Assessing The Future Of The HIPAA Reproductive Health Rule

By **Liz Heddleston** (October 20, 2025)

Entities regulated by the Health Insurance Portability and Accountability Act continue to face uncertainty regarding the fate of the HIPAA Privacy Rule to Support Reproductive Health Care Privacy, following a decision from the <u>U.S. District Court for the Northern</u> <u>District of Texas</u> that **<u>struck down</u>** most of the reproductive health rule in Purl v. U.S. Department of Health and Human Services on June 18.

In Purl, the court declared most of the reproductive health rule unlawful and issued a nationwide injunction releasing HIPAAregulated entities from having to comply with the rule's requirements related to reproductive health information. Purl vacated the reproductive health rule almost one year after it became effective on June 25, 2024.

These developments have led to uncertainty and compliance challenges for HIPAA-regulated entities. Following the adoption of the reproductive health rule, many HIPAA-regulated entities devoted significant legal and compliance resources to updating their privacy practices and processes to comply with the enhanced protections for reproductive health information.

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After the Purl decision, regulated entities need to unwind compliance updates related to reproductive health information to ensure compliance with other laws, such as the information blocking rule.

The reproductive health rule, and its subsequent reversal under Purl, has placed regulated entities in the middle of a chaotic legal landscape following the overturning of Roe v. Wade. The complexity is heightened by the patchwork of state laws that now apply to abortion, gender-affirming care and similar issues.

Background on the Reproductive Health Rule

Since its passage in 1996, HIPAA has been regarded as a largely neutral framework designed to protect patient privacy, while allowing for the necessary flow of information for treatment and other purposes. Its emphasis on data security and patient rights has consistently earned bipartisan support and broad acceptance within the health care community.

Enacted under the Biden administration, the reproductive health rule effectively placed HIPAA at the center of the culture wars regarding reproductive healthcare.

The stated goal of the reproductive health rule was to amend the HIPAA privacy rule to strengthen privacy protections for patients' reproductive health information following the <u>U.S. Supreme Court</u>'s 2022 decision in Dobbs v. Jackson Women's Health Organization, which overturned Roe v. Wade and ended the federal constitutional right to abortion.

According to an April 2024 fact sheet published by the U.S. Department of Health and Human Services — the agency that issued the regulations and is responsible for enforcing HIPAA — the reproductive health rule was intended to "protect access to and privacy of

reproductive health care after the Supreme Court's decision in Dobbs," which HHS stated has "led to extreme state abortion bans and other restrictions on reproductive freedom."

The reproductive health rule amendments moved HIPAA into more partisan territory, and quickly led to legal challenges. The universal injunction issued in Purl has put a pause on the reproductive health rule, at least for now.

With respect to the reproductive health-related provisions that were vacated in Purl, HHS stated on its website that it will "determine next steps after a thorough review of the court's decision." HHS has not formally withdrawn or amended the reproductive health rule.

The Purl decision arrived just nine days before the U.S. Supreme Court decision in Trump v. CASA Inc., which held that federal courts lack statutory authority under the Judiciary Act of 1789 to issue nationwide injunctions blocking executive orders beyond an individual plaintiff's case.

Significantly, the Northern District of Texas' universal injunction of the reproductive health rule continues to have nationwide effect. The Supreme Court in CASA expressly declined to address the issue of whether federal courts have the authority to issue universal injunctions to block a federal agency rule or action under the Administrative Procedure Act.

The Purl decision forecasted that the Supreme Court may eventually weigh in on this issue, citing a concurring opinion in U.S. v. Texas, in which Justices Neil Gorsuch, Clarence Thomas and Amy Coney Barrett wrote that whether the APA authorizes vacatur is not open and shut, and that there are "thoughtful arguments and scholarship" on both sides.

As long as the universal injunction in Purl remains in effect, regulated entities do not have to comply with the reproductive health rule's provisions regarding reproductive health information.

However, in a notice currently posted on its website, HHS stated that the reproductive health rule's amendments to the HIPAA privacy rule concerning substance use disorder information remain in effect with a compliance deadline of Feb. 16, 2026.

The amendments require covered entities that handle substance use disorder records governed by Title 42 of the Code of Federal Regulations, Part 2, to revise their notice of privacy practices to include specific disclosures about how those records may be used and disclosed, and patients' rights concerning those records.

In addition, HIPAA's core privacy rule requirements remain intact. Regulated entities must continue to abide by the privacy rule's long-standing requirements governing the use and disclosure of protected health information.

Breaking Down the Key Issues in Purl

The vacated portion of the reproductive health rule prohibits the use or disclosure of protected health information related to reproductive healthcare for the purpose of conducting criminal, civil or administrative investigations, or imposing liability on individuals seeking, obtaining, providing or facilitating legal reproductive healthcare.

The rule's broad definition of reproductive healthcare encompasses protected health information related to a wide range of reproductive health services, such as contraception, pregnancy-related care, fertility and infertility treatments, and gender-affirming care.

To strengthen patient privacy protections, the vacated portion of the rule prohibits covered entities from disclosing protected health information that is potentially related to reproductive healthcare unless they first obtain a signed attestation from the requester affirming that the protected health information will not be used for prohibited purposes.

The attestation requirement applies when the requested protected health information is for: (1) healthcare oversight activities; (2) law enforcement purposes; (3) judicial and administrative proceedings; and (4) disclosures to coroners and medical examiners.

The attestation requirement posed operational and compliance challenge for covered entities, who were at risk of running afoul of the reproductive health rule if they disclosed protected health information potentially related to reproductive healthcare without first obtaining a valid attestation.

In practice, this required covered entities to develop a process of identifying and withholding any PHI "potentially related" to reproductive healthcare unless a compliant attestation was received. The broad and ambiguous scope of PHI that could potentially fall into this bucket could lead covered entities to take a conservative approach and withhold more PHI than necessary.

In a 64-page opinion, the court in Purl struck down these provisions — and related requirements related to protected health information concerning reproductive healthcare — because it found that HHS exceeded its statutory authority in promulgating the reproductive health rule.

Among several grounds for invalidating the rule, the court found that the rule was impermissibly designed to "accomplish political ends like protecting access to abortion and gender-transition procedures," which falls outside the scope of authority of a federal agency.

The opinion focused heavily on the tension between federal privacy protections, such as the reproductive health rule, and state public health laws. The decision raised concerns that the reproductive health rule could lead to restrictions in disclosures of protected health information even when state law might otherwise require reporting or access.

By scrutinizing how the federal rule interacted with authority of the states, the court's decision reflects how the reproductive health rule transformed the HIPAA privacy rule from a primarily technical privacy regime into a flashpoint in political and legal debates over reproductive healthcare.

In Purl, the plaintiffs included Carmen Purl, a physician, and his outpatient medical clinic, which regularly treats children, young women and pregnant women for a range of medical issues.

The clinic also regularly treats child abuse victims and routinely responds to requests from Texas Child Protective Services when it investigates suspected child abuse. The rationale is that certain public safety objectives, such as protecting children, take precedence over patient privacy protections.

In the lawsuit, Purl argued that the reproductive health rule would impair her ability to comply with its state-mandated obligation to report child abuse or participate in public health investigations.

The HIPAA privacy rule has a long-standing exception that allows covered entities to disclose protected health information to government authorities, such as child protective services, that are authorized by law to receive reports of child abuse.

While the reproductive health rule did not amend the exception for disclosure related to child abuse, Purl argued that the reproductive health rule prevented her from fulfilling her state-mandated duty to report suspected child abuse by imposing "layers of 'incomprehensible standards'" that limit or prevent her ability to make such reports.

The reproductive health rule's prohibition on disclosing protected health information related to reproductive healthcare for certain prohibited purposes only applies if the care was lawfully obtained, and allows covered entities to presume that the care was lawful unless the regulated entity has actual knowledge that the care was not lawful.

Noting that the legal landscape governing abortion and other reproductive health issues is rapidly evolving, the court found that requiring a covered entity to determine whether reproductive healthcare is lawful under federal, state or constitutional law involves nuanced legal judgments and raises an "intolerable impediment to disclosing that ... information under a public health law."

This analysis underscores the court's concern that the rule imposes undue legal and administrative burdens on covered entities, a significant factor in its decision to invalidate much of the rule.

The court also argued that the reproductive health rule's attestation requirement imposes "bureaucratic barricades" on states exercising their "lawful public health investigation power."

The court asserted that the reproductive health rule prohibits covered entities from reporting child abuse if such a report is based solely on reproductive healthcare. It also found that the rule "prohibits States from ever considering reproductive health alone as abuse or part of a public health investigation."

Ultimately, the court viewed the reproductive health rule as potentially overriding or constraining state public health law. States have long-standing authority to investigate child abuse and perform other public health activities, and the rule's restrictions on protected health information disclosures could interfere with that authority.

The opinion illustrates a fundamental clash: the federal interest in protecting patient privacy versus state interest in enforcing public health laws. This tension is central to why the court ultimately vacated much of the rule.

This case is a harbinger for future conflicts between federal privacy laws and state laws governing abortion, gender-affirming care and other reproductive health issues. Tensions are likely to continue for the foreseeable future.

Enforcement Risk and Compliance in the Future

At least temporarily, HIPAA-regulated entities are relieved from having to comply with the rule's provisions related to protected health information involving reproductive health. The only provisions still in effect are the completely unrelated requirements related to substance use disorder records and Title 42 of the Code of Federal Regulations, Part 2.

HHS has not yet formally withdrawn or amended the reproductive health rule. As a result, additional guidance may be forthcoming.

Although the reproductive health rule was struck down, HIPAA still imposes significant compliance obligations on covered entities and business associates to protect the privacy and security of PHI.

HIPAA enforcement activity has remained active under the Trump administration, with HHS continuing to actively investigate and enforce violations of HIPAA. Thus far, HHS has announced at least 13 HIPAA settlement actions and fines in 2025, with more potentially to come by the year's end.

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