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' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

Defendants the U.S. Department of Health & Human Services, Xavier Becerra, in his official capacity as Secretary of Health & Human Services, the Office for Civil Rights of the U.S. Department of Health & Human Services, and Melanie Fontes Rainer, in her official capacity as Director of the Office for Civil Rights of the U.S. Department of Health & Human Services, hereby move to dismiss or, in the alternative, for summary judgment. Because the Court lacks subject-matter jurisdiction over Plaintiffs' claims, this case should be dismissed. In the alternative, the Court should enter judgment for Defendants under Rule 56. Each of the matters required by Local Rule 56.3(a) is set forth in Defendants' accompanying brief. A proposed order is enclosed herein.

Dated: January 17, 2025

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 January 17, 2025, 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

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 SUPPORT OF MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

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

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes, Rules, and Regulations

Other Authorities

INTRODUCTION

As part of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. 104-191, 110 Stat. 1936, Congress directed the U.S. Department of Health and Human Services (collectively with the other Defendants, 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 "Protected Health Information" ("PHI") can be used and disclosed and permitting specified uses and disclosures for certain important purposes. *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) (the "2000 Privacy Rule"). In April 2024, in light of widespread concern from providers and patients about the disclosure of PHI relating to reproductive health, the Department revised the Privacy Rule to strengthen protections for PHI pertaining to lawful reproductive health care. *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32976-01 (Apr. 26, 2024) (the "2024 Rule"). The 2024 Rule has been in effect since June 25, 2024, and covered entities have generally been required to comply with the rule since December 23, 2024. *Id.*

Dr. Carmen Purl and her medical practice (collectively, "Dr. Purl") now seek an order vacating and permanently enjoining the Department from enforcing the 2024 Rule across the country—eliminating vital privacy protections for sensitive PHI nationwide. The relief that Dr. Purl requests would apply to doctor's offices, health plans, and hospitals across the country, and to information relating to subjects as varied as contraception, prenatal care, in vitro fertilization, infertility, and menopause. Of course, the Department acknowledges that the Court has already held that Dr. Purl is likely to prevail on one of her objections to the Rule. *See* Mem. Op. & Order, ECF No. 34 ("PI Op."). However, the "conclusions of law made by a court granting a preliminary injunction are not binding" on summary judgment, *Univ. of Texas v. Camenisch*, 451

U.S. 390, 395 (1981), and both the breadth of Dr. Purl's request and the weakness of her claims warrant another look.

Even assuming that Dr. Purl can demonstrate that she possesses Article III standing to challenge the 2024 Rule, all of her claims fail on the merits. The Court ruled for Dr. Purl at the preliminary-injunction stage on the sole ground that she was likely to show that the Rule unlawfully limited child abuse reporting in violation of 42 U.S.C. § 1320d-7(b). *See* PI Op. 15. But that is simply incorrect. The 2024 Rule does not rescind, modify, or disturb the very provision of the 2000 Privacy Rule that the Court noted "specifically protects reports of 'child abuse' to those 'authorized by law' to receive such reports." *Id.* at 4 (quoting 45 C.F.R. § 164.512(b)(1)(ii)). The 2024 Rule does restrict how entities comply with law enforcement *requests*, to the extent those requests seek to investigate or impose liability for the mere act of receiving lawful reproductive health care. But § 1320d-7(b) does not speak to that subject at all; it only precludes the Department from issuing rules that "limit the authority, power, or procedures established under any law providing for the *reporting* of … child abuse" (emphasis added). Moreover, there is no evidence or indication that the 2024 Rule's framework will, in fact, make it more difficult for law enforcement to obtain information about suspected child abuse or other crimes.

The remainder of Dr. Purl's claims are similarly meritless. HIPAA unambiguously confers authority upon the Department to promulgate and modify rules regarding permissible "uses and disclosures" of PHI, *see* 42 U.S.C. §§ 1320d-2 note (codifying Pub. L. 104-191, title II, § 264) (Recommendations with Respect to Privacy of Certain Health Information), 1320d-3(b)(1), including rules that appropriately provide heightened protection to forms of medical information that are widely considered to carry heightened sensitivity. The Department also

correctly defined the terms "person" and "public health." And the Department fully explained each of its decisions in promulgating the 2024 Rule, including why it chose to prohibit disclosures related to imposing liability for lawful reproductive care and how it addressed commenters' concerns about potential compliance burdens. Finally, neither the non-delegation doctrine nor vagueness—which Dr. Purl does not raise as claims or even mention in her Complaint—provides a basis for invalidating the 2024 Rule, let alone HIPAA itself. The Court should refrain from issuing an order that would risk the exposure of Americans' private medical information nationwide.

For these reasons, the Court should grant the Department's motion and dismiss this case. In the alternative, it should enter judgment for the Department.

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 uniform standards and requirements for the electronic transmission of certain health information." 42 U.S.C. § 1320d note (Purpose). HIPAA applies to "covered entities," which are 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. 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 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 law enforcement 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, 599-600 (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 2000 Privacy Rule sets out detailed standards for the use and disclosure of "protected health information" ("PHI"), which is defined as "individually identifiable health information" that is "[t]ransmitted" or "maintained" in "electronic media" or "any other form or medium." 45 C.F.R. § 160.103. Under the Rule, PHI is generally protected from use or disclosure without an individual's written authorization. *Id.* § 164.502(a). However, an individual's PHI can be used and disclosed for a number of purposes, including treatment,

payment, and health care operations, without the individual's written authorization. *Id.* §§ 164.502(a)(1)(ii), 164.506.

The 2000 Privacy Rule also permits the disclosure of PHI without the individual's written authorization to government agencies, including both federal and state agencies, in limited, clearly defined circumstances. *Id.* § 164.512. In particular, the Rule permits the disclosure of PHI 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); for "health oversight activities," *id.* § 164.512(d); as required by "judicial and administrative proceedings," *id.* § 164.512(e); for "law enforcement purposes," *id.* § 164.512(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 law enforcement agencies, as well as considering approximately 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 regulated entities generally had 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.

In the wake of *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), 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 narrowly protects sensitive information by prohibiting regulated 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 defines "[r]eproductive health care" as "health care," previously defined in HIPAA's existing regulations, "that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes." *Id.* § 160.103. The Rule also contains a "[r]ule of applicability" directing that 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" 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" from the relevant state or federal agency 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 also explicitly preserves the 2000 Privacy Rule's existing provisions permitting the disclosure of PHI for public health activities, including the reporting of child abuse. 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 Department therefore clarified 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." *Id.* As to the Privacy Rule's provision concerning disclosures about adult abuse victims, the 2024 Rule similarly adds a "[r]ule of construction" that "[n]othing 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). Finally, the 2024 Rule defines "[p]ublic 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. *Id.* § 160.103.

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. *See* App. in Supp. of Pls.' Mot. for Prelim. Inj. at 001-004, ECF No. 25 ("PI App."). Dr. Purl's clinic provides "everyday" medical services like sick visits, flu/COVID testing, basic sutures, and vaccines. *Id.* 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.*; *see also* Dr. Purl's Fast Care Clinic, https://drpurlfastcare.com/ (last visited Jan. 16, 2025).

On October 21, 2024, Dr. Purl filed her Complaint, which alleges that the 2024 Rule is contrary to law and arbitrary and capricious. *See* Compl., ECF No 1. She filed a motion for a preliminary injunction on November 12. *See* Pls.' Mot. for Prelim. Inj. & Br. in Supp., ECF No. 24 ("PI Mot."). On December 22, the Court granted a preliminary injunction limited to Dr. Purl,

holding that she was likely to succeed on her claim that, although the 2024 Rule neither "*bar[s]* reporting of child abuse" nor "'seek[s]' that outcome," it "slows down" and thereby "limits" such reporting in violation of 42 U.S.C. § 1320d-7(b). PI Op. 15. The Court also ordered the parties to file summary judgment briefing, including supplemental briefing "explaining how (1) the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), (2) the major questions doctrine, and (3) the nondelegation doctrine affect the constitutionality or legality of HIPAA *and* HHS's authority to issue the 2024 Rule," as well as briefing explaining how the Rule's definition of reproductive health care "is or is not 'void for vagueness.'" *Id.* at 21-22.[1]

LEGAL STANDARD

"The burden of proof for a Rule 12(b)(1) motion to dismiss is on the party asserting jurisdiction." *Laufer v. Mann Hosp., L.L.C.*, 996 F.3d 269, 271 (5th Cir. 2021) (quotations omitted). "Lack of subject matter jurisdiction may be found in any one of three instances: (1) the complaint alone; (2) the complaint supplemented by undisputed facts evidenced in the record; or (3) the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001). To the extent the Court has subject-matter jurisdiction, summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986).

[1] The Department addresses the Court's questions concerning *Loper Bright* and the major-questions doctrine in Section II.A.4, and addresses the Court's questions concerning the non-delegation doctrine and vagueness in Section II.C.

ARGUMENT

I. The Court should dismiss this case for lack of subject-matter jurisdiction.

Dr. Purl has not met her burden to demonstrate that she has Article III standing to challenge the 2024 Rule, and so the Court lacks subject-matter jurisdiction to adjudicate her claims. "Article III of the Constitution limits federal courts' jurisdiction" to the adjudication of "'Cases' and 'Controversies.'" *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 408 (2013). "[A]n essential and unchanging part of the case-or-controversy requirement" is that plaintiffs must have "standing to invoke the authority of a federal court." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 (2006) (citation omitted). Standing is therefore a "threshold jurisdictional question[,]" *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102 (1998), determining "the power of the court to entertain the suit," *Warth v. Seldin*, 422 U.S. 490, 498 (1975).

Dr. Purl, as the party "invoking federal jurisdiction[,] bears the burden of establishing" standing. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). "While 'general factual allegations of injury resulting from the defendant's conduct may suffice' at the pleadings stage," at summary judgment, a plaintiff "must point to specific summary judgment evidence showing that it was directly affected" by the challenged action. *Texas State LULAC v. Elfant*, 52 F.4th 248, 255 n.4 (5th Cir. 2022) (quoting *ACORN v. Fowler*, 178 F.3d 350, 354 (5th Cir. 1999)); *see also Texas v. United States*, 50 F.4th 498, 513-14 (5th Cir. 2022) ("At summary judgment, [a plaintiff] can no longer rest on mere allegations, but must set forth by affidavit or other evidence specific facts.") (quotation omitted). Specifically, to prevail at summary judgment, Dr. Purl must present specific evidence showing that she has "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). An injury in fact

cannot be "speculative, conjectural, or hypothetical." *Abdullah v. Paxton*, 65 F.4th 204, 208 (5th Cir. 2023).

None of Dr. Purl's theories of injury demonstrate that she has Article III standing.

Ability to Disclose Information About Child Abuse to State Authorities. Dr. Purl's theory of harm continues to rest heavily on a fundamental misunderstanding that the 2024 Rule interferes with the reporting of suspected child abuse to state authorities. *See* PI Mot. 2, 4, 12, 21-22. As the Court recognized in granting Dr. Purl's motion for a preliminary injunction, the Rule does not "bar" or "seek" to bar Dr. Purl—or any other doctor—from reporting suspected child abuse. PI Op. 15. Specifically, the Rule does not repeal or modify 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); *see* PI Op. 4 ("The Privacy Rule specifically protects reports of 'child abuse' to those 'authorized by law' to receive such reports."). 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. And to the extent that Dr. Purl is concerned that the Rule might harm her by "slow[ing] down" her efforts to report child abuse, PI. Op. 15, she provides no evidence, or even allegations, to support that assertion. *See* Compl. ¶¶ 74-106. Indeed, the Court did not conclude otherwise in granting Dr. Purl's motion, instead reasoning that the Rule subjected her to various compliance costs. *See* PI Op. 8-12.

To reiterate, the 2024 Rule's preamble provides numerous examples to make clear that it does not interfere with reporting suspected child abuse in any way. An 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." PI App. 002. And it can do so where it suspects that a child has been subjected to "sexual abuse." 89 Fed. Reg. at 33004; *see* PI App. 003. 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). In other words, a covered entity could not disclose PHI if it thought the treatment for a sexually transmitted infection was *itself* child abuse, but it could disclose the PHI if it thought, for example, the parent had sexually abused the child and given her that infection.

The 2024 Rule also does not interfere with Dr. Purl's ability to disclose information in response to valid law enforcement requests. 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)(A), (B). 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 in Texas, the 2024 Rule does not prohibit her from disclosing that information in response to a law enforcement request as permitted before the 2024 Rule.

Given the narrow scope of the 2024 Rule, it is unsurprising that Dr. Purl still 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* PI 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 receipt of reproductive health care. *Id.* Nor does she claim that she has ever received a subpoena or any other request for PHI pertaining to reproductive health care. *Id.* To the extent Dr. Purl is concerned about her ability to disclose information pertaining to "gender-transition procedures," PI Mot. 1; *see* Compl. ¶ 88, she admits that she has never even treated a pediatric patient receiving such care. PI App. 004. Nor has Dr. Purl identified any reason to think that she will face disclosure requests for PHI related to reproductive health care in the future, 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. *Id.* at 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 somehow be subject to liability despite being lawful under state law 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 asserted compliance costs also continue to be speculative and unsubstantiated, and therefore provide no basis for Article III standing at summary judgment. *Cf.* Compl. ¶¶ 99-106; PI. Mot. 22. The Department recognizes that the Court previously concluded that Dr. Purl's costs were adequate to demonstrate harm at the preliminary-injunction stage, and respectfully preserves their disagreement with that conclusion. Even still, at summary judgment, "plaintiffs can't stand on old standing," *Nuziard v. Minority Bus. Dev. Agency*, 721 F. Supp. 3d 431, 455 (N.D. Tex. 2024), and are required to provide sufficient evidence to demonstrate that the potential harms they fear will come to pass, *Texas State LULAC*, 52 F.4th at 255 n.4. Although Dr. Purl's showing may have been adequate at the more abbreviated preliminary-injunction stage, she must now explain exactly *how* she will suffer the injuries she claims.

Specifically, Dr. Purl has failed to demonstrate that the 2024 Rule will actually cause her to suffer any of the costs that she alleges. As Dr. Purl did not dispute (and the Court did not address), she will have to update her privacy notice by February 16, 2026, to comply with a separate, unchallenged rulemaking pertaining to substance use disorder records. 89 Fed. Reg. at 32976, 32979. In addition, Dr. Purl has not provided any evidence, aside from conclusory assertions and references to the generalized estimates in the 2024 Rule, to corroborate her claims about the costs, in time or money, that any training or procedural updates will consume. *Cf. Crane v. Johnson*, 783 F.3d 244, 252 (5th Cir. 2015) (rejecting costs that were "not supported by any facts"). To adequately demonstrate standing at the summary-judgment stage, Dr. Purl must provide evidence regarding how *her* procedures or training requirements will have to change. Not every provider will face the costs that HHS estimated in the Rule's regulatory-impact

analysis, and Dr. Purl cannot rely on *general* estimates calculated with respect to a wide range of providers, including major hospital chains, to support her *particular* claim to standing.

The Court's prior determination also did not address "the general rule that 'standing cannot be conferred by a self-inflicted injury.'" *Ctr. for Biological Diversity v. EPA*, 937 F.3d 533, 541 (5th Cir. 2019) (quoting *Zimmerman v. City of Austin*, 881 F.3d 378, 389 (5th Cir. 2018)). The principle that a plaintiff cannot "spend its way into standing," *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 394 (2024), applies with equal force to costs incurred for the purpose of opposing government action and to costs incurred through unnecessarily onerous compliance measures. *Cf.* PI Op. 10. For example, the Fifth Circuit held that the federal government's assertions of harm from restarting the Migrant Protection Protocols "d[id] not count" because the government "could have avoided this problem by waiting to unwind MPP until th[e] litigation was resolved." *Texas v. Biden*, 10 F.4th 538, 558 (5th Cir. 2021). If Dr. Purl can comply with the 2024 Rule by taking measures that are easy and costless, then the costs she would incur from taking more onerous measures are traceable to her own voluntary decisions, not the 2024 Rule. Because Dr. Purl has failed to show that the 2024 Rule will *require* her to incur compliance costs, she does not possess Article III standing to challenge it, and so this case should be dismissed for lack of subject-matter jurisdiction.

II. In the alternative, the Court should enter judgment for the Department.

Even if the Court were to conclude that it has subject-matter jurisdiction, the Department is entitled to judgment on the claims asserted in Dr. Purl's Complaint.

First, the 2024 Rule does not exceed the Department's authority under HIPAA. *Cf.* Compl. ¶¶ 114-27. The Rule simply does not limit the reporting of child abuse or other public health matters. *Cf. id.* ¶¶ 117, 121-23. Moreover, the Department had authority to promulgate standards that take into account the sensitivity of specific categories of information. *Cf. id.*

¶¶ 118, 124. And the Department's definitions of "person" and "public health" are also fully consistent with HIPAA's usage of those terms. *Cf. id.* ¶¶ 119-20. Neither *Loper Bright* nor the major questions doctrine render the Rule unlawful. *Cf.* PI Op. 21.

Second, the 2024 Rule is not arbitrary or capricious. *Cf. id.* ¶¶ 128-39. The Department fully explained each of its choices in promulgating the 2024 Rule, and Dr. Purl's disagreement with those choices does not amount to a meritorious claim under the APA.

Finally, the Court's questions regarding the application of the non-delegation doctrine and the purported vagueness of the 2024 Rule's definition of "reproductive health care" provide no basis for invalidating HIPAA or the 2024 Rule. *Cf.* PI Op. 21-22. Plaintiffs do not advance any such claims in their Complaint and it would be inappropriate for the Court to address them in this posture. And even if Plaintiffs had alleged those claims, they would be unfounded: HIPAA lawfully delegates authority to the Department to promulgate and modify rules concerning permissible uses and disclosures of PHI, and the Rule's definition of reproductive health care is both clear and familiar to the public.

For these reasons, the Court should enter judgment for the Department.

A. The 2024 Rule does not exceed the Department's authority under HIPAA.

1. The Rule does not limit the ability to report child abuse.

Dr. Purl's repeated assertion that the 2024 Rule restricts reporting about child abuse or public health matters to state authorities, PI Mot. 13; Compl. ¶ 117, is simply incorrect. The Rule in no way alters the 2000 Privacy Rule's existing provision permitting the use or disclosure of information for such activities. *See* 45 C.F.R. § 164.512(b). As the Court explained, that provision "specifically protects reports of 'child abuse' to those 'authorized by law' to receive such reports." PI Op. 4. Dr. Purl has the same ability to report suspected child abuse that she had before the 2024 Rule was promulgated. Thus, the Rule does not "limit 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).

The Court's contrary conclusion at the preliminary-injunction stage—that, although the 2024 Rule does not "*bar* reporting of child abuse" or "'seek' that outcome," it "slows down and thereby "limits" reporting, PI Op. 15—was premised on several errors. Most importantly, HIPAA specifically prohibits limits on affirmative "*reporting* of … child abuse" by covered entities. 42 U.S.C. § 1320d-7(b) (emphasis added). It does not, however, prohibit limitations on disclosures in response to a state's *requests for information*, even if those requests relate to suspected child abuse. The Privacy Rule has long acknowledged this distinction, with different provisions relating to affirmative reports, *see* 45 C.F.R. § 164.512(b), and to disclosures of information in response to law enforcement requests, which are subject to additional requirements, *see id.* § 164.512(f).

None of the "limits" that the Court identified apply to affirmative reporting of child abuse. *Cf.* PI Op. 15-19. The 2024 Rule's disclosure prohibition applies to disclosures in response to *requests*, submitted either as part of an investigation or with the aim of imposing liability. 45 C.F.R. § 164.502(a)(iii)(A). Indeed, that prohibition only applies where "the covered entity or business associate that *received the request for protected health information* has reasonably determined" that the care was lawful under state or Federal law. *Id.* § 164.502(a)(5)(iii)(B) (emphasis added). Thus, 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. Similarly, the attestation requirement expressly applies only to requests "for purposes specified in § 164.512(d) [("health oversight activities")], (e) [("judicial and administrative proceedings")], (f) [("law enforcement

purposes")], or (g)(1) [("identifying … deceased person[s]")]. *Id.* § 164.509(a). It does not apply to reports of child abuse (and could not, given that such reports are submitted before any request for which an attestation could be made). *See id.* § 164.512(b). In sum, neither Dr. Purl nor any other doctor is required to "navigate these requirements" before affirmatively reporting suspected child abuse. PI Op. 18.

To be sure, the 2024 Rule 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). Neither federal law nor Texas law defines "child abuse" to include activities related to reproductive health care, such as abortion. *See* 89 Fed. Reg. at 33004; *see also* Tex. Fam. Code § 261.001 (defining "child abuse" without referring to reproductive health care). Thus, the mere pursuit of reproductive health care does not, standing alone, indicate that a minor has been subject to abuse—in the same way that seeking a cast for a broken bone is not necessarily an indication of battery. However, a provider can report child abuse if it has any other indication that abuse has occurred, *see* 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," PI App. 002, or where the provider suspects that a child has been subjected to "sexual abuse." 89 Fed. Reg. at 33004; *see* PI App. 003. And such a report can still note the fact that reproductive health care was sought, to the extent relevant to making the report. *See* 89 Fed. Reg. at 33042. All the 2024 Rule requires is that a provider have some basis for suspecting child abuse other than a parent's decision to seek medical care for their child, as in any other context.

Even if § 1320d-7(b) could, contrary to its plain terms, be understood to apply to law enforcement requests in addition to affirmative reports, the 2024 Rule does not materially restrict disclosures in response to requests relating to investigations of suspected child abuse or any other crimes. 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." 89 Fed. Reg. at 32994. To the extent Texas law prohibits abortions, in general or with respect to minors specifically, and federal law does not protect such care, those procedures would not constitute lawful reproductive health care and could properly be subject to a request for information. 89 Fed. Reg. at 33012. Nor is there any evidence in the record to establish that the 2024 Rule's framework "slows down," PI Op. 15, compliance with law enforcement requests of any sort, let alone those related to suspected child abuse.

The Court's conclusion that *any* conditions on reporting constitute unlawful limits is also not susceptible to a clear limiting principle. As the Court noted, the Rule does not "bar" disclosures to law enforcement relating to child abuse. PI Op. 15. And the Court acknowledged that "a more nuanced reading of the 2024 Rule" might pose no barrier. *Id.* at 18. But the Court nonetheless concluded that "a HIPAA regulation" constitutes an unlawful limit "*anytime*" it can be construed to "raise[] impediments, restraints, or curtailments to eventual disclosure." *Id.* at 19 (emphasis added). On that theory, HIPAA precludes even regulations that require a provider to have a valid basis for reporting child abuse, or that require a provider to take steps to limit the disclosure of PHI to information necessary and material to the report. The more sensible reading of the statute is that, by prohibiting regulations that would "invalidate or limit the *authority, power, or procedures* established" under any reporting statute, 42 U.S.C. § 1320d-7(b)

(emphasis added), Congress sought to prohibit rules that would preempt or supersede reporting statutes, not any rule with an incidental effect on the reporting process.

Dr. Purl advances several other objections to the 2024 Rule's disclosure prohibition, but they are equally unavailing. She 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, PI Mot. 14; Compl. ¶ 49, but her argument relies on a misinterpretation of the 2024 Rule. The 2000 Privacy Rule has long 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). The quoted language from the 2024 Rule's preamble does not expand these permissions, but instead describes a change from the proposed rule to the final rule designed to avoid a construction of the 2024 Rule that might *limit* those permissions. *See* 89 Fed. Reg. at 33010-11. Moreover, the 2024 Rule does not prohibit the disclosure of PHI in connection with the unlawful provision of care at all, so such information may be disclosed by an entity whether for the purpose of defending against a claim or pursuant to an otherwise-valid request from law enforcement. *See* 45 C.F.R. § 164.502(a)(5)(iii)(B). In any event, Dr. Purl never explains why a purported lack of symmetry between the 2024 Rule's disclosure provisions has any bearing on their lawfulness.

Finally, even if the Court were to determine that the 2024 Rule unlawfully restricts child-abuse reporting, the proper remedy would be to enjoin the Department from enforcing the Rule with respect to such reports when made in compliance with the requirements of state law. HIPAA's implementing regulations contain 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. Any restrictions the 2024 Rule might impose on reporting or requests related to subjects other than child abuse or public health would plainly not run afoul of the limited exception provided by § 1320d-7(b). A purported conflict with that provision therefore does not warrant an injunction of the entire rule, as applied to all potential facts and circumstances.

2. The Department had authority to promulgate the 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. Congress not only directed the Secretary to promulgate "standards with respect to … [t]he uses and disclosure of [PHI] that should be authorized or required," 42 U.S.C. § 1320d-2 note; it 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). *See* 45 C.F.R. § 160.104. 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. *Cf.* Compl. ¶ 118; PI Mot. 17-18. 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 Saints Peter & Paul Home 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 & Hum. Servs. (Sep. 10, 1997), https://perma.cc/FQ4S-Y45C. NCVHS, the public

advisory body to the Secretary 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.

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 "[t]ransmitted" or "[m]aintained" 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. The 2024 Rule therefore falls well within how the Department's authority to promulgate regulations concerning permissible uses and disclosures has long been understood.

3. The Rule correctly interprets "person" and "public health."

Dr. Purl also criticizes how the 2024 Rule defines two of HIPAA's terms, but her criticisms misinterpret multiple federal statutes. *Cf.* Compl. ¶¶ 119-20.

To start, 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.* PI 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 fetuses, Congress would have had no reason to specifically include children born alive. *See Tex. Bankers Ass'n v. Off. of the Comptroller*, 728 F. Supp. 3d 412 (N.D. Tex. 2024) ("'[E]xpressing 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 embryos or fetuses under HIPAA, because HIPAA does not itself include any language that could properly be construed as extending to them. Indeed, health information about the fetus is included in the pregnant individual's records. 89 Fed. Reg. 32997 & n.191. Accordingly, in the context of medical records related to a pregnancy, the individual to whom HIPAA creates obligations is the pregnant person.

Every case interpreting the Dictionary Act has adopted 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. Apr. 28, 2004). Dr. Purl provides no reason to hold otherwise.

The Department also correctly defined "[p]ublic 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. "[S]ince 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 violated the law." *Id.* at 33001-02. 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," PI 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). Regardless of whether the Rule contains a definition of these two terms, the remainder of the Rule's framework, including its prohibition on the disclosure of information relating to lawful reproductive health care, can continue to apply.

4. *Loper Bright* and the major questions doctrine are inapplicable.

The Court ordered the parties to brief whether the Supreme Court's decision in *Loper Bright* or the major questions doctrine affect the legality of the 2024 Rule. *See* PI Op. 21. They do not. As to *Loper Bright*, the Department did not invoke *Chevron* deference in the 2024 Rule, nor does it seek such deference here; the Department contends that the 2024 Rule is consistent with the correct interpretation of the relevant HIPAA provisions and other applicable statutes. *Cf. Loper Bright*, 603 U.S. at 413 (overruling *Chevron* and instructing that "courts need not and

under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous").

For similar reasons, the 2024 Rule does not run afoul of the major questions doctrine. Rules concerning when private medical information can be disclosed do not involve "a public controversy of *vast* 'economic and political significance,'" PI Op. 21 (quoting *West Virginia v. EPA*, 597 U.S. 697, 720-21 (2022)), nor is the 2024 Rule "transformative," a "radical or fundamental change," or a "wholesale restructuring" of the Department's authority under HIPAA, *West Virginia*, 597 U.S. at 716, 723-24. Moreover, this is not a circumstance where the agency has discovered "newfound power in the vague language of an ancillary provision of [an] Act.'" *Id.* at 724 (quotation omitted). The 2024 Rule's disclosure prohibition is an exercise of the Department's core authority under HIPAA to promulgate rules concerning permissible "uses and disclosures" of PHI, 42 U.S.C. § 1320d-2 note, and to adopt appropriate modifications to those rules, *id.* § 1320d-3(b)(1), as the Department 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) (Kacsmaryk, J.). Dr. Purl objects that HIPAA does not mention "specific medical procedures," PI 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 Cnty.*, 590 U.S. 644, 669 (2020). The statute that Congress enacted therefore permits the Department's action.

B. The 2024 Rule is not arbitrary and capricious.

The Department also fully explained its decisions in promulgating the 2024 Rule. 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).

To start, the Department fully explained why it chose to adopt the "prohibitions on disclosure in the 2024 Rule." Compl. ¶ 132. The Department found that "th[e] 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.*; *see also id.* at 32984-91. The Department also explained how those prohibitions were consistent with HIPAA's limited "reservation of authority to states," Compl. ¶ 132: pursuant to § 1320d-7(b), entities would remain able to report suspected child abuse, but would need to comply with the 2024 Rule before disclosing additional PHI in response to a request from law enforcement. 89 Fed. Reg. at 33004. And the Department made plain that the 2024 Rule's prohibitions do not apply to investigations into forms of care that are unlawful. *See* 45 C.F.R. § 164.502(a)(5)(iii)(B); 89 Fed. Reg. at 33012-13.

Next, the Department explained the Rule's requirements, articulating the basis for its "tests and presumptions," *see* Compl. ¶¶ 133-34, and providing descriptions and examples of how covered entities would be expected to comply with the Rule's provisions, *see* Compl. ¶¶ 135, 137-38. *See, e.g.*, 89 Fed. Reg. at 33009-25. 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.* PI Mot 18-21; Compl. ¶¶ 133, 35. The 2024 Rule simply requires covered entities to ensure the request meets the requirements of an applicable permission and is accompanied by a valid attestation. 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 whether disclosures are permissible without an authorization, 45 C.F.R. §§ 164.508, 164.512, assessing the authority of a putative "[p]ersonal representative," *id.*§ 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 validity of the government's request for PHI is "not." PI Mot. 19.

The Department also 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. Dr. Purl presumably must already determine the legality of any care that *her clinic provides*. 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 "[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." 45 C.F.R. § 164.502(a)(5)(iii)(C). Indeed, the Department added that presumption precisely to address "commenters' concerns" about third parties having to determine the lawfulness of care they did not provide. 89 Fed. Reg. at 33014. Dr. Purl has never explained 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. *See* PI 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 33012. Nor is it unreasonable to require health care providers to determine whether the care they have provided was protected, required, or authorized by Federal law. *Id.* at 33024. Again, simply as a matter of course, health care providers must already determine whether they can legally provide any particular care to their patients. 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).

Contrary to Dr. Purl's assertions, *see* Compl. ¶ 137, the Department provided a lengthy explanation of how entities should comply with the attestation requirement. *See* 89 Fed. Reg. at 33029-32. The Department recognized that "it may be difficult for regulated entities to distinguish between requests for the use and disclosure of PHI based on whether the request is for a permitted or prohibited purpose, which could lead regulated entities to deny use or

disclosure requests for permitted purposes." *Id.* at 33029. The attestation provision therefore requires a requester who seeks information potentially related to reproductive health care to provide certain forms of information to the entity, so that the entity can determine whether the request is for a prohibited purpose. *See id.* at 33030; 45 C.F.R. § 164.509(a)(1). The Department specifically declined to extend the attestation requirement to requests that do not involve PHI related to reproductive health care to avoid undue interference with law enforcement. *See* 89 Fed. Reg. at 33029. The Department also thoroughly addressed comments regarding the attestation requirement, *see id.* at 33032-42, and even provided a model attestation and multiple other resources (including fact sheets, compliance videos, model presentation webinars, and slides) to make it easier for parties to apply the Rule's requirements. *See, e.g.*, *Model Attestation*, HHS, https://www.hhs.gov/sites/default/files/model-attestation.pdf; *HIPAA and Reproductive Health*, HHS, https://www.hhs.gov/hipaa/for-professionals/special-topics/reproductive-health/index.html.

Finally, Dr. Purl's objections to how the Department defined various terms are again unfounded. The Department adequately explained its definitions of "person" and "public health." *See supra* Section II.A.3. And the Department also explained why it adopted a broad definition of reproductive health care for the purpose of applying the 2024 Rule's prohibitions, *cf.* Compl. ¶ 136: because it sought to "encompass[] the full range of health care related to an individual's reproductive health." 89 Fed. Reg. at 33005. That "approach is consistent with the approach the Department took when it adopted the definition of 'health care' in the HIPAA Rules," which was framed broadly to avoid "the risk that important activities would be left out," creating "confusion." *Id.* The Department also reasoned that a broad definition "may decrease the perceived burden to regulated entities of complying with the rule by helping them determine

whether a request for the use or disclosure of PHI includes PHI that is implicated by this final rule." *Id.* at 33005-06.

In sum, Dr. Purl has not identified any aspect of the 2024 Rule that the Department failed to reasonably explain. Dr. Purl may disagree with the Department's explanations and policy choices, but that is not nearly enough to prevail on an arbitrary-and-capricious challenge.

C. Neither the non-delegation doctrine nor vagueness provide a basis for invalidating HIPAA or the 2024 Rule.

The Department is entitled to judgment on the two claims that Dr. Purl has asserted in her Complaint. It would be inappropriate for the Court to venture beyond those claims and to invalidate HIPAA or the 2024 Rule based on theories not alleged or even mentioned in the Complaint (or in any prior briefing), including the non-delegation doctrine or the purported vagueness of the definition of "reproductive health care." *Cf.* PI Op. 21. "In our adversarial system of adjudication, [courts] follow the principle of party presentation," under which courts "rely on the parties to frame the issues for decision" and serve as solely a "neutral arbiter of matters the parties present." *United States v. Sineneng-Smith*, 590 U.S. 371, 375 (2020) (quoting *Greenlaw v. United States*, 554 U.S. 237, 243 (2008)). Courts "do not, or should not, sally forth each day looking for wrongs to right. They wait for cases to come to them, and when cases arise, courts normally decide only questions presented by the parties." *Id.* (quotation omitted). Ruling on claims that neither party has presented would violate that principle.

Doing so would also run afoul of the precept that courts should avoid, rather than invite, constitutional questions, particularly when they implicate the constitutionality of a federal statute that has been on the books for nearly thirty years. *Cf., e.g.*, *Hersh v. U.S. ex rel. Mukasey*, 553 F.3d 743, 754 (5th Cir. 2008) ("Constitutional avoidance is a 'cardinal principal' of constitutional law."); *White v. U.S. Pipe & Foundry Co.*, 646 F.2d 203, 206 (5th Cir. 1981)

("[T]he federal courts should not reach a constitutional question, especially one concerning the validity of an act of Congress, if the merits of the case may be settled on nonconstitutional grounds."). To do so in this posture would be more irregular still: rather than invite Dr. Purl to amend her complaint, and then permit the Department a reasonable amount of time to respond to any new claims she might choose to raise, the Court directed the parties to submit simultaneous motions for summary judgment less than a month after the Court introduced these issues. ECF No. 35.

The Court's order suggests that it may view Rule 65(d) as a source of authority for raising these questions *sua sponte*. *See* PI Op. 2 (ordering "supplemental briefing by the parties to satisfy the specificity and scope requirements of any permanent relief pursuant to Federal Rule of Civil Procedure 65(d)"). But Rule 65(d) simply directs that any order "granting an injunction" must "state the reasons why it issued," "state its terms specifically," and "describe in reasonable detail … the act or acts restrained or required." Nothing in Rule 65(d) authorizes a court to decide constitutional questions not raised by the parties.

If the Court addresses these questions, it should uphold both HIPAA and the 2024 Rule. HIPAA does not violate the non-delegation doctrine. The doctrine requires only that Congress provide an "intelligible principle" to guide the agency's authority, meaning that Congress must "delineate[] the general policy, the public agency which is to apply it, and the boundaries of this delegated authority." *Mayfield v. U.S. Dep't of Lab.*, 117 F.4th 611, 620 (5th Cir. 2024) (rejecting a non-delegation challenge) (quoting *Mistretta v. United States*, 488 U.S. 361, 372-73 (1989)). "'[T]hose standards … are not demanding,' and the Supreme Court has only twice found an excessive delegation of power, doing so in each case because 'Congress had failed to

articulate *any* policy or standard to confine discretion.'" *Id.* at 620-21 (quoting *Gundy v. United States*, 588 U.S. 128, 146 (2019)).

HIPAA provides a clear and detailed framework to guide the Department's exercise of its discretion. As the Fourth Circuit has explained, "there are at least three sources within HIPAA that provide intelligible principles outlining and limiting the Congressional conferral of authority on HHS:" its "mandate[] that HHS implement regulations addressing three particular subjects"; the statute's preamble, which "sets forth the general purpose of HIPAA"; and "Congress's limitation of the Privacy Rule to communications of listed information by particular covered entities." *S.C. Med. Ass'n v. Thompson*, 327 F.3d 346, 351 (4th Cir. 2003). "[T]aken together, the provisions of HIPAA provide a general policy, describe the agency in charge of applying that policy, and set boundaries for the reach of that agency's authority—all in keeping with the intelligible principle test." *Id.* That elaborate framework poses no non-delegation problem. *See also*, *e.g.*, *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 447 (5th Cir. 2020); *Leal v. Azar*, 2020 WL 7672177, at *16 (N.D. Tex. Dec. 23, 2020) (Kacsmaryk, J.), *vacated and remanded*, 2022 WL 2981427 (5th Cir. July 27, 2022).

Nor is the 2024 Rule's definition of reproductive health care void for vagueness. "A law is unconstitutionally vague if it (1) fails to provide those targeted by [it] a reasonable opportunity to know what conduct is prohibited, or (2) is so indefinite that it allows arbitrary and discriminatory enforcement." *McClelland v. Katy Indep. Sch. Dist.*, 63 F.4th 996, 1013 (5th Cir. 2023) (quoting *A.M ex rel. McAllum v. Cash*, 585 F.3d 214, 224-25 (5th Cir. 2009)). Moreover, a plaintiff can only prevail on a facial challenge "if the enactment is impermissibly vague in all of its applications." *Id.* (quoting *Home Depot, Inc. v. Guste*, 773 F.2d 616, 627 (5th Cir. 1985)). The Department not only defined reproductive health care in clear and familiar terms by treating it as

a subset of "health care," as it has long been defined under HIPAA, "that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes." 45 C.F.R. § 160.103; *see also Reproductive System*, Merriam-Webster ("[T]he system of organs and parts which function in reproduction…."). It also provided a "non-exclusive list of examples that fit within the definition" to "further clarify what is included." 89 Fed. Reg. at 33005-06. Although "[i]t will always be true that the fertile legal 'imagination can conjure up hypothetical cases in which the meaning of (disputed) terms will be in nice question," *Grayned v. City of Rockford*, 408 U.S. 104, 110 n.15 (1972), that is not nearly enough to render a regulation facially invalid on vagueness grounds. The 2024 Rule should therefore be upheld.

III. Any relief should be limited to Dr. Purl and to the specific provisions the Court concludes are unlawful and harmful.

The Court should enter judgment for the Department. But if it enters judgment for Dr. Purl, it should not grant the extraordinarily sweeping relief that she seeks. Dr. Purl requests that the Court "[h]old the 2024 Rule unlawful and set it aside and permanently enjoin Defendants from enforcing the 2024 Rule." Compl., Prayer for Relief ¶ D; *see id.* ¶ 8. That request for universal relief would transgress basic principles of jurisdiction, equity, and judicial review under the APA.

As an initial matter, the APA's provision for courts to "set aside" unlawful agency actions, 5 U.S.C. § 706(2), does not authorize the type of universal vacatur that Dr. Purl seeks. As a matter of first principles, the "set aside" language in § 706(2) should not be read as authorizing remedies, which are governed by § 703 of the APA. Section 703 states that "[t]he form of proceeding for judicial review" of agency action is either a "special statutory review proceeding" or, in "the absence or inadequacy thereof," any "applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or

habeas corpus." 5 U.S.C. § 703. Because Dr. Purl does not purport to identify any applicable "special statutory review proceeding," § 703 affords her only traditional equitable remedies like injunctions. In contrast, § 706(2) does not address remedies at all. Rather, § 706(2) is properly understood as a rule of decision directing the reviewing court to disregard unlawful "agency action, findings, and conclusions" in resolving the case before it, consistent with basic principles of judicial review. Universal vacatur is therefore not an available remedy under the APA. *See United States v. Texas*, 599 U.S. 670, 693-99 (2023) (Gorsuch, J., concurring in the judgment).

The Department recognizes that the Fifth Circuit has held that the "APA 'empowers and commands courts to set aside unlawful agency actions,' allowing a district court's vacatur to render a challenged agency action 'void.'" *Texas Med. Ass'n v. U.S. Dep't of Health & Hum. Servs*., 110 F.4th 762, 779 (5th Cir. 2024) (internal citation omitted). The Department nevertheless preserves the argument that vacatur is not a permissible remedy under the APA for the purposes of appeal. Even assuming that vacatur is permissible, however, the APA does not require courts to vacate federal rules. *See Staley v. Harris Cnty*., 485 F.3d 305, 310 (5th Cir. 2007) ("[V]acatur is to be determined on a case-by-case basis, governed by facts and not inflexible rules."). As the Fifth Circuit has held, whether vacatur is appropriate depends on "the seriousness of the deficiencies of the action" and "the disruptive consequences of vacatur." *Texas v. Biden*, 20 F.4th 928, 1000 (5th Cir. 2021). Here, as described above, the 2024 Rule is lawful. And to the extent that the Court concludes that the Department failed to adequately explain its decisions in promulgating the 2024 Rule, those errors could be rectified on remand to the agency. *See id.*

Vacatur would also be deeply disruptive to the public's interest in the privacy of sensitive medical information. As the Department found in promulgating the 2024 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 American Medical Association's Principles of Medical Ethics and recommendations of NCVHS). "Many people believe that details about their physical self should not generally be put on display for neighbors, employers, and government officials to see." 65 Fed. Reg. at 82464. Indeed, "[i]nvoluntary or poorly-timed disclosures can irreparably harm relationships and reputations, and even result in job loss or other negative consequences in the workplace." 89 Fed. Reg. at 33057. Nor are the 2000 Privacy Rule's requirements adequate to safeguard the public's interest in the privacy of reproductive health information; as the Department found, citing, among other sources, a recent study and letters from the public, even patients seeking purely *lawful* reproductive care increasingly fear the unauthorized disclosure of their information. *See, e.g.*, 89 Fed. Reg. at 32987; 88 Fed. Reg. at 23519 & n.167, 23528.[2]

Setting the 2024 Rule aside would also reduce the trust that individuals have in the medical system, reducing the likelihood that they will seek or receive appropriate care. "[I]ndividuals 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); *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

[2] Nor is the basis for the Department's concern that "select states have curtailed or banned select abortion services." PI Op. 20. Again, the 2024 Rule prohibits the disclosure of information related to *lawful* reproductive health care, 45 C.F.R. § 164.502(a)(5)(iii), including health care that states, exercising their "medical judgment[]," PI Op. 20, have chosen to permit.

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. Given these potential nationwide harms, universal vacatur would be unwarranted.

The Court also has equitable alternatives to vacatur. Rather than vacating the 2024 Rule nationwide, the Court could simply enjoin the Department from enforcing the Rule against Dr. Purl, which would alleviate any compliance concerns she may have. In contrast, the problems caused by overbroad universal remedies are well catalogued and apply whether such a remedy takes the form of a universal vacatur or a nationwide injunction. "'[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.).

Whatever remedy the Court enters, it should also tailor any relief in light of the severability provision contained in HIPAA's implementing regulations. That provision directs 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. Moreover, as the Department explained in the preamble, it "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. To the extent the Court concludes that the 2024 Rule limits the ability to report child abuse, for example, it could simply enjoin the Department from enforcing the Rule with respect to legitimate reports of child abuse. Or if the Court concludes that the 2024 Rule improperly defines certain terms, those definitions could be severed from the remainder of the Rule's provisions. Any further relief would transgress both equitable principles and the Department's clear intention of severability, and would unnecessarily jeopardize safeguards that are vital to the protection of Americans' sensitive medical information.

CONCLUSION

For these reasons, the Court should grant the Department's motion and dismiss this case. In the alternative, it should enter judgment for the Department.

Dated: January 17, 2025

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 January 17, 2025, 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