials

Briefing materials and recording will be provided after event.



Survey

Survey will prompt at the end of webinar.

About Your Presenters



Presenter

Andrew Mahler, JD, AIGP, CIPP/US,
CHC, CHPC, CHRC

Vice President, Consulting Services

- Over 10 years experience as a privacy, compliance, and research compliance program leader for complex health care systems, health plans, universities, and other organizations
- Former Investigator for the U.S. Department of HHS, Office for Civil Rights (OCR)
- Publishes and presents on topics including health law, healthcare compliance, data privacy and HIPAA, research compliance, third-party risk management, and cybersecurity practices
- Member of HCCA/SCCE, AHLA, IAPP, ABA, and others



Presenter

Wes Morris, CHPS, CIPM, HCISPP, CC

Senior Director, Consulting Services

- 20 years in Clinical Care/Social Services, with emphasis in management of organizations under 42 CFR Part 2 (Confidentiality of Substance Use Disorder records and patients)
- 21 years in HIPAA Privacy and Security as Privacy Officer, Security Officer and Subject Matter Expert in large systems and governmental agencies
- 11 years with Clearwater providing consultation and management to hospitals, health systems and their supporting businesses
- Extensive experience with AHIMA as a Certification Exam Developer and Privacy/Security Practice Council Leader

Scenario – What Would You Do?

- Obstetrics practice – Pullman, Washington
- Serving patients in Pullman and Moscow, Idaho
- The Privacy Officer is out of office for the next 5 days attending a conference
- It's 4:45 pm on a Friday, and Registration notifies you that there is an official claiming to be from the Idaho Attorney General's office, and demanding to speak with someone in HIM
- The representative from the Idaho Attorney General provides a badge and a written demand for the records about a patient who is attending college at the University of Idaho in Moscow
- You quickly review the Release of Information policy, which says that the clinic has to release the records for court-orders, but it says that all court orders must be reviewed and approved by the Privacy Officer before release
- The official demands the records NOW and says if you fail to deliver them you will be arrested

Break Down the Issues From the Scenario

The Rule is live, but the policies haven't been created or updated. The Privacy Officer is still analyzing.

The Policy directive can't be followed since the Privacy Officer is out of office and must review the demand.

Washington State and Idaho are at odds with their perspectives, particularly related to termination.

You do not know why the records are being demanded, nor if this is specific to a pregnancy or another matter.

The Information Blocking Rule and other requirements do not appear to apply.

You are not an attorney and are unable to provide legal guidance or to know whether the threat of arrest is valid.

Historical Perspective - HIPAA

Privacy Rule

- In effect since 2003
- We've gotten comfortable with disclosure processes
- Policies are in place

Required to disclose

- At request of the individual
 - To them
 - To certain 3rd parties
- To HHS for compliance review or investigation

May disclose

- Required is a "must" - **may** is "allowed"
- All others are may - but...

Examples of MAY Disclose

Required By Law

- A legal mandate that is enforceable in court
- Limited to relevant requirements of that law, and not more
- Disclosures not meeting the definition above do not qualify as permissible disclosures

Abuse reporting, gunshot wounds, etc. varies by state and jurisdiction.

Judicial/Administrative Proceedings

- Responding to a court order, administrative tribunal, subpoena, discovery request or other lawful process

Can include criminal AND civil proceedings, tribal courts, military courts, etc.

Now There is a Disclosure Prohibition – Why?

Proposed Rule published weeks after Dobbs v. Jackson overturned Roe v. Wade

In response to 2 Executive Orders to protect access to reproductive care

HHS directed to take action, including under HIPAA, to better protect sensitive information related to reproductive health care and bolster patient-provider confidentiality

Starts with April 2023 Notice of Proposed Rulemaking (NPRM) with 60 days for public comment.

HIPAA Privacy Rule to Support Reproductive Health Care Privacy (Final Rule)

Published in the Federal Register - April 26, 2024

- Effective Date – **June 25, 2024**
- Compliance Date – **December 23, 2024**
- Notice of Privacy Practices Compliance Date – **February 16, 2026**

Key Point from HHS (link below)

- Access to comprehensive reproductive healthcare services, including abortion, is essential to individual health and well-being
- HIPAA supports such access by giving individuals confidence that their PHI, including that related to sexual and reproductive healthcare, will be kept private

[HIPAA for Professionals Guidance - Reproductive Health](#)

Final Rule – Prohibition and Applicability

Prohibition

Prohibits use or disclosure:

- To conduct a criminal, civil or administrative investigation to impose liability on any person for seeking, obtaining, providing, or facilitating reproductive care where it is lawful
- Prohibits identifying any person for the same purposes

Rule of Applicability

Prohibition applies:

- Where the activity is in connection with same and
- The entity receiving the request determines one or more of the following exists:
 - Care is lawful where and when it was provided;
 - Care is protected, required, or authorized by federal law, including the US Constitution, regardless of the state in which it was provided

[HIPAA for Professionals Guidance - Reproductive Health](#)

Must Get an Attestation!

Final Rule requires a Covered Entities (and Business Associates)¹ :

- When it receives a request for PHI potentially related to reproductive healthcare,
- To obtain a **signed attestation** that the use or disclosure is not for a prohibited purpose

This attestation requirement applies when the request is for PHI for any of the following:

- ◆ Health oversight activities
- ◆ Law enforcement purposes
- ◆ Judicial and administrative proceedings
- ◆ Disclosures to coroners and medical examiners

¹ 45 CFR 164.509 *Uses and Disclosures for Which an Attestation Is Required*

[Reproductive Health Final Rule Fact Sheet](#)

Model Attestation - Information for the Covered Entity or Business Associate

You may **not** rely on the attestation to disclose the requested PHI if **any** of the following is true:

1. It is missing any required element or statement or contains other content that is not required
2. It is combined with other documents, except for documents provided to support the attestation (ex. bad compound authorization)
3. Knowledge that material information in the attestation is false
4. A reasonable covered entity or business associate in the same position would not believe the requestor's statement that the use or disclosure is not for a prohibited purpose as described above

Model Attestation

Final Rule - Presumption

Reproductive healthcare provided by a person other than the regulated entity that receives the request for PHI is presumed lawful unless the entity has either of the following:

1. Actual knowledge that the reproductive healthcare was not lawful under the circumstance in which it was provided
2. Factual information supplied by the person requesting the PHI that demonstrates to the regulated entity a substantial factual basis that the care was not lawful under the specific circumstances

Why does this presumption exist? Regulated Entities and Non-Regulated Entities.

[HIPAA for Professionals Guidance - Reproductive Health](#)

Final Rule – Required by Law Disclosures

HIPAA **permits** but doesn't require – can be held accountable by the other law...

Can only disclose PHI limited to the relevant law

May require guidance from counsel familiar with these laws

Example

- An individual goes to a hospital emergency department while experiencing complications related to a miscarriage during the tenth week of pregnancy
- A hospital workforce member suspects the individual of having taken medication to end their pregnancy
- State or other law prohibits abortion after six weeks of pregnancy but does not require the hospital to report individuals to law enforcement
- Where state law does not **expressly require such reporting**, the Privacy Rule would **not** permit a disclosure to law enforcement under the “required by law” permission
- Therefore, such a disclosure would be **impermissible** and constitute a breach of unsecured PHI requiring notification to HHS and the individual affected

Final Rule – Law Enforcement (LE) Disclosures

- HIPAA permits - provided that all conditions specified in the Privacy Rule for LE Disclosures are met
- Final Rule does not permit a disclosure to LE where a hospital or other health care provider's workforce member chose to report an individual's abortion or other reproductive health care - **regardless of hospital initiated or at LE request**
- *Generally*, state laws **do not** require doctors or other health care providers to report an individual who self-managed the loss of a pregnancy to LE
- State fetal homicide laws *generally* do not penalize the pregnant individual, and “appellate courts have overwhelmingly rejected efforts to use existing criminal and civil laws intended for other purposes (e.g., to protect children) as the basis for arresting, detaining, or forcing interventions on pregnant individuals”

[HIPAA for Professionals Guidance - Reproductive Health](#)

Law Enforcement Disclosure Examples from HHS Guidance

LE Request

- A LE official goes to a reproductive healthcare clinic and requests records of abortions performed at the clinic
- Request is not accompanied by a court order or other mandate enforceable in a court of law
- Privacy Rule would **not** permit the clinic to disclose PHI in response to the request
- Therefore, such a disclosure would be **impermissible**

Court Order

- LE official presents a reproductive healthcare clinic with a court order requiring the clinic to produce PHI about an individual who has obtained an abortion
- Because a court order is enforceable in a court of law, the Privacy Rule would permit but not require the clinic to disclose the requested PHI
- The clinic may disclose only the PHI expressly authorize by the court order

Disclosure to Avert a Serious Threat to Health or Safety

Privacy Rule permits but **does not require** a covered entity (CE):

- Consistent with applicable law and standards of ethical conduct,
- To disclose PHI if the CE, in good faith, believes the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public,
- And the disclosure is to a person who is reasonably able to prevent or lessen the threat

Case Example

- Pregnant individual in a state that bans abortion informs their healthcare provider that they intend to seek an abortion in another state where abortion is legal
- The provider wants to report the statement to law enforcement to attempt to prevent the abortion from taking place
- Privacy Rule would **not** permit disclosure of PHI to LE under this permission for several reasons, including:
 - A statement indicating an individual's intent to get a legal abortion, or any other care tied to pregnancy loss, ectopic pregnancy, or other complications related to or involving a pregnancy **does not qualify** as a "serious and imminent threat to the health or safety of a person or the public"
 - It generally **would be inconsistent with professional ethical standards** as it compromises the integrity of the patient–physician relationship and may increase the risk of harm to the individual



When in Doubt Regarding Disclosure Obligations...

Consult qualified legal counsel!



So, What Needs to be Accomplished?

Define your Reproductive Health Data

- Use the Value Set Authority Center (VSAC)
<https://vsac.nlm.nih.gov/>
- VSAC value sets can be downloaded for incorporation into your EHR

Update Your Policies and procedures

- Use the VSAC value sets as a starting point for policies
- Develop and deploy the Model Attestation

Train Your Workforce

- Policies are worthless until they have been implemented & the workforce is trained
- Don't wait for annual training cycles

Start Planning Updates to Your Notice of Privacy Practices

- Don't forget about your online Notice
- Consider how and when you will deploy the revised Notice
- Required date February 16, 2026

What Changes in the Notice of Privacy Practices (NPP)?

- 45 CFR 164.520(b)(1)(ii)
- Adds Paragraphs (F), (G), & (H)
 - (F) – NPP must contain a description, including at least one example, of the types of uses and disclosures **prohibited** under 45 CFR 164.502 (a)(5)(iii) in sufficient detail for an individual to understand the prohibition
 - (G) – NPP must contain a description, including at least one example, of the types of uses/disclosures **for which an attestation is required** under the new 45 CFR 164.509
 - (H) – Must include a statement explaining that PHI disclosed pursuant to the Privacy Rule may be subject to redisclosure and no longer protected by the Privacy Rule

What Changes in the NPP for Part 2 Organizations?

- If **also** subject to Part 2 – must revise the notice to cover both rules
- 45 CFR 164.520(b)(1)(ii)
 - Revises paragraphs (C) & (D)
 - (C) – Clarifies where NPP’s descriptions of uses/disclosures for TPO or without an authorization must reflect “other applicable law” that is more stringent than the Privacy Rule, including Part 2.
 - (D) – Clarifies that Part 2 is specifically included in “other applicable law” to describe uses/disclosures that are permitted for TPO or without authorization to place the individual on notice of the uses/disclosures that are permitted by the Privacy Rule and other applicable law.
 - (D) – Also requires notice that Part 2 records or testimony may not be used or disclosed in a civil, criminal, administrative, or legislative proceeding against the individual absent written consent from the individual or a court order consistent with part 2.

Compliance Resource – Defining Reproductive Health Data

HHS OCR HIPAA Privacy Rule to Support Reproductive Health Care Privacy

Background

The Biden-Harris Administration, through the US Department of Health and Human Services (HHS) Office for Civil Rights (OCR), released the [HIPAA Privacy Rule to Support Reproductive Health Care Privacy Final Rule](#) on April 22, 2024. The final rule modifies the HIPAA Privacy Rule to strengthen privacy protections for individuals' protected health information (PHI) related to reproductive healthcare. The final rule made several adjustments to the proposed requirements in response to public comments, including [comments provided by AHIMA](#). The final rule became effective on June 25, 2024, and **the compliance date is December 22, 2024**. Updates to the provider's Notice of Privacy Practices (NPP) are due February 16, 2026, giving providers additional time to comply.

Modifications to the HIPAA Privacy Rule include a prohibition on regulated entities using or disclosing an individual's PHI for the purpose of conducting a criminal, civil, or administrative investigation into or imposing criminal, civil, or administrative liability on any person for the act of seeking, obtaining, providing, or facilitating reproductive healthcare that is lawful under the circumstances in which it is provided. The rule requires regulated healthcare providers, health plans, clearinghouses, and business associates (BAs) to obtain signed attestations from individuals requesting PHI potentially related to reproductive healthcare. The attestation must state that the information will not be used against a provider or patient in legal cases related to the provision of reproductive healthcare.

To comply with these new requirements by December 22, 2024, healthcare organizations should begin to develop policies and procedures pertaining to "reproductive healthcare" that could be used to make initial determinations of whether PHI is potentially related to reproductive healthcare and whether an attestation is required. Healthcare organizations should document these policies and create decision matrices that assess whether PHI is potentially related to reproductive healthcare, whether an attestation is required, and incorporates release of information processes. This resource is intended to assist with the first step of this work, assessing what data constitutes "reproductive healthcare."

Defining "Reproductive Healthcare" Data

HHS OCR defines "reproductive healthcare" as, "healthcare that affects the health of the individual in all matters relating to the reproductive system and to its functions and processes. The definition should not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive healthcare."¹

Non-exclusive list of examples of reproductive healthcare provided by OCR in the final rule include: contraception, including emergency contraception; preconception screening and counseling; management of pregnancy and

¹45 CFR 160.103.

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To take advantage of the VSAC value sets, organizations may download the VSAC value sets for incorporation into an organization's electronic health record (EHR) and create, document, and implement policies and procedures for evaluating requests for PHI potentially related to reproductive healthcare and potentially disclosing information to a requestor.

Just as an organization determines their designated record set (DRS), organizations must also determine what data they consider to be potentially related to reproductive healthcare. Additionally, the organization must work with patients to determine whether the organization's definition excludes data that a patient considers potentially related to reproductive healthcare. The value sets in the VSAC data sets may be used by an organization as a starting point to develop their own data set. However, it is important to note that the VSAC data set does not contain all information that may be potentially related to reproductive healthcare.

Provider organizations should work with their health information experts, clinicians, compliance professionals, and legal staff to determine and finalize their data set potentially related to reproductive healthcare. Organizations should ensure the most recent version of their data set is codified in the policies and procedures regarding the release of information process and attestation. New technologies, treatments, and methodologies will need to be added to the data set as reproductive healthcare evolves. Organizations should consider establishing a routine process to review and update data sets as needed. Establishing such practices in policies and procedures will help ensure a more consistent application of requirements across all data requests.

How to Access, Navigate, and Use VSAC

Individuals can [request a free UMLS License](#) to access the VSAC value sets. Please note it may take one to five business days to obtain a license. In creating a license, consider who the owner of the account should be, as the individual's login will be the only way to access the value sets. Logins are created for individuals, not organizations. Organizations can take the following steps to find the NACHC authored value sets in VSAC related to reproductive health and export them for use:

- Visit vsac.nlm.nih.gov and login with your UMLS account.
- Click "Search" in the "All Value Sets" box in the lower left area.
- Navigate to the "Refine by" section at the top and under the drop-down box for "Steward" select "NACHC" and click the orange "Search" button.
- Under "Search Results" below the search boxes, you will find value sets comprised of various codes, organized by topic.
- To view a value set, click on the OID number which will take you to a webpage with that value set. Scroll down and navigate through the pages to view the codes included in a value set.
- To download the value set, under "Value Set Details" click the "Export Value Set Results" with the green Excel icon. This will download an excel sheet with the full value set and codes for your use.
 - You can export multiple value sets at once by clicking the white box on the left of each value set row and clicking "Export Value Set Results."

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AHIMA's Non-exclusive Examples of Reproductive Healthcare

- Contraception, including emergency contraception;
- Preconception screening and counseling;
- Management of pregnancy and pregnancy-related conditions, including:
 - pregnancy screening, prenatal care, miscarriage management, treatment for preeclampsia, hypertension during pregnancy, gestational diabetes, molar or ectopic pregnancy, and pregnancy termination;
 - fertility and infertility diagnosis and treatment, including assisted reproductive technology and its components (e.g., in vitro fertilization (IVF));
 - diagnosis and treatment of conditions that affect the reproductive system (e.g., perimenopause, menopause, endometriosis, adenomyosis);
 - and other types of care, services and supplies used for the diagnosis and treatment of conditions related to the reproductive system (e.g., mammography, pregnancy-related nutrition services, postpartum care products).

AHIMA's Guidance

- Just as an organization determines their designated record set (DRS), organizations must also determine what data they consider to be potentially related to reproductive healthcare.
- Additionally, the organization must work with patients to determine whether the organization's definition excludes data that a patient considers potentially related to reproductive healthcare.
- The value sets in the VSAC data sets may be used by an organization as a starting point to develop their own data set.
- However, it is important to note that the VSAC data set does not contain all information that may be potentially related to reproductive healthcare.
- Organizations should work with their HIM experts, clinicians, compliance professionals, and legal staff to determine and finalize their data set potentially related to reproductive healthcare.



Q&A



Upcoming Industry Events



Health Sector Coordinating Council Joint Cybersecurity Working Group All-Hands Meeting | November 19-20, 2024 – San Diego, CA

- Jon Moore, Chief Risk Officer and Head of Consulting Services & Client Success, and Dave Bailey, Vice President of Security Services are attending, and Clearwater is a proud sponsor of the event.
- [Learn More & Register](#)



ADSO Next Level Conference | Dec 2 – 4 | Austin, TX

- Don't miss the opportunity to stop by our sponsor table and engage with industry leaders.
- Dave Bailey, Vice President of Security Services will present 5 Critical Cybersecurity Practices for a Growing DSO at 4:00 pm on December 3.
- [Learn More & Book a Meeting With us](#)

Upcoming Webinars



The State of Vulnerability Management in Healthcare | Monthly Cyber Briefing on December 5 @ 12:00 CST

- Clearwater Corporate CISO and Managed Security Services (MSS) leader Steve Akers will review vulnerability data across different segments of the healthcare ecosystem, leveraging real-world data from our MSS team.
- [Register Here](#) (Cyber Briefing attendees are already registered)



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