

The HIPAA Privacy Rule Post-Dobbs: Understanding the Proposed Rule Changes

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Overview



- Current Privacy Law Framework
- Purpose and Scope of Proposed HIPAA Privacy Rule Changes
- Practical Implications for Health Care Providers
- Patient Civil Liberties
- Comments from HHS Advisory Body
- State Privacy Law Initiatives

Current Privacy Law Framework



HIPAA Privacy Rule Fundamentals



- Basic prohibition:
 - "Covered entities" (health care providers and health insurance plans) and their service providers ("business associates") may not use or disclose individually identifiable health information ("protected health information" or "PHI") except:
 - when the individual to whom the PHI pertains provides a valid written authorization; or
 - pursuant to one of certain specified exceptions in the Privacy Rule.
- Exceptions: PHI may be used or disclosed for purposes of, among other things:
 - Complying with laws or regulations
 - Obeying court or administrative orders
 - Responding to subpoenas, warrants, summons, or authorized investigative demands

Permissive v. Mandatory Disclosures



- Although Privacy Rule *allows* disclosures of PHI to comply with court orders, law enforcement warrants and subpoenas,
 - The Rule is *permissive*
 - Each covered entity may make its own decision about a permitted disclosure
 - Only the minimum amount of PHI necessary to fulfill a permissible purpose may be disclosed, except as required by law.
- The HIPAA Privacy Rule does not require any disclosures of PHI except:
 - To the individual who is the subject of the PHI, upon request
 - To the Secretary of HHS to determine compliance

Contrasting State Law Example: California



- The California Confidentiality of Medical Information Act (CMIA) generally parallels the HIPAA Privacy Rule
 - Prohibits uses and disclosures of personal health information without a written authorization of the individual who is the subject of the information
 - Provides for various exceptions for public policy purposes
- BUT the CMIA mandates disclosures where:
 - Compelled by a court order or investigative subpoena
 - Compelled by a search warrant lawfully issued to a governmental law enforcement agency
 - Otherwise specifically required by law

CMIA Amendments Post-Dobbs



- Post-Dobbs, the CA Legislature amended the CMIA to prohibit health care providers and employers from:
 - releasing personal health information about an individual seeking or obtaining an abortion in response to a subpoena or request if that subpoena or request is based on either:
 - another state's laws that interfere with a person's rights under the CA Reproductive Privacy Act, or
 - a foreign penal civil action.
 - o releasing any such information to law enforcement for purposes of enforcement of any such other state's law or a foreign penal civil action.

The NPRM: Purpose and Scope



Need for the Rulemaking



- Post-Dobbs, HHS Office for Civil Rights (OCR) issued guidance explaining the non-mandatory nature of the Privacy Rule's provisions regarding disclosures of PHI where required by law or order
- Heard concerns from health care entities that stronger regulation is necessary to protect reproductive health care privacy
- OCR also held listening sessions
 - o providers nationwide
 - major medical associations (AHA, AMA, AAFP, ACOG, AAP)
 - abortion providers

Need for the Rulemaking (cont'd)



- Providers flagged where PHI is being used to target doctors and patients
- Without federal intervention, the targeting of PHI will likely continue

Proposed Modifications to the HIPAA Privacy Dula



- NPRM released on April 12, 2023
- Public comment period closed on June 16, 2023
- HHS received ~25,900 comments



23506

Federal Register/Vol. 88, No. 73/Monday, April 17, 2023/Proposed Rules

DEPARTMENT OF HEALTH AND **HUMAN SERVICES**

Office of the Secretary

45 CFR Parts 160 and 164 RIN 0945-AA20

HIPAA Privacy Rule To Support Reproductive Health Care Privacy

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking: notice of Tribal consultation.

SUMMARY: The Department of Health and Human Services (HHS or "Department") is issuing this notice of proposed rulemaking (NPRM) to solicit comment on its proposal to modify the Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule") under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology

by any of the following methods. Please do not submit duplicate comments.

To participate in the Tribal consultation meeting, you must register in advance at https:// www.zoomgov.com/meeting/register/ vIItf-2haD8iHfdtmYaUoWidv9 odBZMYO4O.

- · Federal eRulemaking Portal: You may submit electronic comments at http://www.regulations.gov by searching for the Docket ID number HHS-OCR-0945-AA20. Follow the instructions at http://www.regulations.gov for submitting electronic comments. Attachments should be in Microsoft Word or Portable Document Format (PDF).
- · Regular, Express, or Overnight Mail You may mail written comments to the following address only: U.S. Department of Health and Human Services, Office for Civil Rights, Attention: HIPAA and Reproductive Health Care Privacy NPRM, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue

Docket ID number HHS-OCR-0945-AA20.

FOR FURTHER INFORMATION CONTACT: Lester Coffer at (202) 240-3110 or (800) 537-7697 (TDD).

SUPPLEMENTARY INFORMATION: The discussion below includes an Executive Summary, a description of relevant statutory and regulatory authority and history, the justification for this proposed regulation, a section-bysection description of the proposed modifications, and a regulatory impact analysis and other required regulatory analyses. The Department solicits public comment on all aspects of the proposed rule. The Department requests that persons commenting on the provisions of the proposed rule label their discussion of any particular provision or topic with a citation to the section of the proposed rule being addressed and identify the particular request for comment being addressed, if applicable.

I. Executive Summary

Key Proposals in NPRM



- Prohibit regulated entities from using or disclosing PHI for a criminal, civil, or administrative investigation into or proceeding against any person for
 - seeking
 - o obtaining
 - o providing, or
 - o facilitating
- reproductive health care in certain circumstances

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Proposed Prohibition



- Prohibition applies only where the investigation or proceeding is in connection with reproductive health care that:
 - Is provided outside of the state where the investigation or proceeding is authorized and where such health care is lawful in the state in which it is provided (TX v. CO)
 - o Is protected, required, or authorized by federal law, regardless of the state in which such care is provided (EMTALA)
 - Is provided in the state where the investigation or proceeding is authorized and that is permitted by the law of the state in which the health care is provided

Key Proposals in NPRM



 Prohibit regulated entities from using or disclosing PHI to identify any person to initiate such an investigation or proceeding (same restrictions)

 Require a signed attestation for PHI potentially related to reproductive health care that the request is not for a prohibited purpose.

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Proposed Rule of Construction



 No prohibition on use or disclosure of PHI otherwise permitted unless it is primarily for the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care

• Examples:

- In defense of a person, including a regulated entity, against a lawsuit for providing lawful reproductive health care
- Against a person for knowingly submitting a false claim for reproductive health care for payment to the government

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Proposed Attestation



- Require covered entity (or its business associate) to obtain a signed attestation from the person requesting PHI potentially related to reproductive health care, if the PHI is requested for any of the following purposes:
 - Health oversight activities
 - Judicial and administrative proceedings
 - Law enforcement purposes
 - To coroners or medical examiners
- Attestation may be electronic
- Attestation may not be combined with another document

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Practical Implications: Provider Perspectives

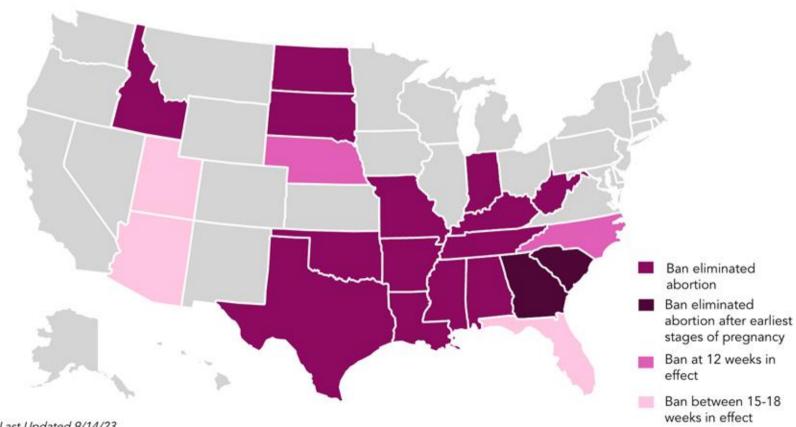




- 1. State of Abortion Restrictions post-*Dobbs*
- 2. Case example
- 3. PPFA Comments
- 4. Republican Attorneys General Comments



Abortion Bans Status





OBGYN Experiences Post-Dobbs



- 68% of respondents said Dobbs worsened their ability to manage pregnancy-related emergencies
- 64% said Dobbs worsened pregnancy-related mortality
- 70% said the decision worsened racial and ethnic inequities in maternal health.
- Half of ob-gyns in states with bans reported having a patient who was unable to get an abortion they sought.*
- More than half of OBGYNs practicing in states with gestational limits (59%) and abortion bans (61%) are concerned about their own legal risk when making decisions about patient care and the necessity of abortion

Kaiser Family Foundation National Survey, June 2023

Fund Texas Choice v. Paxton et al.



The Dallas Morning News

NEWS PPOLITICS

Why Texas abortion funds are on pause after the end of Roe vs. Wade

Many Texans need financial help as they seek services in other states, but legal questions abound.



Abortion rights supporters gather at the Dallas City Hall after marching in downtown Dallas on Wednesday, June 29, 2022, (Lola Gomez / Staff Photographer)

Statement in Fund Texas Choice v. Paxton et al.



"[C]riminalization is a means to an end—the protection of human life, including the life of the unborn. That interest continues whether the Texan mother seeks an abortion in Denver or Dallas, in Las Cruces or Lamesa. When that procurement takes the form of a bus ticket for the pregnant Texan to an abortion clinic, or the paying from Texas of the cost of a pregnant Texan's hotel room adjacent to that clinic, it does not matter if the travel and hotel are in Albuquerque or Austin—the procurement in Texas of the means of an abortion has intruded upon the State's interest in the protection of human life."

(Def. Paxton et al Mot. Dismiss, Dkt. 110, at 24).

Demands for Data from Abortion Funds



Texas lawyer asks abortion funds for details of every procedure since 2021

Architect of state's six-week ban asks for information including identity of people who may have helped patient get abortion



Abortion rights protesters march outside the Texas state capitol in Austin. Photograph: The Washington Post/Getty Images

Fund Texas Choice Case – Discovery Requests



Sept. 12, 2023: Defendant served each Plaintiff with extensive discovery requests

INTERROGATORIES

Interrogatory No. 1: Identify every abortion that you have assisted or facilitated in any way since September 1, 2021. This includes every abortion that you paid for in whole or in part, subsidized in any way, or reimbursed or defrayed the costs of, including payments, subsidies, or reimbursements made for travel costs, lodging, child care, or any other cost or expense associated with an abortion or a person's efforts to obtain an abortion. This also includes abortions for which you provided any type of practical, logistical, and emotional support.

For each of these abortions, provide the following information:

- a. The date or dates (or the approximate dates) on which the abortion occurred;
- The name, address, and telephone number of the abortion provider who performed the abortion or provided the abortion-inducing drugs;
- c. The method by which the abortion was performed, i.e., whether the abortion was a surgical abortion (sometimes called procedural abortion) or a drug-induced abortion (sometimes called a "medication" abortion).
- d. Whether the abortion was self-managed, i.e., whether the woman who aborted or who sought to abort her unborn child did so without the assistance or supervision of licensed medical professionals;
- e. The gestational age (or approximate gestational age) of the fetus that was aborted;

- f. The city and state of residence of the woman who aborted or who sought to abort her unborn child;
- g. If the abortion was a drug-induced abortion, the locations where each of the abortion pills was ingested or swallowed by the woman who aborted or who sought to abort her unborn child;
- The identity of every person at Fund Texas Choice, and every person associated in any way with Fund Texas Choice, who was involved in assisting or facilitating the abortion;
- The precise manner in which Fund Texas Choice assisted or facilitated the abortion;
- j. If Fund Texas Choice assisted the abortion by paying for or facilitating abortion-related travel, describe where the abortion-related travel began and ended and identify every county in Texas where the abortion-related travel passed through.

Fund Texas Choice Case-Discovery Requests (cont'd)

- Privacy+ Security Forum
- k. The identity of every person, other than the woman who aborted or who sought to abort her unborn child and her family members, who assisted or facilitated the abortion in any way, and describe how that person assisted or facilitated the abortion.
- 1. The identity of every person who assisted or facilitated the abortion by: (a) using the mails for the mailing, carriage in the mails, or delivery of: (i) any article or thing designed, adapted, or intended for producing abortion, or (ii) any article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion; or (b) using any express company or other common carrier or interactive computer service for carriage in interstate or foreign commerce of any drug, medicine, article, or thing designed, adapted, or intended for producing abortion, or knowingly taking or receiving, from such express company or other common carrier or interactive computer service, any such matter or thing.
- m. The identity of every person who performed any act within the state of Texas that "procured" the abortion, regardless of where the abortion ultimately took place, and describe how that person "procured" the abortion. The word "procure" is to be interpreted to encompass each of the first two meanings assigned in Black's Law Dictionary, 11th edition: "procure vb. (14c) 1. To obtain (something), esp. by special effort or means. 2. To achieve or bring about (a result)."

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PPFA Comments on HHS Proposed Rule





- Recommend maintaining in a final rule:
 - A broad definition of reproductive healthcare
 - The protections for providers, patients, and their assisters
 - The clear explanations of proper and improper uses of repro health care data

PPFA Recommendations for Proposed Rule







- Define repro health care at the encounter v. service level for the purposes of disclosures
- Strengthen attestation requirements concerning lawfulness of care to support regulated entities' compliance with the rule
- Require requesters to be specific about the PHI they are requesting
- Strengthen attestation requirements to prevent third parties from misusing PHI

PPFA Additional Recommendations





- Add specific data protections for gender affirming care
- OCR should work with other agencies to create penalties for violations of the rule by requesters

Potential Legal Challenge?



"There is "absolutely" a potential for legal challenges, said Roger Severino, who served as the head of HHS' Office for Civil Rights under former President Donald Trump and is now vice president of domestic policy at the Heritage Foundation. "I would imagine, at the very least, that a challenge would come from state attorneys general, because the administration is interfering with their ability to enforce their own laws."

- Politico, July 18, 2023



Comments of Republican Attorneys General



AGs from 18 states:

Alabama, Alaska, Arkansas, Georgia, Idaho, Indiana, Kentucky, Louisiana, Missouri, Montana, Nebraska, North Dakota, Ohio, South Carolina, South Dakota, Tennessee, Texas, and Utah

- "The proposed rule defies the governing statute, would unlawfully interfere with States' authority to enforce their laws, and does not serve any legitimate need."
- Framing: "the Biden Administration" has "sought to wrest control over abortion back from the people and their elected representatives."
- Take issue with the basic idea that abortion is a form of health care



Patient Civil Liberties



ACLU Recommendations for Proposed Rule



- Prohibit PHI related to gender affirming health care;
- Prohibit disclosure of all PHI in response to a request for a prohibited purpose;
- Explicitly limit the definition of "public health";
- Strengthen the attestation requirement, including by adding a notice provision and prohibiting derivative or secondary uses;
- Consider protections for individuals who request their own PHI at the request of law enforcement; and
- Protect access to protected health information for defensive purposes.

Our Focus Today



- Prohibit disclosure of all PHI in response to a request for a prohibited purpose.
- Strengthen the attestation requirement, including by adding a notice provision and prohibiting derivative or secondary uses.

Protect All PHI In Covered Circumstances



"Prohibiting the disclosure of all PHI if it is for a prohibited purpose will make the Rule easier to enforce and more effective. The Department already recognizes the challenges of segregating health information related to reproductive health care, particularly as "many types of PHI may not initially appear to be related to an individual's reproductive health but may in fact reveal information about an individual's reproductive health or reproductive health care." For example, weight gain, nausea and vomiting, high blood pressure, and glucose found in urine may all be indications of particular pregnancy conditions "

Strengthen the Attestation Requirement



- Require notice to the individual
- Prohibit derivative or secondary prohibited uses of protected health care information
- Liability for misrepresentations in attestations

"[T]he Proposed Rule should be amended to require the requesting entity to attest... that the requestor will not later use or disclose PHI for a prohibited purpose, even if such later use or disclosure is not contemplated at the time of the initial request."

Comments from HHS Advisory Body



Role of NCVHS



- HHS requested comments on the NPRM from the National Committee on Vital and Health Statistics (NCVHS)
 - NCVHS is the HHS Secretary's advisory body on health data, statistics, national health information policy, privacy, and HIPAA
- NCVHS made recommendations on which the original Privacy Rule is largely based.
- In the 2006-2010 NCVHS made a series of recommendations on especially sensitive information in medical records, including reproductive health.

NCVHS Comments on Breadth of NPRM



- To reduce the likelihood health records may be employed to harm patients or others for seeking, obtaining, providing, or facilitating health care, HHS should consider not making a distinction between care provided that is illegal v. legal.*
- HHS should consider prohibiting disclosures for a criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating any health care, not just reproductive health care
 - o or consider reworking **the definition of "reproductive health care**" to include specific, encompassing, and clear terms.

^{*} Emphasis added

NCVHS Comments on Attestations



- HHS should consider requiring attestations for all requests for PHI, rather than limiting the requirement to requests that are "potentially related to reproductive health care" because the definition is so broad that in practice it would approach encompassing all PHI
 - or consider reworking the definition of "reproductive health care" to include specific, encompassing, and clear terms and provide examples of diverse types of reproductive health care.
- HHS should consider requiring that attestations include a statement that the recipient of health records pledges not to **redisclose** the records to another party for any of the prohibited purposes named in the attestation

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NCVHS Comments on Broad Impact of NPRM



- HHS should consider clarifying the relationship between the Privacy Rule's definitions of "public health" (as it applies to surveillance, investigation, and intervention) and "civil or authorized investigative demands" to ensure the rule does not produce unintended consequences on public health activities.
- HHS should consider addressing the relationship of the rule to health information access and exchange, including in telehealth, telemedicine, medical devices, apps, wearables, interoperability, information blocking, and the 21st Century Cures Act Trusted Exchange and Common Agreement (TEFCA).

Comments of NCVHS



- HHS should consider specifying language for the Notice of Privacy Practices in plain language that is clear and understandable to all patients.
- HHS should examine whether the definition of "de-identified data" in the proposed rule is appropriate and should consider NCVHS's recommendations on de-identified data made in 2017

State Privacy Law Initiatives



Washington State My Health My Data Act



1.

- Requires explicit consent to collect, use, or share consumer health data except as needed to provide a requested product or service to the consumer
- "Consumer health data" includes:
 - Reproductive or sexual health information
 - Precise location information that could reasonably indicate a consumer's attempt to acquire or receive health services or supplies;
 - o Data that identifies a consumer seeking health care services; or
 - Any information used to associate a consumer with health data, such as proxy, derivative, inferred, or emergent data by any means, including algorithms or machine learning).

Geofencing Prohibitions



- Washington State, Connecticut, Nevada and New York all prohibit "geofencing" around a facility that provides health care services.
- "Geofencing":*
 - Employing technology that uses global positioning coordinates, cell tower connectivity, cellular data, radio frequency identification, Wifi data, and/or any other form of spatial or location detection to establish a virtual boundary around a specific physical location, or to locate a consumer within a virtual boundary.
 - o For purposes of this definition, "geofence" means a virtual boundary that is 2,000 feet or less from the perimeter of the physical location.

^{*} Washington State definition

California Consumer Privacy Act Amendment



- CCPA generally permits disclosures of personal information in order to:
 - Cooperate with a government agency request for emergency access to a consumer's personal information if a natural person is at risk or danger of death or serious physical injury
 - o Collect, sell, or share a consumer's personal information if every aspect of that commercial conduct takes place wholly outside of California.
- As amended in 2023:
 - o a consumer accessing, procuring, or searching for services regarding contraception, pregnancy care, and perinatal care, including, but not limited to, abortion services, **shall not constitute** a natural person being at risk or danger of death or serious physical injury.
 - The exemption for out-of-state collection, selling or sharing does not apply if the consumer's personal information contains information related to accessing, procuring, or searching for services regarding contraception, pregnancy care, and perinatal care, including, but not limited to, abortion services.

HIPAA Privacy Rule NPRM Resources



- NPRM may be viewed or downloaded at:
 - https://www.federalregister.gov/documents/2023/04/17/2023-07517/hipaa-privacy-rule-tosupport-reproductive-health-care-privacy
- NPRM Fact Sheet may be viewed or downloaded at:
 - o https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/hipaa-reproductive-healthfact-sheet/index.html
- Comments on the NPRM may be viewed at:
 - o https://www.regulations.gov/document/HHS-OCR-2023-0006-0001
- OCR updates on HIPAA rulemaking, guidance, and enforcement activities:
 - https://www.hhs.gov/hipaa/for-professionals/list-serve/
- HHS Reproductive Health Care website:
 - https://reproductiverights.gov/

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