IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

Purl, M.D., et al.,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	**Civil Action No. 2:24-cv-228-Z**
	§	
United States Department of Health and Human Services, et al.,	§	
	§	
Defendants.	§	

PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Constitutional Provisions

Other Authorities

INTRODUCTION AND SUMMARY

Through the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Congress delegated authority to the Department of Health and Human Services ("HHS") to issue privacy standards. It instructed HHS to protect the privacy of *all kinds* of health information while allowing disclosure for appropriate purposes, like reporting child abuse or protecting public health. But last year, HHS put up content-based barriers around "reproductive health care" information. *See* HIPAA Privacy Rule to Support Reproductive Health Care Privacy, 89 Fed. Reg. 32,976 (Apr. 26, 2024) ("the 2024 Rule"). And rather than respect states' long-recognized authority to investigate crime and prevent abuse—as Congress instructed—HHS has created unlawful limits on compliance with state reporting procedures and investigations. This is unlawful. This Court should vacate the 2024 Rule because it is statutorily and constitutionally unlawful as well as arbitrary and capricious. *See* Pls.' Mot. Summ. J. [ECF No. 44].

Plaintiffs have explained that the 2024 Rule is statutorily unlawful for three reasons. *First*, it contradicts the restriction in its organic statute that HIPAA rules may not "limit" reporting procedures for abuse and public health. That alone led this Court to conclude the 2024 Rule is likely contrary to law. *See* Mem. Op. & Order, *Purl v. HHS*, No. 2:24-cv-228-Z, 2024 WL 5202497, at *8–10 (N.D. Tex. Dec. 22, 2024), ECF No. 34. *Second*, the 2024 Rule exceeds HHS's statutory authority, particularly under the major questions doctrine and federalism canon. It redefines statutory terms and creates a content-based regime for "reproductive health care" that has no statutory basis. *Third*, accepting HHS's interpretation would give rise to grave constitutional concerns. The agency's reading goes against federalism principles and the Vesting Clause, and the 2024 Rule's expansive standards alongside its criminal penalties raise serious vagueness concerns under the Due

Process Clause. *See* Pls.' Br. [ECF No. 45] at 19–37.[1] On top of that, the 2024 Rule is arbitrary and capricious. *See* Pls.' Br. at 37–39.

The Department of Health and Human Services, then-Secretary Becerra, and the other defendants moved to dismiss for lack of subject-matter jurisdiction and, in the alternative, for summary judgment. *See* Defs.' Mot. Dismiss or Summ. J. [ECF No. 39]; Defs.' Br. [ECF No. 40]. The Court should reject the idea that Dr. Purl and the Clinic cannot so much as challenge HHS's unlawful action. *See* Defs.' Br. at 11–16. Plaintiffs, after all, are objects of HIPAA and its regulations, and the 2024 Rule both requires them to act objectionably and forbids them from acting as they wish. They easily satisfy the injury-in-fact, causation, and redressability requirements for Article III standing. And Defendants' arguments on the merits are unavailing—the 2024 Rule is contrary to law and should be set aside.

BACKGROUND

In the 1990s, Congress enacted HIPAA to "improve portability and continuity" and "simplify the administration of health insurance." Pub. L. No. 104-191, 110 Stat. 1936, 1936 (1996). As Plaintiffs have discussed, Congress instructed HHS to recommend standards addressing, among other things, "[t]he uses and disclosures of [individually identifiable health] information that should be authorized or required." 42 U.S.C. § 1320d-2 note (Recommendations With Respect to Privacy of Certain Health Information) (memorializing Pub. L. 104-191, title II, § 264, 110 Stat. at 2033) ("HIPAA § 264(b)")); *see* Pls.' Br. at 6–8.

---

[1] To avoid repetition, this brief uses the notation "Pls.' Br. at [__]" to incorporate relevant pages of Plaintiffs' Brief in Support of Motion for Summary Judgment, ECF No. 45. Similarly, this brief uses the notation "Defs.' Br. at [__]" to refer to pages in Defendants' Brief in Support of Motion to Dismiss or, in the Alternative, for Summary Judgment, ECF No. 40.

The Secretary acknowledged that privacy standards would have to balance competing interests. *See Recommendations of the Secretary of Health and Human Services, pursuant to section 264 of the Health Insurance Portability and Accountability Act of 1996* (Sep. 10, 1997), https://perma.cc/FQ4S-Y45C ("*Recommendations*"). "On the one hand, patients have a legitimate need for assurance of the confidentiality that permits them to be frank with their physicians about their health conditions and behavior." *Id.* But "[o]n the other hand, participants in the health care system … have legitimate needs for access to health records," as do "those pursuing broad social purposes," such as "medical researchers, public health workers, [and] governmental policy makers." *Id.* So the Secretary recommended that disclosure be permitted for "public health, oversight of the health care system, research, and law enforcement." *Id.* Otherwise, privacy restrictions "would create significant obstacles in our efforts to fight crime, protect public health, or understand disease." *Id.* Indeed.

The Secretary could not have said otherwise. Congress forbade HHS from "constru[ing]" HIPAA "to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." 42 U.S.C. § 1320d-7(b). As this Court noted when granting preliminary relief, this provision is a "broad rule of construction that directs judges, regulators, and all others to make sure to protect laws that provide for the enumerated public health activities." 2024 WL 5202497, at *2, ECF No. 34 (quoting Barbara J. Evans, *Institutional Competence to Balance Privacy and Competing Values: The Forgotten Third Prong of HIPAA Preemption Analysis*, 46 U.C. Davis L. Rev. 1175, 1200 (2013)).

The Secretary also acknowledged in 1997 that HIPAA privacy standards would not appear on a blank slate. There were already "other Federal legal

protections that control how information about individuals is disclosed or used," the Secretary explained. *Recommendations*, *supra*. And many states had privacy laws, including "statutes to protect information about HIV infection and AIDS patients, and about mental health patients, designed after wide public debate to suit local needs." *Id.* The Secretary recommended creating a "meaningful minimum floor of privacy protections in Federal law for all types of health information." *Id.* This floor "would ensure that everyone has an adequate level of privacy protection, and if the people of the several States wish more, or see special privacy needs which are not being met, they can retain or enact additional safeguards." *Id.* The Secretary noted that "additional types of particularly sensitive information may be identified for special protection in the future," and stated that the agency "look[ed] forward to working with the Congress in determining when such protections are appropriate." *Id.*

As this Court has noted, "Congress did not meet its deadline" to set out privacy standards by statute. 2024 WL 5202497, at *2, ECF No. 34. So it fell to HHS to enact privacy regulations. *See* HIPAA § 264(b). Issued in 2000, HHS's Privacy Rule created a "federal floor" of privacy protections, *see* Standards of Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,560 (Dec. 28, 2000), even as it permitted PHI to be used and disclosed for law enforcement and public health purposes. *See* Pls.' Br. at 7–8. HHS has not strayed from these basic principles in the quarter-century since.

After the *Roe* and *Casey* regime was toppled in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), HHS suddenly thought differently. It worried that because of "states' recent efforts to regulate and criminalize the provision of or access to reproductive health care," new privacy protections were needed. HIPAA Privacy Rule to Support Reproductive Health Care Privacy, 88 Fed. Reg. 23,506, 23,518–19 (proposed Apr. 17, 2023) ("Proposed Rule"). In the final 2024

Rule, HHS gave its reason for regulating: because "[t]he Supreme Court's decision in *Dobbs* … enabl[es] states to significantly restrict access to abortion." 89 Fed. Reg. at 32,987. Secretary Becerra proclaimed, "[w]e're making it clear: you have the right to privacy—*Dobbs* did not take it away." App. 008, ECF No. 46.

As Plaintiffs have described, the 2024 Rule creates an overlay for all PHI reflecting "reproductive health care." *See* Pls.' Br. at 10–15. It says regulated entities may not "use or disclose" information about reproductive health care "[t]o conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care"; [t]o impose criminal, civil, or administrative liability" for the same acts, or "[t]o identify any person [for these purposes]." 45 C.F.R. § 164.502(a)(5)(iii)(A). This "prohibited purposes" rule applies unless the regulated entity has actual knowledge the "reproductive health care" was unlawful or its unlawfulness is established with a "substantial factual basis." *Id.* § 164.502(a)(5)(iii)(C). Otherwise, the regulated entity must presume any "reproductive health care" was lawful. *Id.* And when public health officials or law enforcement officers request PHI—even by court order—regulated entities cannot disclose it without an "attestation" swearing that the request is not for a prohibited purpose. *Id.* § 164.509(a).

Dr. Purl and the Clinic are covered entities under HIPAA who challenged the 2024 Rule. *See* Pls.' Br. at 2–5. They regularly share PHI with external healthcare systems, such as hospital systems and other healthcare providers, as permitted by HIPAA and the 2000 Privacy Rule. *See* Purl Second Supp. Decl. ¶ 2, Resp. App. 001. For example, patient information sharing is routine and important when one of Dr. Purl's primary-care patients becomes pregnant. *Id.* ¶ 3, Resp. App. 001. Dr. Purl and clinic staff typically continue to provide a pregnant woman's care through the first trimester of pregnancy. *Id.* When an obstetrician takes over prenatal care (which is typically in the second trimester), the Clinic routinely provides the

patient's chart to the obstetrician to facilitate continuity of care. *Id.* ¶ 3, Resp. App. 001–002. After the patient delivers her child, the Clinic may obtain her chart from the obstetrician to continue the mother's primary care. *Id.* ¶ 3, Resp. App. 002. Dr. Purl refers to a patient's obstetrical chart when, for example, the patient was diagnosed with gestational diabetes or experienced complications during delivery that need to be followed. *Id.* The Clinic also has business associate agreements with third-party payers (such as insurance companies), software vendors, and others, and it regularly shares PHI with its business associates as permitted by the 2000 Privacy Rule (*e.g.*, 45 C.F.R. § 164.504(e)). *See* Purl Second Supp. Decl. ¶ 5, Resp. App. 002.

Exempting Plaintiffs alone from enforcement of the 2024 Rule would interfere with the Clinic's ability to enter into business associate agreements and otherwise share PHI as allowed by the 2000 Privacy Rule. *Id.* It would damage Plaintiffs' operations and ability to care for patients if they could not share PHI with external healthcare systems and business associates. *See id.* ¶ 4, Resp. App. 002. Dr. Purl worries that if the rest of the healthcare system must comply with the 2024 Rule, other medical providers will be unwilling or unable to share complete patient information with the Clinic. *See id.* ¶¶ 4–6, Resp. App. 002. As HHS acknowledges in the 2024 Rule, 89 Fed. Reg. at 32,985, lack of clear and complete medical records hinders patient care and can cause great harm. *See* Purl Second Supp. Decl. ¶ 4, Resp. App. 002. Dr. Purl also worries that her patients could be endangered if external healthcare systems and business associates refuse to report suspected abuse or crime or respond to lawful requests for PHI because of the 2024 Rule. *Id.*

To comply with the 2024 Rule, Plaintiffs would have to evaluate and revise the Clinic's policies and practices to account for the 2024 Rule's new requirements. 89 Fed. Reg. at 32,976; Purl Decl. ¶¶ 15–18, App. 005–06, ECF No. 46. By February

16, 2026, Plaintiffs would have to amend the Clinic's notice of privacy practices to reflect the new policies required by the 2024 Rule. 89 Fed. Reg. at 32,976; Purl Decl. ¶ 18, App. 006, ECF No. 46. Meanwhile, before any "use or disclosure" of PHI Plaintiffs would have to search for potential "reproductive health care" information and apply the 2024 Rule's new "prohibited purpose" requirements. *See, e.g.*, 89 Fed. Reg. at 33,018; *id.* at 33,059–60. And any time PHI is requested, Clinic staff would have to evaluate an "attestation" from the person requesting PHI—such as law enforcement or Child Protective Services—to determine whether in staff's judgment the request is not for a "prohibited purpose."

This Court issued preliminary relief, enjoining Defendants from enforcing the 2024 Rule against Plaintiffs while this lawsuit proceeds. The Court concluded the 2024 Rule is likely unlawful at least because it improperly limits reporting of child abuse under state procedures in contravention of 42 U.S.C. § 1320d-7(b). 2024 WL 5202497, at *10, ECF No. 34. Plaintiffs have moved for summary judgment on this and other grounds. ECF Nos. 44, 45. Defendants also moved to dismiss or, in the alternative, for summary judgment. ECF Nos. 39, 40.

The 2024 Rule is substantively contrary to law and is arbitrary and capricious. It should be vacated or its enforcement permanently enjoined.

ARGUMENT

I. Plaintiffs have standing, and the Court has subject-matter jurisdiction.

Dr. Purl and the Clinic have Article III standing. *See* Pls.' Br. at 18–19. "The imposition of a regulatory burden itself causes injury," and the 2024 Rule imposes regulatory burdens on Plaintiffs. *Tennessee v. EEOC*, No. 24-2249, 2025 WL 556191, at *3 (8th Cir. Feb. 20, 2025). Indeed, "regulations that require or forbid some action

by the plaintiff almost invariably satisfy both the injury in fact and causation requirements." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 382 (2024).

The 2024 Rule both requires and forbids action by Dr. Purl and the Clinic. Plaintiffs will have to change policies and procedures to include extra restrictions for "reproductive health care," including by assessing agreements with business associates; training staff about identifying "reproductive health care" PHI and applying the 2024 Rule's extra restrictions; and amending the Clinic's notice of privacy practices. *See* Purl Decl. ¶¶ 15–18, App. 005–06, ECF No. 46; Purl Second Supp. Decl. ¶ 5, Resp. App. 002. On top of that, the 2024 Rule forbids Plaintiffs from disclosing "reproductive health care" PHI unless its new conditions (like overcoming the presumption of lawfulness) are met, or from cooperating with law enforcement requests unless the attestation requirement is met. *See* Pls.' Br. at 18–19. These regulatory burdens will be lifted if the 2024 Rule is vacated or its enforcement enjoined. Plaintiffs have standing.

Disputing this, Defendants argue *first* (at 12) that Plaintiffs "misunderstand[ ]" the 2024 Rule, and properly understood, it never "interferes with the reporting of suspected child abuse to state authorities." Even if that were accurate (though it's not), Defendants' approach would impermissibly "bootstrap standing analysis to issues that are controverted on the merits." *In re Navy Chaplaincy*, 697 F.3d 1171, 1178 (D.C. Cir. 2012) (cleaned up); *accord Duarte ex rel. Duarte v. City of Lewisville*, 759 F.3d 514, 520 (5th Cir. 2014). Whether the 2024 Rule obstructs reporting in contravention of 42 U.S.C. § 1320d-7(b) is a "merits question." *OCA-Greater Hous. v. Texas*, 867 F.3d 604, 613 (5th Cir. 2017). When assessing standing, the Court is to "accept as valid the merits of [Plaintiffs'] legal claims." *FEC v. Cruz*, 596 U.S. 289, 298 (2022). That means "accept[ing] the plaintiff's legal theory as correct," *Citizens for Resp. & Ethics in Wash. v. U.S. Dep't of Homeland Sec.*, 507 F. Supp. 3d 228, 238 (D.D.C. 2020), and any disputed jurisdictional facts

in the plaintiff's favor, *see, e.g.*, *Navy Chaplaincy*, 697 F.3d at 1178. So for standing purposes, this Court is to assume the 2024 Rule unlawfully "invalidate[s] or limit[s]" disclosures when reporting child abuse and other public health matters in violation of 42 U.S.C. § 1320d-7(b).

Next, Defendants say (at 14) that Plaintiffs' injury is not "actual or imminent" because the 2024 Rule may not "ever prohibit Dr. Purl from making a disclosure" or cooperating with a law enforcement request for PHI. But as noted above, that is not the standard—Dr. Purl is an object of the regulation and the 2024 Rule immediately forbids and prohibits her conduct. *All. for Hippocratic Med.*, 602 U.S. at 382. And even if every one of Plaintiffs' desired disclosures of PHI will ultimately be permitted under the 2024 Rule, the increased regulatory burden is enough for standing. Each time disclosure is considered, Plaintiffs will have to spend time "screen[ing] … PHI for whether it contain[s] information potentially related to reproductive health care." 89 Fed. Reg. at 33,060; *see also id.* at 33,018 (HHS "reminds regulated entities that they must evaluate all requests made by a third party for the use or disclosure of PHI to ensure that they are not for a prohibited purpose").

Courts cannot ignore how a regulation affects regulated entities "as a practical matter." *Tennessee*, 2025 WL 556191, at *3; *cf. Rest. L. Ctr. v. U.S. Dep't of Lab.*, 66 F.4th 593, 598 (5th Cir. 2023) (discussing practicalities). Because the 2024 Rule's new requirements are content-based, there's no way a regulated entity can distinguish between prohibited and permissible disclosure of a record without analyzing the underlying PHI. *See, e.g.*, 89 Fed. Reg. at 33,004 (disclosure permitted "where there is suspicion of sexual abuse that could be the basis of permitted reporting," but not if suspicion "[is] based solely on the fact that a parent seeks reproductive health care … for a child"). Even if disclosure ultimately is allowed, having to screen for "reproductive health care" and question the requestor's motives

and purpose is "[a]n increased regulatory burden," which "satisfies the injury-in-fact-requirement." *Texas v. Becerra*, 577 F. Supp. 3d 527, 555 (N.D. Tex. 2021); *see also Tennessee v. EEOC*, 2025 WL 556191, at *3.

Independently, Plaintiffs are injured by the immediate costs of compliance. HHS "recognize[s] that regulated entities will need to revise and implement changes to their policies and procedures in response to the modifications in this final rule." 89 Fed. Reg. at 32,979. Adopting policies, training staff, and amending the Clinic's notice of privacy practices to conform to the 2024 Rule will take time and cost money, as the Court has already explained. 2024 WL 5202497, at *5–6, ECF No. 34; *see*, Purl Decl. ¶¶ 15–18, App. 005–06, ECF No. 46. Pecuniary harm like this is a quintessential injury-in-fact. *Young Conservatives of Tex. Found. v. Smatresk*, 73 F.4th 304, 310 (5th Cir. 2023).

That injury is actual and imminent. Without the preliminary injunction, Plaintiffs already would have had to incur some of these costs of compliance. And Defendants' attack on Plaintiffs' evidence of compliance costs is untenable. Contrary to Defendants' characterization (at 15), Plaintiffs submitted evidence "about the costs, in time or money, that … training or procedural updates will consume." As this Court recognized at the preliminary injunction stage, "Plaintiffs estimate the specific costs they would incur from training and procedure updates." 2024 WL 5202497, at *6, ECF No. 34; *see* Purl Decl. ¶¶ 15–18, App. 005–06, ECF No. 46. In any event, there is no genuine factual dispute that Plaintiffs will incur *some* costs to comply with the 2024 Rule. And "[f]or standing purposes, a loss of even a small amount of money is ordinarily an 'injury.'" *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017).

Plaintiffs necessarily established Article III standing at the preliminary stage, or this Court would not have issued relief. *See Speech First, Inc. v. Fenves*, 979 F.3d 319, 329 (5th Cir. 2020) ("A preliminary injunction, like final relief, cannot

be requested by a plaintiff who lacks standing to sue."). They easily meet that burden here. "A preliminary injunction is an extraordinary remedy," *Siders v. City of Brandon*, 123 F.4th 293, 300 (5th Cir. 2024), but for standing a loss of just $5 will suffice, *Czyzewski*, 580 U.S. at 464. While Plaintiffs do not dispute that they "must demonstrate standing with the manner and degree of evidence required at the successive stages of the litigation," *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021) (cleaned up), Defendants do not dispute or contradict Plaintiffs' evidentiary showing. Plaintiffs will incur the very compliance costs estimated in the 2024 Rule. Purl Decl. ¶¶ 15–18, App. 005–06, ECF No. 46. On top of that, the 2024 Rule threatens to interfere with Plaintiffs' ability to share PHI with other healthcare providers and business associates. Purl Second Supp. Decl. ¶¶ 2–5, Resp. App. 001–02.

As to updating the Clinic's notice of privacy practices, it does not matter that another HHS regulation requires a different amendment. *See* Defs.' Br. at 15. The two regulations address different topics, so updating notices of privacy practice in both areas is more burdensome than updating them for just one. Indeed, HHS did not dispute (in response to comments) that the two proposed rules independently "would involve operational changes requiring significant resources and effort." 89 Fed. Reg. at 32,980. The marginal increases in cost and regulatory burden are cognizable injuries. *Cf. Career Colleges & Schs. of Tex. v. U.S. Dep't of Educ.*, 98 F.4th 220, 234 (5th Cir. 2024) (cleaned up), *cert. granted in part* No. 24-413, 2025 WL 65914 (U.S. Jan. 10, 2025) (injury-in-fact established where the regulation would require "at least some degree of preparatory analysis, staff training, and reviews of existing compliance protocols").

Finally, Defendants renew their theory that Plaintiffs could comply more cheaply than Dr. Purl estimates. Defs.' Br. at 15–16. This Court has already rejected that idea and should have no trouble doing so again. 2024 WL 5202497, at *6, ECF No. 34. The language Defendants cite (at 16) from *Texas v. Biden*, 10 F.4th

538 (5th Cir. 2021), is not about Article III standing—it's about the federal government's failure to show irreparable harm when seeking to stay an injunction. *Id.* at 557–58. For standing, even a small cost suffices, *Czyzewski*, 580 U.S. at 464, and "[s]tanding is defeated only if … the injury is *so completely due* to the plaintiff's own fault as to break the causal chain," *Young Conservatives*, 73 F.4th at 310 (quoting Charles Alan Wright & Arthur R. Miller, 13A Federal Practice and Procedure § 3531.5 (3d ed. 2008 & Supp. 2022)). That cannot be the case here, where avoiding all costs of compliance would require Plaintiffs to, for example, "flout Page 33056 of the 2024 Rule and *not* create or modify [the Clinic's] office policies." 2024 WL 5202497, at *5, ECF. No. 34. As this Court has already explained, "nothing requires Plaintiffs to explain in excruciating detail exactly *how* their compliance costs will materialize." *Id.* "They simply must not be speculative or *de minimis*," and "Plaintiffs' compliance costs are neither." *Id.* Having cleared the higher standard for establishing irreparable harm, Plaintiffs reach the minimal threshold necessary for Article III standing.

II. The 2024 Rule is substantively contrary to law.

Defendants alternatively move for summary judgment. That should be denied. Instead, the Court should grant summary judgment for Plaintiffs. The 2024 Rule is unlawful and should be vacated. 5 U.S.C. § 706(2).

A. The 2024 Rule conflicts with 42 U.S.C. § 1320d-7(b).

HIPAA says HHS cannot "invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." 42 U.S.C. § 1320d-7(b). As this Court explained when granting preliminary relief, the 2024 Rule is likely contrary to that directive because, at the very least, it limits reporting of child abuse. 2024 WL 5202497, at

*10, ECF No. 34. Now, Defendants argue Plaintiffs and the Court have misunderstood what the 2024 Rule does, and, properly understood, it doesn't even apply to reporting covered by 42 U.S.C. § 1320d-7(b).

1. Defendants' primary theory is that "[t]he Rule simply does not limit the reporting of child abuse or other public health matters." Defs.' Br. at 16. They offer two arguments. Neither one undermines the Court's preliminary analysis.

Defendants begin by pointing out that the 2024 Rule did not delete the preexisting regulatory permission to disclose PHI when reporting child abuse to the appropriate authorities. Defs.' Br. at 17–18; *see* 45 C.F.R. § 164.512(b). Because reporting suspected child abuse is still allowed, they argue, the 2024 Rule can't possibly flout section 1320d-7(b). To be sure, the 2024 Rule didn't eliminate the abuse-reporting permission—instead, the 2024 Rule transformed it.

Defendants theory (at 18) is that "[t]he 2024 Rule's disclosure prohibition applies [only] to disclosures in response to *requests*, submitted either as part of an investigation or with the aim of imposing liability." That doesn't square with the regulatory text or what HHS has already said about it.

Beginning with the regulatory text, what Defendants (at 18) call the "disclosure prohibition," read in full, prohibits any "use or disclos[ure]" of PHI by a regulated entity for prohibited purposes. 45 C.F.R. § 164.502(a)(5)(iii)(A). The text does not say "affirmative disclosure" only. And *using* PHI in a report falls within the text's plain meaning.[2]

---

[2] The physician challenging Indiana's abortion-reporting requirements certainly thinks the 2024 Rule applies—she contends it preempts Indiana's longstanding law. *See* Brief in Support of Motion for Preliminary Injunction at 19–24, *Scifres v. Comm'r, Ind. Dep't of Health*, No. 1:24-cv-02262 (S.D. Ind. Dec. 31, 2024), ECF No. 11; Plaintiff's Reply in Support of Motion for Preliminary Injunction at 6–10, *Scifres*, No. 1:24-cv-02262 (S.D. Ind. Feb. 21, 2025), ECF No. 47.

Moreover, section 1320d-7(b)'s list does contemplate requests for information from state agencies. It broadly refers to "the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, death, public health surveillance, or public health investigation or intervention." 42 U.S.C. § 1320d-7(b). "Public health *investigation*" or "*surveillance*," in particular, suggest responding to or cooperating with public health agencies or law enforcement. *See Investigate*, *Black's Law Dictionary* (8th ed. 1999) ("To inquire into (a matter) systematically" or "[t]o make an official inquiry[.]"); *Surveillance*, *id.* ("Close observation or listening of a person or place in the hope of gathering evidence."). And the subject is "the authority, power, or procedures established under *any law*." 42 U.S.C. § 1320d-7(b) (emphasis added). There is no reason state laws cannot include both "affirmative reporting" and ongoing cooperation in their "authority, power, or procedures" for the listed public health purposes.

Turning to the 2024 Rule's preamble, HHS recognized that when it comes to "public policy goals," including "the reporting of child abuse," the 2024 Rule is "more protective of privacy interests in certain circumstances than the previous Privacy Rule." 89 Fed. Reg. at 32,995–96. That is an acknowledgment that the 2024 Rule will prohibit some reports that used to be permitted. Having recognized this, Defendants cannot now claim the 2024 Rule does not affect "affirmative reporting" generally or child-abuse-reporting specifically.

Defendants offer one textual argument (at 18): the "disclosure prohibition" doesn't apply "to affirmative reporting of child abuse" because 45 C.F.R. § 164.502 (a)(5)(iii)(B) refers to "the covered entity or business associate *that received the request for [PHI]*." But the provision right before this says a regulated entity "may not *use or disclose* [PHI]" for a prohibited purpose, full stop. 45 C.F.R. § 164.502(a)(5)(iii)(A) (emphasis added). Defendants would read in a limitation—may not use or disclose PHI "in response to *requests*"—not mentioned in the

statutory language. And if HHS meant to circumscribe the core prohibited-use provision using a dependent clause hidden halfway through the new regulatory text—especially given the 2024 Rule's many other discussions of prohibited purposes in relation to reporting abuse—it acted arbitrarily and capriciously.

Defendants say (at 18) that "a provider making an affirmative report of child abuse that happens to involve reproductive health care is not required to make any determination of whether that care was lawful before submitting a report." That would require ignoring the practical reality of compliance. The provider is barred from reporting child abuse based "solely" on lawful "reproductive health care," 89 Fed. Reg. at 33,004, but not if the "reproductive health care" was unlawful. So she must determine lawfulness or risk a violation.

But even if Defendants were correct that the "disclosure prohibition" does not directly apply to the child-abuse-reporting permission, the 2024 Rule would still conflict with 42 U.S.C. § 1320d-7(b) in at least two ways. *First*, it prohibits disclosing PHI "when the sole basis of the report of abuse, neglect, or domestic violence is the provision or facilitation of reproductive health care." 45 C.F.R. § 164.512(c)(3). Similarly, when it comes to child abuse, HHS says regulated entities may not "disclose PHI as part of a report of suspected child abuse based solely on the fact that a parent seeks reproductive health care … for a child." 89 Fed. Reg. at 33,004. So under the 2024 Rule, an abortion or sterilizing gender-transition intervention could never be reported as suspected child abuse. That invalidates state laws and limits states' authority. *See, e.g.*, Tex. Op. Att'y Gen. No. KP-0401, 2022 WL 579379, at *1, 9–10 (Feb. 18, 2022) (construing the statutory definition of abuse); *accord* Tex. Op. Att'y Gen. No. KP-0481, 2025 WL 464922, at *4 (Feb. 6, 2025).

Such limits countermand Congress's instruction. HHS's privacy regulations "shall [not] get in the way of any law—state or federal—that serves various enumerated public health purposes." Evans, *supra*, at 1201; *see* 42 U.S.C. § 1320d-7(b). It is the purview of the states, not HHS, to decide what constitutes abuse or threatens public health under their laws. HIPAA gives HHS no authority to get in the way. Texas and many other states have determined that gender-transition procedures and abortions threaten the health of children, including unborn children. And if an abortion was performed on a young girl in a state where elective abortion is legal, doctors should be able to report that possible abuse case. But the 2024 Rule says it would violate HIPAA to disclose PHI reflecting this "reproductive health care." This change limits states' authority to protect children—and adult patients—through reporting mechanisms. That is something HHS cannot do.

Second, the 2024 Rule conflicts with section 1320d-7(b) by redefining statutory terms to exclude unborn children. *See* 89 Fed. Reg. at 33,062–63 (revising 45 C.F.R. § 160.103). It removes unborn children from the class of persons who may be protected by such a report, so disclosure to report abuse of an unborn child is now barred. *See* Pls.' Br. at 25–26. That, too, gets in the way of child-abuse-reporting procedures. *See infra* II.B.1.

2. Defendants do not dispute that the 2024 Rule's prohibited-purpose provision applies to law enforcement requests, such as warrants and administrative subpoenas. And as this Court explained, the parties agree that the 2024 Rule bars compliance with some such requests. 2024 WL 5202497, at *8, ECF No. 34 (quoting 89 Fed. Reg. at 32,993). Defendants offer two theories, but neither helps.

First, Defendants say (at 18) that 42 U.S.C. § 1320d-7(b) "does not … prohibit limitations on disclosures in response to a state's *requests for information*." To reach that conclusion, they necessarily read § 1320d-7(b) to say there can be no invalidation or limit on "affirmative '*reporting* of … child abuse,'" Defs.' Br. at 18, but

nothing about responding to requests or cooperating with investigations into such abuse. Again, the statute does not say, "affirmative reporting," and it's far from obvious that section 1320d-7(b) is limited in this way. *See infra* at 18.

Second, Defendants contend (at 20) that even if section 1320d-7(b) applies to requests (and not just "affirmative disclosures"), "the 2024 Rule does not materially restrict disclosures in response to requests." Whatever Defendants mean by "materially restrict"—that term is found nowhere in the statute or regulatory text—their theory is untenable. The problem is not how the 2024 Rule applies to investigating "reproductive health care" that everyone agrees is unlawful—that is, what Defendants would call "legitimate investigations," *see* Defs.' Br. at 13—but how it applies when lawfulness is unclear or disputed. HHS admits that "situations may arise where a regulated entity reasonably determines that reproductive health care was lawfully provided, while at the same time, the person requesting the PHI (e.g., law enforcement) reasonably believes otherwise." 89 Fed. Reg. at 32,993; *see also, e.g.*, *id.* at 33,012. In those cases, the 2024 Rule forbids doctors from cooperating with law enforcement. *Id.*

HIPAA cannot "be construed to invalidate or limit" the listed public health laws. 42 U.S.C. § 1320d-7(b). As this Court has explained, the best reading of § 1320d-7(b) is that any hindrance or obstruction to reporting procedures is an improper "limit" under HIPAA. 2024 WL 5202497, at *8, ECF No. 34. Defendants do not provide a different definition of the provision's terms. Instead, they criticize the Court's interpretation as lacking "a clear limiting principle," and declare the "more sensible reading" to be that "Congress sought to prohibit rules that would preempt or supersede reporting statutes, not any rule with an incidental effect on

the reporting process." Defs.' Br. at 20–21. They do not provide any textual or contextual explanation of their "more sensible reading."[3]

Defendants' interpretation (such as it is) ignores the text of the statute. It takes the polysemous word "limit" and narrows it to only some potential meanings. In Defendants' view, to "limit" means to "preempt" or "supersede," Defs.' Br. at 20–21, but not to "restrain[ ]," "to curtail or reduce in … extent," or "to bound, restrict." 2024 WL 5202497, at *8, ECF No. 34 (citing, respectively, *Limit*, *Black's Law Dictionary* (12th ed. 2024); *Limit*, *Merriam-Webster's Collegiate Dictionary* (11th ed. 2014); *Limit*, *Oxford English Dictionary* (3d ed. rev. 2024)). When Congress wants to say a statute does not "preempt" state laws, it says "preempt." *See, e.g.*, 42 U.S.C. § 1395dd(f) ("The provisions of this section do not preempt any State or local law requirement."). In § 1320d-7(b), Congress did not say "preempt," it said, "invalidate or limit." And as this Court has explained, "laws that curtail or restrain the activity—even if the activity is not completely prohibited—*limit* the activity through imposing obstructions." 2024 WL 5202497, at *8, ECF No. 34.

With this language, Congress ensured both that HIPAA would not totally invalidate, or preempt, certain state laws, and that HIPAA would not even partially limit, or obstruct, such laws. And given HHS's recognition that the 2024 Rule precludes states from including abortion and other "reproductive health care" in their abuse and public health reporting regimes, *see, e.g.*, 89 Fed. Reg. at 33,003, 33,004, the inevitable consequence is that the 2024 Rule improperly "limits" those regimes. So even if Defendants' undeveloped reading of 42 U.S.C. § 1320d-7(b) were correct, the 2024 Rule would violate it.

---

[3] As Defendants acknowledge (at 26–27), HHS does not claim deference to its interpretation of 42 U.S.C. § 1320d-7(b), and it could not do so under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 400 (2024).

Finally, Defendants say (at 21) that even if "the 2024 Rule unlawfully restricts child-abuse reporting, the proper remedy would be to enjoin the Department from enforcing the 2024 Rule with respect to such reports when made in compliance with the requirements of state law." If what Defendants mean is that some provisions or applications of the 2024 Rule are severable, that argument fails for the reasons Plaintiffs have explained. *See infra* at 38; Pls.' Br. at 40.

B. The 2024 Rule unlawfully redefines statutory terms.

HHS lacks authority to redefine the statutory terms "person" and "public health." These regulatory changes, too, are contrary to law.

1. The 2024 Rule unlawfully redefines "person."

HHS does not dispute that its new definition of "person" excludes unborn children. *See* 89 Fed. Reg. at 33,062 (revising 45 C.F.R. § 160.103's definition of "person"). So under the 2024 Rule, an unborn child cannot be "a victim of abuse, neglect, or domestic violence." *Id.* at 32,997. That redefinition prevents doctors from acting to protect their unborn patients from harm. *See, e.g.*, 45 C.F.R. § 164.512(j)(1)(i)(A) (permitting disclosure "to prevent or lessen a serious and imminent threat to the health or safety of a person").

HIPAA regulations cannot override rights that states grant to the unborn. *Dobbs* affirmed that states have the authority to give unborn children status and rights. Many have done so. *See, e.g.*, Ala. Const. Art. I, § 36.06; Ga. Code Ann. § 1-2-1 (West 2024); Kan. Stat. Ann. § 65-6732 (2024); Ky. Rev. Stat. Ann. § 311.720 (West 2024); La. Stat. Ann. § 14:2(A)(7), (11) (2024); Mo. Rev. Stat. § 1.205 (2025); 18 Pa. Stat. and Cons. Stat. Ann. § 3202(c) (West 2025); S.D. Codified Laws § 22-1-2 (2025); Tenn. Code Ann. § 39-15-214 (West 2024); Tex. Penal Code § 1.07(a)(26), (49) (2023). As Plaintiffs have explained, many states—including some with permissive "reproductive health care" laws—protect unborn children from crime and abuse.

Pls.' Br. at 26; *see also, e.g.*, Ariz. Rev. Stat. § 8-201(25)(c) (2024) (defining "neglect" based on prenatal drug exposure); Cal. Penal Code § 187(a) (West 2024). But the 2024 Rule's redefinition of "person" places improper limits on doctors' ability to report such abuse. And Congress did not give HHS statutory authorization to redefine "persons" so that unborn children receive no protection or rights.

To justify its definition under the Dictionary Act, Defendants claim (at 24) that 1 U.S.C. § 8 wouldn't need to mention infants who are "born alive" if "person" includes an unborn child. *But see* Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 132–33 (2012). But Congress said 1 U.S.C. § 8 cannot be construed to "deny … any legal status or legal right applicable" to unborn children. *Id.* § 8(c). Yet that is how Defendants construe it. *See, e.g.*, 89 Fed. Reg. at 32,997. And contrary to Defendants' suggestion (at 24–25), section 8(c)'s rule of construction is not limited to status or rights conferred "under HIPAA" or even to status or rights under federal law writ large. Instead, it applies to "*any legal status or legal right*." 1 U.S.C. § 8(c) (emphasis added). That includes an unborn child's status and rights under state law.

2. The 2024 Rule unlawfully redefines "public health" as used in the statute.

The 2024 Rule unlawfully narrows the meaning of "public health." As Plaintiffs have explained (at 26–29), under the 2024 Rule's interpretation of "public health surveillance, or public health investigation or intervention," states cannot collect information to investigate or impose liability for "reproductive health care." 89 Fed. Reg. at 32,999. It is the purview of states, not HHS, to decide how to investigate threats to public health. HIPAA gives HHS no authority to decide which of those procedures count and which do not. On the contrary, 42 U.S.C. § 1320d-7(b) says HIPAA cannot interfere with such state laws. *See supra* II.A.

Defendants offer little in defense of the new definition. They say, "the 2024 Rule simply clarifies that efforts to investigate or impose liability on specific persons, regardless of the particular type of care, do not themselves constitute any of the enumerated 'public health' activities in the statute." Defs.' Br. at 25–26 (citing 89 Fed. Reg. at 33,001–02). That is still an improper "limit" on how states can investigate threats to public health. Indeed, under the 2024 Rule, state agencies arguably cannot so much as collect reports about abortions. *See* Pls.' Br. at 28–29; *supra* n.2. And the 2024 Rule reportedly is interfering with states' ability to enforce consumer protection statutes, pursue Medicare fraud, and take other investigative measures aimed at protecting public health.[4] In Tennessee, for example, the 2024 Rule has stalled investigations into a patient's death after treatment at a psychiatric facility and consumer protection violations by a fertility clinic that abruptly closed without notice to patients.[5] HHS's interference is contrary to law.

C. The 2024 Rule exceeds statutory authority by imposing special rules for "reproductive health care."

The 2024 Rule is independently contrary to the statute because HIPAA does not treat—and does not let HHS treat—PHI differently based on whether it contains information about "reproductive health care." *See* Pls.' Br. at 30–37.

---

[4] *See* Complaint for Injunctive & Declaratory Relief ¶¶ 91–112, *Tennessee v. HHS*, No. 3:25-cv-00025 (E.D. Tenn. Jan. 17, 2025), ECF No. 1; Memorandum in Support of Plaintiffs' Motion for Summary Judgment & Preliminary Relief at 9–10, 14, 22, No. 3:25-cv-00025 (E.D. Tenn. Feb. 7, 2025), ECF No. 26; Complaint for Declaratory & Injunctive Relief ¶¶ 81–83, *Missouri v. HHS*, No. 4:25-cv-00077 (E.D. Mo. Jan. 17, 2025), ECF No. 1.

[5] *See* Declaration of Kelley Groover, No. 3:25-cv-00025 (E.D. Tenn. Feb. 7, 2025), ECF No. 26-1; Declaration of Katherine Zeigler, *id.*, ECF No. 26-2; *see also* Declaration of Larry Johnson, Jr., *id.*, ECF No. 26-5 (similar evidence about Iowa's healthcare licensing agency); Declaration of Marina Spahr, *id.*, ECF No. 26-6 (similar evidence about North Dakota investigations into Medicaid fraud).

1. To justify the 2024 Rule's content-based rules for "reproductive health care" PHI, Defendants point (at 22) to its general delegation of authority to promulgate privacy standards. Congress instructed HHS to issue regulations governing "[t]he uses and disclosures of [PHI] that should be authorized or required." HIPAA § 264(b). "[N]othing in HIPAA's text," Defendants argue, "requires the Department to impose the same protections for all forms of health information, regardless of their sensitivity." Defs.' Br. at 22. This is not important enough to implicate the major questions doctrine, they claim, and it would be "inappropriate" for the Court to consider the nondelegation or vagueness doctrines. *Id.* at 17, 32–35.

Defendants' framing reveals the 2024 Rule's disconnect. The new definition of "reproductive health care" does not describe a "form of health information," *contra* Defs.' Br. at 22, it defines a broad category of medical conditions and treatments. This content may be reflected in any form of record, from a handwritten chart to Medicaid billing. The 2024 Rule is not about protecting privacy for particularly vulnerable forms of information, like electronic transmissions susceptible to hacking, *see, e.g.*, 45 C.F.R. §§ 164.304, 164.312 (standards for electronically stored PHI). This Rule is about the content of medical records. HIPAA is not about content.

Defendants offer two supposed precedents for the 2024 Rule's exceptionalism. They first point (at 23–24) to "special protection[s]" for "psychotherapy notes." *See* 45 C.F.R. §§ 164.501, 164.508(a)(2). Standards for a type of health record fall within HIPAA's broader aim, but special content-based conditions do not. *See* Pls.' Br. at 31. Indeed, psychotherapy notes are "by definition maintained separately from an individual's medical record." 89 Fed. Reg. at 32,986. Regardless of their content, psychotherapy notes are defined by their form. *See id.*

It is no answer to observe that the 2024 Rule's new conditions also apply to "*records*." *See* Defs.' Br. at 24. Of course they do. The problem is how the 2024 Rule

determines which records qualify for new restrictions—based on their content. Indeed, HHS acknowledged the difference: "[U]nlike psychotherapy notes, which by their very nature are easily segregated, reproductive health information is not easily segregated." 89 Fed. Reg. at 32,990. A form-based standard applicable to all "psychotherapy notes" is not precedent for the 2024 Rule's content-based standards.

Next, Defendants point (at 23) to HHS's 1997 recommendations to Congress. *Recommendations*, *supra*. The Recommendations support Plaintiffs. In 1997, HHS recognized that special protections for particularly sensitive medical information—like "HIV status, substance abuse patient information, and mental health records"—came from *other laws*, not HIPAA. *Id.* That is why the Secretary of HHS referred to preexisting laws that "already provide" special protection. *Id.* But HHS does not claim the 2024 Rule is based on any other "Federal [or] State law" that "provide[s] stronger protections," *id.*, for information about "reproductive health care." And in 1997, the Secretary did not claim HIPAA gave HHS authority to create such protections by regulation; instead, the Secretary contemplated HHS "working *with the Congress* in determining when [additional] protections are appropriate." *Id.* (emphasis added). That is a strong indication HHS has no such authority. *See Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) ("When an agency claims to discover in a long-extant statute an unheralded power to regulate … [courts] typically greet its announcement with a measure of skepticism."); *cf. Loper Bright*, 603 U.S. at 386, 394 (longstanding agency interpretations command respect not afforded to novel interpretations offered late).

If Congress wished to enact "stronger protections" for information about "reproductive health care," in principle it could do so (setting aside other constitutional concerns). *See* Pls.' Br. at 32–33. But HHS cannot extend HIPAA where Congress did not by using HIPAA's general delegation of authority to create

special protections for politically favored activities. The 2024 Rule exceeds HHS's constitutional power and privilege under the APA.

2. HIPAA's silence about particular categories of health care or medical conditions does not justify the 2024 Rule. Just the opposite. If Congress meant to authorize HHS to use HIPAA regulations to promote the agency's favored medical procedures, rather than to set privacy standards, then Congress would have said so clearly. *See* Pls.' Br. at 30–32. Putting up special walls around "reproductive health care" content is a major question Congress would not have silently delegated to an administrative agency. So the major questions doctrine forbids reading HIPAA to allow exceptionalism for "reproductive health care" in reaction to *Dobbs*.

To wave off the major questions doctrine, Defendants *first* say (at 27) that "[r]ules concerning when private medical information can be disclosed" are not significant enough to trigger the major questions doctrine. To the contrary, embedding abortion exceptionalism into a regulatory standard about privacy for medical records is a matter of "vast … political significance." *West Virginia v. EPA*, 597 U.S. 697, 716 (2000) (cleaned up). And interfering with states' enforcement of their abortion laws, and every doctor's ability to comply with state law, is of "economic" significance as well. The 2024 Rule is infused with political and economic significance for American society.[6]

---

[6] A report by the American Principles Project estimates that "the sex-reassignment surgery market size was $4.12 billion in 2022. That is expected to grow at a compound annual growth rate of 8.4 percent from 2023 to 2030." American Principles Project, *The Gender Industrial Complex* 29, https://americanprinciplesproject.org/wp-content/uploads/2024/06/Gender-Industrial-Complex-Full-Report.pdf. Meanwhile, IBISWorld reports that the family planning and abortion clinic industry earns $4.3 billion in annual revenue. *Family Planning & Abortion Clinics in the US—Market Research Report (2014–2029)*, IBISWorld, https://www.ibisworld.com/united-states/industry/family-planning-abortion-clinics/1567/ (last updated May 2024).

Second, Defendants argue "this is not a circumstance where the agency has discovered 'newfound power in the vague language of an ancillary provision.'" Defs.' Br. at 27 (quoting *West Virginia*, 597 U.S. at 724). Yes, it is. The 2024 Rule is an exercise of newfound power. It has no precedent in the history of HIPAA. HHS admits the 2024 Rule is a reaction to *Dobbs* and was crafted because "states have much broader power to criminalize and regulate" reproductive health care than the *Roe*/*Casey* regime allowed. 89 Fed. Reg. at 32,987. If HIPAA has always been about special treatment of "reproductive health care" content in medical records, or even about content generally, Congress would have said so, and HHS would not have waited nearly three decades to discover or even mention this authority.

3. If the 2024 Rule reflected HIPAA, it would raise serious questions of constitutionality. To avoid conflict with the nondelegation and void-for-vagueness doctrines, the Court should reject HHS's reading.

Everyone agrees that Congress delegated to HHS legislative power over what "uses and disclosures of [individually identifiable health] information … should be authorized or required." HIPAA § 264(b). *See* Defs.' Br. at 33–34; Pls.' Br. at 33–36. But if this delegation did not come with an intelligible principle sufficient to prevent HHS from crafting special rules to favor or disfavor politically charged medical fields, then HIPAA would have a nondelegation problem and could violate the major questions doctrine deriving from Article I's Vesting Clause. *See West Virginia*, 597 U.S. at 739 (Gorsuch, J., concurring). Since HIPAA says nothing about PHI's content, different medical conditions and procedures, or categories like "reproductive health care," deriving authority from that statute to justify this rule presumes a blank check given by Congress to HHS.[7]

---

[7] Defendants declare (at 17) that "it would be inappropriate for the Court to address" the nondelegation doctrine or vagueness. But the Court's query is indeed

The 2024 Rule's nondelegation problems are not fixed by *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657 (2020). Citing *Little Sisters*, Defendants argue a court should not "impos[e] limits on [the] agency's discretion that are not supported by the text." Defs.' Br. at 23 (citing 591 U.S. at 677). To be sure, in *Little Sisters* the Court explained that "it was Congress' deliberate choice to issue an extraordinarily 'broad general directiv[e]'" to the agency, but it took care to observe that the constitutionality of "the breadth of the delegation" was not at issue. 591 U.S. at 679. Unbounded discretion may well be the correct interpretation of a statutory delegation, but that could make the statute unconstitutional.

The Court should avoid reading HIPAA to unconstitutionally delegate legislative power. Defendants offer no intelligible principle to cabin HHS's discretion. Indeed, their description of the statute (at 22–23) suggests HHS recognized no such limits when crafting the 2024 Rule.

To counter the nondelegation problem, Defendants also cite (at 34) *South Carolina Medical Association v. Thompson*, 327 F.3d 346 (4th Cir. 2003). Plaintiffs have explained why the Fourth Circuit's decision is unpersuasive when it comes to the 2024 Rule's content-based requirements, redefinitions of core terms, or disregard for 42 U.S.C. § 1320d-7(b)'s rule of construction. *See* Pls.' Br. at 35–36. Defendants offer no independent analysis that could justify following the Fourth Circuit's decision here.

---

appropriate. Contrary to Defendants' characterization (at 32), the nondelegation doctrine or a void-for-vagueness argument are not claims—the "claim" under the APA is that agency action is contrary to law. 5 U.S.C. §§ 704, 706(2). The nondelegation and void-for-vagueness doctrines are legal theories that show how agency action is contrary to law, and "[l]egal theories … need not be raised in a complaint to be considered." *Nat'l Press Photographers Ass'n v. McCraw*, 90 F.4th 770, 797 n.158 (5th Cir. 2024).

Finally, Defendants say (at 32), "courts should avoid" constitutional questions, suggesting that means this Court cannot consider the nondelegation doctrine or vagueness. Defendants misapply constitutional avoidance. The doctrine requires acknowledging, rather than ignoring, serious questions of constitutionality. It counsels rejecting an agency interpretation that renders the statute suspect. That means narrowing the Court's interpretation of a statute—and therefore of the agency's authority—to avoid creating doubt about whether Congress acted within its authority. *Mex. Gulf Fishing Co. v. U.S. Dep't of Com.*, 60 F.4th 956, 966–67 (5th Cir. 2023); *see* Scalia & Garner, *supra*, at 249 (explaining that constitutional avoidance is appropriate when "the factor that gives rise to the constitutional doubt arose *after* the statute was enacted"). That includes respecting what the major questions doctrine, federalism canon, and nondelegation doctrine say about HHS's expansive reading of HIPAA. Constitutional avoidance favors reading HIPAA to constrain the agency's determination of what "uses and disclosures of [certain PHI] … should be authorized or required." HIPAA § 264(b). Defendants recognize no such constraints.

III. The 2024 Rule is arbitrary and capricious.

A regulation must be both "reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). The 2024 Rule is arbitrary and capricious. It imposes unworkable and politically tinged requirements on doctors, forcing them to make legal judgments about the unlawfulness of abortions and gender transition procedures on children. It puts a presumption of legality on such procedures, requiring doctors to use HHS's ideological lens. And it requires doctors to second-guess subpoenas and even court orders. *See, e.g.*, 89 Fed. Reg. at 33,015–16 (the 2024 Rule prohibits compliance with a hypothetical "subpoena for … PHI"), 33,032 (similar for a "court ordered warrant").

Defendants cannot show the 2024 Rule meets the APA's standards. To explain the 2024 Rule's core prohibited purpose (e.g., "to impose … liability on any person for the mere act of … providing … reproductive health care," 45 C.F.R. § 164.502(a)(5)(iii)(A)(2)), Defendants say it's enough for HHS to cite the "'changing legal landscape'" after *Dobbs*. Defs.' Br. at 28 (quoting 89 Fed. Reg. at 32,978). That illustrates the problem. Defendants insist the new prohibition is not about abortion restrictions because it doesn't apply to *unlawful* reproductive health care. But if that is so, then it's hard to see why *Dobbs* made a new regulation necessary or how its new prohibition applies. After all, the prohibition has practical impact where legality is uncertain or disputed, not where everyone agrees. The presumption of legality is not a solution—it's part of the problem. *See* Pls.' Br. at 22–23.

HHS also failed to address how HIPAA-regulated entities are supposed to apply the federal government's claims that federal law "authorizes, requires, or protects" types of "reproductive health care" prohibited by state law. *See* Pls.' Br. at 21–22 (discussing claims about "reproductive health care" under the Constitution and federal statutes, e.g., EMTALA). Commenters brought this issue to HHS's attention, yet the agency said nothing.[8] Failure to consider this "important aspect of the problem" is arbitrary and capricious. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

---

[8] *See* ADF, Comment Letter at 6–9 (June 16, 2023), 2024AR-0018433–51, ECF No. 43-28; EPPC Scholars, Comment Letter at 15 (June 16, 2023), 2024AR-0018820–39, ECF No. 43-29; Roger Severino, Comment Letter at 5 (June 16, 2023), 2024AR-0019843–55, ECF No. 43-30.

Indeed, commenters supporting the 2024 Rule emphasized its interaction with HHS's position on EMTALA. *See, e.g.*, Legal Action Ctr., Comment Letter at 9–10 (June 16, 2023), 2024AR-0019084–99, ECF No. 43-29; Am. College of Emergency Physicians, Comment Letter at 3 (June 16, 2023), 2024AR-0019104–08, ECF No. 43-29; Nat'l P'ship for Women & Families, Comment Letter at 10 (June 16, 2023), 2024AR-0019264–79, ECF No. 43-29.

To defend the 2024 Rule, Defendants *first* insist it does not "limit" child-abuse reporting or other public health disclosures in conflict with 42 U.S.C. § 1320d-7(b). Defs.' Br. at 28. Even if that were accurate, *but see supra* at 13–16, the 2024 Rule still interferes with states' child abuse reporting and public health procedures. HHS says that "reproductive health care," so long as it is legal where performed, can never constitute child abuse or be disclosed to protect unborn children. 89 Fed. Reg. at 33,004. That redefinition limits states' public health reporting mechanisms. *See supra* II.B.1. It is arbitrary and capricious to tell doctors they still may freely report suspected abuse in compliance with state law.

Second, Defendants claim HHS's explanation is adequate because the 2024 Rule "made plain that the 2024 Rule's prohibitions do not apply to investigations into forms of care that are unlawful." Defs.' Br. at 28 (citing, *among other things*, 89 Fed. Reg. at 33,012–13). That is no help. Such questions have been mired in controversy for decades and "fluctuate with the political winds." 2024 WL 5202497, at *9. Consider gender-transition procedures on children, which today are prohibited or restricted in 27 states.[9] Are these procedures "forms of care that are unlawful," Defs.' Br. at 28, as state law provides, or "protected, required, or authorized by Federal law," 45 C.F.R. § 164.502(a)(5)(iii)(B)(2), as the United States argued in the Supreme Court last December? *See* Pls.' Br. at 21–22. Are they unlawful again if the United States abandons its Equal Protection theory? *See* Petitioner's Letter, *United States v. Skrmetti*, No. 23-477 (U.S. Feb. 7, 2025).

Or consider the interaction of state prohibitions on abortion with EMTALA, which the United States claims preempts state laws. *See* Pls.' Br. at 21 & n.14, 38–

[9] Just last month, Kansas became the 27th state to prohibit doctors from performing gender-transition interventions like cross-sex hormones, puberty blockers, and surgery on children. *See* Help Not Harm Act, 2025 Kan. Sess. Laws, ch. 1, Bill 63 (effective Feb. 20, 2025).

39. The United States recently argued Idaho law "prohibits [abortion] in some circumstances where EMTALA requires it." Consolidated Brief for the United States at 37, *United States v. Idaho*, Nos. 23-35440, 23-35450 (9th Cir. Oct. 15, 2024), ECF No. 194, *argued en banc* Dec. 10, 2024. Should a doctor treat such an abortion as lawful or unlawful? It depends on whether she asks Idaho or the Department of Justice. The 2024 Rule's standard is incomprehensible, which makes the 2024 Rule arbitrary and capricious.

Next, Defendants insist (at 28–29) that requiring doctors to make such complex legal determinations is of no moment because there are other legal questions relevant to HIPAA compliance. To be sure, Dr. Purl is equipped to "determine[s] the legality of any care that *her clinic provides*," Defs.' Br. at 29, but that does not include abortions and gender transition procedures on children, which are illegal under Texas law, and are procedures she does *not* provide. It is these sorts of "reproductive health care" that motivated the 2024 Rule but are insufficiently addressed by HHS. And the legal determinations the 2024 Rule requires are unlike Defendants' examples (at 29). Identifying a patient's "personal representative," or releasing PHI about a decedent, are straightforward situations in ordinary medical practice. Not so here. Nor is there a parallel in 45 C.F.R. § 164.512(j), which allows disclosure of PHI if "[n]ecessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public." *Id.* § 164.512(j)(1)(i)(A). That is a factual question, not a legal inquiry like the 2024 Rule's. Indeed, this provision exemplifies the 2024 Rule's unlawfulness—unborn children now cannot be protected through this provision. *See supra* at 19.

Defendants argue doctors will have no trouble applying the 2024 Rule when it comes to records of "reproductive health care" performed by someone else. A regulated entity "is entitled to 'presume[ ]' that the care is 'lawful,'" Defendants say, "unless it has '[a]ctual knowledge' or '[f]actual information supplied by the person

requesting the use or disclosure … that demonstrates a substantial factual basis that the reproductive health care was not lawful.'" Defs.' Br. at 29–30 (quoting 45 C.F.R. § 164.502(a)(5)(iii)(C)). That is not a reasoned explanation—that presumption is itself arbitrary.

The presumption ignores context: a patchwork of state laws, many of which prohibit abortion and gender-transition interventions on children. Identifying a "substantial factual basis" and applying complex and oft-changing law to the facts are inquiries that divide jurists and law professors. Indeed, these are complex questions disputed even in the Supreme Court. *See, e.g.*, *Moyle v. United States*, 603 U.S. 324 (2024) (per curiam); *District of Columbia v. Wesby*, 583 U.S. 48, 56–57 (2018) (addressing probable cause to believe a crime has been committed). But the 2024 Rule tells doctors they must ignore inferences drawn from state law and cannot rely on law enforcement's assessment or a judge's conclusion that there is a substantial factual basis. Instead, they must place a thumb on the scale *against* disclosure, risking state law liability for contempt or, worse, endangering their patients. *See* Pls.' Br. at 22–23. It is unreasonable to require medical practitioners to conduct such a complicated legal inquiry and ignore state process. It is arbitrary and capricious to require that they do so in the light of the Government's conflicting and erroneous legal claims.

Finally, Defendants defend the 2024 Rule's broad definition of "reproductive health care," saying HHS sought to "'encompass[ ] the full range of health care related to an individual's reproductive health,'" and to "'decrease the perceived burden to regulated entities … by helping them determine whether a request for the use or disclosure of PHI'" implicates the 2024 Rule. Defs.' Br. at 31–32 (citing 89 Fed. Reg. at 33,005–06). These defenses do not help. They instead illustrate the definition's overbreadth. As Plaintiffs have explained (at 36–37), the definition is riddled with modifiers that render it vague—it encompasses anything that so much

as "relate[es]" to the reproductive system and "its functions and processes." If HHS meant to "decrease the perceived burden to regulated entities," 89 Fed. Reg. at 33,005–06, by showing that *everything* is reproductive health care, that would be one thing. But that can't be it. Elsewhere HHS claims "reproductive health care" is not limitless in scope and describes it as "a subset of the term 'health care.'" *See* 89 Fed. Reg. at 33,005. This is arbitrary and capricious.

For all these reasons, the 2024 Rule is arbitrary and capricious. It should be held unlawful and set aside for that independent reason.

IV. The Court should vacate or permanently enjoin enforcement of the 2024 Rule.

Because the 2024 Rule is contrary to law, the Court should hold it unlawful and set it aside. 5 U.S.C. § 706(2). That means vacating the entire 2024 Rule or universally enjoining its enforcement. *See* Pls.' Br. at 39–41.

A. The APA "empowers and commands courts to 'set aside' unlawful agency actions," which "render[s] [the] challenged agency action void." *Tex. Med. Ass'n v. HHS*, 110 F.4th 762, 779 (5th Cir. 2024) (cleaned up). Such vacatur is the "proper remedy" under Fifth Circuit precedent. *Rest. L. Ctr. v. U.S. Dep't of Lab.*, 120 F.4th 163, 177 (5th Cir. 2024). Vacatur "is not party-restricted." *Career Colls.*, 98 F.4th at 255. Unlike an injunction, which operates in personam, Congress directed that vacatur "operate[ ] on the status of agency action in the abstract." *Braidwood Mgmt., Inc. v. Becerra*, 104 F.4th 930, 951 (5th Cir. 2024), *cert. granted*, No. 24-316, 2025 WL 65913 (U.S. Jan. 10, 2025); *accord Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 838 (2024) (Kavanaugh, J., concurring) (observing that the APA "empower[s] the judiciary to act directly against the challenged agency action" (cleaned up)); *id.* at 829–30 (and explaining that the reviewing court sets aside agency action "in much the same way that an appellate court vacates the judgment of a trial court"). The illegal agency action here is the 2024 Rule, and it is

"unlawful as to all participants, not just the Plaintiffs." *Texas v. Becerra*, No. 6:24-cv-211, 2024 WL 4490621, at *1 (E.D. Tex. Aug. 30, 2024) (issuing a universal stay of agency action under 5 U.S.C. § 705). The 2024 Rule should be vacated.

Defendants begin by arguing (at 35–36) that vacatur is not a remedy under the APA. As they recognize, however, that argument is foreclosed by Fifth Circuit precedent. So, they ask the Court to exercise its discretion not to vacate the 2024 Rule.

None of Defendants' four arguments for discretion would justify deviating from the default. *First*, Defendants say (at 36) that the Court should not vacate the 2024 Rule because it "is lawful." But if the 2024 Rule were lawful—and it's not—the Court wouldn't be considering remedies.

Second, Defendants say (at 36) that if the problem is HHS's "fail[ure] to adequately explain its decisions in promulgating the 2024 Rule, those errors could be rectified on remand," and the 2024 Rule should remain in place in the meantime. This argument against vacatur is relevant only to a procedural deficiency under the APA; it has no application if the 2024 Rule is substantively unlawful—which it is. To be sure, the Fifth Circuit has allowed remand *without vacatur* "when there is at least a serious possibility that the agency will be able to substantiate its decision given an opportunity to do so." *Tex. Ass'n of Mfrs. v. U.S. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 389 (5th Cir. 2021). But this is an exception to the default rule (vacatur). *Data Mktg. P'ship, LP v. U.S. Dep't of Lab.*, 45 F.4th 846, 860 (5th Cir. 2022). There is no "serious possibility" here. HIPAA does not authorize HHS to gerrymander content-based rules for "reproductive health care," and that is all this rule does. The legal problems with the 2024 Rule cannot be shored up with more process; they require uprooting it root and branch. *See* Pls.' Br. at 38–39.

The argument is also unavailing. Even if the only grounds for unlawfulness were Plaintiffs' arbitrary and capricious claim, *see supra* III, HHS's failure to

reasonably explain is so fundamental that it would be unworkable to require doctors to attempt compliance while the agency goes back to try again. Without the necessary instruction, regulated entities would be just as unable to apply the 2024 Rule in the meantime. Remand without vacatur is not a viable option here.

Third, Defendants raise "the public's interest in the privacy of sensitive medical information." Defs.' Br. at 36–37. But "the Privacy Rule already protects reproductive healthcare information the same as *all other* sensitive medical information." 2024 WL 5202497, at *10, ECF No. 34. HIPAA existed for over two decades without this rule's politically motivated limits.

Defendants say the status quo is not good enough: HHS concluded, "even patients seeking purely *lawful* reproductive care increasingly fear the unauthorized disclosure of their information." Defs.' Br. at 37. Even assuming some individuals harbor these fears, the administrative record does not show such fears are reasonable. Indeed, HHS could not bring itself to claim more than a "*potential* increased demand for PHI" after *Dobbs*. 89 Fed. Reg. at 32,987 (emphasis added). More than two years after *Dobbs*, there is no evidence this "potential increased demand" has appeared, much less that it has caused harmful disclosures of private medical information.

The administrative record does not help Defendants. In this Court, they refer to "a recent study and letters from the public" as support. Defs.' Br. at 37 (citing 89 Fed. Reg. at 32,987; 88 Fed. Reg. at 23,519 & n.167, 23,528). As to "letters from the public," Defendants' brief cites none, and none are mentioned on the cited pages of the 2024 Rule's preamble. The Proposed Rule stated HHS "has received letters from the public, indicating confusion and concern as to the ability of regulated entities to use or disclose PHI for the purposes described above." 88 Fed. Reg. at 23,528. But Defendants do not point to any such letters, and the Court need not scour the record for evidence that might support Defendants' request to deviate from the default rule

of vacatur. *Cf. Murthy v. Missouri*, 603 U.S. 43, 67 n.7 (2024). In any event, that some individuals are concerned is not evidence the subject of that concern will materialize. And the subjective fears of individuals would not be an appropriate basis for leaving an unlawful agency action in place.

As to the "recent study," Defendants do not name it. They seem to be citing the abstract of a qualitative analysis of interviews with 16 women published after Texas's Heartbeat Bill prohibited most abortions in September 2021. 88 Fed. Reg. at 23,519 n.167 (*see* 2024AR0014171–72, ECF No. 43-20). Even if such a qualitative analysis could bear weight—which is doubtful—relying on an abstract alone is arbitrary and capricious. And notably, HHS cited neither abstract nor article in the final rule. *See* 89 Fed. Reg. at 32,987 (discussing the relevant issue). If this is the "recent study," it is unpersuasive.

Another possible "recent study" is a 2020 article that has eluded counsel's search of the administrative record. *See* 89 Fed. Reg. at 32,987 n.151 (citing Laura J. Faherty et al., *Consensus Guidelines and State Policies: The Gap Between Principle and Practice at the Intersection of Substance Use and Pregnancy*, 2 Am. J. Obst. & Gyn. Maternal-Fetal Med. (Aug. 2020)). At best guess, this article argues against penalizing substance abuse by pregnant women that injures their unborn children. That hardly supports the policy HHS chose in the 2024 Rule. And in any event, HHS cannot properly rely on material that is either outside the 45,896-page administrative record or buried in its many unsearchable PDF pages.[10]

Finally, the 2024 Rule's preamble cites 2022 law review articles and commentary from abortion advocates predicting dire consequences from the then weeks-old *Dobbs* decision. *See* 89 Fed. Reg. at 32,987 nn.147, 148, 151 & 152. That,

---

[10] Plaintiffs' counsel inquired with counsel for Defendants about the location of this article but has received no guidance.

too, is no evidence that the existing Privacy Rule is inadequate to prevent harm from disclosure of PHI.

In short, Defendants point to nothing in the administrative record showing that PHI reflecting "*lawful* reproductive care," Defs.' Br. at 37, will be used or disclosed at all, much less for the "prohibited purposes" at the heart of the 2024 Rule. This Court is not compelled to adopt the agency's conclusions when addressing the appropriate remedy. It should not do so here.

Fourth, Defendants claim that vacating the 2024 Rule "would … reduce the trust that individuals have in the medical system." Defs.' Br. at 37. That too is unavailing. As the Court put it, "[i]f Defendants are concerned that denying *surplus* protection to 'reproductive health care' information will dissuade some patients, it is because select states have curtailed or banned select abortion services." 2024 WL 5202497, at *10, ECF No. 34. It is just as likely that reversing Defendants' abuse of their statutory authority will restore the public's trust in the ability of HHS to administer its statutes according to law instead of ideology.

Defendants insist the Court was wrong to draw the connection between HHS's opposition to abortion restrictions and the 2024 Rule. Defs.' Br. at 37 n.2. The 2024 Rule only "prohibits the disclosure of information related to *lawful* reproductive health care," they argue. *Id.* This ignores what HHS has acknowledged all along. HHS justified the rulemaking based on "states' recent efforts to regulate and criminalize the provision of or access to reproductive health care." 88 Fed. Reg. at 23,518–19; *see* 89 Fed. Reg. at 32,978; Defs.' Br. at 28. It admits the 2024 Rule is a reaction to "[t]he Supreme Court's decision in *Dobbs*" that "enable[ed] states to significantly restrict access to abortion." 89 Fed. Reg. at 32,987. HHS cannot claim the 2024 Rule has nothing to do with states' post-*Roe* abortion regulations.

The 2024 Rule is contrary to law and should be vacated.

B. In the alternative, a universal injunction on enforcement of the 2024 Rule would be appropriate. *See* Pls.' Br at 40–41. Defendants' discretion-based arguments are just as unconvincing when weighing the equities and the public interest. And because the 2024 Rule is unlawful as to all regulated entities, not just Plaintiffs, enforcement should be enjoined universally. An administrative agency cannot properly act as to *anyone* without statutory authority.

Defendants argue, "the Court could simply enjoin the Department from enforcing the Rule against Dr. Purl, which would alleviate any compliance concerns she may have." Defs.' Br. at 38. It would not. As allowed by HIPAA and the 2000 Privacy Rule, Plaintiffs regularly share PHI with other healthcare providers and with business associates like insurance companies and software providers. Purl Second Supp. Decl. ¶¶ 2–5, Resp. App. 001–02; *see* 45 C.F.R. §§ 164.502(a)(5)(iii)(A), 164.509(c); 89 Fed. Reg. at 33,020, 33,034. If these regulated entities are subject to the 2024 Rule, a Plaintiffs-only injunction will be little relief. If Plaintiffs cannot exchange PHI with other healthcare providers, they cannot practice medicine in the modern world. That would be, to put it mildly, a barrier to caring for patients. And HHS acknowledges that business associate agreements likely need to be amended to comply with the 2024 Rule. *See* 89 Fed. Reg. at 32,996. Current and future business associates likely will not be willing to share PHI without those terms. And if business necessity forces Plaintiffs to adopt the 2024 Rule's policies anyway, the Court's injunction will be nothing but paper.

If Plaintiffs are to be protected from complying with the illegal rule, any other entity with which they share PHI also needs protection from the 2024 Rule. It is neither viable nor necessary to attempt to identify that universe of entities when under Fifth Circuit precedent the proper remedy is to vacate the 2024 Rule universally anyway. Otherwise, Plaintiffs could be forced to choose between entering agreements that incorporate the 2024 Rule's harmful provisions and giving up

productive relationships. Beyond that, Dr. Purl's patients could be endangered if other medical providers refuse to report abuse or cooperate with law enforcement by responding to lawful requests for PHI reflecting "reproductive health care." Purl Second Supp. Decl. ¶ 6, Resp. App. 002; *see* 89 Fed. Reg. at 33,015–16 (describing such a hypothetical).

Defendants are also not the only government officials with authority to enforce HIPAA and the Privacy Rule. State attorneys general also have enforcement power. *See* 42 U.S.C. § 1320d-5(d). An injunction preventing Defendants from enforcing the 2024 Rule against Plaintiffs—an in personam remedy—would not prohibit state attorneys general from taking enforcement action. Vacatur, however, would "render the [2024 Rule] void," *Tex. Med. Ass'n*, 110 F.4th at 779, thus providing complete relief—a void regulation cannot be enforced by anyone.

C. Finally, Defendants suggest the 2024 Rule is severable, arguing (at 38–39) that only the applications or provisions found unlawful should be vacated or enjoined. But severability has no work to do here. Each regulatory change made in the 2024 Rule either creates the new "reproductive health care" regime or conforms the 2000 Privacy Rule to its new standard. HHS does not explain how any of the changes concern something else or could be partially implemented. *See Louisiana v. U.S. Dep't of Educ.*, No. 24-30399, 2024 WL 3452887, at *2 (5th Cir. July 17, 2024). There is no basis for severance here.

CONCLUSION

The Court should deny Defendants' motion, enter judgment for Plaintiffs for the reasons addressed in their motion for summary judgment and brief in support, and vacate or enjoin enforcement of the 2024 Rule.

Respectfully submitted this 3rd day of March 2025.

/s/ Natalie D. Thompson
Natalie D. Thompson
TX Bar No. 24088529
DC Bar No. 90026665
Matthew S. Bowman
DC Bar No. 993261
ALLIANCE DEFENDING FREEDOM
440 First Street NW, Suite 600
Washington, DC 20001
Telephone: (202) 393-8690
Facsimile: (202) 347-3622
nthompson@ADFlegal.org
mbowman@ADFlegal.org

Julie Marie Blake
VA Bar No. 97891
ALLIANCE DEFENDING FREEDOM
44180 Riverside Parkway
Lansdowne, Virginia 20176
Telephone: (571) 707-4655
Facsimile: (571) 707-4790
jblake@ADFlegal.org

Counsel for Plaintiffs