#### 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,

Proposed Intervenor-Defendants. Civil Action No. 2:24-cv-00228

REPLY IN SUPPORT OF PROPOSED INTERVENOR-DEFENDANTS'
MOTION FOR SUMMARY JUDGMENT

#### PRELIMINARY STATEMENT

Plaintiffs have persistently asserted an interpretation of the preemption provision in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. 104-191, 110 Stat. 1936, that contradicts both its clear purpose and its plain terms. First, Plaintiffs approach the preemption analysis as though authority is broadly reserved for the states and only narrowly allows for preemption—but the opposite is true. Congress drafted the HIPAA statute with a clear, express, and broad preemption provision. It establishes that HIPAA "shall supersede any contrary provision of State law." 42 U.S.C § 1320d-7(a)(1) (emphasis added). Preemption is therefore the default and the final rule promulgated by the Department of Health and Human Services ("HHS" or the "Department") is not contrary to HIPAA unless it invalidates or limits one of the specific authorities excepted from the general rule of preemption. 42 U.S.C §§ 1320d-7(b), (c); Proposed Intervenor-Defs.' Appx. to Br. in Supp. of Mot. for Summ. J., ECF No. 49-4 (hereinafter "Appx.") 372-462 (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"). It does not. Second, Plaintiffs claim that the 2024 Rule may violate certain of these exceptions relies on a strained and atextual construction of statutory terms. 42 U.S.C. § 1320d-7(b).

The 2024 Rule is a clear constitutional exercise of the Department's core and express authority under HIPAA to promulgate and modify rules concerning the "uses and disclosures" of protected health information ("PHI"). Appx. 561 (42 U.S.C. § 1320d-2 note) (codifying Pub. L. 104-191, title II, § 264, 110 Stat. 2033 (1996)); 42 U.S.C. § 1320d-3(b)(1). The Department carefully considered and explained the 2024 Rule, easily meeting the highly deferential arbitrary and capricious standard. And the 2024 Rule is narrow in scope and does not purport to regulate or legalize any form of reproductive health care. Plaintiffs' assertion that the Rule is arbitrary and capricious and beyond HHS's authority amounts to no more than a disagreement with the

Department's policy choices.

#### ARGUMENT

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

## A. Plaintiffs' Interpretation of HIPAA's Preemption Provision Is Contrary to the Statute's Plain Text

Plaintiffs' claim that the 2024 Rule ignores basic principles of preemption and the careful balance between federal and state power that Congress explicitly established in HIPAA cannot be squared with the statutory language. *See* Pls.' Br. in Opp., ECF No. 66 at 1 ("Pls.' Br."); Intervenor-Defendants' Mem. in Opp. to Summ. J., ECF No. 69 at 14 ("Interv.-Defs.' Mem."). Congress included a broad, express preemption provision, which Congress made clear was necessary to further the core purpose of HIPAA, and the rules promulgated thereunder: namely, to provide uniform, nationwide standards for the secure exchange of private health information. Appx. 549 (42 U.S.C. § 1320d note) (codifying Pub. L. 104–191, title II, § 261, 110 Stat. 2021 (1996)); 42 U.S.C. § 1320d-2(a)(1), (d); Appx. 561 (42 U.S.C. § 1320d-2 note).

Equally clearly, Congress identified only limited exceptions to this rule of broad general preemption. Congress did not exempt state police powers, or include any other open-ended language, the penumbras of which could justify broader preemption exceptions than the limited ones listed. There are only six specific and identified exceptions to the broad preemption explicitly provided for by the statute. 42 U.S.C. § 1320d-7(b). These exceptions include, as relevant here, "the reporting of . . . child abuse," or "public health surveillance, or public health investigation or intervention." *Id.* They do *not* include "states' long recognized authority to investigate crime," and "state reporting procedures and investigations" or Plaintiffs' opinions regarding what "doctors should be able to do." Pls.' Br. at 1, 16. Plaintiffs fail to show that the 2024 Rule implicates one of the enumerated

carveouts. 42 U.S.C. § 1320d-7 (b), (c).

## B. The 2024 Rule Does Not Conflict with Any Carveouts to HIPAA's Preemption Provision

#### (a) "Child Abuse"

The 2024 Rule is narrowly designed to regulate disclosure of records relating to *lawful* reproductive care when sought for the *purpose* of *investigating or imposing liability* on a person for *merely* seeking or providing that care. 45 C.F.R. § 164.502(a)(5)(iii). It does not impermissibly restrict "the reporting . . . of child abuse." 42 U.S.C. § 1320d-7(b). Plaintiffs' arguments otherwise fail for three reasons: 1) they misconstrue the scope of preemption carveouts in 42 U.S.C. § 1320d-7(b); 2) they fail to demonstrate a clear conflict between Plaintiffs reporting obligations and the 2024 Rule; and 3) they ignore the original meaning of federal statutory terms.

First, HIPAA excepts from preemption laws which "provid[e] for the reporting of . . . child abuse[.]" *Id.* (emphasis added). HIPPA does not except from preemption states' requests for PHI—and so any such laws are preempted. 42 U.S.C. § 1320d-7(a)(1); Appx. 561 (42 U.S.C. § 1320d-2 note) (requiring standards regarding the "the uses and disclosures of [PHI] that should be authorized or required"). In arguing that this distinction is unsupported by the statutory text (Pls.' Br. at 14), Plaintiffs ignore HIPAA's implementation history and statutory scheme. See Defs.' Mem. in Supp. of Mot. for Summ. J., ECF No. 40, at 18 ("Defs.' Mem.") (explaining, for example, how different statutory sections govern reporting pursuant to a general reporting obligations and responding to police requests); Appx. 561 (42 U.S.C. § 1320d-2 note); 42 U.S.C. §§ 1320d-7(a)(1), 1320d-7(b))

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This does not mean the 2024 Rule imposes a blanket prohibition on state requests for health information, including reproductive health information. Rather, the Rule outlines the "procedures" regulating which state requests "should be authorized or required," per HIPAA's mandate in 1320d-2 note, and those regulatory procedures "supersede contrary state law." 42 U.S.C § 1320d-7(a); see, e.g., 45 C.F.R. § 164.512(f) (regulatory section titled "Standard: Disclosures for law enforcement purposes").

(exempting "reporting" and not 'requests' from preemption). The hypothetical actions Plaintiffs point to—that Plaintiffs may "respond[] to or cooperat[e] with" law enforcement requests for protected health records, Pls.' Br. at 14—are all responses to state requests, which are not subject to any preemption exception.

Second, Plaintiffs have failed to demonstrate an actual conflict between the narrow class of PHI protected by the 2024 Rule and any affirmative reporting obligations contemplated in 42 U.S.C. § 1320d-7(b)'s preemption exception. Nor can they. The 2024 Rule specifically leaves child abuse reporting in place. See Pls.' Br. at 13 ("the 2024 Rule didn't eliminate the abuse-reporting permission"); Appx. 400 (89 Fed. Reg. 33004) ("the Rule "[does] not . . . disrupt longstanding state or Federal child abuse reporting requirements that apply to regulated entities," and providers continue to be "permitted to make such disclosure [of reproductive care records] where there is suspicion of sexual abuse that could be the basis of permitted reporting"). Plaintiffs' do not and cannot demonstrate that there is a conflict between maintaining the privacy of records of lawful health care on the one hand (as HIPAA and the Rules require), and reporting suspected abuse (as state law requires, and HIPAA enables), on the other. And if Plaintiffs were to encounter care that is not lawful under either state or federal law, the 2024 Rule has no bearing on their ability to report, as it only addresses "lawful" care. See Defs.' Mem. at 20; 45 C.F.R. § 164.502(a)(5)(iii)(b).

Plaintiffs stop short of claiming that they are required to report *lawful* reproductive health care as child abuse absent extenuating circumstances (in which case the 2024 Rule, on its face, permits reporting). Instead, Plaintiffs invoke their personal beliefs about what "doctors should be able to report." Pls.' Br. at 16. But Plaintiffs' personal preferences about what lawful care "should" be reportable as abuse have no bearing on whether a reporting conflict exists with the 2024 Rule. *Id.*; Appx. 558 (42 U.S.C. § 1320d-7(b)).

Third, if the meaning of a term in a federal statute is contested, the federal—not the state or an individual's—understanding of the term is the correct definition. 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"); see also Lambro v. United States, 90 F.4th 1375, 1379 (Fed. Cir. 2024) (federal statutes and regulations providing specific definitions and standards that are authoritative for federal purposes). Here, "child abuse" as used in HIPAA's preemption provision cannot be read to include lawful reproductive care for two reasons: 1) statutory terms retain the meaning they had "at the time of . . . enactment," Bostock v. Clayton Cnty., 590 U.S. 644, 654 (2020)—and at the time Congress enacted HIPAA, abortion was a constitutionally protected right and not encompassed within the term "child abuse"; and 2) definitions in federal statutes should be construed to be consistent with other federal statutes—which, as Proposed-Intervenor Defendants have explained, also counsel that "child abuse" does not mean lawful reproductive care. Intervence in the interpretation of a 30-year-old federal statute. Pls. Br. at 19–20.

#### (b) "Public Health"

As established in Intervenor-Defendants' opposition, the term "public health" has a clear, consistent, and well-established plain meaning of referring to *population-level* efforts. *See* Interv.-Defs.' Mem. at 9-11. Public health "surveillance," and "investigation or intervention," Appx. 558 (42 U.S.C. § 1320d-7(b)), may rely on information concerning individuals' health status and

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<sup>&</sup>lt;sup>2</sup> 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"); 1 U.S.C. § 8(a) (defining "child" across all federal statutes and regulations to mean someone "born alive."); *see also* Appx. 400 (89 Fed. Reg. 33004) ("the term 'child' in the Privacy Rule is consistent with th[e] definition [in 1 U.S.C. § 8]").

treatments—but that information is typically aggregated and anonymized, and used to benefit the overall population, not to prosecute individuals for lawful health care. See, e.g., Appx. 397 (89 Fed. Reg. 33001 nn.233-34) (citing "Public Health," STEDMAN'S MEDICAL DICTIONARY 394520). Yet plaintiffs propose reading in such an understanding. Plaintiffs' interpretation would manufacture a court-made expansion of § 1320d-7(b) by limiting HIPAA's ability to address state attempts to "investigate" individuals and "impose liability" under the banner of "public health." Pls.' Br. at 20; Interv.-Defs.' Mem. at 10-11. Contrary to this interpretation, HIPAA from its inception was premised on striking a balance, 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 Amicus Brief of Am. Coll. of Obstetricians and Gynecologists and Soc'y for Maternal-Fetal Med., ECF No. 77-1 at 8–10. The statute's preemption exception ensures that states authority to act to improve population-level "public health"—is not in dispute. Interv.-Defs.' Mem. at 11–12. And 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. Appx. 397 (89 Fed. Reg. 33001); see also 45 C.F.R. § 160.103 (defining "public health"). By definition, information provided to further legitimate population-level health protections is not implicated by the 2024 Rule because that information is not provided solely to prosecute individuals for obtaining legal health care.

# C. The 2024 Rule Does Not "Limit" Any Law Exempted from HIPAA's Preemption Provision

Even if Plaintiffs were to identify a state law that relates to "child abuse" or "public health surveillance . . . investigation or intervention" under HIPAA, Appx. 558 (42 U.S.C. § 1320d-7(b)), the 2024 Rule would not unlawfully "limit" that law's authority. *First*, Plaintiffs rely exclusively on

dictionaries to declare "limit" to be a "polysemous" word with many "potential meanings," suggesting that an impermissible "limit" ensures both that HIPAA could invalidate "certain state laws" nearly completely and, simultaneously, "not even partially limit, or obstruct, such laws." Pls.' Br. at 18. However, "[t]he meaning of a word 'may only become evident when placed in context." Sackett v. EPA, 598 U.S. 651, 674–75 (2023) (quoting FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132 (2000)); see also Interv.-Defs.' Mem. at 4. In relying on a dictionary divorced from the statutory context, Plaintiffs ignore well-established principles of statutory interpretation. Interv.-Defs.' Mem. at 4–5. For example, Plaintiffs' definitions of the term "limit" ignores that the word "limit" is paired with the word "invalidate." Pls.' Br. at 18. "Invalidate" means an elimination of authority. Read in the context of its neighboring words, "limit" must mean a substantial impairment of the same. Interv.-Defs.' Mem. at 4-5. The interpretive rule that words should not be rendered superfluous reinforces this meaning of "limit" because it preserves the effect of "invalidate." See Ysleta Del Sur Pueblo v. Texas, 596 U.S. 685, 698-699 (2022). And second, as both Defendant and Proposed Intervenor-Defendant have explained at length, the actual impact of the 2024 Rule is minimal. See, e.g., Interv.-Defs.' Mem. at 12; Defs.' Mem. at 17–22.

#### II. THE 2024 RULE IS CONSTITUTIONAL

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, Appx. 554 (42 U.S.C. § 1320d-3(b)(1)). The Department has exercised those very authorities for decades. *See* Appx. 378–79 (89 Fed. Reg. 32982–83), Interv.-Defs.' Mem. at 13 n.7. Plaintiffs' constitutional arguments regarding major questions doctrine, non-delegation, and purported vagueness mischaracterize the scope of the Rule and do nothing to disturb the Rule's validity.

The Rule does not trigger the major questions doctrine. *See* Interv.-Defs.' Mem. at 16–20. It concerns only the narrow question of whether HIPAA-covered entities can disclose medical information regarding reproductive health care in limited circumstances. *See, e.g.*, 45 C.F.R. 164.502(a)(5)(iii)(A); Appx. 390–91 (89 Fed. Reg. 32994–95). The Rule does not broadly implicate the national debate on abortion or gender identity policy, let alone "allow exceptionalism for 'reproductive health care," Pls.' Br. at 24, regarding the legality, access, or regulation over the provision of such care. Nor is an issue of "economic significance" implicated—Plaintiffs' reliance on generic statistics regarding the nationwide size of the gender reassignment and abortion clinic markets, *id.* at 24 n.6, have no nexus to the Rule's narrow and tailored disclosure prohibitions.

The Department's promulgation of the 2024 Rule is squarely within the statutory authority expressly delegated to it by Congress in HIPAA and does not raise any "serious questions of constitutionality." Pls.' Br. at 25; see Interv.-Defs.' Mem. at 20-22. 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," Appx. 561 (42 U.S.C. § 1320d-2 note), and to "adopt modifications to the standards (including additions to the standards), as determined appropriate." Appx. 554 (42 U.S.C. § 1320d-3(b)(1)). That is precisely what HHS did in promulgating the 2024 Rule consistent with HIPAA's purpose "to improve the efficiency and effectiveness of the health care system, which includes ensuring that individuals have trust in the health care system," Appx. 385 (89 Fed. Reg. 32989). And Plaintiffs' assertion that HIPAA fails the intelligible principle test because Congress did not specify, for example, the "different medical"

conditions and procedures" covered by the statute, Pls.' Br. at 25, "ask[s] for a level of specificity that the law does not currently demand." *Mayfield v. United States Dep't of Lab.*, 117 F.4th 611, 620, 622 (5th Cir. 2024); *see also* Interv.-Defs.' Mem. at 20–22.

#### III. THE 2024 RULE IS NOT ARBITRARY AND CAPRICIOUS

The 2024 Rule is not arbitrary and capricious. *See* Interv.-Defs.' Mem. at 24–27. 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 also 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 relevant reproductive health 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 as to how the Department defined "reproductive health care" are unfounded. Pls.' Br. at 31–32. 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 surpassing 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 may disagree with the Department's explanations and policy choices, but that is not sufficient to prevail on an arbitrary and capricious challenge. *See Huawei Techs. USA, Inc. v. Fed. Comme'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").

#### **CONCLUSION**

For the reasons stated above and Defendants' and proposed Intervenor-Defendants' previous briefing, the Court should deny Plaintiffs' Motion for Summary Judgment and grant proposed Intervenor-Defendants' Motion for Summary Judgment.

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Date: March 17, 2025

Respectfully submitted,

#### /s/ Shannon R. Selden

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### **CERTIFICATE OF SERVICE**

I hereby certify that on March 17, 2025, a copy of the foregoing was filed electronically via the Court's ECF system, which effects service upon counsel of record.

/s/ Shannon R. Selden Shannon Rose Selden