Federal Judge Vacates HIPAA Reproductive Health Care Privacy Rule

Amita Sanghvi and Kristen Rosati, Coppersmith Brockelman PLC
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On June 18, 2025, the U.S. District Court for the Northern District of Texas struck down a key rule issued by the U.S. Department of Health and Human Services (HHS) that strengthened privacy protections for protected health information (PHI) related to reproductive health care under the HIPAA regulations. The decision in *Purl v. Dep't of Health and Human Servs.* [1] vacates the rule nationwide,[2] except for provisions updating Notice of Privacy Practices (NPPs) related to the Part 2 substance use disorder (SUD) treatment records.[3]

Vacating the 2024 Rule lifts compliance burdens for many covered entities, including the need to obtain attestations from requestors for records that may contain reproductive health-related PHI and to determine when the prohibition of disclosures applies. While some entities must still update their NPPs for the Part 2 SUD provisions, covered entities will not be required to update their NPPs related to reproductive health care.

Background and Decision

The 2024 "HIPAA Privacy Rule to Support Reproductive Health Care Privacy"[4] (the 2024 Rule) aimed to strengthen privacy protections for records related to lawful reproductive health care by prohibiting the use or disclosure of such records for investigations or actions related to that care. Specifically, the 2024 Rule prevents PHI from being used to investigate or impose liability on individuals for seeking, providing, or facilitating lawful reproductive health care, or to identify individuals in connection with such investigations.

Judge Matthew J. Kacsmaryk ruled that the 2024 Rule unlawfully preempted state public health laws by prohibiting reporting of child abuse, violating the Administrative Procedure Act (APA).[5] The court found that the 2024 Rule's interpretation of HIPAA's preemption provisions was too narrow and conflicted with Congress's directive to protect state public health and child abuse investigations, even though the prohibition only applied where the act of alleged abuse is based solely on lawfully provided reproductive health care.[6]

The court also found that HHS exceeded its statutory authority by defining "person" to include only "natural persons (meaning a human being who is born alive)," emphasizing that some states confer legal status on fetuses for child abuse reporting purposes, and as such, under the Dictionary Act,[7] federal regulations "cannot be construed to 'deny' 'legal status'" to them.[8] Additionally, the court found that HHS impermissibly interpreted "public health" and concluded that the statute does authorize HHS to preempt state laws that define and regulation public health activities.[9]

Finally, the court invalidated the 2024 Rule under the "major questions doctrine," which limits agency authority over politically significant matters without clear Congressional authorization.[10] First finding that the regulation

was a matter of political significance, the court then characterized the broad authority granted to the Secretary under the HIPAA statute as too vague to grant "clear congressional authority" to the Secretary to create differing standards to "highly sensitive forms" of PHI, such as PHI related to reproductive health care. This finding may have significant implications for future rulemaking under the HIPAA statute, given the lack of specificity in the statute.

It remains to be seen if the federal government will appeal the *Purl* decision,[11] or whether non-parties will be allowed to intervene to appeal. Of course, HHS may also decide to withdraw the 2024 rule immediately, without notice and comment, in line with a White House memorandum[12] directing agencies to repeal unlawful regulations.

Other Related Legal Challenges

HHS faces additional challenges to the 2024 Rule, including lawsuits filed by the State of Missouri, a coalition of 15 states in Tennessee, and the Texas Attorney General in *State of Texas v. Dep't of Health and Human Servs.*, a separate challenge filed in the Northern District of Texas. While the latter lawsuit initially sought to vacate the entire original 2000 HIPAA Privacy Rule,[13] the Texas AG now moves only on his claims against the 2024 Rule.[14] On June 27, HHS and Texas filed a joint motion to stay this case while the government decides whether to appeal the decision in *Purl*.[15] If granted, the parties propose to file a joint status report by Aug. 25. If the *Purl* decision is not appealed, we anticipate the additional lawsuits will be dismissed.

Considerations for Regulated Entities

The vacatur of the 2024 Rule lifts compliance burdens for many covered entities, including the need to obtain attestations from requestors for records that may contain reproductive health-related PHI and to determine when the prohibition of disclosures applies. While some entities must still update their NPPs for the Part 2 SUD provisions, covered entities will not be required to update their NPPs related to reproductive health care.

However, the 2024 Rule gave shelter to regulated entities interacting with law enforcement or others seeking PHI related to reproductive health care by providing a clear legal basis to refuse disclosures of this PHI. Without the 2024 Rule in place, the HIPAA baseline protections remain in place, but navigating patient privacy in this context will become more complex.

It is important to note that the HIPAA regulations never *required* a covered entity to disclose PHI to law enforcement; rather, the rules *permit* such disclosures when "required by law" or in response to law enforcement requests that meet strict HIPAA regulatory conditions. Moreover, refusing to produce PHI is not a violation of the federal information blocking rule (IBR) where an exception applies. For example, under the recently finalized Protecting Care Access exception, it is not an IBR violation to withhold information that reduces a person's legal exposure for seeking, obtaining, providing or facilitating reproductive health care, so

long as the applicable regulatory conditions are met.[16] Additionally, refusing to disclose PHI is not an IBR violation, where a legal condition that permits the disclosure is not met under the HIPAA regulations, such as where an administrative request for the information is not specific or limited in scope.[17] As a result, regulated entities may still be able to withhold the disclosure of PHI of reproductive health care information, but they must carefully navigate federal and state law and weigh their patients' privacy interests against the legal risks of refusing to release requested information.

Amita Sanghvi and Kristen Rosati, Coppersmith Brockelman PLC

About the Authors

Amita Sanghvi advises clients on health data privacy, cybersecurity, and digital health innovation. Before returning to private practice, she served as a senior attorney at the U.S. Department of Health and Human Services, where she advised the Office for Civil Rights on administering and enforcing the HIPAA privacy, security, and breach notification rules. She now helps clients translate evolving regulatory requirements into practical strategies that support care delivery, protect patient trust, and advance innovation in health care.

Kristen Rosati is considered one of the nation's leading "Big Data" and HIPAA compliance attorneys. She has deep experience in data governance and strategy, data sharing for research and innovation, and biobanking and genomic privacy. Kristen is a Past President (2013-2014) and Fellow (2021) of the American Health Law Association (AHLA), the nation's largest health care legal organization. She has received numerous recognitions in Chambers USA, Best Lawyers in America and Super Lawyers, and has been recognized in "Most Outstanding Women in Business," "Most Influential Women in Arizona Business," and Arizona's Top 100 Lawyers.

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[1] N.D. Tex., 2:24-CV-228-Z, Jun. 18, 2025 (the "Decision").
[2] *Id*. at p. 58. Separately, on June 27, 2025, the Supreme Court limited the ability of federal judges to issue nationwide injunctions, but clarified the ruling did not apply to a separate legal question as to whether the Administrative Procedure Act (APA) authorizes federal courts to vacate agency action under its authority to hold an action unlawful and set it aside. *See* 5 U.S.C. §706(2). *Trump, et al. v. CASA, Inc., et al*., No. 24A884, note 10 (Jun. 27, 2025). Because the holding in *Purl* was based on this APA authority, the *CASA* limitation on nationwide injunctions does not apply to this case.
[3] 42 U.S.C. § 1320d-7(b).
[4] 89 Fed. Reg. 32976-01 (Apr. 26, 2024).
[5] 5 U.S.C. § 706(2), (2)(A).
[6] *Decision* at pp. 20-21.
[7] 1 U.S.C. § 8.
[8] *Decision* at p. 40.
[9] *Id*.
[10] *Id.* at pp. 46-56. Of note, Complainant did not raise that the 2024 Rule violated this doctrine in her Complaint. The Court instead raised this question *sua sponte* to "satisfy the specificity and scope requirements of any permanent relief." Mem. Op. & Order, 2:24-CV-228-Z, ECF No. 34, Dec. 24, 2024.

[11] HHS has 60 days from the date of the decision to appeal. The Department notes that it "will determine next steps after a thorough review of the court's decision." https://www.hhs.gov/hipaa/for-professionals/special-topics/reproductive-health/index.html.
[12] https://www.whitehouse.gov/presidential-actions/2025/04/directing-the-repeal-of-unlawful-regulations/
[13] "Standards for Privacy of Individually Identifiable Health Information," 65 Fed. Reg. 82,462 (Dec. 28, 2000).
[14] *State of Texas v. Dep't of Health and Human Servs.*, "Response and Motion for Partial Summary Judgment," N.D. Tex., 5:24-cv-00204, Jun. 9, 2025.
[15] *State of Texas v. Dep't of Health and Human Servs.*, "Joint Motion to Stay Proceedings," N.D. Tex., 5:24-cv-00204, Jun. 27, 2025.
[16] 45 C.F.R. § 171.206 (Protecting Care Access).
[17] See 45 C.F.R § 164.512(f)(1)(ii)(C)(2) and 45 C.F.R § 171.202(b) (Privacy Exception, pre-condition not satisfied sub-exception). To qualify for this IBR protection, the provider must implement this practice in a consistent and non-discriminatory way and document the practice in its organizational policies and procedures or on a case-by-case basis.