IN THE UNITED STATES OF AMERICA
NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

Carmen Purl, M.D.; and Carmen Purl, M.D., PLLC d/b/a Dr. Purl's Fast Care Walk In Clinic, *Plaintiffs*, v. United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; Office for Civil Rights of the United States Department of Health and Human Services; and Melanie Fontes Rainer, in her official capacity as Director of the Office for Civil Rights of the United States Department of Health and Human Services, *Defendants*, and City of Columbus, Ohio; City of Madison, Wisconsin; and Doctors for America, *Amici Curiae.*	Civil Action No. 2:24-cv-00228

BRIEF OF *AMICI CURIAE* CITY OF COLUMBUS, OHIO, CITY OF MADISON, WISCONSIN, AND DOCTORS FOR AMERICA IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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STATEMENT OF INTERESTS OF AMICI CURIAE

This proceeding involves one physician's dispute with the final rule promulgated by the Department of Health and Human Services ("HHS" or the "Department") in 2024, the *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32976 (Apr. 26, 2024) (codified at 45 C.F.R. pts. 160, 164) (the "2024 Rule" or the "Rule"). The Rule provides additional protections for particularly sensitive health information related to reproductive health.

Amici curiae include the City of Columbus, Ohio, a municipal corporation organized under Ohio law, the City of Madison, Wisconsin, a municipal corporation organized under Wisconsin law, and Doctors for America, a nonpartisan, nonprofit organization of more than 27,000 health professionals. The cities' public health departments operate as HIPAA-covered entities and provide health care services to their residents.

Amici submit this brief to explain how the Health Insurance Portability and Accountability Act ("HIPAA"), Pub. L. 104-191, 110 Stat. 1936, and the 2024 Rule lawfully facilitate access to, and the provision of, essential health care. *Amici* operate health care centers that provide care or represent health care providers who have a direct stake in the issues raised by these proceedings. *Amici* and their members are directly involved in patient care and treatment as impacted by HIPAA and the 2024 Rule. HIPAA and the 2024 Rule are vital for protecting patient confidentiality and, in turn, ensuring that patients trust their clinicians and that their clinicians can provide them with needed medical care. Fostering trust and honesty between clinicians and their patients is essential to overall public health—a key task for the cities. Accurate data allows providers and public health departments to identify and address troubling public health trends.

This challenge raises questions regarding the 2024 Rule and the construction and

legitimacy of HIPAA itself. Without HIPAA or the 2024 Rule, the health care industry would be left to navigate a patchwork of state privacy laws, many of which refer to, rely on, or contain carveouts for HIPAA-regulated protected health information ("PHI"). Congress created an overarching federal standard that protects the confidentiality, use, and disclosure of PHI, including that involving lawful reproductive care as set forth in the 2024 Rule. The confidentiality of PHI is a cornerstone of effective health care. The provision of medical care will be adversely impacted and patients will suffer without these protections. *Amici* file this brief to protect their interests in ensuring that all PHI is adequately safeguarded, in furtherance of quality care and public health.

PRELIMINARY STATEMENT

The confidentiality of patient health information is a cornerstone of effective health care. For twenty-five years, patient privacy protections have been governed by HIPAA, and patients and clinicians alike rely on the protections afforded by the statute to use and disclose patient information efficiently, effectively, and confidentially. HIPAA and its implementing regulations (the "Privacy Rules") ensure that identifiable patient information is used and disclosed appropriately.

Plaintiffs target the 2024 Rule promulgated by the Department, even though that Rule is consistent with the statutory authority expressly delegated to it by Congress in HIPAA. Congress directed the Department to "promulgate final regulations" containing "standards with respect to the privacy of individually identifiable health information," including specifically as pertains to the "rights that an individual who is a subject of individually identifiable health information should have," "[t]he procedures that should be established for the exercise of such rights," and "[t]he uses and disclosures of such information that should be authorized or required." Amici's Appx. to Br.

(hereinafter "Appx.") 561 (42 U.S.C. § 1320d-2 note) (codifying Pub. L. 104-191, title II, § 264). Congress further directed the Department to "adopt modifications to the standards (including additions to the standards), as determined appropriate." 42 U.S.C. § 1320d-3(b)(1). In promulgating the 2024 Rule, the Department did just that—it considered the relevant factors and acted well within its discretion.

Plaintiffs (one physician and her private practice) now request an order vacating and permanently enjoining the 2024 Rule nationwide and have raised questions about the constitutionality of HIPAA itself. They ask this Court to prioritize their preferences over the clearly articulated will of Congress as represented by the text of the governing HIPAA statute. Plaintiffs cannot justify this extraordinary request.

Plaintiffs offer no meaningful argument that the 2024 Rule violates the Administrative Procedure Act. The 2024 Rule is entirely consistent with 42 U.S.C. § 1320d-7(b) and does not unlawfully limit disclosures regarding child abuse and public health reporting to state authorities. In arguing otherwise, Plaintiffs urge an interpretation of "limit" read entirely out of context and contrary to multiple canons of interpretation. Plaintiffs also fundamentally misapprehend the import of the 2024 Rule; under this Rule, law enforcement continues to be able to access protected health information, *including* reproductive health care information, pursuant to the Privacy Rules' exceptions, as long as the disclosure is not sought for the prohibited purpose of imposing criminal, civil, or administrative investigation or liability on someone for merely seeking, obtaining, providing, or facilitating lawful reproductive health care.

The remainder of Plaintiffs' claims are equally invalid. The Department correctly defined the terms "person" and "public health," and one physician's beliefs about what constitutes child abuse and public health cannot be the source of the meaning of federal statutory

and regulatory terms. The administrative record conclusively demonstrates that the Department engaged in extensive, reasoned analysis and fully explained the 2024 Rule. Further, the major questions, non-delegation, and vagueness doctrines provide no basis for invalidating the Rule (or the underlying HIPAA statute). Finally, universally vacating, enjoining nationwide, and setting aside the 2024 Rule, as Plaintiffs demand, is not appropriate relief and would be devastating for patients, providers, cities, and all that participate in the health care system. That relief would contravene equitable principles and defy the Department's clear statement of severability.

ARGUMENT

I. THE 2024 RULE DOES NOT CONFLICT WITH THE PLAIN STATUTORY TEXT OF HIPAA

The 2024 Rule is fully consistent with the express terms of HIPAA. By its text, HIPAA and the regulations promulgated thereunder explicitly preempt contrary state law. 42 U.S.C. § 1320d-7(a) ("[A] provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1320d-1 through 1320d-3 of this title, shall supersede any contrary provision of State law . . . ."). This general preemption provision is subject only to limited exceptions, including:

> Nothing 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).

As this Court has made clear, "[q]uestions of statutory interpretation begin and end, as they

must, with the text itself."[1] *Kelley v. Azar*, 2021 WL 4025804 at *10 (N.D. Tex. Feb. 25, 2021). Here, pursuant to their plain meaning, the contested terms—"invalidate or limit," "child abuse," and "public health surveillance, or public health investigation or intervention"—comfortably authorize the 2024 Rule, which narrowly impacts records involving the provision of legal reproductive care. Allowing the investigation or punishment of health care that is lawfully provided and obtained is not among the limited, statutory exceptions to HIPAA's general preemption provision. *See* 42 U.S.C. § 1320d-7(b).

A. The 2024 Rule Has a Narrow Scope.

The 2024 Rule is narrow in scope and effect. It sets new standards governing requests for information about *lawful* reproductive health care for the *purposes of investigating or imposing liability* on a person for the *mere act* of seeking or providing the care. 45 C.F.R. § 164.502(a)(5)(iii)(A) (emphasis added). Under any reasonable reading of the HIPAA statute, the 2024 Rule does not run afoul of any of the enumerated powers reserved to the states in the statute's exceptions to preemption. 42 U.S.C. § 1320d-7(b). To the contrary, 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 [lawful] reproductive health care." Appx. 390 (89 Fed. Reg. 32994) (emphasis added). And Plaintiffs mischaracterize the practical impact the 2024 Rule will have on them, painting it as broader than it actually is.

The 2024 Rule does not prevent the reporting of child abuse, as Plaintiffs claim, because a

[1] Plaintiffs' claim that "*Loper Bright* prevents HHS from receiving deference for its novel interpretation of HIPAA," Pls.' Br. in Supp. of Mot. Summ. J., ECF. No. 45 at 25 (hereinafter "Pls.' Br."), misses the mark. No deference is requested or required here—the meaning is clear from the text of the statute.

provider who suspects abuse based on their contacts with a patient, including contacts that relate to their patients' reproductive health care, may continue to report that suspicion. *See* Appx. 400 (89 Fed. Reg. 33004) ("the regulated entity is permitted to make such disclosure [reporting suspected child abuse] where there is suspicion of sexual abuse that could be the basis of permitted reporting"). Nor does the 2024 Rule curtail disclosures related to public health efforts. Population-level public health efforts are "distinguish[ed]" from activities punishing individuals for the legal health care they seek or provide, and the 2024 Rule intentionally leaves intact state powers over the former. *See* Appx. 397–98 (89 Fed. Reg. 33001–02); 45 C.F.R. § 160.103. Indeed, the Rule supports public health efforts. Appx. 387 (89 Fed. Reg. 32991) (describing how the 2024 Rule will improve health care providers' provision of care and improve health outcomes at both the individual and population level). As explained, the 2024 Rule only prevents disclosure of records regarding lawful reproductive health care when the purpose of the request is to investigate or prosecute an individual on the sole basis of having obtained or provided that lawful care. Appx. 390 (89 Fed. Reg. 32994).

B. The 2024 Rule Does Not "Limit" Valid State Public Health or Abuse Reporting Authority Within the Meaning of HIPAA.

Plaintiffs define "limit" as used in the phrase "invalidate or limit" in 42 U.S.C. § 1320d-7(b) so broadly that any HHS requirement—from the use of new reporting software to the presence of a new attestation form—could be an impermissible "limit" on state authority. Pls.' Br. at 19–20. Such a reading is only possible because Plaintiffs read the word "limit" in a vacuum and ignore the word's context. But "[t]he meaning of a word 'may only become evident when placed in context.'" *Sackett v. EPA*, 598 U.S. 651, 674 (2023) (quoting *FDA v. Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 132 (2000)); *see* ANTONIN SCALIA & BRYAN A. GARNER, READING

LAW: THE INTERPRETATION OF LEGAL TEXTS 195 (2012).

The word "limit" follows the word "invalidate," and, applying the *noscitur a sociis* canon of construction, it must be understood with reference to its partner. "Invalidate" means that rules promulgated under HIPAA may not literally eliminate the "authority, power, or procedures established under any law" outlined in 42 U.S.C. § 1320d-7(b). "Limit," then, is best understood to refer to *substantial impairment* of the same. In other words, HHS may not effectively eliminate one of the enumerated powers, even if it has not been literally invalidated. To find otherwise would read the former term out of the statute in violation of the "rule against 'ascribing to one word a meaning so broad' that it assumes the same meaning as another statutory term." *Ysleta Del Sur Pueblo v. Texas*, 596 U.S. 685, 686 (2022) (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995)). Courts are instructed to reject a statutory interpretation that would leave a term "with no work to perform" and should instead "seek to construe Congress's work so that effect is given to all provisions." *Id.* (internal quotations omitted). Ultimately, context is key. Read in context, "limit" must here impute some level of meaningful interference—or at least something more than even the barest of impacts, as Plaintiffs have argued.

C. "Child Abuse" as Used in HIPAA Does Not Include Lawful Reproductive Care.

The 2024 Rule does not limit reporting of "child abuse" as that term is used in HIPAA. The 2024 Rule is a narrow prohibition of disclosure of a very specific class of PHI: records of lawful reproductive care that are requested for the purpose of investigating or imposing liability on a patient or provider for the mere act of seeking or providing that care. 45 C.F.R. § 164.502(a)(5)(iii)(A). This narrow limitation on disclosure in no way impinges on the "procedures . . . for reporting . . . child abuse," and therefore is not contrary to the statute. 42

U.S.C. § 1320d-7(b).

Put simply, lawful reproductive care is not "child abuse" within the meaning of HIPAA. Dr. Purl claims that the 2024 Rule, despite its narrow scope,[2] impermissibly "interfere[s] with [her] ability and legal obligation to disclose information about unborn children when they are victims of crime or abuse." Compl. at ¶ 87. But HIPAA's preemption exception for reporting child abuse has nothing to do with the unborn.

First, Congress has explicitly defined the term "child"—across all federal laws—to mean someone "born alive." 1 U.S.C. § 8(a) ("In determining the meaning of any Act of Congress, or of any ruling, regulation, or interpretation of the various administrative bureaus and agencies of the United States, the words 'person', 'human being', 'child', and 'individual', shall include every infant member of the species homo sapiens who is born alive at any stage of development.").[3] That same statute goes on to specify that being "born alive" requires exiting a uterus. *Id.* § 8(b). This definition applies in every federal statute and every federal rule and regulation, including HIPAA and the 2024 Rule. *Id.* § 8(a). The same meaning of "child" applies when the word appears in the phrase "child abuse." Appx. 400 (89 Fed. Reg. 33004) ("[T]he term 'child' in the Privacy Rule is

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[2] As discussed in *infra* Section I(A), the 2024 Rule does not limit disclosure of child abuse where any indicia of abuse are present—other than the mere fact of receiving legal reproductive care.

[3] This section of the Dictionary Act also resolves Plaintiffs' contention that the 2024 Rule includes an impermissible definition of person, because the regulatory definition of person matches the definition mandated by Congress. 1 U.S.C. § 8(a); 45 C.F.R. § 160.103. The inclusion of an express definition of "person" among the Privacy Rule's defined terms (*see*, *e.g.*, 45 C.F.R. §§ 160.103 (defining 48 terms), 164.501 (defining 14 terms)), properly matches the federal statutory definition. 1 U.S.C. § 8(a) (the definition of "child" and "person" applies in federal regulations); *see also Meese v. Keene*, 481 U.S. 465, 484 (1987) ("It is axiomatic that the statutory definition of the term excludes unstated meanings of that term." (citation omitted)).

consistent with th[e] definition [in 1 U.S.C. § 8]").

Second, "child abuse" as used in HIPAA cannot implicate legal abortion because, at the time Congress enacted HIPAA, abortion was a constitutionally protected right. Courts "interpret[] a statute in accord with the ordinary public meaning of its terms *at the time of its enactment.*" *Bostock v. Clayton Cnty.*, 590 U.S. 644, 654 (2020) (emphasis added); *see Texas v. Biden*, 646 F. Supp. 3d 753, 767 (N.D. Tex. 2022) (Kacsmaryk, J.) (*citing New Prime Inc. v. Oliveira*, 586 U.S. 105, 113 (2019)). Lawful health care for pregnant people is not "child abuse" in and of itself and was certainly not considered as such at the time HIPAA was enacted. *See* Appx. 400 (89 Fed. Reg. 33004) ("[T]he Department . . . has long interpreted 'child abuse' as used in the Privacy Rule and . . . HIPAA [42 U.S.C. § 1320d-7(b)] . . . to exclude conduct based solely on a person seeking, obtaining, providing, or facilitating reproductive health care."). That understanding of the term should not be judicially remodeled two decades later. *See Bostock*, 590 U.S. at 654–55 ("If judges could add to, remodel, update, or detract from old statutory terms inspired only by extratextual sources and our own imaginations, we would risk amending statutes outside the legislative process reserved for the people's representatives.").

That Dr. Purl or even Texas law may define "person" differently has no bearing on the meaning of this term in a federal statute. *See Hopkins v. Cornerstone Am.*, 545 F.3d 338, 347 (5th Cir. 2008) (finding that federal and state labor laws may support different interpretations of "employee" and "independent contractor"). To hold otherwise—and allow states or individuals to supplant Congress's intentions with their own—violates core principles of federalism and runs roughshod over the explicit preemption provision in HIPAA. By analogy, a doctor may deeply hold a belief that another procedure—say, male circumcision—is abusive in any circumstance. Those views do not mean that circumcisions now fit within the statutory carveout that allows

disclosure of PHI in reporting child abuse and for public health. That doctor is not entitled to report the protected health information relating to legal circumcisions as "abuse" simply because they have personally concluded it is. It is the original meaning of the words that Congress used that matters. *See Bostock*, 590 U.S. at 654; *see also United States v. Am. Trucking Ass'ns, Inc.*, 310 U.S. 534, 542 (1940) (holding that in interpreting statutes, courts should construe the language as to give effect to the intent of Congress). And it is self-evident that in 1996, when Congress used the words "child abuse," those words did not relate to fetuses or lawful reproductive care without other indicia of abuse. *See* Appx. 400 (89 Fed. Reg. 33004) (identifying federal statutes that address child abuse reporting that were in place at the time HIPAA was enacted, and noting "[a]s used in these statutes, the term 'child abuse' does not include activities related to reproductive health care, such as abortion").

D. The Plain Meaning of the Word "Public Health" Indicates That It Relates to Population-Level Health Information.

"Public health" is a well-established term of art used to describe population-level efforts to study and promote health. The dictionary definition of public health is: "the art and science dealing with the protection and improvement of community health by organized community effort and including preventive medicine and sanitary and social science." "Public Health," MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY (11th ed. 2014). Definitions of the term from medical and legal dictionaries as well as the Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry accord with this understanding. Appx. 397 (89 Fed. Reg. 33001) (citing "Health, Public Health," BLACK'S LAW DICTIONARY (11th ed. 2019) and "Public Health," STEDMAN'S MEDICAL DICTIONARY 394520). The 2024 Rule itself defines "public health" as meaning "population-level activities." Appx. 396–97 (89 Fed. Reg. 33000–01).

The 2024 Rule, which concerns individuals' health records and the investigation or imposition of liability on *specific individuals* for the mere act of seeking or providing legal health care, therefore has no connection to the public health-related exceptions in the HIPAA statute. Public health surveillance, investigation, and intervention may rely on information concerning individuals' health status and treatments, but that information is typically aggregated and anonymized, and used to benefit the overall population, not to investigate or prosecute individuals for lawful health care. From its inception, HIPAA was premised on striking a balance between protecting individual privacy without impeding the flow of information used to benefit the broader public—for example, through research or the management and control of infectious disease outbreaks. *See* Brief of Am. Coll. Of Obstetricians and Gynecologists and Soc'y for Maternal-Fetal Med. at 8–10, ECF No. 77-1. The 2024 Rule is fully consistent with this directive. Population-level public health efforts like public health investigations or interventions are distinguished from activities punishing individuals for the legal health care they seek or provide, with the 2024 Rule intentionally leaving intact state powers over the former. Appx. 397–98 (89 Fed. Reg. 33001–02); *see also* 45 C.F.R. § 160.103. Indeed, such public health interventions and investigations rely on the ability of medical practitioners and public health departments to obtain accurate information from patients—an ability that is furthered by the 2024 Rule and patients' understanding of its protections and the broader HIPAA scheme. In short, when an individual receives or provides lawful health care, and the state seeks that data for no purpose other than to investigate that individual, the state does not act under any "public health" purpose contemplated by Congress.

II. THE 2024 RULE IS CONSISTENT WITH HIPAA'S LAWFUL DELEGATION OF AUTHORITY TO HHS

A. The 2024 Rule Is Consistent with HIPAA's Express Delegation of Authority to the Department.

HHS promulgated the 2024 Rule pursuant to an express grant of authority from Congress. Congress, through HIPAA, directed HHS to promulgate standards with respect to the privacy of individually identifiable health information. Appx. 561 (42 U.S.C. § 1320d-2 note). Congress provided detailed guidance about what these standards should do: improve "the efficiency and effectiveness of the health care system, 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." Appx. 549 (42 U.S.C. § 1320d note). To fulfill this directive, Congress directed the HHS Secretary to recommend privacy standards that addressed "[t]he rights that an individual who is a subject of individually identifiable health information should have," "[t]he procedures that should be established for the exercise of such rights," and "[t]he uses and disclosures of such information that should be authorized or required." Appx. 561 (42 U.S.C. § 1320d-2 note). Congress also set itself a deadline. If it failed to act on the Secretary's recommendations and enact legislation within three years, it empowered the Secretary to "promulgate final regulations containing such standards." *Id.* Of importance here, Congress "contemplated that [HHS's] rulemaking would not be static," and "specifically built in a mechanism to adapt such regulations as technology and health care evolve." Appx. 377 (89 Fed. Reg. 32981). To this end, Congress directed "the Secretary [to] review the standards adopted . . . and [to] adopt modifications to the standards (including additions to the standards), as determined appropriate." 42 U.S.C. § 1320d-3(b)(1).

That is precisely what HHS did in promulgating the 2024 Rule. As directed by Congress,

the Secretary adopted modifications that he determined were appropriate in light of the "changing legal landscape."[4] Appx. 374 (89 Fed. Reg. 32978). The Secretary explained in detail that, in the aftermath of the Supreme Court's decision in *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022), "the likelihood that an individual's PHI may be disclosed in ways that cause harm to the interests that HIPAA seeks to protect" had increased, because fear of disclosure for purposes of conducting an investigation or imposing liability "is likely to chill an individual's willingness to seek lawful health care treatment or to provide full information to their health care providers . . . . " Appx. 374 (89 Fed. Reg. 32978). This, in turn, hampers the "efficiency and effectiveness of the health care system," Appx 549 (42 U.S.C. § 1320d note), that HIPAA endeavors to protect and without which individuals' ability to continue obtaining lawful health care services is impaired. Appx. 374 (89 Fed. Reg. 32978).

The Rule is consistent with Congress's express delegation of authority, and the Department has always been clear as to how covered entities should continue to make permissible disclosures in response to law enforcement requests. *See*, *e.g.*, Appx. 405–21 (89 Fed. Reg. 33009–25).

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[4] The 2024 Rule is merely the latest in a history of lawful updates to the baseline HIPAA Privacy Rules, adopted in accordance with HIPAA's mandate that HHS "promulgate," "review," and "adopt modifications," to the Privacy Rules. Appx. 561 (42 U.S.C. § 1320d-2 note); 42 U.S.C. § 1320d-3. As here, modifications to the HIPAA Privacy Rules have historically been made in accordance with changes to the health law landscape. For example, in 2009, the Breach Notification Rule was added to the Privacy Rules in response to passage of the HITECH Act. 74 Fed. Reg. 42740 (Aug. 24, 2009). In 2013, the Omnibus Rule modified the Privacy Rules to strengthen protection of genetic information in response to the Genetic Information Non-Discrimination Act. 78 Fed. Reg. 5566 (Jan. 25, 2013). In 2014, the Privacy Rules were modified in response to the Clinical Laboratory Improvement Amendments (CLIA) regulations. 79 Fed. Reg. 7290 (Feb. 6, 2014). And a 2016 Privacy Rule change allowed covered entities to disclose PHI to the National Instant Criminal Background Check System. 81 Fed. Reg. 382 (Jan. 6, 2016).

B. The 2024 Rule Is Consistent with General Principles of Federalism.

Although Plaintiffs argue that the 2024 Rule is contrary to federalism principles, it is Plaintiffs who seek to upend the balance between federal and state authority that Congress established in 1996 with the passage of HIPAA. *See* Pls.' Br. at 32. HIPAA *expressly preempts* contrary state laws. 42 U.S.C. § 1320d-7(a); *see supra* Section I. Congress must make only a plain statement making "'clear and manifest'" its intention to "pre-empt the historic powers of the States." *See Will v. Mich. Dep't. of State Police*, 491 U.S. 58, 65 (1989) (citation omitted). HIPAA clearly satisfies this requirement. 42 U.S.C. § 1320d-7(a) specifies that any "provision or requirement" or "standard or implementation specification adopted or established" under the Rule "shall supersede any contrary provisions of State law." Because the 2024 Rule does not trigger any of the limited preemption carveouts, it does not run afoul of any federalism principles.

C. None of the Issues Raised *Sua Sponte* by the Court Warrant Vacating the 2024 Rule.

(a) HHS Clearly Acted Within the Bounds of Congress's Delegation of Authority.

Loper Bright Enterprises v. Raimondo sets forth a framework for how courts should assess questions of legal interpretation where a statute is silent or ambiguous. 603 U.S. 369, 404 (2024). And while the Court made clear that deference was not to be afforded to an agency's interpretation of such legal questions (that is left to the courts), Congress still had the ability to delegate authority to an agency. *Id.* at 395; *see also Bondi v. VanDerStok*, 145 S. Ct. 857, 864 (2025) (upholding agency regulation where agency "invoked authority Congress granted to it"). "Where, as here, Congress has clearly delegated discretionary authority to an agency," *Mayfield v. U.S. Dep't of Lab.*, 117 F.4th 611, 617 (5th Cir. 2024), the Court's duty is to "fix[] the boundaries of the delegated authority" and "ensur[e] the agency has engaged in 'reasoned decision making' within

those boundaries." *Loper Bright*, 603 U.S. at 395 (2024) (citation omitted). *First*, HIPAA is facially clear and unambiguous in delegating to HHS the responsibility of promulgating standards regarding the privacy of individuals' health information, which it did by promulgating the 2024 Rule. Appx. 561 (42 U.S.C. § 1320d-2 note); *see also Loper Bright*, 603 U.S. at 394–95 (stating that a statute may authorize an agency to exercise discretion by "empower[ing] an agency to prescribe rules to fill up the details of a statutory scheme" (citation omitted)). *Second*, HHS indisputably engaged in reasoned decision-making when promulgating the 2024 Rule. *See infra* Section III.

(b) The 2024 Rule Does Not Trigger a "Major Question."

The 2024 Rule does not implicate the major questions doctrine. It regulates only the disclosure of health care records pursuant to powers the agency has had since 1996, when HIPAA mandated the Secretary to promulgate rules that address the "uses and disclosures" of personal health information. Appx. 561 (42 U.S.C. § 1320d-2 note).

The major questions doctrine applies, if at all, only when an agency "'claims the power to resolve a matter of great political significance' . . . 'seeks to regulate a significant portion of the American economy or require billions of dollars in spending by private persons or entities' . . . [or] 'seeks to intrude into an area that is the particular domain of state law.'" *Mayfield*, 117 F.4th at 616 (quoting *West Virginia v. EPA*, 597 U.S. 697, 743–44 (2022) (Gorsuch, J., concurring)). When evaluating whether an agency violates the major questions doctrine, courts must examine whether the agency derives its authority from "the vague language of an ancillary provision of the Act," *West Virginia*, 597 U.S. at 724 (citation omitted), or "whether the agency has previously claimed the authority at issue," *Mayfield*, 117 F.4th at 617; *see West Virginia*, 597 U.S. at 724. An agency action is more likely to violate the major questions doctrine when it effectuates "'a fundamental

revision of the statute, changing it from [one sort of scheme] of . . . regulation' into an entirely different kind," *West Virginia*, 597 U.S. at 728 (brackets in original) (citation omitted), or when the "'agency has no comparative expertise' in making certain policy judgments." *Id.* at 729 (citation omitted); *see King v. Burwell*, 576 U.S. 473, 474 (2015) ("It is especially unlikely that Congress would have delegated this decision to the IRS, which has no expertise in crafting health insurance policy of this sort."). None of these circumstances apply here.

First, the agency did not "exercise power of vast . . . political significance" in promulgating the 2024 Rule, *Alabama Ass'n of Realtors v. U.S. Dep't of Health & Hum. Servs.*, 594 U.S. 758, 764 (2021) (internal quotations and citation omitted), nor does it seek to "resolve a matter of great political significance." *Mayfield*, 117 F.4th at 616. The 2024 Rule merely reinforces privacy protections regarding the disclosure of health care records for lawful care. *See*, *e.g.*, 45 C.F.R. § 164.502(a)(5)(iii)(B) (prohibiting disclosure when the "reproductive health care is lawful *under the law of the state* in which such health care is provided," or "protected, required, or authorized by Federal law" (emphasis added)). Promulgation of the Rule is consistent with HHS's well-established authority under HIPAA because it only regulates how health care records are handled *after* care has been sought—not whether that care should be sought in the first instance. *See*, *e.g.*, *id.* § 160.103 (stating that the reproductive health care definition "shall not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive health care"); *id.* § 164.502 (regulating "uses and disclosures of protected health information"). The Rule does not "create special rules about abortion or gender transitions," or purport to or actually legalize any type of reproductive health care through HIPAA, as Plaintiffs maintain. Pls.' Br. at 30. The Rule does not wade into the national debate on abortion or gender affirming care, let alone create a "nationwide policy shift" about the legality, access, or regulation of reproductive

health care, Pls.' Br. at 30, and so does not implicate a matter of great political significance.

Second, the economic impact of the 2024 Rule, an estimated $595 million in the first year, Appx. 445 (89 Fed. Reg. 33049), bears no similarity to the "billions of dollars in spending" that have triggered the doctrine in other instances. *See*, *e.g.*, *Mayfield*, 117 F.4th at 616 (finding that a Rule impacting $472 million in the first year does "not warrant applying the major questions doctrine . . . based on economic significance."); *see also Biden v. Nebraska*, 600 U.S. 477, 500–503 (2023) (finding the major questions doctrine to be implicated when the government cancelled $430 billion in student loans, resulting in costs to the taxpayer estimated to be "between $469 billion and $519 billion"); *Alabama Ass'n of Realtors*, 594 U.S. at 764 (finding that the major questions doctrine applied to the COVID-19 eviction moratorium, the economic impact of which was estimated to be around "$50 billion"). The Rule does not "substantially restructure" any market or have any impact on GDP at all. *West Virginia*, 597 U.S. at 715, 724 (noting that the Clean Power Plan was projected to "reduce GDP by at least a trillion 2009 dollars by 2040").

Finally, the 2024 Rule does not "intrude[] into an area that is the particular domain of state law." *Alabama Ass'n of Realtors*, 594 U.S. at 764. Nor has HHS grounded its authority in "the vague language of an 'ancillary provision[]' of the Act," or "effected a 'fundamental revision of the statute, changing it from [one sort of] scheme of . . . regulation' into an entirely different kind." *West Virginia*, 597 U.S. at 724, 728 (brackets in original) (citations omitted). Rather, 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, Appx. 561 (42 U.S.C. § 1320d-2 note), and to adopt appropriate modifications to those rules. 42 U.S.C. § 1320d-3(b)(1). It has done these things for decades. *See* Appx. 378–79 (89 Fed. Reg. 32982–83). Finally, HHS is not only the agency with "comparative expertise in making certain policy judgments," *West*

Virginia, 597 U.S. at 729 (internal quotations omitted), but is also the agency to which Congress *explicitly* delegated rulemaking authority in the plain language of HIPAA. Appx. 561 (42 U.S.C. § 1320d-2 note). HHS acted well within its Congressional mandate.

(c) HIPAA Contains an Intelligible Principle to Guide HHS's Promulgation of the Rule.

HIPAA's delegation of authority to HHS expresses a clear intelligible principle to guide the agency's rulemaking such that it is "well within the outer limits" of the non-delegation doctrine. *S.C. Med. Ass'n v. Thompson*, 327 F.3d 346, 351–52 (4th Cir. 2003) (citation omitted).

It is well-established that Congress can "delegate[] discretionary authority to an agency," including by "'expressly delegat[ing]' to an agency the authority to give meaning to a particular statutory term . . . empower[ing] an agency to prescribe rules to 'fill up the details' of a statutory scheme . . . or to regulate subject to the limits imposed by a term or phrase that 'leaves agencies with flexibility' . . . such as 'appropriate' or 'reasonable.'" *Loper Bright*, 603 U.S. at 394–95 (citation omitted). To delegate this discretionary authority, Congress must provide an "intelligible principle," and as the Fifth Circuit has explained, the "intelligible-principle test requires Congress to set out guidance that 'delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority,'" *Mayfield*, 117 F.4th at 620 (quoting *Mistretta v. United States*, 488 U.S. 361, 372–73 (1989)). This standard is "'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 (emphasis in original) (quoting *Gundy v. United States*, 588 U.S. 128, 146 (2019)) (requiring only "*some*" guidance, even if not straightforward, clear, or uncontroversial).

First, as Plaintiffs admit, their non-delegation argument is contradicted by the Fourth

Circuit's decision in *South Carolina Medical Association*, which identified "at least three sources within HIPAA that provide intelligible principles outlining and limiting the Congressional conferral of authority on HHS." 327 F.3d at 351. These track exactly the three requirements articulated in *Mayfield*, 117 F.4th at 620: (1) the mandate that the regulations address three specific topics, 42 U.S.C. § 1320d-2 note, (2) the preamble of the statute that sets forth the general purpose of HIPAA, *id.* § 1320d note, and (3) the limitations on "whom the Privacy Rule was to cover, …what information was to be covered, … what types of transactions were to be covered, …what penalties would accrue for violations of HIPAA, … and what time lines and standards would govern compliance with HIPAA." *S.C. Med. Ass'n*, 327 F.3d at 351 (citing 42 U.S.C. §§ 1320d-1(a), 1320d-2(a)(2), 1320d-3, 1320d-4, 1320d-5, 1320d-6).

In addition to the guidance identified in *South Carolina Medical Association*, 327 F.3d at 351, 42 U.S.C. § 1320d-7(b) itself constrains HHS's ability to limit the "reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." *See Big Time Vapes, Inc. v. Food & Drug Admin.*, 963 F.3d 436, 445 (5th Cir. 2020) (finding that delegation is appropriate when "Congress plainly limited the authority that it delegated"). Thus, HIPAA sets out exactly what the Supreme Court and the Fifth Circuit require for an intelligible principle: Congress articulated "the general policy," including in 42 U.S.C. § 1320d note, "the public agency which is to apply it," which HIPAA set out to be HHS in *id.* §§ 1320d-2 note, 1320d-3(b)(1), and "the boundaries of this delegated authority," including in *id.* § 1320d-7(b). *Mistretta*, 488 U.S. at 372–73; *see also Mayfield*, 117 F.4th at 620. In sum, Plaintiffs "ask for a level of specificity that the law does not . . . demand." *Mayfield*, 117 F.4th at 622.

(d) The Rule's Definition of Reproductive Health Care Is Not Void for Vagueness.

The 2024 Rule articulates definite and easily understood prohibitions and, thus, is not void for vagueness. The void for vagueness doctrine requires "sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement." *Gonzales v. Carhart*, 550 U.S. 124, 148–149 (2007) (citation omitted). Additionally, the Supreme Court has relied on scienter requirements as a way to "alleviate vagueness concerns," as they may "narrow the scope of the . . . prohibition and limit prosecutorial discretion." *Id.* at 149–50. In the Fifth Circuit, for a rule to be found void for vagueness in a facial challenge, a party must allege that the definition meets the high bar of being "impermissibly vague in all of its applications." *McClelland v. Katy Indep. Sch. Dist.*, 63 F.4th 996, 1013 (5th Cir. 2023). Plaintiffs have not done so here. Pls.' Br. at 36–37. While the Supreme Court has indicated a more lenient standard,[5] this still does not apply in the absence of *any* non-conclusory allegations of vagueness. *See* Pls.' Br. at 36–37.

First, HIPAA's criminal penalties provision includes a clear scienter requirement such that a violation of the Rule would only result in criminal penalties if the individual engaged in a *knowing* violation of the Rule. 42 U.S.C. § 1320d-6(a). Far from "heightening" Due Process concerns, Pls.' Br. at 37, this scienter requirement "alleviate[s] vagueness concerns." *Gonzales*, 550 U.S. at 149–50.

Second, the 2024 Rule is clear on its face and offers detailed definitions and examples of

[5] *See Johnson v. United States*, 576 U.S. 591, 595, 602 (2015) (holding that while a vague provision is not unconstitutional merely because some conduct clearly falls within the provision, the law may not "fail[] to give ordinary people fair notice of the conduct it punishes, or [be] so standardless that it invites arbitrary enforcement").

the covered care. The Rule defines "reproductive health care" as a subset of the term "health care," which has long been defined by HHS. *See* Appx. 341 (65 Fed. Reg. 82799 (Dec. 28, 2000) (defining "health care")); 45 C.F.R. § 160.103. Reproductive health care is even more precisely defined as health care "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. A "non-exclusive list of examples that fit within the definition" provides even further clarity as to what types of records are covered under the Rule. Appx. 402 (89 Fed. Reg. 33006). In addition to this definition, the Department also provided ample explanation for how covered entities can comply with the requirements of the 2024 Rule. *See infra* Section III.

III. THE RULE IS NOT ARBITRARY AND CAPRICIOUS

The 2024 Rule is not arbitrary and capricious. HHS provided ample explanation for the 2024 Rule, including "th[e] changing legal landscape" that increases the risk of PHI disclosure that would "cause harm to the interests that HIPAA seeks to protect." Appx. 374 (89 Fed. Reg. 32978); *see also* Appx. 387–92 (89 Fed. Reg. 32991–96). HHS reasonably explained the Rule's requirements, including how covered entities determine the legality of reproductive health care when applying the 2024 Rule's disclosure prohibition. *See* Appx. 405–28 (89 Fed. Reg. 33009–32). "[W]here a request for PHI is made to the regulated entity that provided" the care, that entity should review "all available relevant evidence bearing on whether the reproductive health care was lawful under the circumstances in which it was provided." Appx. 411 (89 Fed. Reg. 33015). Conversely, when a covered entity did not provide the reproductive care at issue and does not have the relevant information, it may "presume[]" that the care is "lawful." Appx. 410 (89 Fed. Reg. 33014); 45 C.F.R. § 164.502(a)(5)(iii)(C). Far from arbitrary, this presumption addresses "concerns about obligating regulated entities to determine whether reproductive health care that

occurred outside of the regulated entity is lawful." Appx. 410 (89 Fed. Reg. 33014).

Moreover, Plaintiffs' objections about how the Department defined "reproductive health care" are unfounded. Pls.' Br. at 36–37. The Department provided a detailed explanation of the definition, which was intended to "encompass[] the full range of health care related to an individual's reproductive health" in order to, among other reasons, "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." Appx. 401–02 (89 Fed. Reg. 33005–06). 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 "confusion" and "the risk that important activities would be left out." Appx. 401 (89 Fed. Reg. 33005). In promulgating the 2024 Rule, the Department "articulate[d] a satisfactory explanation for [the] action including a rational connection between the facts found and the choice made," easily satisfying the arbitrary-and-capricious standard. *Little Sisters of the Poor Saints Peter & Paul Home v. Pa.*, 591 U.S. 657, 682 (2020) (citation omitted).

At bottom, Plaintiffs have not identified any aspect of the 2024 Rule that HHS failed to reasonably explain. Plaintiffs' disagreement with the Department's explanations and policy choices is not sufficient to prevail on an arbitrary and capricious challenge. *See Huawei Techs. USA, Inc. v. Fed. Commc'ns Comm'n*, 2 F.4th 421, 451 (5th Cir. 2021) (rejecting APA claim where "agency weighed the evidence differently than [plaintiff] and reached contrary but reasonable policy conclusions").

IV. ANY REMEDIES SHOULD BE LIMITED TO PLAINTIFFS AND COMPLY WITH HIPAA'S SEVERABILITY PROVISION

For the reasons stated, this Court should deny Plaintiffs' motion in its entirety and grant

Defendants' motion, entering judgment for the Defendants. But if the Court enters judgment for Plaintiffs, the Court should limit any relief to the Plaintiffs themselves. Any further relief would contravene equitable principles and defy the Department's clear intention of severability.

Under Article III, "a plaintiff's remedy must be 'limited to the inadequacy that produced [their] injury in fact.'" *Gill v. Whitford*, 585 U.S. 48, 66 (2018) (quoting *Lewis v. Casey*, 518 U.S. 343, 357 (1996)); *see United States v. Nat'l Treasury Emps. Union*, 513 U.S. 454, 477–78 (1995) ("[W]e neither want nor need to provide relief to nonparties when a narrower remedy will fully protect the litigants."); *Texas v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 700 F. Supp. 3d 556, 572 (S.D. Tex. 2023).

An injunction with respect to Dr. Purl and her private practice alone would fully remedy Plaintiffs' asserted injuries by permanently barring Defendants from enforcing the 2024 Rule against Plaintiffs. *See Bureau of Alcohol, Tobacco, Firearms & Explosives*, 700 F. Supp. 3d at 572 ("'Equitable remedies, like remedies in general, are meant to redress the injuries sustained by a particular plaintiff in a particular lawsuit.'" (citation omitted)); *California v. Texas*, 593 U.S. 659, 672 (2021) (valid Article III remedies generally "'operate with respect to specific parties'" rather than in the abstract (citation omitted)); *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979) ("[I]njunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs."); *Texas v. United States*, 126 F.4th 392, 420 (5th Cir. 2025) ("Remedies must be 'tailored to redress' a plaintiff's injury . . . and equitable remedies . . . should not provide more relief than 'necessary to give the prevailing party the relief to which [it] is entitled'" (citations omitted)).

Regardless of whether courts may vacate or enjoin agency action universally, they "should 'think twice—and perhaps twice again—before granting' such sweeping relief." *United States v.*

Texas, 599 U.S. 670, 702 (2023) (Gorsuch, J., concurring) (citation omitted). Whether vacatur is appropriate turns 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).

Universal vacatur in a challenge brought by one provider and her affiliated private practice would also have deeply disruptive consequences and cause nationwide harms to all of the other regulated parties, as well as the public's interest in the privacy of sensitive medical information. As set forth in Defendants' Brief, disclosures of such information would "irreparably harm relationships and reputations"; "result in the job loss or other negative consequences in the work place"; "deter[] [individuals] from seeking needed health care if they do not trust that their sensitive information will be kept private"; and withhold probative information from providers "necessary . . . for an appropriate treatment plan." Defs.' Br. in Supp. of Mot. to Dismiss or for Summ. J., ECF No. 40 (hereinafter "Defs.' Br.") at 37–38 (quoting 89 Fed. Reg. 32984, 32990–91, 33057). The Court should deny Plaintiffs' blanket request. *See Cargill v. Garland*, 57 F.4th 447, 472 (5th Cir. 2023) (en banc) (plurality opinion) *aff'd*, 602 U.S. 406 (2024) (remanding and stating that the district court could consider on remand "a more limited remedy" than universal vacatur, and should "determine what remedy . . . is appropriate to effectuate" the judgment); *Central & S.W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000) (remanding without vacatur).

Any remedy the Court orders should also account for the unambiguous severability provision contained in HIPAA's implementing regulations, which directs 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. Whether a regulation is severable depends upon (1) "the intent of the agency" and (2) "whether the remainder of the regulation could function sensibly without the stricken

provision." *Texas v. United States*, 126 F.4th at 419 (cleaned up). Courts "'adhere to the text of a severability clause in the absence of extraordinary circumstances.'" *Id.* (citation omitted).

The 2024 Rule meets both prongs. The Rule unequivocally provides that the 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." Appx. 444 (89 Fed. Reg. 33048). And the severability provision explicitly contemplates injunctions as to "persons" and "plaintiffs," indicating that any injunctive relief should apply only to the plaintiffs before the Court. 45 C.F.R. § 164.535.

As explained in the 2024 Rule and Defendants' brief, the Court could simply enjoin the Department from enforcing the Rule with respect to legitimate reports of child abuse to the extent the Court concludes that the 2024 Rule limits the ability to report child abuse, or the Court can sever definitions of certain terms from the remainder of the Rule's provisions if it finds they are improper. *See* Appx. 444 (89 Fed. Reg. 33048); Defs.' Br. at 39. Any relief ordered should not transgress the Department's clear intention of severability, which would imperil protections that are vital to safeguard Americans' sensitive medical information.

CONCLUSION

For these reasons and those articulated in Defendants' Brief, Defs.' Br. at 11–39, we strongly urge the Court to deny the relief sought in the Complaint.

* * *

Date: May 2, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 2, 2025, a copy of the foregoing was filed electronically via the Court's ECF system, which effects service upon counsel of record.

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