

Reproductive Health Data

Responding to requests for records
under the Vermont Shield Law and the
HIPAA Privacy Rule To Support
Reproductive Health Care Privacy

VITL

ATTORNEYS
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For over 25 years, John Wallace has served as in-house counsel, general counsel, and chief compliance officer for health care entities, and as a health care attorney at Primmer Piper Eggleston & Cramer PC.

John's practice focuses primarily on helping clinicians, administrators, and health care related entities navigate complex regulatory and compliance issues. He regularly advises clients on compliance with HIPAA, the Part 2 Confidentiality of Substance Use Disorder Patient Records Rule, and other privacy and information security laws.

John earned his BA from St. Lawrence University, his MS from Johns Hopkins University, and his JD from Vermont Law School.



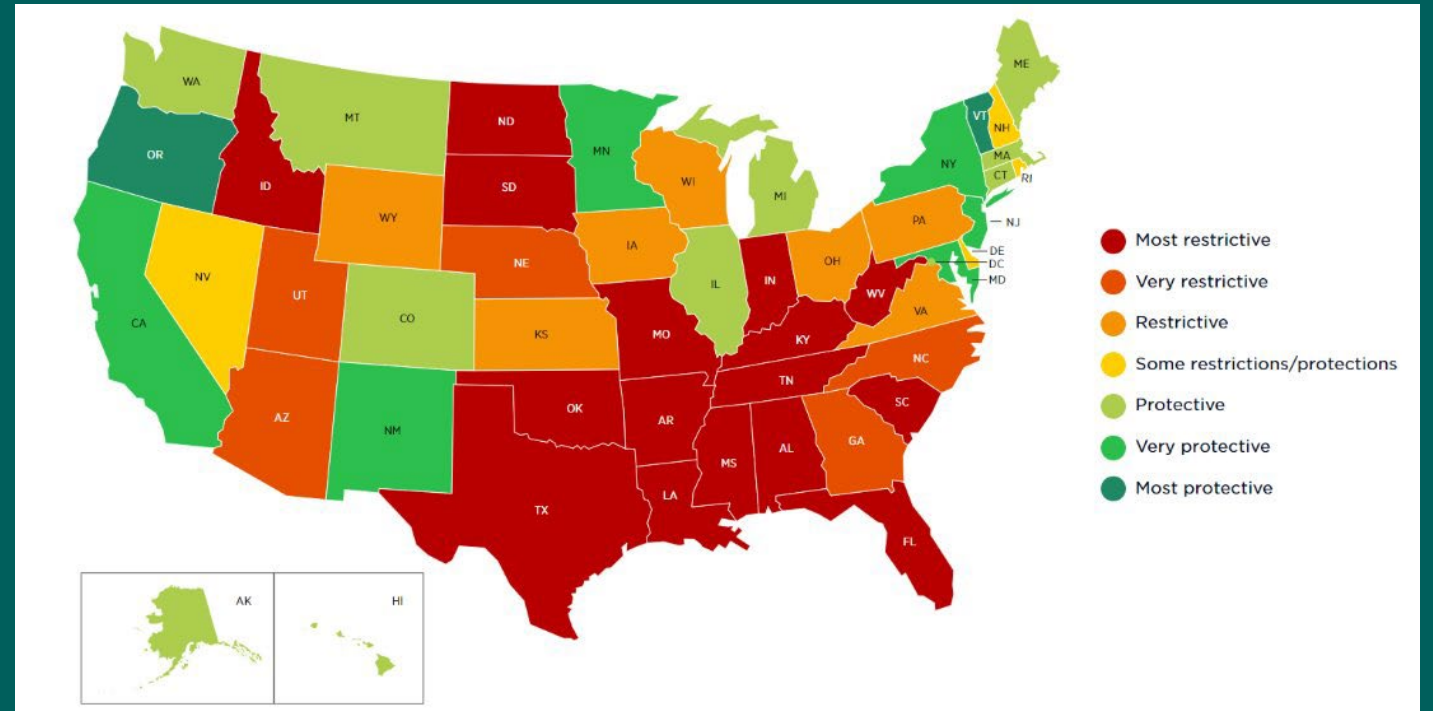
Session Overview

- Legal context for protecting reproductive records: 2022-23
- Actions to protect reproductive data: Vermont Shield Law and the new HIPAA Privacy Rule
- Difference between purpose-based-prohibitions and “sensitive information”
- Required changes to Notice of Privacy Practices (NPP)
- Evaluating and responding to requests for records and testimony involving reproductive data
- Implications for Information Blocking
- VHIE Approach
- What’s Next
- Questions



Dobbs and the Rapidly Changing Legal Landscape

- 21 States enact laws to ban or restrict abortion
- 4 States seek to prosecute assistance with out-of-state abortions (AL, TX, OK, ID)
- 6 States enact laws to protect data privacy for reproductive health (CA, CT, ME, MD, VT and WA)
- Landscape will continue to change

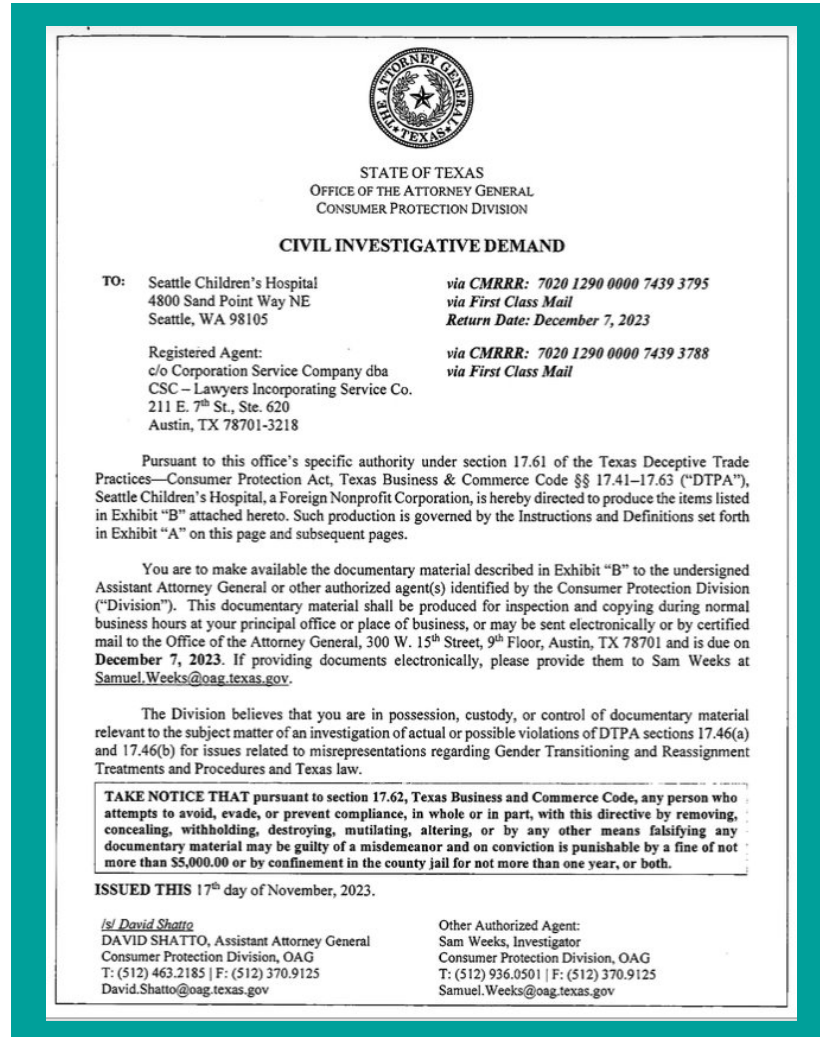


Legal Context



Texas

AG seeks medical records for care in another state under the Texas Deceptive Trade Practice Act



Texas Attorney General Ken Paxton issued a Civil Investigative Demand and Request for Sworn Written Statement to Seattle Children’s Hospital regarding “Gender Transitioning and Reassignment Treatments and Procedures”

- Texas Deceptive Trade Practices Act
- Demand for information about Texas residents treated by Seattle Children’s
- Records regarding diagnoses, medications, lab testing, and treatment protocols of individual patients



Washington State

Responds to Texas AG with Shield Law



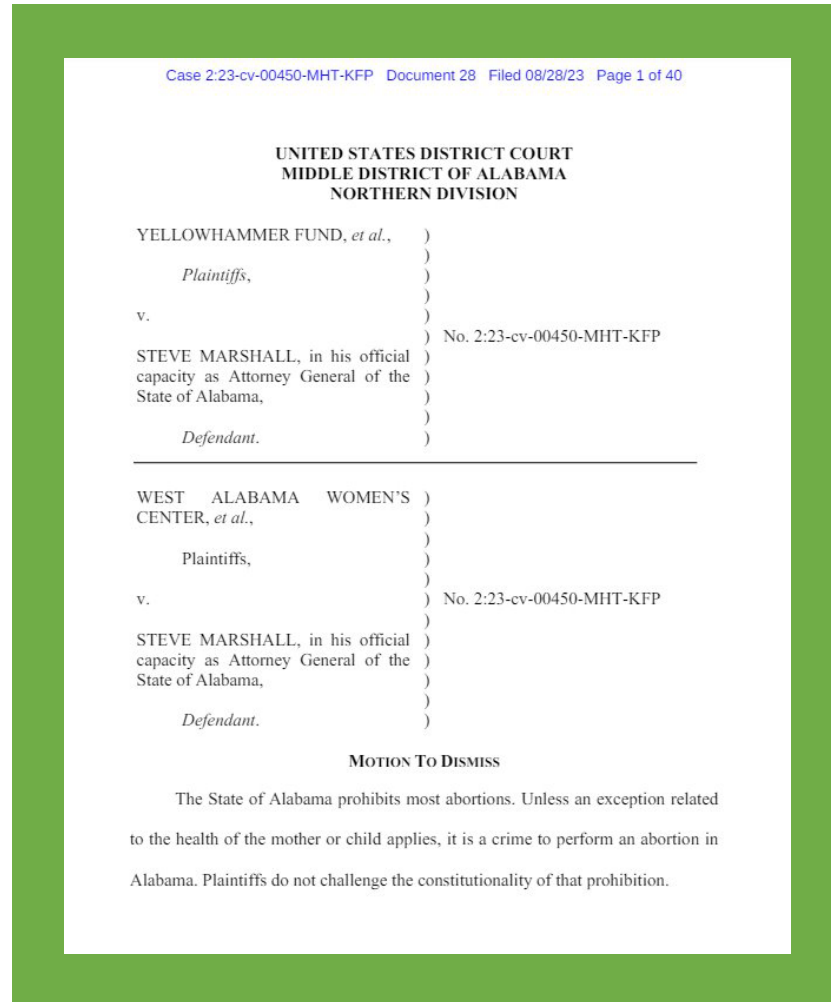
Prohibits Washington entities from responding to requests for information for legal proceedings in other states (ban states) that restrict or criminalize reproductive and gender-affirming care.



Requestor must provide an attestation that they are not seeking information for an investigation or enforcement of another state's law that asserts criminal or civil liability for a protected health care service that is lawful in the State of Washington.

Alabama

Considering or obtaining an abortion out-of-state may involve a criminal conspiracy



Alabama Attorney General Steve Marshall communicating within Alabama about an out-of-state abortion is indictable and punishable in Alabama as a criminal conspiracy.

- A conspiracy formed in Alabama to have an abortion performed out-of-state is the same criminal act as conspiring to have an elective abortion performed in Alabama, which would be a criminal offense.
- AG Marshall threatened to prosecute women considering out-of-state abortions and anyone who helps them.
- Two “helper” groups filed a lawsuit to enjoin prosecution that threatened their rights to free speech, association, travel, due process, and extraterritorial application of state law.

Idaho and Tennessee

“Abortion Trafficking”

Case 1:23-cv-00323-DKG Document 51 Filed 01/04/24 Page 1 of 8

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF IDAHO

LOURDES MATSUMOTO, NORTHWEST ABORTION ACCESS FUND, and INDIGENOUS IDAHO ALLIANCE, Plaintiffs, v. RAÚL LABRADOR, in his capacity as the Attorney General for the State of Idaho, Defendant.	Case No. 1:23-cv-00323-DKG ORDER RE: MOTION TO STAY (DKT. 44)
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INTRODUCTION

Before the Court is Defendant’s Motion to Stay the Court’s Preliminary Injunction pending appeal. (Dkt. 44.) Plaintiffs oppose the motion, and the matter is fully briefed and ripe for consideration. (Dkt. 49, 50.) The facts and legal arguments are adequately presented in the record. Accordingly, in the interest of avoiding delay, and because the decisional process would not be significantly aided by oral argument, the motion will be decided based on the record. For the reasons that follow, the Court will deny the motion.

Idaho and Tennessee enacted “anti-abortion trafficking” laws that prohibit adults from helping minors access abortions without parental consent.

- Law applies to “recruiting, harboring, or transporting minors for abortions with intent to conceal actions from parents.”
- Helper organizations filed suit and obtained a preliminary injunction to delay enforcement due to constitutional restrictions on free speech.
- Injunction pending before US Court of Appeals



State and Federal Actions to Prohibit Misuse of Reproductive Data

- Vermont Shield Laws
- New HIPAA Privacy Rule to Support Reproductive Health Care Privacy

Prohibiting Misuse of Reproductive Health Information

Vermont Shield Laws

- Vermont Shield Laws passed, effective May 10, 2023
- Act 14 shields providers and patients from abusive criminal and civil litigation related to protected health care activity (reproductive or gender affirming care)
- Act 15 (18 VSA 1881(c)) limits disclosures of protected health information (PHI) related to protected health care activity for use in a legal proceeding
- Laws address:
 - Reproductive health care information (RHC)
 - Gender-affirming health care information (GAC)

Prohibiting Misuse of Reproductive Health Information

New HIPAA Privacy Rule on Reproductive Data

HIPAA Privacy Rule for Reproductive Health Care

- Proposed rule published April 17, 2023
- Final rule published April 26, 2024
- Compliance date December 23, 2024
- Federal rule prevents HIPAA covered entities and business associates from using or disclosing PHI related to reproductive health care for a prohibited purpose – use in a legal proceeding



Definition of Reproductive Health Care Information

Vermont Shield Law

RHC means *all* supplies, care, and services, of a medical, behavioral health, mental health, surgical, psychiatric, therapeutic, diagnostic, preventative, rehabilitative, or supportive nature, including medication, *relating to pregnancy, contraception, assisted reproduction, pregnancy loss management, or the termination of a pregnancy.*

HIPAA

RHC means health care that affects the health of an individual *in all matters relating to the reproductive system and to its functions and processes.* This definition shall not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive health care.

Prohibitions of Each Law

Vermont Shield Law

Prohibits disclosure of reproductive health care information (RHC) for use in legal proceedings without patient authorization unless the disclosure is required by law or compelled by a court order.

HIPAA

Prohibits disclosure of RHC for use in legal proceedings without patient authorization, unless the *requestor provides an attestation that information will not be used against patient or provider*, and under Vermont law obtains a court order.

Restriction on Disclosure

Vermont Shield Law

Prohibits disclosure of RHC for use in a civil or criminal action or probate, administrative or legislative proceeding unless the disclosure of RHC is (1) authorized by the patient; (2) required by federal or Vermont law; (3) compelled by a court order.

HIPAA

Prohibits disclosure of RHC to conduct an investigation or to impose criminal, civil, or administrative liability for the mere act of seeking, obtaining, providing, or facilitating RHC when the CE determines that the RHC is lawful under state and/or Federal law.

Process to Permit Disclosure Without Patient Authorization

Vermont Shield Law Court Order

Unless the disclosure is required by law, a covered entity or business associate shall not disclose PHI *related to* a protected health care activity (RHC or GAC) without a court order compelling disclosure based on a court's determination that good cause exists to require disclosure.

HIPAA

Attestation + Court Order

Prohibits disclosure of PHI “*potentially related to reproductive health care*” for use in legal proceedings without patient authorization unless the *requestor provides an attestation that information will not be used against patient or provider*. The Vermont patient privilege statute requires a judge to sign a subpoena or court order requiring the disclosure of medical records.

HIPAA Disclosures Required By Law

Covered entities may disclose PHI without patient authorization where the disclosure is required by law, such as:

- Abuse and neglect reporting and investigation
- **Medical examiners***
- Gun shot wounds
- **Pursuant to a court order, or certain law enforcement purposes***
- **Health oversight: licensing, certification, and regulation***
- Public health reporting
- Duty to report motor vehicle accident blood alcohol level blood test results

*** If the PHI to be disclosed includes reproductive information, the individual seeking the information must attest that not seeking information for a prohibited purpose.**

Vermont Shield Law, 18 VSA 1881(c)(3)

Under the Shield Law, a covered entity may disclose RHC where the disclosure is required by law. A court order requiring disclosure RHC must include the court's determination of "good cause" to require disclosure of information related to a legally protected health care activity.

Vermont 18 VSA § 1881(c)(3)

A valid court order must include the court's determination of "good cause"

A court order compelling disclosure of PHI related to Reproductive Health Care or Gender Affirming Care shall include the court's determination that good cause exists to require disclosure of the information related to legally protected health care activity.

Whether good cause exists is a mixed question of fact and law:

1. The party seeking the records bears the burden of establishing the facts to support a finding of good cause.
2. Court's determination that good cause exists must be supported by an evidentiary record and factual findings.
3. Before disclosing records, CE/BA will need to confirm that court order includes:
 - The factual basis for the court's determination that good cause exists; and
 - Specifies the records to be disclosed.



Attestation for requested disclosure of RHI

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

1. CE/BA receives request for PHI that is potentially related to RHC
 - RHC may not be disclosed for a **prohibited purpose**:
to identify a person, to conduct an investigation, or impose liability for the mere act of seeking, obtaining, providing, facilitating lawful reproductive care.
2. Person requesting RHC must sign attestation (CE/BA's duty to obtain)
 - Attest that not requesting RHC for a prohibited purpose
 - Acknowledge that criminal penalties may apply if attestation is untrue
3. Attestation **must** include:
 - (1) name of investigator/agency
 - (2) individual(s) subject to request,
 - (3) CE/BA required to disclose PHI, and
 - (4) description of requested phiModel attestation: <https://www.hhs.gov/sites/default/files/model-attestation.pdf>
4. Attestation may not be combined with other documents unless they are necessary to support attestation



Difference Between Purpose-Based-Prohibitions and “Sensitive Information”



Purpose-Based Prohibition



The Shield Law and HIPAA do not create a new category of sensitive information like psychotherapy notes or Part 2 records.

Unlike psychotherapy notes and Part 2 records, reproductive information is an inextricable part of general medical record.



For treatment, payment, and health care operations, RHI is treated the same as any other type of PHI



RHI is only treated differently when someone is seeking to use or obtain the information for a prohibited purpose in a legal proceeding.

Sensitive Information v. Purpose-Based

HIPAA does not classify reproductive information as sensitive information

Laws that create a category of sensitive information impose requirements for how information is accessed and used

For example, Part 2 substance use disorder(SUD) information, psychotherapy notes, and SUD counseling notes.

Sensitive information treated differently

- Protected by break glass access
- May require patient consent for all disclosures (Part 2)
- May require (legally or practically) information to be segmented from non-sensitive information to ensure that any use or disclosure complies with the law

Purpose-Based Prohibition (the non-health care purpose of the use or disclosure is the trigger for the protection)

- Information is only treated differently when it may be used or disclosed for a potentially prohibited purpose
 - Use or disclosure to conduct an investigation or impose liability on a person for seeking, obtaining, providing, or facilitating reproductive health care.
 - An attestation is required for certain disclosures required by law - 45 CFR 164.512 (d) health oversight, (e) judicial and administrative proceedings; (f) law enforcement purposes; (g) related to decedents for medical examiners

Required Changes to Notice of Privacy Practices (NPP)



HIPAA Changes to Notice of Privacy Practices

Compliance Date: February 16, 2026

NPP must include:

- Description of laws that are more stringent than HIPAA
 - 42 CFR Part 2 and Vermont Shield Laws
- Description and at least one example of the uses and disclosures of RHC that are prohibited by the rule
- Description and at least one example of disclosures that require an attestation
- Statement that PHI that is disclosed may be redisclosed in a way that is no longer protected by HIPAA
- If covered entity creates or receives Part 2 record, NPP must state that Part 2 information may not be disclosed for a legal proceeding without consent or a court order after notice and an opportunity to be heard.
- Review whether NPP provides notice of EHR's connection to EMR vendor's health information exchange or other HIE.

Information Blocking Implications



Information Blocking

Prohibits providers, HIT developers, HIEs, and others (Actors) from interfering with access, exchange, or use of electronic health information (EHI)

- Providers are required to share EHI with other providers, HIT developers, and others unless an exception applies

Exceptions to info blocking – reasonable and necessary practices to restrict access to EHI (five exceptions)

- Privacy exception – Actor not required to use or disclose EHI in a way that is prohibited under state or federal privacy law

Privacy Exception to Info Blocking

Withholding EHI to protect an individual's privacy is not info blocking

- Unsatisfied state or federal legal precondition to release of EHI
 - Actor's practice is tailored to applicable precondition to release EHI
 - Restriction on release is implemented in a consistent and non-discriminatory manner; and
 - Conforms to written organizational policy or documented on a case-by-case basis.
- Withholding EHI is based on individual's request not to share information
 - Aligns with HIPAA right to request restrictions on access, use, or disclosure
 - Actor may not improperly encourage or induce individual to deny access

VITL and Reproductive Data



VITL and Reproductive Data

- VITL continues to share data with health care organizations in Vermont or providing care for Vermonters through a services agreement
- Not currently participating in national exchange or TEFCA, except for point-to-point connections with individual organizations through eHealth Exchange
- Exploring options for enabling national participation while also protecting sensitive data of Vermonters

Next Steps



What Health Care Organizations Should Do Before December 2024

1. By February 16, 2026, update Notice of Privacy Practices to refer to special protections for RHI and gender-affirming care information
2. Before December 2024, review business associate agreements (BAA) policy and checklist
 - a. Decide whether BAA should require BA to review and respond directly to legal requests for records; or (HIPAA allows BAs to be directly liable for obtaining attestation)
 - b. BAA may require BA to forward request for records to covered entity

What Health Care Organizations Should Do Before December 2024

3. Develop policy and training to identify disclosures that will require attestations
 - a. Adapt HHS model attestation form for own use
 - b. Assign responsibility for obtaining and reviewing attestations
4. Update release of information policies to include procedures to:
 - a. Review subpoenas and other legal requests for records that are not for treatment, payment, or health care operations
 - b. Review records to determine if they include RHC or GAC and if they are being requested for a potentially prohibited purpose
 - c. Review court orders to ensure they include necessary determination of “good cause”
 - d. Work with legal counsel on process development and in responding to defective legal requests for records

Consider Developing Reporting Process to Identify Records with RHC and GAC

Report could be used to identify records that are or are not subject to restrictions on disclosure for prohibited purposes

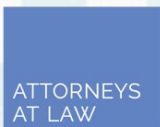
1. Relevant ICD-10 medicals diagnosis codes
2. Relevant CPT/HCPCS codes that are reported in combination with relevant ICD-10 codes
3. Relevant DRG codes (Diagnosis Related Group)
4. Medication Codes – National Drug Codes (NDC) reported in combination with relevant ICD-10 codes



Questions



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