Reproductive Health Information Privacy

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A Few Preliminary Thoughts

- Sensitive information...Sensitive topic.
- Focus on Reproductive Health Care...All Types of Reproductive Health Care.
- Stated goals of OCR:
 - Recognizing "changing legal landscape" after Dobbs v. Jackson Women's Health Organization.
 - HIPAA encourages trust so individuals are comfortable accessing high quality health care.
 - Lack of trust can result in individuals not seeking health care (even when lawful), incomplete medical records affecting both quality of care and public health efforts, etc.
 - Finding the balance between the interests of society and the privacy interests of individuals.

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Overview of Amendments Prohibition on certain disclosures related to lawful reproductive health care. Attestation requirement for certain requests. Revisions to notices of privacy practices. Additional requirement for law enforcement requests. Changes/clarifications to some definitions and situations. DWT.COM 3

The New Prohibition on Use and Disclosure DWT.COM

- State law bans all abortions except to save life of the pregnant person, or in cases of rape or incest that have been reported to law enforcement.
- Physician performs abortion on pregnant woman who indicated that she was raped but had not reported the rape to law enforcement.
- Hospital receives request from the state attorney general's office for the medical records related to the procedure, accompanied by a warrant.

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- A Texas woman traveled to Colorado to have an abortion, where the procedure was legal.
- Ex-partner seeks to pursue wrongful death claim against anyone involved in the procedure.
- Texas court order requires the Colorado health system to disclose the medical record of the procedure.

The Washington Post

Democracy Dies in Darknes

Texas man files legal action to probe ex-partner's out-of-state abortion

The previously unreported petition reflects a potential new antiabortion strategy to block women from ending their pregnancies in states where abortion is legal.



By Caroline Kitchener

May 3, 2024 at 5:00 a.m. EDT

As soon as Collin Davis found out his ex-partner was planning to travel to Colorado to have an <u>abortion</u> in late February, the Texas man retained a high-powered antiabortion attorney — who court records show immediately issued a legal threat.

If the woman proceeded with the abortion, even in a state where the procedure remains legal, Davis would seek a full investigation into the circumstances surrounding the abortion and "pursue wrongful-death claims against anyone involved in the killing of his unborn child," the lawyer wrote in a letter, according to records.

Now, Davis has disclosed his former partner's abortion to a state district court in Texas, asking for the power to investigate what his lawyer characterizes as potentially illegal activity in a state where almost all abortions are

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The New HIPAA Prohibition

Subject to the Rule of Applicability and the Presumption, a covered entity or business associate may not use or disclose PHI for any of the following activities:

- 1. To conduct a criminal, civil, or administrative investigation ("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 ("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.

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Rule of Applicability

The prohibition applies only where the relevant activity is in connection with any person seeking, obtaining, providing, or facilitating reproductive health care, and the covered entity or business associate that received the request for PHI has reasonably determined that one or more of the following conditions exists:

- 1. 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.
- The reproductive health care 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.

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With appropriate attestation (to be discussed), HIPAA will <u>not</u> prohibit the disclosure of PHI because:

- The reproductive health care was not lawful under the circumstances in which it was provided; and
- Was not protected, required, or authorized by federal law.

State law bans all abortions except to save life of the pregnant person, or in cases of rape or incest that have been reported to law enforcement.

Physician performs abortion on pregnant woman who indicated that she was raped but had not reported the rape to law enforcement.

Hospital receives request from the state attorney general's office for the medical records related to the procedure, accompanied by a warrant.

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HIPAA* <u>will</u> prohibit the disclosure of PHI because:

- The reproductive health care was lawful under the circumstances in which it was provided; and
- The requested disclosure is to impose liability on persons for seeking, obtaining, providing, or facilitating reproductive health care.
- * Colorado law also would prohibit the disclosure for numerous reasons.

A Texas woman traveled to Colorado to have an abortion, where the procedure was legal.

Ex-partner seeks to pursue wrongful death claim against anyone involved in the procedure.

Texas court order requires the Colorado health system to disclose the medical record of the procedure.

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- A Nebraska health care provider treats a new patient and downloads a copy of her medical record from a health information exchange.
- The record includes information about an abortion that she received in South Carolina at 7 weeks gestation.
- The Nebraska health care provider receives a court order from a Nebraska court (originating from a South Carolina court) requiring disclosure of the patient's complete medical record.

THE YALE LAW JOURNAL FORUM

steps to close the loopholes that allow this.

OCTOBER 18, 2022

The Abortion Interoperability Trap Carleen M. Zubrzycki

ABSTRACT. Legislatures in blue states are trying to shield patients' medical records from being used against them in antiabortion litigation and persecutions. The problem is, as medical records increasingly follow the patient, those records are likely to end up in the hands of actors who are

INTRODUCTION

There is a serious gap in blue states' efforts to create abortion "safe havens" for the post-Roe world. Medical care procured outside a patient's home state increasingly leaves a digital trail that will easily make its way back to the patient's domicile. In the context of abortion—and other controversial forms of healthcare, like gender-affirming treatments—this means that cutting-edge legislative protections for medical records fall short.

not subject to safe-haven laws and who can easily be required to hand over the records to law

enforcement or private litigants. Legislatures, policymakers, and private actors should all take

In advance of the anticipated fall of *Roe v. Wade*, ¹ some state legislatures began to bar in-state medical providers from directly handing over abortion records for use in out-of-state lawsuits or prosecutions in an effort to protect abortion seekers and providers. ² After the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, ³ more states are joining the fray. ⁴ But these

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The Presumption

The reproductive health care provided by another person is presumed lawful under the Rule of Applicability unless the covered entity or business associate has any of the following:

- 1. Actual knowledge that the reproductive health care was not lawful under the circumstances in which it was provided.
- Factual information supplied by the person requesting the use or disclosure of protected health information that demonstrates a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided.

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- The Nebraska health care provider, who does not know the law of South Carolina, should presume that the reproductive health care was lawful and should <u>not</u> disclose the requested PHI.
- If the court provides factual evidence, such as an affidavit from someone who witnessed the procedure, demonstrating that the procedure was unlawful, then the provider may disclose the PHI.

A Nebraska health care provider treats a new patient and downloads a copy of her medical record from a health information exchange.

The record includes information about an abortion that she received in South Carolina at 7 weeks gestation.

The Nebraska health care provider receives a court order requiring disclosure of the patient's complete medical record.

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- HHS Office of the Inspector General sends to a health care provider a request for the full medical records of 20 individuals.
- The request states that the OIG is conducting an audit of the health care provider's billing to Medicare and Medicaid.
- Two records include information about:
 - A female patient's menstrual cycle and pap smear results.
 - A male patient treatment for a sexually transmitted disease.
- May the health care provider disclose the requested PHI?

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When an Attestation Is Required

A covered entity or business associate may not use or disclose protected health information **potentially related to reproductive health care** for the below purposes without obtaining a valid attestation from the person requesting the use or disclosure and complying with all applicable conditions:

- Uses and disclosures for health oversight activities;
- Disclosures for judicial and administrative proceedings;
- Disclosures for law enforcement purposes; or
- Uses and disclosures about decedents coroners and medical examiners.

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Requirements of an Attestation

- Description of PHI. A description of the requested PHI, including:
 - The name of any individual(s) whose PHI is sought, if practicable; or
 - If including the name(s) of any individual(s) whose PHI is sought is not practicable, a description of the class of individuals whose PHI is sought.
- Disclosing Entity. The name or class of persons requested to make the use or disclosure.
- Requestor. The name or class of persons to whom the covered entity is to make the requested use or disclosure.
- Not Prohibited. A clear statement that the use or disclosure is not for a purpose prohibited by the new prohibition.
- Criminal Penalties. A statement that a person may be subject to criminal penalties for knowingly and in violation of HIPAA obtaining or disclosing individually identifiable health information.
- **Signature.** Signature of requestor and date. If the attestation is signed by a representative of the person requesting the information, a description of such representative's authority to act for the person must also be provided.

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HHS 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,

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- The provider must request an attestation from the OIG because the request is for health oversight and the requested PHI relates to reproductive health care.
 - Note: An attestation would not be required if the request was from CMS or a state Medicaid agency as part of its payment activities.
- The provider may make the disclosure upon receiving a valid attestation.

HHS OIG sends a health care provider a request for the full medical records of 20 individuals.

The request states that the OIG is conducting an audit of the health care provider's billing to Medicare and Medicaid.

Records about two individuals include information on reproductive health care.

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- Ohio medical board issues subpoena to an Ohio physician for information about whether the physician performed an abortion out-of-state.
- The physician requests an attestation from the medical board.
- The board refuses to provide the attestation and threatens to revoke the physician's license for failure to respond.

Ohio Rev. Code Ann. § 4731.22 provides that the state medical board shall discipline a physician for "commission of an act that constitutes a felony in this state, regardless of the jurisdiction in which the act was committed.

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- HIPAA will not permit the physician to provide the subpoenaed PHI for health oversight purposes without a valid attestation.
- HIPAA may permit the physician to disclose the PHI for defensive purposes as part of its health care operations (e.g., conducting legal services).

Ohio medical board issues subpoena to an Ohio physician for information about whether the physician performed an abortion out-of-state.

The physician requests an attestation from the medical board indicating that the request is not to impose liability for providing reproductive health care.

The board refuses to provide the attestation and threatens to revoke the physician's license for failure to respond.

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- Law enforcement officers request the full records of an incapacitated patient because they suspect the patient may be the victim of a crime.
- The records include information that the patient received an abortion that was lawful in the state it was performed.
- The hospital has determined, in the exercise of its professional judgement, that
 disclosure is in the best interests of the patient but is unable to obtain the individual's
 agreement because of the incapacity. To meet the requirements for a permissible
 disclosure to law enforcement, the hospital adds to the attestation a representation
 from law enforcement that:
 - The information is needed to determine whether a violation of law by a person other than the victim has occurred, and the information is not intended to be used against the victim.
 - Immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.

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Defective Attestations



"Everything on your attestation is true ... right?"

- Too little. Lacks a required element or statement;
- Too much. Includes an additional element or statement;
- Compound attestation. Combined with another document;
- Actual knowledge. Covered entity or business associate has actual knowledge that material information in the attestation is false; or
- Unreasonable. A reasonable covered entity or business associate would not believe the attestation is true with respect to not being for a prohibited purpose.

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The disclosure of the full record by the hospital would not be permissible because the inclusion of additional statements renders the attestation form defective. Law enforcement requests the records of an incapacitated patient because they suspect the patient may be the victim of a crime.

The records reference that patient received an abortion that was lawful in the state.

The hospital adds to an attestation certain representations required under HIPAA.

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Additional Requirement for Law Enforcement Requests

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Law Enforcement Administrative Requests

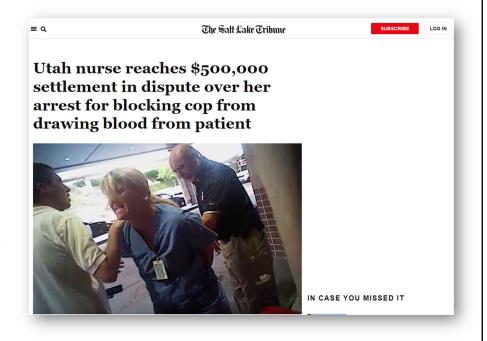
A covered entity may disclose protected health information: ...

- (ii) In compliance with and as limited by the relevant requirements of: ...
- (C) An administrative request <u>for which response is required by law</u>, 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.

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Law Enforcement Administrative Requests

- Applies to any law enforcement administrative request (not just related to reproductive health care)
- HHS indicated that this was always intent and does not represent a substantive change.
- If written law enforcement request includes required elements, when is it obstruction of justice to not respond?



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Revisions to Notices of Privacy Practices

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Notice of Privacy Practices (NPP)

- A description, including at least one example, of the types of uses and disclosures prohibited related to reproductive health care in sufficient detail for an individual to understand the prohibition.
- A description, including at least one example, of the types of uses and disclosures for which an attestation is required.
- A statement about the potential for PHI disclosed pursuant to the Privacy Rule to be redisclosed by the recipient and no longer be protected by the Privacy Rule.

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Notice of Privacy Practices – Part 2 Updates

- HIPAA Notice of Privacy Practices updates include:
 - Information about additional protections for substance use disorder (SUD) records subject to 42 C.F.R. part 2.
 - If covered entity intends to use SUD records subject to 42 C.F.R. part 2 for fundraising, then clear and conspicuous opportunity to opt out.
- The compliance date for updating the NPP aligns with the compliance date for the February 2024 amendments to 42 C.F.R. part 2.

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Definitions and Clarifications

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Definitions

- Reproductive health care means health care, as defined in this section, 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.

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Definitions

- 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.
- Public health, as used in the terms "public health surveillance," "public health investigation," and "public health intervention," means population-level activities to prevent disease in and promote the health of populations. Such activities include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of protected health information. But such activities do not include those with any of the following purposes:
 - 1. To conduct an Investigation into any person for the mere act of seeking, obtaining, providing, or facilitating health care.
 - 2. To impose Liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care.
 - 3. To identify any person for any of the activities described at paragraphs (1) or (2) of this definition.

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Clarifications

- Personal Representatives:
 - A covered entity does not have to treat a person as a personal representative if it has a reasonable belief that the individual has been or may be subjected to domestic violence, abuse, or neglect by the person or that treating the person as a personal representative could endanger the individual
 - The covered entity does not have a reasonable belief if the basis for their belief is the provision or facilitation of reproductive health care by the person for and at the request of the individual.
- Permissible Disclosures about Victims of Abuse, Neglect, or Domestic Violence:
 - Clarifying that provision or facilitation of reproductive health care by itself is not abuse, neglect, or domestic violence.

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Compliance Dates, Next Steps, and Challenges Ahead

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Compliance deadlines

- December 23, 2024 (Merry Christmas), except...
- February 16, 2026 (Happy Valentine's Day), for changes to notice of privacy practices.



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Next Steps – Covered Entities

- Revise policies and procedures.
- Train relevant workforce (e.g., release of information department) on the details, including on:
 - Identifying and avoiding a prohibited disclosure;
 - Recognizing PHI that potentially relates to reproductive health care; and
 - Obtaining and evaluating attestations.
- Train workforce on general requirements



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Next Steps – Covered Entities

- Prepare for educating third parties of new requirements.
- Revisit risk analysis for risk of impermissible disclosures of PHI potentially related to reproductive health care.
- Revise notice of privacy practices.
 - Follow material change requirements.
 - BAAs may require informing business associates.



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Next Steps – Business Associates

- Like Covered Entities,
 Business Associates have direct compliance obligations under the amendment.
 - Unusual for Privacy Rule.
- Consider revising policies and procedures.
- Consider training relevant workforce.
- Review BAAs.
- Prepare for informing third parties of new requirements.



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Next Steps – Covered Entity and Business Associate Arrangements

- Review existing Business Associate Agreements and templates.
 - Depending on the BAA language, modifications may be needed.
- Verify whether any reporting is necessary under the BAA.
 - For example, does the Covered Entity have to inform the Business Associate of changes to how the Business Associate uses and discloses PHI?
- Conversation so all parties are on the same page.



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Challenges Ahead

- Identifying when PHI may "potentially relate" to reproductive health care.
 - Could be peppered through a medical record, e.g., medication list, medical history...
 - Some business associates may not have visibility into nature of PHI.
- Refusing or challenging government and other requests that are contrary to prohibition or do not include attestation.
- Determining when it is unreasonable to believe an attestation.



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United States District Court Northern District of Texas Lubbock Division

VII. DEMAND FOR RELIEF

Texas respectfully requests that the Court:

- a. Declare that the 2000 Privacy Rule and the 2024 Privacy Rule violate the Administrative Procedure Act because they exceed statutory authority;
- b. Declare that the 2000 Privacy Rule and the 2024 Privacy Rule violate the Administrative Procedure Act because they are arbitrary and capricious;
- c. Vacate and set aside the 2000 Privacy Rule and the 2024 Privacy Rule and permanently enjoin Defendants from enforcing them;
- d. Grant Texas an award of attorneys' fees and other litigation costs reasonably incurred in this action; and
- e. Grant Texas such other relief as the Court deems just and proper and as justice so requires.

effective in 2001. This lawsuit challenges the portion of the 2000 Privacy Rule that purports to

limit disclosures to State investigators (45 C.F.R. § 164.512(f)(1)(ii)(C)).

3. The second is entitled "HIPAA Privacy Rule to Support Reproductive Health Care

Privacy," 89 Fed. Reg. 32,976 (April 26, 2024) (the "2024 Privacy Rule") and became effective

on June 25, 2024.

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Questions

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