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

CARMEN PURL, M.D., et al.,

*Plaintiffs*,

v.

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, et al.,

*Defendants*.

No. 2:24-cv-228-Z

**DEFENDANTS' BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

ERIC B. BECKENHAUER
Assistant Branch Director

JOHN T. LEWIS (TX Bar No. 24095074)
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, D.C. 20530
Tel: (202) 353-0533
Fax: (202) 616-8460
E-mail: john.t.lewis.iii@usdoj.gov

*Attorneys for Defendants*

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## INTRODUCTION

As part of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. 104-191, 110 Stat. 1936, Congress directed the Department of Health and Human Services (the "Department") to craft standards to protect the privacy of Americans' sensitive medical information. To that end, in 2000, the Department promulgated a regulation, known as the Privacy Rule, restricting how such information can be used and disclosed. *Standards for Privacy of Individually Identifiable Health Information*, 65 Fed. Reg. 82462-01 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164). In April 2024, in light of widespread public concern about the potential disclosure of information relating to reproductive health, the Department revised the Privacy Rule to strengthen protections for information pertaining to an individual's use of lawful reproductive health care. *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32976 (Apr. 26, 2024) (the "2024 Rule" or the "Rule"). The 2024 Rule has been in effect since June, and providers generally must comply with it beginning December 23. *Id.*

A single physician, Dr. Carmen Purl, and her medical clinic (collectively, "Dr. Purl") now seek to preliminarily enjoin the 2024 Rule on a nationwide basis. Her request should be rejected. To start, Dr. Purl falls well short of identifying any imminent, irreparable harm that warrants emergency relief. The Rule does nothing to prevent her from reporting suspected child abuse, the central issue at the heart of her motion. The Rule also does not require her to update her Notice of Privacy Practices *until 2026*. And her other alleged compliance costs are wholly unsubstantiated and speculative. Given the nature of her medical practice, Dr. Purl is highly unlikely to ever encounter a conflict between her obligations under state law and under the Rule, much less imminently, and she may never face any real costs to provide additional training or update procedures. Her delay in seeking relief simply confirms the lack of any real emergency.

The remaining preliminary injunction factors likewise weigh against relief. Dr. Purl fails to show a likelihood of success on the merits because the 2024 Rule in no way restricts providers from complying with abuse reporting statutes. The Department also lawfully and reasonably exercised its authority to promulgate standards concerning the disclosure of health information.

Finally, the equities weigh strongly against Dr. Purl's requested relief, which would undermine the physician-patient relationship, erode HIPAA's privacy objectives, and discourage patients from accessing lawful health care. At a minimum, the Court should limit any relief to Dr. Purl, whose purported injuries would be fully redressed by party-specific relief.

For these reasons, the Court should deny Dr. Purl's motion for a preliminary injunction.

## BACKGROUND

### I. The Health Insurance Portability and Accountability Act

HIPAA was enacted by Congress in 1996. Subtitle F of Title II, entitled "Administrative Simplification," sought to improve health care systems by "encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information." 42 U.S.C. § 1320d note. HIPAA applies to "covered entities," which include health plans, health care clearinghouses, and health care providers who transmit any health information electronically in connection with a standard transaction under HIPAA (e.g., billing insurance electronically). *Id.* § 1320d-1.

To protect confidentiality and ensure trust in the health care system, Congress directed the Department to submit "detailed recommendations on standards with respect to the privacy of individually identifiable health information" within one year of HIPAA's enactment. *Id.* § 1320d-2 note (codifying Pub. L. 104-191, title II, § 264). Congress instructed HHS to cover "at least" the following three subjects:

> (1) The rights that an individual who is a subject of individually identifiable health information should have.
>
> (2) The procedures that should be established for the exercise of such rights.
>
> (3) The uses and disclosures of such information that should be authorized or required.

*Id.* Congress provided that if it did not enact legislation covering these matters within three years, "the Secretary … shall promulgate final regulations containing such standards." *Id.* Recognizing that unforeseen developments might warrant revisions to HIPAA's privacy

regulations, Congress also charged the Secretary to "review th[ose] standards" and "adopt modifications to the standards (including additions to the standards), as determined appropriate, but not more frequently than once every 12 months." *Id.* § 1320d-3(b)(1).

Congress also included an express preemption provision in HIPAA. That provision mandates that "a provision or requirement under [HIPAA], or a standard or implementation specification adopted under [HIPAA] … , shall supersede any contrary provision of State law," with limited exceptions. *Id.* § 1320d-7(a)(1). Among other things, the statute provides that the privacy regulations promulgated by the Department "shall not super[s]ede a contrary provision of State law" if the state law imposes "more stringent" requirements. *Id.* §§ 1320d-2 note, 1320d-7(a)(2)(B). The statute also includes a "public health" exception, providing that "[n]othing in this part shall be construed 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." *Id.* § 1320d-7(b).

## II. The 2000 Privacy Rule

In response to Congress's directive, the Department submitted detailed recommendations on September 11, 1997. 65 Fed. Reg. at 82470. When Congress did not enact legislation within three years, the Department, after extensive consultation with the National Committee on Vital and Health Statistics ("NCVHS") and federal and state agencies, proposed and ultimately promulgated regulations in 2000 concerning medical privacy in the form of the Privacy Rule. *Id.*

In promulgating the 2000 Privacy Rule, the Department recognized the right to privacy in personal information that has historically found expression in American law and observed that "many people believe that individuals should have some right to control personal and sensitive information about themselves." *Id.* at 82464; *see also Whalen v. Roe*, 429 U.S. 589, 600 (1977) (identifying "the individual interest in avoiding disclosure of personal matters," including "matters vital to the care of their health"). The Department noted that advances in information technology "have reduced or eliminated many of the financial and logistical obstacles that

previously served to protect the confidentiality of health information and the privacy interests of individuals," 65 Fed. Reg. at 82465, and concluded that "protection of privacy must be built into the routine operations of our health care system." *Id.* at 82467. The Department also found that medical privacy is "necessary for the effective delivery of health care, both to individuals and to populations," because "the entire health care system is built upon the willingness of individuals to share the most intimate details of their lives with their health care providers." *Id.*

To that end, the Privacy Rule sets out detailed standards related to the use and disclosure of "protected health information" ("PHI"), which is defined as "individually identifiable health information" that is "transmitted" or "maintained" in "electronic media" or "any other form or medium." 45 C.F.R. § 160.103. Under the Privacy Rule, PHI is generally protected from use or disclosure without an individual's authorization. *Id.* § 164.502(a). However, PHI can be used and disclosed for a number of purposes, including treatment, payment, and health care operations, without written patient authorization. *Id.* §§ 164.502(a)(1)(ii), 164.506.

The Privacy Rule also permits the disclosure of PHI without patient authorization, and in narrow, clearly defined circumstances, to public health agencies and law enforcement. *Id.* § 164.512. Those circumstances include where necessary for "public health activities," such as "the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions," as well as to make reports of "child abuse or neglect," *id.* § 164.512(b); where necessary to make reports of "abuse, neglect, or domestic violence," to the extent such reports are "required by law," *id.* § 164.512(c); in response to legally authorized demands for information, including warrants and subpoenas, *id.* § 164.512(e), (f); and where 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).

## III. The 2024 Rule

In April 2023, the Department proposed to amend the 2000 Privacy Rule. 88 Fed. Reg. 23506, 23506 (Apr. 17, 2023). Again after extensive consultation with NCVHS and federal and

state agencies, as well as considering over 25,900 comments, the Department promulgated the 2024 Rule on April 26, 2024. *See* 89 Fed. Reg. at 32978, 32991. The 2024 Rule became effective on June 25, 2024, and covered entities generally have until December 23, 2024, to comply with its requirements. *Id.* at 32976. However, covered entities have until February 16, 2026, to make required amendments to their Notices of Privacy Practices. *Id.* at 32976, 32979.

Contrary to Dr. Purl's assertions, the Department did not promulgate the 2024 Rule because it disagrees with *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022). Rather, the Department concluded that the "changing legal landscape increases the likelihood that an individual's PHI may be disclosed in ways that cause harm to the interests that HIPAA seeks to protect, including the trust of individuals in health care providers and the health care system." 89 Fed. Reg. at 32978. The 2024 Rule therefore "amends provisions of the Privacy Rule to strengthen privacy protections for highly sensitive PHI about the reproductive health care of an individual, and directly advances the purposes of HIPAA by setting minimum protections for PHI and providing peace of mind that is essential to individuals' ability to obtain lawful reproductive health care." *Id.*

Specifically, the 2024 Rule protects sensitive information by prohibiting covered entities from "us[ing] or disclos[ing] protected health information for any of the following activities:

> (1) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.
>
> (2) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.
>
> (3) To identify any person for any purpose described in [(1) or (2)]."

45 C.F.R. § 164.502(a)(5)(iii)(A). The Rule also contains a "rule of applicability" directing that its prohibition applies only where "the reproductive health care is lawful under the law of the state in which such health care is provided" or "is protected, required, or authorized by Federal law." *Id.* § 164.502(a)(5)(iii)(B). Finally, the Rule directs that "[t]he reproductive health care

provided by another person is presumed lawful … unless the covered entity" has "[a]ctual knowledge that the reproductive health care was not lawful" or "[f]actual information supplied by the person requesting the use or disclosure of [PHI] that demonstrates a substantial factual basis that the reproductive health care was not lawful." *Id.* § 164.502(a)(5)(iii)(C).

"To assist in effectuating this prohibition," 89 Fed. Reg. at 32990, the 2024 Rule also contains a requirement that a covered entity "obtain[] an attestation" before it may "use or disclose [PHI] potentially related to reproductive health care" for the purposes of health oversight, judicial and administrative proceedings, law enforcement, and disclosures to coroners and medical examiners, 45 C.F.R. § 164.509(a). Among other things, the attestation must contain "[a] description of the information requested" and "[a] clear statement that the use or disclosure is not for a purpose" prohibited by the 2024 Rule. *Id.* § 164.509(c)(1)(i), (iv). An attestation is "[d]efective" if "[t]he covered entity … has actual knowledge that material information in the attestation is false" or "[a] reasonable covered entity … would not believe that the attestation" is for a permitted purpose. *Id.* § 164.509(b)(2)(iv), (v).

The 2024 Rule preserves the 2000 Privacy Rule's existing provisions permitting the use or disclosure of PHI for public health activities but clarifies that they do not permit the disclosure of information solely to impose liability for lawful reproductive health care. Specifically, the 2024 Rule defines "public health as used in the terms 'public health surveillance,' 'public health investigation,' and 'public health intervention,'" to mean "population-level activities to prevent disease in and promote the health of populations," rather than efforts to "conduct … investigation[s]" or "impose … liability" on individuals. 45 C.F.R. § 160.103. Similarly, the Department explained that, when HIPAA was enacted, "most, if not all, states had laws that mandated reporting of child abuse or neglect to the appropriate authorities," that Congress had already addressed such reporting in other laws, and that the term "child abuse," as used in these statutes, "does not include activities related to reproductive health care, such as abortion." 89 Fed. Reg. at 33004. The term "child abuse" therefore "exclude[s] conduct based solely on a person seeking, obtaining, providing, or facilitating reproductive health care." *Id.* As to the

Privacy Rule's provision concerning disclosures about adult abuse victims, the 2024 Rule adds a "[r]ule of construction" that "nothing in this section shall be construed to permit disclosures prohibited by § 164.502(a)(5)(iii) 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).

## IV. This Lawsuit

Dr. Purl is the sole owner of Dr. Purl's Fast Care Walk In Clinic, a clinic in Dumas, Texas that employs three nurse practitioners and about a dozen support personnel. App. 001-004. Dr. Purl's clinic provides "everyday" medical services like sick visits, flu/COVID testing, basic sutures, and vaccines. *Id.*[1] Dr. Purl does not claim to provide obstetric or gynecological services (other than testing for pregnancy), and she has never treated a pediatric patient "expressing gender dysphoria or undergoing a medicalized gender transition." *Id.*

On October 21, Dr. Purl filed her Complaint, which alleges that the 2024 Rule is contrary to law and arbitrary and capricious. ECF No 1. On November 12, she moved the Court to "grant a stay under 5 U.S.C. § 705 or issue a preliminary injunction preventing enforcement of the 2024 Rule." Pls.' Mot. For Prelim. Inj. & Br. in Supp. ("Mot.") 1, ECF No. 24.

## LEGAL STANDARD

"A preliminary injunction is an extraordinary and drastic remedy" that should "never be awarded as of right." *Munaf v. Geren*, 553 U.S. 674, 689-90 (2008) (cleaned up). A plaintiff may obtain this "extraordinary remedy" only "upon a clear showing" that it is "entitled to such relief." *Winter v. NRDC*, 555 U.S. 7, 22 (2008). The party seeking a preliminary injunction bears the burden to show "a substantial likelihood of success on the merits," "a substantial threat of irreparable injury," "that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted," and "that the grant of an injunction will not disserve the public interest." *Jordan v. Fisher*, 823 F.3d 805, 809 (5th Cir. 2016) (citation omitted).

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[1] *See Dr. Purl's Fast Care Clinic*, https://drpurlfastcare.com/ (last visited Dec. 2, 2024).

## ARGUMENT

### I. Dr. Purl's motion for a preliminary injunction should be denied.

Dr. Purl cannot show any of the preliminary-injunction factors: she has not shown that she faces a substantial threat of irreparable harm while this case is litigated; she cannot show that she is likely to prevail on the merits of her claims; and the equities tilt decisively against relief.

#### A. Dr. Purl has not shown a substantial threat of irreparable injury.

To start, Dr. Purl's failure to show irreparable harm is fatal to her motion. "A plaintiff seeking a preliminary injunction must 'demonstrate that irreparable injury is likely in the absence of an injunction.'" *Anibowei v. Morgan*, 70 F.4th 898, 902 (5th Cir. 2023) (quoting *Winter*, 555 U.S. at 22). To meet that high bar, Dr. Purl must show not only an injury that is "actual or imminent," rather than "speculative, conjectural, or hypothetical," as is required to demonstrate Article III standing, *Abdullah v. Paxton*, 65 F.4th 204, 208 (5th Cir. 2023) (cleaned up)—something there is reason enough to doubt. She must also show that this injury is "substantial" and "immediate," *Los Angeles v. Lyons*, 461 U.S. 95, 111 (1983), such that absent emergency relief it would befall her before the case could be litigated on the merits in the normal course. Dr. Purl falls well short of making this heightened showing.

***Ability to Disclose Information About Child Abuse to State Authorities.*** Dr. Purl's theory of harm rests heavily on a fundamental misunderstanding that the 2024 Rule interferes with the reporting of suspected child abuse to state authorities. *See* Mot. 2, 4, 12, 21-22. To be clear, the Rule does not prohibit Dr. Purl—or any other doctor—from reporting suspected child abuse. The Rule does not repeal the longstanding provision in the 2000 Privacy Rule that permits covered entities to make disclosures about "child abuse or neglect." 45 C.F.R. § 164.512(b)(1). Under that provision, doctors may continue to report suspected child abuse even when reproductive health care is involved. The 2024 Rule does nothing to change that.

To the contrary, the 2024 Rule's preamble provides numerous examples to make clear that it does not interfere with reporting suspected child abuse. A covered entity can make a report "where the provision of reproductive health care to the individual is but one factor prompting the

suspicion," 89 Fed. Reg. at 33042, including where, for example, "medical examination of and conversation with the patient" indicates that abuse is "imminent," or where "examination of X-rays … show old fractures or other indications of physical trauma," App. 002. It can do so where it suspects that a child has been subjected to "sexual abuse." 89 Fed. Reg. at 33004; *see* App. 003. And it can do so where the care is unlawful in the state where it was provided or where someone was coerced into receiving care, to the extent state law defines those acts as abuse. *See* 45 C.F.R. §§ 164.502(a)(5)(iii), 164.512(c)(1); *see also* 89 Fed. Reg. at 32995 ("This rule does not prohibit the disclosure of PHI for investigating allegations of or imposing liability for sexual assault, sex trafficking, or coercing minors into obtaining reproductive health care."). The Rule simply clarifies that a covered entity 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 (e.g., treatment for a sexually transmitted infection) for a child." 89 Fed. Reg. at 33004 (emphasis added); *see also* 45 C.F.R. § 164.512(c)(3) (similar for other reports of abuse, neglect, or domestic violence).

More generally, the 2024 Rule does not interfere with Dr. Purl's ability to disclose information pertaining to other crimes in appropriate circumstances. The Rule only prohibits entities from disclosing PHI sought for the limited purpose of conducting an investigation or imposing liability for the "mere act of seeking, obtaining, providing, or facilitating reproductive health care," where that care *is lawful* under state or federal law. 45 C.F.R. § 164.502(a)(5)(iii). It does not prohibit entities from complying with legitimate investigations into *unlawful* reproductive health care, or from complying with requests not directed at imposing liability for the mere act of receiving lawful care. 89 Fed. Reg. at 33012. For example, if Dr. Purl discovers information that a patient received an unlawful abortion—or any other unlawful care, such as unlawful gender-affirming care—in Texas, the 2024 Rule does not prohibit her from disclosing that information.

Given the narrow scope of the 2024 Rule, it is unsurprising that Dr. Purl has not identified any prior instance in which she made a disclosure that was allowed under the 2000 Rule that would have been prohibited under the 2024 Rule. *See* App. 001-004. For example, Dr. Purl does not allege that she has ever reported suspected child abuse—or any other crime—based

solely on a patient's voluntary receipt of lawful reproductive health care. *Id.* Nor does she claim that she has ever received a subpoena or any other request pertaining to reproductive health care. *Id.* To the extent Dr. Purl is concerned about her ability to disclose information pertaining to "gender-transition procedures," Mot. 1, she admits that she has never even treated a pediatric patient receiving such care. App. 004. Nor has Dr. Purl identified any reason to think that she will face disclosure requests related to reproductive health care in the future, as is required for the prospective relief she seeks, given that she operates a small walk-in clinic that provides flu testing and other treatment that is far afield from the concerns she raises. App. 001. Regardless, to the extent a patient received unlawful care, the Rule does not prohibit disclosures of PHI in response to a subpoena, discovery request, or other lawful process or administrative request.

In addition to misapprehensions about the scope of the 2024 Rule, Dr. Purl's fear of conflict between the 2024 Rule and her obligations under state law rests on multiple layers of speculation and conjecture. For such a conflict to materialize, Dr. Purl would have to encounter a situation where: (1) a patient received lawful reproductive healthcare from another provider; (2) the patient discloses information about that care to Dr. Purl when seeking other treatment from her; (3) that care could properly be subject to liability despite being lawful under state law and/or protected by federal law; (4) an investigation or lawsuit is initiated; and (5) that investigation or lawsuit seeks information from Dr. Purl. It is thus wholly "speculative, conjectural, [and] hypothetical" that the Rule will ever prohibit Dr. Purl from making a disclosure, much less that it will do so imminently. *Abdullah*, 65 F.4th at 208; *cf. Lujan*, 504 U.S. at 564 ("Such 'some day' intentions … do not support a finding of the 'actual or imminent' injury that our cases require.").

***Compliance Costs.*** Dr. Purl's claimed "compliance costs" also do not warrant relief. Mot. 22. To constitute irreparable harm, any such costs "must be based on more than 'speculation' or 'unfounded fears,'" and their amount "must be 'more than de minimis.'" *Rest. L. Ctr. v. U.S. Dep't of Lab.*, 66 F.4th 593, 600 (5th Cir. 2023) (quotation omitted).

Any costs related to Dr. Purl's Notice of Privacy Practices are plainly not imminent. Dr. Purl has over fourteen months—until February 16, *2026*—to update her notice. 89 Fed. Reg. at

32976, 32979. And regardless of whether Dr. Purl prevails in this litigation, she will need to update that notice by the same date to comply with a separate, unchallenged rulemaking pertaining to substance use disorder records. *Id.* Dr. Purl therefore has not identified any costs related to updating her privacy notice that she would avoid by obtaining preliminary relief.

Dr. Purl's other alleged compliance costs are either speculative, unsubstantiated, or de minimis. *Cf. Second Amend. Found., Inc. v. ATF*, 702 F. Supp. 3d 513, 539-42 (N.D. Tex. 2023) ($200 tax was de minimis). Dr. Purl generally relies on the Rule's cost estimates, *see id.* at 22, but those estimates are an average across entities of widely differing sizes based on assumptions about how they might choose to comply with the Rule, *see* 89 Fed. Reg. at 33049-54, and do not indicate that any particular entity will suffer particular costs. To obtain preliminary relief, Dr. Purl must identify imminent injury to her; she cannot simply rely on average estimates described in the Rule without showing that those estimates reflect her situation. *See Barber v. Bryant*, 860 F.3d 345, 353 (5th Cir. 2017) (requiring challengers to present "evidence of an injury-in-fact").

For example, Dr. Purl fails to show that she will incur imminent and irreparable costs related to training her staff. Mot. 22; App. 005-006. Dr. Purl does not provide any evidence to corroborate her assertion about the costs, in time or money, that any training will consume. *Cf. Crane v. Johnson*, 783 F.3d 244, 252 (5th Cir. 2015) (rejecting financial costs that were "not supported by any facts"). In particular, Dr. Purl does not provide any details about her current HIPAA training procedures. This failure is critical given the nature of her practice. Dr. Purl runs a small medical practice, employing three nurse practitioners and about a dozen other support personnel, App. 001, and her staff training may well consist of asking staff to forward any disclosure requests for her to evaluate personally. App. 003. Without information about how Dr. Purl currently trains her staff, her allegations of increased training costs are purely speculative.

Nor can Dr. Purl establish imminent and irreparable training costs by choosing to implement the 2024 Rule in an unnecessarily onerous manner. The Rule does not require her to conduct any particular training on its requirements. Given the nature of her practice and the fact that the 2024 Rule is unlikely to affect her in any real-world situation, Dr. Purl could reasonably

adopt a procedure to handle any requests related to the 2024 Rule herself, thereby avoiding staff training. *See* 45 C.F.R. § 164.530 (requiring only "necessary and appropriate" training). To the extent Dr. Purl chooses to conduct staff training, "[t]he Department anticipate[d] that covered entities will be able to incorporate new content into existing HIPAA training requirements," rather than conduct a bespoke training solely for the 2024 Rule. 89 Fed. Reg. at 33056. Dr. Purl also could stagger training or integrate it into her procedures without disrupting her operations. If Dr. Purl chooses to close her clinic to conduct a new training for all her staff, that is her choice, but she cannot establish imminent and irreparable injury based on "a self-inflicted injury." *Zimmerman v. Austin*, 881 F.3d 378, 389 (5th Cir. 2018); *see FDA v. Alliance for Hippocratic Med.*, 602 U.S. 367, 394 (2024) (explaining that a plaintiff "cannot spend its way into standing").

Dr. Purl likewise fails to show that she will incur imminent and irreparable costs to develop "new or modified policies and procedures" or related to lost profits. She has not explained what her current policies are or why they would have to change in response to the 2024 Rule. To the extent Dr. Purl handles requests from law enforcement or reporting obligations herself, changing any written policies would be unnecessary. Similarly, because Dr. Purl has not substantiated any way in which the 2024 Rule will require her to expend time on training or updating her policies, any potential lost profits related to lost time are speculative.

Finally, Dr. Purl's delay in moving for a preliminary injunction—waiting six months after the Rule was promulgated to file suit, and another month to file her motion—strongly undercuts any claim of irreparable harm. "[A] party requesting a preliminary injunction must generally show reasonable diligence." *Benisek v. Lamone*, 585 U.S. 155, 159 (2018); *see, e.g.*, *George v. Abbott*, 2024 WL 4468506, at *5 (S.D. Tex. 2024) (explaining that "irreparable harm may be vitiated by a delay in seeking relief."); *Pastel Cartel, LLC v. FDA*, 2023 WL 9503484, at *3 (W.D. Tex. 2023) ("A delay undercuts the need that a party is facing irreparable harm."). Dr. Purl's delay is particularly significant because, by waiting six months to file her case, and then an additional month to seek preliminary relief, she ensured that her motion might not be fully briefed until December 17, just *six days* before the 2024 Rule's December 23 compliance date.

Having waited until the eleventh hour, Dr. Purl cannot seriously contend that any costs of complying with the 2024 Rule are so severe as to warrant emergency relief.

**B. Dr. Purl has not shown a substantial likelihood of success on the merits.**

Even if Dr. Purl could show irreparable harm, she fails to establish that she is likely to prevail on the merits. First, the Rule does not infringe upon state authority to investigate child abuse or public health. Second, the Department had authority to promulgate standards that take into account the sensitivity of specific categories of information. And third, the Department reasonably explained how covered entities can apply the Rule's disclosure prohibition.

**1. The 2024 Rule is consistent with HIPAA's preservation of state investigative authority.**

**a. The Rule does not prohibit disclosures about child abuse or public health matters to state authorities.**

Dr. Purl's assertion that the 2024 Rule restricts disclosures about child abuse or public health matters to state authorities, Mot. 13, faces the same problem as her allegations of harm: the Rule does nothing of the sort. As explained above, the Rule "does not seek to prohibit disclosures of PHI where the request is for reasons other than investigating or imposing liability on persons for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided," including for lawful investigations relating to child abuse or public health. 89 Fed. Reg. at 32994. To the contrary, the Rule maintains the Privacy Rule's existing provisions permitting the use or disclosure of information for such activities. *See* 45 C.F.R. § 164.512(b), (c). Because the Rule in no way "limit[s] the authority, power, or procedures established under any law providing for the reporting of … child abuse, … public health surveillance, or public health investigation or intervention," 42 U.S.C. § 1320d-7(b), it does not transgress HIPAA's preemption carveouts, and so Dr. Purl's reliance on cases about those carveouts is unavailing. Mot. 13.

By claiming that the 2024 Rule, which only prohibits certain disclosures pertaining to lawful reproductive health care, conflicts with her state law reporting obligations, Dr. Purl's

argument turns on the illogical premise that the mere act of facilitating *lawful* care constitutes child abuse under state law. But she provides no basis for that assertion. Mot. 14. It is also inconsistent with Texas law, which does not enumerate lawful care as a form of "abuse." *See* 89 Fed. Reg. at 33004; *see also* Tex. Fam. Code § 261.001 (defining "child abuse" without referring to reproductive health care). Nor is imposing liability generally a feature of a "public health" activity. 89 Fed. Reg. at 33001-02 & nn.233-40 (describing the ways that state criminal codes are distinct and separate from their public health reporting laws). In any event, the fact that some provisions of the 2024 Rule might hypothetically conflict with certain unknown state laws in some circumstances provides no basis to enjoin the entirety of the Rule in all circumstances; the Rule contains a severability provision directing that "[i]f any provision … is held to be invalid or unenforceable … as applied to any person, plaintiff, or circumstance, it shall be construed to give maximum effect to the provision permitted by law." 45 C.F.R. § 164.535.

Dr. Purl also complains that "the 2024 Rule is not evenhanded" because it permits covered entities to disclose information to defend themselves against investigations into the "unlawful provision" of reproductive health care, Mot. 14, but whether the 2024 Rule's prohibitions are "evenhanded" is irrelevant to whether they comply with the statute's reservation of state authority. Regardless, the 2024 Rule does not prohibit the disclosure of PHI in connection with the *unlawful* provision of care at all, so it is entirely symmetrical. 45 C.F.R. § 164.502(a)(5)(iii)(B). And the 2000 Privacy Rule has always permitted entities to make certain disclosures to obtain legal services or for the purposes of legal proceedings. 45 C.F.R. §§ 164.501 (definition of "health care operations"), 154.502(a)(1)(ii), 164.506(c)(1), 164.512(e).

**b. The Rule correctly interprets "person" and "public health" as used in HIPAA.**

Next, Dr. Purl criticizes how the 2024 Rule defines two of HIPAA's terms, but her criticisms misinterpret multiple federal statutes.

***First***, the Department's clarification that a "natural person" is "a human being who is born alive," 45 C.F.R. § 160.103, is entirely consistent with both longstanding practice and with

the Dictionary Act. *See* 89 Fed. Reg. at 32997; *cf.* Mot. 15-16. The Dictionary Act, as amended by the Born-Alive Infants Protection Act, instructs that, "in determining the meaning of any act of Congress," the term "person" "shall include every infant member of the species homo sapiens who is *born alive* at any stage of development." 1 U.S.C. § 8(a) (emphasis added). If the natural meaning of "person" already included the unborn fetus, Congress would have had no reason to specifically include children born alive. *See Tex. Bankers Ass'n v. Off. of the Comptroller*, 2024 WL 1349308, at *6 (N.D. Tex. 2024) ("'Expressing one item of an associated group or series excludes another left unmentioned.'") (quoting *Baptist Mem'l Hosp. - Golden Triangle, Inc. v. Azar*, 956 F.3d 689, 694 (5th Cir. 2020)). Nor does the Department's interpretation "deny … any legal status or legal right," 1 U.S.C. § 8(c), that might otherwise apply to the unborn under HIPAA, because HIPAA does not itself include any language that could properly be construed as extending to the unborn. Indeed, unborn fetuses typically do not have their own medical records, so it would be anomalous for HIPAA to cover them. *See* 89 Fed. Reg. 32997 & n.191.

Every case interpreting the Dictionary Act has sided with the Department's reading. As the Tenth Circuit explained, "Congress used the word *include* to emphasize that the term *person* extended to any infant born alive, not to suggest that a fetus could be a *person* without being born alive." *United States v. Adams*, 40 F.4th 1162, 1170 (10th Cir. 2022); *see Dupuch-Carron v. HHS*, 969 F.3d 1318, 1328 (Fed. Cir. 2020) ("Section 8(a) of Title 1 limits the term 'child,' as used in all acts of Congress, to those born alive."); *Gomez Fernandez v. Barr*, 969 F.3d 1077, 1087 (9th Cir. 2020) ("The term 'human being' thus does not include a fetus."); *United States v. Montgomery*, 635 F.3d 1074, 1086 (8th Cir. 2011) ("Under a literal reading of the statute, the term 'person' does not include fetuses."); *Warnock v. Off. of Servicemembers' Grp. Life Ins.*, 2004 WL 1087364, at *2 (S.D. Ind. 2004). Dr. Purl provides no reason to hold otherwise.

***Second***, the Department correctly defined "public health, as used in the terms 'public health surveillance,' 'public health investigation,' and 'public health intervention,'" to mean "population-level activities to prevent disease in and promote the health of populations," rather than efforts to "conduct … investigation[s]" or "impose … liability" on individuals. 45 C.F.R.

§ 160.103. "Since the time of HIPAA's enactment, public health activities … have been widely understood to refer to activities aimed at improving the health of a population," like "vaccination campaigns" or "investigation of the source of an outbreak of food poisoning." 89 Fed. Reg. at 33001 & nn.233-38 (citing, e.g., *Public Health*, Black's Law Dictionary (11th ed. 2019)). In contrast, "criminal investigations … primarily focus on imposing liability on persons who have broken the law." *Id.* at 33001-02 & n.240. Rather than address the Department's reasoning, Dr. Purl takes aim at a strawman. The Department did not "declare that the harms from abortion, medical gender-transition interventions, or other politically favored procedures do not count as 'public health' concerns," Mot. 16; 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.

Even if Dr. Purl's criticisms as to either term were well-founded, they would provide no basis to invalidate the rest of the Rule. The Department expressly concluded that both interpretations were severable from the rest of the Rule, which should therefore remain "in full force and effect." 89 Fed. Reg. at 33048 (citing 45 C.F.R. § 164.535).

**c. The Rule respects federalism.**

Dr. Purl's reliance on generalized federalism concerns is similarly unavailing. Mot. 16. In enacting HIPAA, Congress expressly preempted contrary State law, subject to limited exceptions that do not apply here. 42 U.S.C. § 1320d-7(a)(1); *see supra* Section I.B.1.a. Moreover, as the Rule acknowledges, states "still have great authority to enforce their laws, including their laws banning abortion," and covered entities may still comply with "state requests for PHI, unless it is for one of the limited prohibited purposes." 89 Fed. Reg. at 33,061. None of the generic federalism cases cited by Dr. Purl have anything to do with the federal interest in the privacy of medical information, with the scope of HIPAA's express preemption provision, or indeed, with HIPAA at all. *See* Mot. 16-17.

**2. The Department had authority to promulgate the 2024 Rule.**

The 2024 Rule is also a lawful exercise of the Department's statutory authority to promulgate and revise standards for the privacy of PHI. *Cf.* Mot. 17-18. Congress authorized the Department to promulgate "standards with respect to the privacy of individually identifiable health information" including "at least … (1) [t]he rights that an individual who is a subject of individually identifiable health information should have"; "(2) [t]he procedures that should be established for the exercise of such rights"; and "(3) [t]he uses and disclosures of such information that should be authorized or required." 42 U.S.C. § 1320d-2 note. Congress also charged the Secretary to "review th[ose] standards" and "adopt modifications to the standards (including additions to the standards), as determined appropriate." *Id.* § 1320d-3(b)(1). That specific grant of authority buttresses the Secretary's general authority to "make and publish such rules and regulations … as may be necessary to the efficient administration of the functions with which [the Secretary] is charged under [HIPAA]." *Id.* § 1302(a). The 2024 Rule falls well within these authorities, which the Rule cited and thoroughly discussed. *See* 89 Fed. Reg. at 32980-84.

Dr. Purl nevertheless insists that the Department lacks authority to promulgate regulations that strengthen protections for specific, highly sensitive forms of protected health information. Mot. 17. But nothing in HIPAA's text requires the Department to impose the same protections for all forms of health information, regardless of their sensitivity. The statute simply directs the Secretary to promulgate "standards with respect to the privacy of individually identifiable health information," including standards regarding "uses and disclosures." 42 U.S.C. § 1320d-2 note. If anything, Congress's instruction that the Secretary formulate "*detailed* recommendations," *id.* (emphasis added), reflects Congress's awareness that the work of standard-setting would involve significant complexity and variation.

Dr. Purl's reading would also transgress the rule that courts "may not engraft [their] own exceptions onto the statutory text." *Henry Schein, Inc. v. Archer & White Sales, Inc.*, 586 U.S. 63, 70 (2019). The "fundamental principle of statutory interpretation that 'absent provisions cannot be supplied by the courts' applies not only to adding terms not found in the statute, but

also to imposing limits on an agency's discretion that are not supported by the text." *Little Sisters of the Poor v. Pennsylvania*, 591 U.S. 657, 677 (2020) (quoting *Rotkiske v. Klemm*, 589 U.S. 8, 14 (2019), in turn quoting Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 94 (2012)). The statute itself does not preclude the Department from strengthening protections for specific forms of information. "By introducing a limitation not found in the statute," Dr. Purl asks the Court "to alter, rather than to interpret," HIPAA. *Id.*

Indeed, the Department's regulations have long provided "special protection" for a specific category of records: "psychotherapy notes, owing in part to the particularly sensitive information those notes contain." 89 Fed. Reg. at 32977-78, 32986-87 (citing 45 C.F.R. §§ 164.501, 164.508(a)(2)); *see* 65 Fed. Reg. at 82497, 82514-15; 64 Fed. Reg. at 59941-42. The Secretary's original recommendations specifically noted that "Federal and State laws already provide stronger protections for certain information, (such as information about HIV status, substance abuse patient information, and mental health records)," and "recognize[d] that additional types of particularly sensitive information may be identified for special protection in the future." *Recommendations of the Secretary of Health and Human Services*, U.S. Dep't of Health & Human Servs. (Sep. 10, 1997), https://perma.cc/FQ4S-Y45C. Dr. Purl notes that "psychotherapy notes are a type of health record," while abortion is a "procedure[]," but that is a red herring. The 2024 Rule restricts the disclosure of PHI, 45 C.F.R. § 164.502(a)(5)(iii)(A), defined as information that is "transmitted" or "maintained" in "electronic media" or "any other form or medium," *id.* § 160.103—i.e., it also restricts the use or disclosure of *records*. And it does so out of the same concern for the sensitivity of those records.[2]

The 2024 Rule also does not run afoul of the major questions doctrine. *Cf.* Mot. 17-18. That doctrine applies only in "extraordinary cases" involving "decisions of vast economic and

[2] NCVHS, with which the Department is statutorily required to consult, *see* 42 U.S.C. § 1320d-2 note, has also repeatedly recommended that the Department strengthen privacy protections for particular categories of information, *see* 89 Fed. Reg. at 32986-87—without facing criticism that doing so would be inconsistent with HIPAA.

political significance," which Dr. Purl does not assert is the case here. *West Virginia v. EPA*, 597 U.S. 697 (2022). Even if it were applicable, the 2024 Rule is an exercise of the Department's core authority under HIPAA to enact protections for protected health information, as it has done for decades. Thus, the 2024 Rule "is neither novel nor unprecedented." *Strickland v. USDA*, 2024 WL 2886574, at *4-5 (N.D. Tex. 2024). Dr. Purl objects that HIPAA does not mention "specific medical procedures," Mot. 18, but there is "no such thing as a 'canon of donut holes,' in which Congress's failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception," *Bostock v. Clayton Cty.*, 590 U.S. 644, 669 (2020). The statute that Congress enacted therefore permits the Department's action.

**3. The 2024 Rule is not arbitrary and capricious.**

Finally, the Department fully explained how it crafted the Rule's prohibition to protect individuals' heightened privacy interest in information relating to lawful reproductive care while acknowledging the legitimate needs of law enforcement and the concerns of providers. *See* 89 Fed. Reg. at 33009-27. To satisfy the arbitrary-and-capricious standard, the agency need only "articulate a satisfactory explanation for the action including a rational connection between the facts found and the choice made." *Little Sisters of the Poor*, 591 U.S. at 682 (quotation omitted). Under this "deferential" standard, a court "simply ensures that the agency has acted within a zone of reasonableness," and "may not substitute its own policy judgment for that of the agency." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

The fact that the 2024 Rule requires covered entities to determine whether governmental requests for information are valid is neither insufficiently explained nor even unusual. *Cf.* Mot 18-21. As the Department explained, the Privacy Rule has long "permit[ted] regulated entities to rely on representations made by public officials where it is reasonable to do so but ma[de] clear that in some instances, documentary or other evidentiary proof is needed." 89 Fed. Reg. at 33016. More broadly, the Privacy Rule requires covered entities to make assessments involving "applicable law" in other contexts, including in determining the authority of a "personal

representative," 45 C.F.R. § 164.502(g), providing information about a deceased patient, *id.* § 164.512(g), and disclosing information relevant to a serious health threat, *id.* § 164.512(j). Dr. Purl provides no reason why these determinations are "within the scope of a healthcare provider's usual competence," but determining the lawfulness of care is "not." Mot. 19.

The Department reasonably articulated how covered entities are to determine whether reproductive health care is lawful for the purpose of applying the 2024 Rule's disclosure prohibition. *Cf. id.* Where the request for information is made to the entity that provided the care at issue, the provider should conduct "a review of all available relevant evidence bearing on whether the reproductive health care was lawful under the circumstances in which it was provided." 89 Fed. Reg. at 33015. Surely Dr. Purl is capable of assessing the legality of care that *her clinic provided*. In contrast, where the request is made to an entity that did *not* provide the care at issue, that entity is entitled to "presume[]" that the care is "lawful" unless it has "[a]ctual knowledge that the reproductive health care was not lawful" or "factual information supplied by the person requesting the use or disclosure … that demonstrates a substantial factual basis that the reproductive health care was not lawful." 45 C.F.R. § 164.502(a)(5)(iii)(C). Indeed, the Department added that presumption precisely to address "commenters' concerns" about determining the lawfulness of care. 89 Fed. Reg. at 33,014. Dr. Purl never explains why that presumption is unworkable or why it fails to alleviate her concerns.

The 2024 Rule certainly does not require covered entities to ignore State law, as Dr. Purl suggests. Mot. 19-20. Its prohibition applies only where "[t]he reproductive health care is lawful under the law of the state in which such health care is provided under the circumstances in which it is provided," or where the care is "protected, required, or authorized by Federal law, including the United States Constitution." 45 C.F.R. § 164.502(a)(5)(iii)(B). If Dr. Purl has actual knowledge or a substantial factual basis to conclude that the care provided by someone else is *un*lawful, "the prohibition would not apply." 89 Fed. Reg. at 33,012. Nor is it unreasonable to require covered entities to determine whether reproductive health care is protected, required, or authorized by Federal law, the last of which occurs "where there is no conflicting state restriction

… or where applicable Federal law preempts a contrary state restriction." *Id.* at 33024.[3] Again, covered entities are required to determine whether the care they provide is legally authorized or required *all of the time*. To the extent that providers cannot determine whether care provided by *another* entity was required or authorized, the presumption of lawfulness was intended to, and should, address those concerns. *See* 45 C.F.R. § 164.502(a)(5)(iii)(C).

The remainder of Dr. Purl's arbitrary-and-capricious arguments are underdeveloped at best. Mot. 21. The Department's interpretations of the terms "person" and "public health" are both adequately explained and, indeed, correct. *See supra* Section I.B.1.b. Similarly, the Department reasonably explained that it chose to adopt a broad definition of "reproductive health care" to be "[c]onsistent with the definition of 'health care' in the HIPAA Rules" and to "encompass[] the full range of health care related to an individual's reproductive health," rather than "create the risk that important activities would be left out" and result in "confusion." 89 Fed. Reg. at 33005. Finally, the Department provided a lengthy explanation of how entities should comply with the attestation requirement, including when they are entitled to rely on an attestation and when further investigation would be warranted. *See id.* at 33029-32. It also provided a model attestation and other resources to make it easier for entities to apply the Rule's requirements. *See, e.g.*, *Model Attestation*, HHS, https://www.hhs.gov/sites/default/files/model-attestation.pdf. Although Dr. Purl may disagree with the Department's explanations and policy choices, mere disagreement provides no basis for setting them aside.

### C. The equities strongly disfavor injunctive relief.

Given Dr. Purl's failure to establish the first two factors, the Court need go no further to deny her motion. *See, e.g.*, *Deerfield Med. Ctr. v. Deerfield Beach*, 661 F.2d 328, 338 (5th Cir.

[3] The Department does not dispute that *Dobbs* controls over the *Roe / Casey* framework. *Cf.* Mot. 20-21 & n.14. The outdated guidance document to which Dr. Purl refers was published in September 17, 2021, approximately nine months before *Dobbs*, and has not been substantively reviewed since its issuance. *See* App. 013.

1981). Regardless, the equities and the public interest, which "merge when the Government is the opposing party," *Nken v. Holder*, 556 U.S. 418, 435 (2009), tilt decisively against relief.

To the extent the 2024 Rule has any implications for Dr. Purl at all, enjoining the Rule would risk the disclosure of her patients' protected health information in a manner that is inconsistent with HIPAA's purpose. As the Department found when promulgating the Rule, "[i]nformation about reproductive health care is particularly sensitive and requires heightened privacy protection." 89 Fed. Reg. at 32990; *see also id.* at 32986-87 (citing AMA's Principles of Medical Ethics and recommendations of NCVHS). Given the shifting legal landscape, 89 Fed. Reg. at 32987, enjoining the 2024 Rule's protections would necessarily increase the likelihood that such information will be exposed. Once exposed, that sensitive information cannot be un-exposed—meaning that an injunction could result in irreparable harm to Dr. Purl's patients. *Cf. FMC Corp. v. Varco Int'l, Inc.*, 677 F.2d 500, 504 (5th Cir. 1982) (finding that irrevocable loss of trade secrets constituted irreparable harm). And if the Court were to enjoin the 2024 Rule nationwide, that harm would similarly extend to individuals across the country.

The possibility of disclosure will also jeopardize access to necessary medical care by generating fear among patients about how their private medical information may be used. As the Department has long recognized, "individuals may be deterred from seeking needed health care if they do not trust that their sensitive information will be kept private." 89 Fed. Reg. at 32984; *see* 88 Fed. Reg. at 23508 & nn.12-16 (citing studies); 65 Fed. Reg. at 82468 (same). The Supreme Court has noted the same concern. *See Whalen*, 429 U.S. at 602 ("Unquestionably, some individuals' concern for their own privacy may lead them to avoid or to postpone needed medical attention."). Other patients may seek care but withhold information from their providers, depriving providers of "necessary information … for an appropriate treatment plan, which may result in negative health outcomes at both the individual and population level." 89 Fed. Reg. at 32991. And even when a provider receives accurate information, the provider may "leave gaps or include inaccuracies when preparing medical records, creating a risk that ongoing or future health care could be compromised." *Id.* at 32985; *see id.* at 33049 (cataloguing Rule's benefits).

Dr. Purl's stated concern for the interests of law enforcement is unfounded. *See* Mot. 23. As explained above, nothing in the 2024 Rule changes the rules for reporting suspected child abuse or similar matters. The Rule also respects a state's legitimate policy judgments by continuing to allow disclosure of information, consistent with the Privacy Rule's longstanding exceptions, in cases of *unlawful* reproductive health care. Indeed, Texas is the only state to have challenged the 2024 Rule in court, and it has not sought a preliminary injunction, suggesting that the possibility of any imminent risk to law enforcement interests is substantially overstated. *See* Jt. Mot. to Enter Briefing Sched., *Texas v. HHS*, No. 5:24-cv-204 (N.D. Tex.), ECF No. 14; *cf.* 45 C.F.R. § 164.512(j)(1)(i)(A) (permitting disclosure where "necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public").

Dr. Purl also asserts that the public interest is served by requiring agencies to comply with the APA, Mot. 24-25, but that attempt to collapse the merits into the public interest factor fails in two ways. First, Plaintiffs have not actually shown an APA violation. *See infra* Section II.A. Second, there is also "inherent harm to an agency" in preventing it from interpreting statutes that "Congress found it in the public interest to direct that [it] develop and enforce." *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008); *cf. Maryland v. King*, 567 U.S. 1301, 1303 (2012) ("[A]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury.") (quotation omitted). If the merits are unclear, the importance of protecting the private medical information of patients should carry the day over Dr. Purl's unfounded concerns about compliance with the 2024 Rule.

## II. Any relief should be appropriately limited.

In the event the Court concludes that relief is appropriate, that relief should not extend beyond Dr. Purl's medical practice. Although Dr. Purl's proposed order asks the Court to "stay[]" the 2024 Rule "under 5 U.S.C. § 705" and "enjoin[]" Defendants "from taking *any* action to enforce the [] Rule," Proposed Order 1 (emphasis added), and thereby appears to seek universal injunctive relief, her motion contains no argument for why such a sweeping remedy

would be appropriate or even permissible. That failure alone provides a basis for rejecting Dr. Purl's request. *Cf. United States v. Scroggins*, 599 F.3d 433, 446 (5th Cir. 2010) ("A party that asserts an argument on appeal, but fails to adequately brief it, is deemed to have waived it. It is not enough to merely mention or allude to a legal theory.").

Regardless, so-called universal injunctions (and universal stays under 5 U.S.C. § 705) exceed basic principles of jurisdiction and equity. "'[S]tanding is not dispensed in gross': A plaintiff's remedy must be tailored to redress the plaintiff's particular injury." *Gill v. Whitford*, 585 U.S. 48, 73 (2018) (quoting *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 353 (2006)). Moreover, "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). However framed, universal relief also threatens to "stymie the orderly review of important questions," "render meaningless rules about joinder and class actions," and "sweep up nonparties who may not wish to receive the benefit of the court's decision." *United States v. Texas*, 599 U.S. 670, 703 (2023) (Gorsuch, J., concurring, joined by Thomas & Barrett, JJ.).[4]

These principles strongly disfavor any such relief in this case. The Court can prevent any purported injury to Dr. Purl by simply enjoining the Department from enforcing the 2024 Rule against her during the pendency of this lawsuit. Under that scenario, Dr. Purl need only comply with the requirements of the 2000 Privacy Rule, as she has presumably done for decades. *See* App. 001. An injunction limited to Dr. Purl would therefore provide her with "complete relief." *Califano*, 442 U.S. at 702. "Nor would party-specific injunctive relief in this case prove unwieldy or cause more confusion for geographic reasons," given that Dr. Purl is based in a single Texas county. *Braidwood Mgmt., Inc. v. Becerra*, 104 F.4th 930, 954–55 (5th Cir. 2024) (cleaned up); *cf. Texas v. United States*, 2024 WL 3405342, at *16 (N.D. Tex. 2024) (limiting relief to plaintiffs).

[4] The Department preserves the argument that the Court cannot issue a § 705 stay where, as here, a rule has gone into effect. *See Texas v. Biden*, 646 F. Supp. 3d 753, 769 (N.D. Tex. 2022).

In contrast, a nationwide injunction would harm a vast array of parties not before the Court. Barring the Department from enforcing the 2024 Rule nationwide would risk exposing the protected health information of Americans across the country, thereby eroding patients' trust and confidence in the health care system and discouraging the public at large from seeking needed medical care. Entering such an injunction immediately before the December 23 compliance date would also harm entities who have already taken steps to comply with the 2024 Rule, potentially forcing entities of all sizes, including major hospital chains and insurance plans with tens of thousands of employees, to rewrite their policies and retrain their staff in a matter of days to revert to the 2000 Privacy Rule. The Court should refrain from sparking that sort of nationwide chaos, particularly where it is utterly unnecessary to redress any of Dr. Purl's alleged harms.

Separately, this Court should appropriately tailor any preliminary relief in light of the 2024 Rule's severability provision. The Rule expressly provides that, "[i]f any provision of the [2024 Rule] is held to be invalid or unenforceable facially, or as applied to any person, plaintiff, or circumstance, it shall be construed to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which case the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances." 45 C.F.R. § 164.535. The preamble similarly explained that "[t]he Department intends that, if a specific regulatory provision in this rule is found to be invalid or unenforceable, the remaining provisions of the rule will remain in effect because they would still function sensibly." 89 Fed. Reg. 33048. Thus, even if Dr. Purl had established imminent and irreparable harm, as well as a likelihood of success with respect to any particular provision of the Rule, the Rule should be preliminarily enjoined only with respect to those provisions.

## CONCLUSION

For these reasons, the Court should deny Dr. Purl's motion for a preliminary injunction.

Dated: December 3, 2024

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

ERIC B. BECKENHAUER
Assistant Branch Director

*/s/ John T. Lewis*
JOHN T. LEWIS (TX Bar No. 24095074)
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, D.C. 20530
Tel: (202) 353-0533
Fax: (202) 616-8460
E-mail: john.t.lewis.iii@usdoj.gov

*Attorneys for Defendants*

**CERTIFICATE OF SERVICE**

I hereby certify that on December 3, 2024, a copy of the foregoing was filed electronically via the Court's ECF system, which effects service upon counsel of record.

*/s/ John T. Lewis*
John T. Lewis