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.	§	

REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

INTRODUCTION

The 2024 HIPAA Rule, 89 Fed. Reg. 32,976 (Apr. 26, 2024), distorts a neutral patient information law to serve a political agenda: facilitating elective abortion and gender transitions on children. Congress wrote HIPAA to allow doctors to protect patients' privacy *and* safeguard health by reporting abuse and public health risks. The Rule directly regulates Dr. Purl and her clinic, and HHS admitted it carries compliance costs. It now disputes those costs, but such "insist[ance] on a precise dollar figure reflects an exactitude our law does not require." *Rest. L. Ctr. v. Dep't of Lab.*, 66 F.4th 593, 600 (5th Cir. 2023). The Court should grant preliminary relief.

ARGUMENT

I. Plaintiffs are likely to show that the 2024 Rule is contrary to law.

The Rule conflicts with HIPAA and the agency's authority by shielding abuse and health risks from investigation and by redefining terms to subvert state law. And it arbitrarily requires doctors to guess at HHS's (erroneous) legal views.

A. The Rule conflicts with HIPAA and exceeds HHS's authority.

1. The Rule limits doctors' ability to cooperate with law enforcement and public health investigations. HHS quibbles about how much or often the Rule's limits would apply. That is irrelevant: HIPAA allows no limits, yet the Rule imposes limits. HHS admits "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. In such situations, the Rule forbids doctors from cooperating with state law enforcement. *Id.* That directly conflicts with HIPAA because it "limit[s] the authority, power, [and] procedures" for "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).

HHS says the Rule does not "prohibit entities from complying with legitimate investigations into *unlawful* reproductive health care." Defs.' Br. [ECF 29] at 9. Even so, this tacitly admits that the Rule limits disclosures of "lawful" procedures—but the whole point of an investigation is to determine *whether* conduct was lawful. That's difficult to know *ex ante*. And when law enforcement or CPS tries to find out, the Rule gives the subject of investigation a veto, 45 C.F.R. § 164.502(a)(5)(iii)(B)(1), (2), or presumes procedures performed by "another person" are lawful, and thus the request illegitimate, *id.* § 164.502(a)(5)(iii)(C). Indeed, that is arguably the Rule's whole purpose. *See, e.g.*, 89 Fed. Reg. at 33,015 (Rule prohibits disclosure if "a law enforcement official from State A issues a subpoena … [seeking PHI about a procedure] in State B that would have been unlawful" in State A).

The Rule's interference with doctors and states is broad and sweeping. Under the Rule, Dr. Purl must presume that an abortion or pediatric gender-transition procedure was lawful despite Texas law. 45 C.F.R. § 164.502(a)(5)(iii). Worse, she must consider such things lawful if "authorized by Federal law, including the United States Constitution, under the circumstances in which [it] is provided, regardless of the state in which it is provided." *Id.* § 164.502(a)(5)(iii)(B)(2). Last week, the United States argued to the Supreme Court that the Equal Protection Clause negates laws like Texas' restriction on gender transition procedures. *United States v. Skrmetti*, No. 23-477 (argued Dec. 4, 2024). Under that view, Dr. Purl must conclude a pediatric gender transition procedure was "authorized by" federal law.

Likewise with abortion. HHS OCR says that abortions are lawful under *Roe, Casey*, and federal statutes. *See* Pls.' Br. [ECF 24] at 6–9. HHS tries (at 21 n.3) to dismiss its extant guidance because it predated *Dobbs*. But the document says otherwise: "last reviewed February 3, 2023." App. 013. In any event, there is no dispute that HHS claims statutes like EMTALA preempt state laws. On this, HHS offers no response.

The Rule suggests it won't be a barrier to what HHS considers a legitimate investigation because investigators will be able to provide sufficient "factual information" about the unlawfulness of procedures. *See* 89 Fed. Reg. at 32,994. Again, that is a limit. And even with such a showing, having to make it interferes with reporting. The Rule requires doctors to second-guess the evidence and make their own determination—even a court order is not good enough. *See id.* at 33,013–14 ("a regulated entity receiving the request for PHI must evaluate the facts and circumstances"), 33,032 (applying this to a "court ordered warrant").

HHS argues the lawfulness distinction supports the Rule's double standard of allowing disclosure to *avoid* liability but not to investigate crime. It's no answer that the government can use PHI "in connection with the *unlawful* provision of care," Defs.' Br. at 14, such as to prove charges at trial. The Rule's barrier goes up at an earlier stage. As the Rule recognizes, 89 Fed. Reg. at 33,014, it puts up barriers to investigating whether "reproductive health care" was lawful or not. *Cf. id.* at 32,987 (justifying the Rule because "states have much broader power to criminalize and regulate" abortion after *Dobbs*). The Rule operates to prevent charges from ever being brought.

2. HHS claims (at 13–14) that disclosures about child abuse or public health will not be restricted because "the mere act of facilitating *lawful* care" cannot possibly "constitute[ ] child abuse under state law." This begs the question. It is the purview of states, not HHS, to decide what constitutes child abuse or threatens public health. HIPAA gives HHS no authority to do so. Texas has determined that gender transition procedures and elective abortions threaten the health of children, including unborn children. But the Rule rigs the definitions of person and public health to exclude unborn children and the sort of "reproductive health care" that HHS finds acceptable. 45 C.F.R. § 160.103. If an instance of what HHS calls "reproductive health care" is what gives rise to a doctor's suspicion of abuse, the

Rule interferes with reporting it. For instance, 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. Construing HIPAA to interfere with state-law reporting obligations upsets federalism and overreads HIPAA's preemption provision. HIPAA's preemptive effect, where it properly applies, need not contradict federalism principles. But HIPAA has a "*limited* express preemption provision," *Wassef v. Tibben*, 68 F.4th 1083, 1089 (8th Cir. 2023), that must be read in light of the explicit restriction on preemption in 42 U.S.C. § 1320d-7(b).

HHS also suggests (at 14) that public health inquiries are unaffected because, unlike criminal investigations, such inquiries are not about "imposing liability." Yet under the Rule's new definition of "public health," HIPAA-covered entities arguably are prohibited from providing information about abortions, gender-transition procedures for minors, and other harms—even where the information is to "promote the health of populations." 89 Fed. Reg. at 33,001–02. Excluding favored "reproductive health care" from public health is another improper "limit" on states' reporting capabilities.

3. HHS does not dispute that its new definition of "person" excludes unborn children. That means an unborn child cannot be "a victim of abuse, neglect, or domestic violence." *Id.* at 32,997. This 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"). This too unlawfully "limit[s]" reporting in violation of HIPAA. 42 U.S.C. § 1320d-7(b). HHS claims (at 15) that 1 U.S.C. § 8(a) wouldn't need to mention infants born alive if "person" includes an unborn child. That's not the meaning of "include." Antonin Scalia & Bryan A. Garner, *Reading Law* 132–33 (2012). And Congress said 1 U.S.C. § 8 cannot be construed to "deny … any legal status or legal right applicable" to unborn children. 1 U.S.C. § 8(c). *Dobbs* affirmed

that states have the authority to consider the unborn as persons. *See, e.g.*, Tex. Penal Code § 1.07(a)(26), (49). HIPAA cannot override state rights accorded to the unborn.

4. The Rule exceeds HHS's statutory authority. HIPAA is a neutral informational law having nothing to do with abortion, gender transitions, or "reproductive health care." It gives HHS no authority to segregate two classes of healthcare: politically favored procedures and everything else. The Rule candidly admits it was drafted to counteract *Dobbs*. *See* 89 Fed. Reg. at 32,987. But that is not a lawful purpose. The Rule is ultra vires under HIPAA.

B. The Rule is arbitrary and capricious.

The 2024 Rule is arbitrary and capricious. It imposes unworkable and politically tinged requirements on doctors, forcing them to make legal judgments regarding the legality of abortions and gender transition procedures on children. It imposes a presumption of legality on such procedures, requiring doctors to use HHS's ideological lens. And it requires doctors to second-guess subpoenas and court orders. *See, e.g.*, 89 Fed. Reg. at 33,015–16 (the Rule prohibits compliance with a hypothetical "subpoena for … PHI"), 33,032 (similar for a "court ordered warrant").

The legal determinations Dr. Purl must make under the Rule are not like other legal questions relevant to HIPAA compliance. *Contra* Defs.' Br. at 19–20. HHS points (at 20) to 45 C.F.R. § 164.512(j), the provision allowing disclosure of PHI if "necessary 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 Rule's. Indeed, this provision exemplifies the Rule's unlawfulness. *See supra* at 4–5. And identifying a patient's "personal representative," or releasing PHI about a decedent, are straightforward situations in ordinary medical practice. Not so here. Doctors must determine whether there is

a "substantial factual basis" that a third party's procedure was unlawful, including under federal law, to overcome the presumption of legality. 45 C.F.R. § 164.502(a)(5)(iii)(C). Jurists and litigants spill lots of ink on such questions. *See, e.g.*, *District of Columbia v. Wesby*, 583 U.S. 48, 56–57 (2018); *Illinois v. Gates*, 462 U.S. 213, 239 (1983). It is unreasonable to require medical practitioners to conduct a complicated legal inquiry before they comply with state reporting laws.

As noted above, the Rule also forces Dr. Purl to guess whether HHS OCR believes a particular abortion or gender transition procedure is lawful under its view of the Constitution. The United States insists the Equal Protection Clause overrides state laws on gender-transition procedures, while OCR guidance says abortion is legal under *Casey*. HHS now says (at 21 n.3) it "does not dispute that *Dobbs* controls." But *the Rule* did not reasonably explain how doctors were to treat contradictory statements like HHS's never-withdrawn guidance or claims that unrelated federal statutes preempt state law. *See supra* at 2. HHS "entirely failed to consider [this] important aspect of the problem," even though commenters raised the issue.[1] *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). That is arbitrary and capricious.

II. Plaintiffs will suffer irreparable harm.

Plaintiffs are directly regulated by the Rule. They have standing to challenge it and they face irreparable harm from complying with it against their wishes. "When a plaintiff is an object of a regulation there is ordinarily little question that the [agency's] action or inaction has caused him injury, and that a judgment

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[1] *See, e.g.*, ADF, Comment Letter on Proposed HIPAA Privacy Rule to Support Reproductive Health Care Privacy at 6–9 (June 16, 2023), https://www.regulations.gov/comment/HHS-OCR-2023-0006-0127; EPPC Scholars, Comment Letter on Proposed HIPAA Privacy Rule to Support Reproductive Health Care Privacy at 15 (June 16, 2023), https://www.regulations.gov/comment/HHS-OCR-2023-0006-0180.

preventing or requiring the action will redress it." *Texas Med. Ass'n v. HHS*, 110 F.4th 762, 773 (5th Cir. 2024) (cleaned up). In flu season Dr. Purl treats up to 10–20 children daily, as well as many pregnant women or women seeking pregnancy tests, and she provides primary care for many more. App. 002, 004. Plaintiffs' harm is not speculative.

Plaintiffs' harm includes compliance costs the Rule admits it imposes. *E.g.*, 89 Fed. Reg. at 33,049, 33,052 tbl.4. "[C]omplying with a regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs." *Rest. L. Ctr.*, 66 F.4th at 597. These costs would be unrecoverable because of sovereign immunity. *Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1142 (5th Cir. 2021). That is irreparable harm. *Rest. L. Ctr.*, 66 F.4th at 599.

HHS's position would upend APA review, preventing even regulated entities with estimated costs from challenging final rules. A sister court recently rejected HHS's "stringent" demand for compliance-cost specifics, explaining "[i]t is enough that each Plaintiff swore … that they will incur compliance costs and legal costs should they have to comply with the [Rule]." *Tex. Top Cop Shop, Inc. v. Garland*, No. 4:24-CV-478, 2024 WL 4953814, at *12 (E.D. Tex. Dec. 3, 2024) (citing *Rest. L. Ctr.*, 66 F.4th at 600). Even the absence of a "specific dollar figure" (which is not absent here) would "in no way reduce[ ] [Plaintiffs'] showing." *Id.*

Here, Dr. Purl testified she would personally spend "5–8 hours to analyze the 2024 Rule and prepare training materials," and "lose between $360 and $480 per hour spent on these compliance-related activities." App. 006. And she estimated marginal costs to train Clinic staff on the new requirements. App. 005–06; *see* 89 Fed. Reg. at 33,056. Time spent to understand the Rule is time *not* spent on patient care. That is true whether the Clinic is closed for all-staff training, as Dr. Purl anticipates, App. 005, or training is "stagger[ed]," as HHS suggests (at 12). Either way, employee time is not free, and the "law does not require" a "precise

dollar figure." *Rest. L. Ctr.*, 66 F.4th at 600. Courts do not ignore the practicalities of compliance. So even if "[t]he Rule does not require [entities] to conduct any particular training," as HHS says (at 11), the idea they could conduct *none* is not credible. *See Rest. L. Ctr.*, 66 F.4th at 598 ("We cannot fathom how an employer could honor [a rule's] specific constraints without recording employee time.").

HHS's counterarguments fail. It first argues (at 11) that the costs are "unsubstantiated," claiming "Dr. Purl does not provide any evidence to corroborate her assertion about the costs, in time or money." Not so. A sworn statement from a business owner is competent evidence, *see Texas A&M Rsch. Found. v. Magna Transp., Inc.*, 338 F.3d 394, 403 (5th Cir. 2003), and HHS does not try to exclude or rebut Dr. Purl's testimony. At the more "informal" preliminary injunction stage, the question is whether the record "support[s]" the injunction, and here it does. *Sierra Club, Lone Star Chapter v. FDIC*, 992 F.2d 545, 551 (5th Cir. 1993).

HHS also argues (at 11) the estimated costs are "speculative," suggesting Dr. Purl can just "ask[ ] staff to forward any disclosure requests for her to evaluate personally." Even if that were practical, it assumes Dr. Purl's own time is valueless—something any small-business owner knows is false. The time Dr. Purl spends "handl[ing]" and "evaluat[ing]" (*id.*) requests is time she otherwise could have spent earning revenue on patient care. App. 006 (estimating the opportunity cost of Dr. Purl's time at around $400 per hour). And the time to evaluate inquiries is significant. For example, the Clinic responds to requests from CPS by providing the entire patient file. App. 004. Under the Rule, for every request Dr. Purl must scour the patient's file for information about "reproductive health care." If such information exists, she must assess its legality. Even if the file contains no such information, the search imposes compliance costs.

Finally, HHS claims (at 11) Plaintiffs' costs are de minimis. The record shows the Clinic will have to change policies and train staff by December 23. Dr. Purl

estimates the opportunity cost for the Clinic to close for one hour is $1,385, that training will take several hours, and that her own time to change policies and prepare training materials could cost the Clinic over $3,000 at her hourly earnings rate. App. 005–006. Added to the ongoing compliance costs, these amounts far exceed the $200 in costs that HHS intimates (at 11) would be de minimis.

III. The equities and public interest favor preliminary relief.

The Court should universally stay or enjoin the Rule during this litigation under 5 U.S.C. § 705. APA relief runs against the Rule, not just to how it affects the parties. *Career Colls. & Schs. of Tex. v. U.S. Dep't of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024); *see Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 144 S. Ct. 2440, 2469 (2024) (Kavanaugh, J., concurring). This makes good sense. The APA is a check on agency power. If the agency has acted illegally, Congress provided that its "action" is to be "held unlawful and set aside." 5 U.S.C. § 706(2). And "the scope of preliminary relief under Section 705 aligns with the scope of ultimate relief under Section 706, which is not party-restricted." *Career Colls.*, 98 F.4th at 255. The illegal "action" here is the 2024 Rule. The Rule 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 under section 705). Unlike an injunction, which operates *in personam*, Congress directed that a stay "operate[ ] on the status of agency action in the abstract." *Braidwood Mgmt. v. Becerra*, 104 F.4th 930, 951 (5th Cir. 2024) (so holding for vacatur).

The Court should also reject any suggestion that relief could extend to some applications only. *See* Defs.' Br. at 14, 16. This is not a rulemaking that does other things. Plaintiffs challenged every change made by the Rule—each change 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. This is a fatal flaw. *See Louisiana v. U.S. Dep't of Educ.*, No. 24-30399, 2024 WL 3452887, at *2 (5th Cir. July 17, 2024). Compliance costs similarly flow from all the Rule's provisions; they all impose the substantive regime. Severability analysis is, at best, premature. *Id.*

The equities favor Plaintiffs, who seek simply to maintain the status quo. *See Hollon v. Mathis ISD*, 491 F.2d 92, 93 (5th Cir. 1974). HHS speculates that the "possibility of disclosure" could generate fear among unnamed patients, who "may be deterred from seeking needed health care," or "withhold information from their providers," and that providers "may leave gaps or include inaccuracies when preparing medical records." Defs.' Br. at 22 (cleaned up). Such speculative concerns do not outweigh the irreparable harm to Plaintiffs. HHS waited nearly two years to issue the Rule in response to *Dobbs*, and the Rule's first compliance deadline has not yet passed. Maintaining the status quo a little longer can hardly be prejudicial.[2]

These hypotheses also obscure the purpose of the Rule. While HHS insists (at 5) it "did not promulgate the 2024 Rule because it disagrees with *Dobbs*," the Rule's history shows HHS and Secretary Becerra originating and contextualizing the rulemaking within their strong disagreement with *Dobbs*. *See* Pls.' Br. at 7–9. "[T]his Court is not required to exhibit a naiveté from which ordinary citizens are free." *Texas v. HHS*, 681 F. Supp. 3d 665, 679 (W.D. Tex. 2023) (cleaned up).

CONCLUSION

The Court should grant Plaintiffs a 705 stay of the 2024 Rule and a preliminary injunction prohibiting enforcement while this litigation proceeds.

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[2] HHS relies (at 22) on statements from abortion proponents; news articles conflating miscarriage care (which no state's law prohibits) with elective abortion; and a brief filed by an activist group trying to overturn Texas' abortion laws. *See* 88 Fed. Reg. at 23,508 nn.12–16. None of these provide a sound basis for the Rule.

Respectfully submitted this 10th day of December, 2024,

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