

IN THE UNITED STATES DISTRICT COURT
FOR THE 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.

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Civil Action No. 2:24-cv-228-Z

COMPLAINT

1. Plaintiffs Carmen Purl, M.D.; and Carmen Purl, M.D., PLLC, d/b/a
Dr. Purl's Fast Care Walk In Clinic, bring this action seeking declaratory and
injunctive relief against enforcement of a final rule issued by the United States
Department of Health and Human Services.

2. The rule inserts abortion, gender identity, and other topics into
regulations implementing the Health Insurance Portability and Accountability Act
of 1996 (HIPAA), which has nothing at all to do with those topics, does not treat

medical information about these topics any differently than other private information, and gives Defendants no authority to regulate in this way.

3. The final rule is entitled “HIPAA Privacy Rule to Support Reproductive Health Care Privacy,” 89 Fed. Reg. 32,976 (April 26, 2024) (the “2024 Rule”). The 2024 Rule became effective on June 25, 2024.

4. Persons subject to the 2024 Rule, including Plaintiffs, must comply with its requirements starting on December 23, 2024.

5. As is relevant here, the 2024 Rule purports to limit the circumstances when a HIPAA-covered entity can share information with government agencies, such as state child-welfare agencies and law enforcement agencies, both state and federal.

6. HIPAA-covered entities that share information in contravention of HHS’s regulations incur criminal liability.

7. Yet the HIPAA statute explicitly preserves government authority to investigate and to require disclosures concerning abuse.

8. The 2024 Rule lacks statutory authority and is arbitrary and capricious. As such, the Court should vacate and set aside the Rule and preliminarily and permanently enjoin its enforcement.

9. The 2024 Rule imposes imminent and irreparable compliance costs on Plaintiffs if it is not enjoined on or before its compliance date of December 23, 2024.

PARTIES

10. Plaintiff Carmen Purl, M.D., is a family medicine physician practicing in Dumas, Moore County, Texas. She is the sole owner of Carmen Purl, M.D., PLLC, d/b/a Dr. Purl’s Fast Care Walk In Clinic, a private family medicine practice.

11. Plaintiff Carmen Purl, M.D., PLLC, d/b/a Dr. Purl's Fast Care Walk In Clinic, is a professional limited liability company incorporated in Texas. Its principal place of business is 1524 Guy Lane Plaza, Dumas, Texas, 79029.

12. Defendant United States Department of Health and Human Services ("HHS") is an executive agency within the federal government of the United States.

13. Defendant Xavier Becerra is the Secretary of HHS and is responsible for enforcing HIPAA and the 2024 Rule. He is sued in his official capacity.

14. Defendant Office for Civil Rights of the United States Department of Health and Human Services ("OCR") is an executive agency within the federal government of the United States and is responsible for enforcing HIPAA and for promulgating the 2024 Rule.

15. Defendant Melanie Fontes Rainer is the Director of OCR and is responsible for enforcing HIPAA and the 2024 Rule. She is sued in her official capacity.

JURISDICTION AND VENUE

16. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action arises under the U.S. Constitution and federal law.

17. This Court has jurisdiction under 28 U.S.C. § 1346(a) because this is a civil action against the United States.

18. This Court has jurisdiction under 28 U.S.C. § 1361 to compel an officer of the United States or any federal agency to perform his or her duty.

19. This Court has jurisdiction to review Defendants' unlawful actions and enter appropriate relief under the Administrative Procedure Act, 5 U.S.C. §§ 553, 701-06.

20. This Court has authority to issue equitable relief to enjoin ultra vires agency action. *See, e.g., Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689–91 (1949).

21. This case seeks declaratory and other appropriate relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, the Administrative Procedure Act, 5 U.S.C. § 701–06, Federal Rule of Civil Procedure 57, and the Court’s inherent equitable powers.

22. This Court may award costs and attorneys’ fees under the Equal Access to Justice Act, 28 U.S.C. § 2412.

23. Venue is proper in this Court under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims occurred in this division of this district, which is where Plaintiffs reside and are regulated by Defendants’ actions.

24. Defendants are United States agencies or officers sued in their official capacities.

BACKGROUND

I. The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

25. HIPAA was enacted by Congress on August 21, 1996, to “improve portability and continuity” and “simplify the administration of health insurance.” Pub. L. No. 104-191, 110 Stat. 1936, 1936 (1996).

26. HIPAA’s operative provision provides that:

A person who knowingly and in violation of this part—

- (1) Uses or causes to be used a unique health identifier;
- (2) Obtains individually identifiable health information relating to an individual; or

- (3) Discloses individually identifiable health information to another person,

shall be punished as provided in subsection (b). For purposes of the previous sentence, a person (including an employee or other individual) shall be considered to have obtained or disclosed individually identifiable health information in violation of this part if the information is maintained by a covered entity (as defined in the HIPAA privacy regulation described in section 1320d-9(b)(3) of this title) and the individual obtained or disclosed such information without authorization.

42 U.S.C. § 1320d-6.

27. Under HIPAA, “[g]enerally, a health care provider cannot disclose [patient health] information ‘without authorization’ from the patient.” *United States v. Wilson*, 98 F.4th 1204, 1217 (10th Cir. 2024) (quoting 42 U.S.C. § 1320(d)-6(a)); *see also Wilson v. UnitedHealthCare Ins. Co.*, 27 F.4th 228, 245 (4th Cir. 2022) (same).

28. But the statute says: “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.” 42 U.S.C. § 1320d-7(b).

29. Congress specifically preserved State authority in the statute.

30. Moreover, nothing in the HIPAA statute authorizes Defendants to construe HIPAA’s bar on disclosure “without authorization” to sweep in compliance with compulsory process, such as a subpoena, requiring disclosure to a government agency.

31. The HIPAA statute does not authorize Defendants to issue regulations treating information relating to abortion, gender identity, or “reproductive health care” in general, differently than information concerning other kinds of care.

32. The HIPAA statute does not authorize Defendants to define “persons” to exclude unborn children.

33. The HIPAA statute does not authorize Defendants to define “public health” to exclude states’ exercise of their authority over medical practice to deem some circumstances related to “reproductive health” as detrimental to health, such as to the health of unborn children or to children subjected to “gender transition.”

II. The Privacy Rule

34. In 2000, HHS adopted Standards for Privacy of Individually Identifiable Health Information (known as the “Privacy Rule” and referred to herein as the “Privacy Rule”). 65 Fed. Reg. 82,462. The Privacy Rule “address[es] the use and disclosure of individuals’ health information”—called “protected health information” or PHI. *See* OCR, *Summary of the HIPAA Privacy Rule 1* (May 2003), <https://www.hhs.gov/sites/default/files/privacysummary.pdf>.

35. The Privacy Rule generally applies to regulated entities—“health plan[s],” “health care clearinghouse[s],” and certain “health care provider[s] who transmit[] ... health information in electronic form.” 45 C.F.R. § 160.102; *see id.* § 164.500.

36. The Privacy Rule’s “major goal” “is to assure that individuals’ health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public’s health and well being.” OCR, *Summary, supra*, at 1.

37. The Privacy Rule sets standards for using and disclosing PHI in certain circumstances without the patient’s approval. These include disclosures: “for a law enforcement purpose to a law enforcement official,” 45 C.F.R. § 164.512(f); “[i]n response to an order of a court” or “a subpoena, discovery request, or other lawful process,” *id.* § 164.512(e)(1)(i), (ii); “to a health oversight agency for oversight

activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate [health care] oversight,” *id.* § 164.512(d)(1); and to a “public health authority ... for the purpose of preventing or controlling disease, injury, or disability,” including “the conduct of public health surveillance, public health investigations, and public health interventions,” *id.* § 164.512(b)(1)(i).

38. A HIPAA-covered entity can share information in response to an administrative subpoena if a three-part test is met.

39. The three-part test requires that:

- (1) The information sought is relevant and material to a legitimate law enforcement inquiry;
- (2) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and
- (3) De-identified information could not reasonably be used.

45 C.F.R. § 164.512(f)(1)(ii)(C).

III. The 2024 Revisions to the Privacy Rule

40. On April 26, 2024, HHS published the 2024 revisions to the Privacy Rule (“the 2024 Rule”).

41. HHS admits that the 2024 Rule is a response to the “[t]he Supreme Court’s decision in *Dobbs* [that] overturned *Roe v. Wade* and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, thereby enabling states to significantly restrict access to abortion.” 89 Fed. Reg. at 32,987.

42. In other words, HHS promulgated the 2024 Rule in order to obstruct States’ ability to enforce their laws regulating abortion and other laws that HHS deems to fall under the rubric of “reproductive health care.”

43. The 2024 Rule restricts HIPAA-covered entities from making disclosures that the previous HIPAA Privacy Rule allowed them to make.

44. The 2024 Rule defines “reproductive health care” broadly, including “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.

45. In the 2024 Rule’s preamble, HHS specifies that “reproductive health care” should be “interpreted broadly and inclusive of all types of health care related to an individual’s reproductive system” and that it “encompasses the full range of health care related to an individual’s reproductive health.” 89 Fed. Reg. at 33,005.

46. Under the 2024 Rule, “reproductive health care” includes, *inter alia*, abortion, as well as hormone and drug interventions for “gender transition” or gender dysphoria, and surgical procedures on an individual’s reproductive system, including surgery as treatment for gender dysphoria.

47. HHS “acknowledges that this final rule may affect certain state interests in obtaining PHI to investigate potentially unlawful reproductive health care.” 89 Fed. Reg. at 32,995.

48. HHS states, however, that the 2024 Rule does not “prevent regulated entities from using or disclosing PHI for the purpose of defending themselves or others against allegations that they sought, obtained, provided, or facilitated reproductive health care that was not lawful under the circumstances in which it was provided.” 89 Fed. Reg. at 33,011.

49. In other words, the 2024 Rule allows for disclosure to *defend against* a claim or prosecution involving “reproductive health care,” as might occur if a medical provider violated state laws against abortion or child “gender transitions,” but it prevents disclosure when a law enforcement agency is investigating to *bring* a claim or enforce a law involving those circumstances.

50. The 2024 Rule prohibits a covered entity or business associate from disclosing PHI where it will be used 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.

45 C.F.R. § 164.502(a)(5)(iii)(A).

51. In sum, the 2024 Rule restricts healthcare professionals and entities from disclosing information to state officials and law enforcement in cooperation with efforts to obtain evidence of a crime, other potential violation of state law, or threats to public health related to “reproductive health care.”

52. This prohibition applies:

where the relevant activity is in connection with any person seeking, obtaining, providing, or facilitating reproductive health care, and the covered entity or business associate that received the request for protected health information has reasonably determined that one or more of the following conditions exists:

- (1) The 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.
- (2) The reproductive health care is protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided.

45 C.F.R. § 164.502(a)(5)(iii)(B).

53. The 2024 Rule imposes a duty on the HIPAA-covered entity to determine whether the “reproductive health care” was lawful.

54. The 2024 Rule imposes on HIPAA-covered entities a presumption that “reproductive health care” provided by another person was lawful—and so not subject to investigation by a government agency—unless the HIPAA-covered entity has either:

- (1) Actual knowledge that the reproductive health care was not lawful under the circumstances in which it was provided[, or];
- (2) Factual information supplied by the person requesting the use or disclosure of protected health information that demonstrates a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided.

45 C.F.R. § 164.502(a)(5)(iii)(C).

55. Section § 164.502(a)(5)(iii)(B) states that if the “reproductive health care” is “protected” or “authorized” by federal law, the HIPAA-covered entity is restricted from disclosing that information.

56. Defendants take the position, for purposes of the 2024 Rule, that *Roe v. Wade* and its progeny represent the true interpretation of the U.S. Constitution, and that *Dobbs* is incorrect.

57. Defendants take the position that federal statutes, such as the Emergency Medical Treatment and Active Labor Act, require medical providers to violate state law regulating the practice of medicine, including state regulation of abortion.

58. Defendants take the position, for purposes of the 2024 Rule, that federal law creates a right for children of any age to receive medical interventions for the purposes of attempting “gender transitions,” and that many of these constitute “reproductive health care” under the 2024 Rule.

59. Therefore, according to the 2024 Rule, an abortion is “protected, required, or authorized by Federal law” according to § 164.502(a)(5)(iii)(B) if federal precedent required it to be legal before *Dobbs*, even if state laws make some of those abortions illegal today, and a “gender-transition” medical intervention is similarly protected and authorized by federal law.

60. Defendants also take the position, for purposes of the 2024 Rule, that some federal laws require healthcare entities to provide some abortions even if they object.

61. The 2024 Rule sharply limits state authority and the freedom of a HIPAA-covered entity to cooperate with that authority.

62. The 2024 Rule’s preamble emphasizes that determining whether “reproductive health care” is “lawful” rests with the HIPAA-covered entity receiving the request.

63. The 2024 Rule forces a HIPAA-covered entity to assume the risk of being wrong about whether an instance of “reproductive health care” was legal under state law, or was “protected” or “authorized” by federal law according to Defendants’ views.

64. The 2024 Rule changes the definition of “person” to a “natural person (meaning a human being who is born alive),” as well as various legal entities. 89 Fed. Reg. at 33,062 (codifying changes to 45 C.F.R. § 160.103).

65. This definition excludes an unborn child.

66. The 2024 Rule states that under this definition an unborn child is categorically excluded from the meaning of “an ‘individual,’ ‘child,’ or ‘victim’ (e.g., a victim of crime) under the HIPAA Rules.” 89 Fed. Reg. at 32,997.

67. The 2024 Rule states that under this definition “the permission to disclose PHI to avert a serious threat to health or safety at 45 C.F.R. § 164.512(j)(i) does not permit disclosures when the perceived threat does not involve the health or

safety of a natural person.” 89 Fed. Reg. at 32,997. Because the rule defines “natural person” to exclude unborn children, that means threats to the health or safety of an unborn child cannot be disclosed. *Id.*

68. The 2024 Rule adds a definition of “public health” that excludes abortion and medical interventions concerning gender identity. Such practices are excluded from “public health surveillance,” “public health investigation,” and “public health intervention.” 89 Fed. Reg. 33,062–63 (codifying changes to 45 C.F.R. § 160.103).

69. The 2024 Rule narrows a provision of the Privacy Rule that previously allowed disclosures of information in response to a state administrative request, limiting them to instances where response to that state administrative request is “*required by law.*” 89 Fed. Reg. 33,064 (codifying changes to 45 C.F.R. § 164.512) (emphasis added).

70. The 2024 Rule makes various other changes to the Privacy Rule in service of its goals, such as by inserting and amending cross-references that take the new and amended provisions into account.

71. This includes the 2024 Rule’s “attestation” requirement, which prevents HIPAA-covered entities from disclosing information to state officials unless the officials supply an attestation according to new criteria. *See* 45 C.F.R. § 164.512(f)(1)–(6).

72. HIPAA-covered entities evaluate an attestation on pain of criminal penalty. If the HIPAA-covered entity guesses wrong about the validity of an attestation, then under the 2024 Rule it is subject to criminal liability.

73. Even if the requesting official does provide an attestation satisfying the 2024 Rule’s criteria, the rule still prohibits the HIPAA-covered entity from disclosing information for any number of other new reasons related to “reproductive health care”.

IV. Harm to Dr. Purl and Her Clinic

74. Dr. Carmen Purl, M.D. is family medicine physician practicing in Dumas, Texas.

75. Dr. Purl is the sole owner of Carmen Purl, M.D., PLLC, which does business as Dr. Purl's Fast Care Walk In Clinic ("clinic"). Dr. Purl directs and manages all of the clinic's operations consistent with her ethical practices and beliefs.

76. Dr. Purl and her clinic are both HIPAA-covered entities.

77. Dr. Purl believes elective abortion is categorically harmful to the mother as well as the unborn child.

78. In Dr. Purl's view, both the mother and the unborn child are persons and, in the case of a pregnant patient, both are her patients. Dr. Purl believes mother and child are both entitled to care according to sound medical judgment and conscience, and both deserve the protection of state and federal law.

79. Dr. Purl also believes medical interventions attempting "gender transition" are categorically harmful to the patient, and can alter a person's healthy body, cause harmful side effects, and worsen or prolong the mental health symptoms associated with gender dysphoria.

80. Dr. Purl regularly encounters patients who have care needs or medical histories relating to their reproductive systems, including patients who have had or are considering abortions or "gender transition" interventions.

81. Dr. Purl has encountered patients whose circumstances, including health information relating to their reproductive systems, suggest they may be victims of abuse.

82. Under Texas law, Dr. Purl and her clinic have a duty to report suspected abuse or neglect of a child to state officials. Tex. Fam. Code § 261.101(a). As a physician, she must report suspected child abuse or neglect within 48 hours,

and she cannot “delegate or rely on another person to make the [necessary] report.” *Id.* § 261.101(b). Under certain circumstances, Dr. Purl also must report based on a reasonable belief that an adult suffered abuse or neglect as a child. *Id.* § 261.101(b-1).

83. Under Texas law, Dr. Purl and her clinic have a duty to report suspected abuse, neglect, or exploitation of a vulnerable adult, such as an elderly person or a person with a disability. Tex. Hum. Res. Code § 48.051.

84. Dr. Purl supervises nurse practitioners in her clinic, and they are similarly required to comply with state abuse-reporting laws.

85. Texas physicians have legal and ethical duties to maintain patient confidentiality and their communications with patients are privileged, but that is not an exception to the duty to report suspected abuse or neglect. Tex. Hum. Res. Code § 48.051(c); Tex. Fam. Code § 261.101(c).

86. In the course of her medical practice, Dr. Purl and her staff learn information about patients, including information about their reproductive medical histories and health care, that requires a report of suspected abuse or neglect to state officials.

87. The 2024 Rule’s new provisions concerning “person,” “public health,” and “reproductive health care” interfere with Dr. Purl’s ability and legal obligation to disclose information about unborn children when they are victims of crime or abuse, to protect unborn children from abuse, neglect, or other victimization, and to protect an unborn child’s health and safety.

88. For example, the 2024 Rule arguably would prevent Dr. Purl from reporting information about a patient being pressured to undergo an abortion, or about patients having received abortions in other states, or about minors under the age of 17 having a sexually transmitted disease, or about minors undergoing or being scheduled for “gender transition” interventions.

89. The 2024 Rule imposes substantive obligations and prohibitions on Dr. Purl and her clinic.

90. The 2024 Rule restricts the conditions under which Dr. Purl and her clinic and staff are permitted to disclose information related to “reproductive health care” concerning abuse reporting and administrative requests.

91. The 2024 Rule restricts the conditions under which Dr. Purl and her clinic and staff are permitted to disclose information about unborn children who may be victims of abuse, neglect, or a crime.

92. The 2024 Rule restricts the conditions under which Dr. Purl and her clinic and staff are permitted to disclose information about unborn children when it comes to public health reporting.

93. Complying with state law in violation of the 2024 Rule would subject Dr. Purl and her clinic to significant civil penalties and even criminal consequences including up to 10 years in prison and \$250,000 in fines. 42 U.S.C. § 1320d-6(b).

94. Under the 2024 Rule’s new conditions and presumption of lawfulness, doctors like Dr. Purl and her clinic bear the risk that complying with lawful process, like a subpoena, will be deemed a violation of HIPAA.

95. The 2024 Rule puts the burden on Dr. Purl and her clinic to make legal judgments about whether any given instance of “reproductive health care” was performed lawfully and whether law enforcement has provided an “attestation” that complies with the 2024 Rule.

96. The 2024 Rule leaves Dr. Purl and her clinic to speculate, at their own legal risk, whether an abortion or gender-identity medical intervention are protected or authorized by federal law in the view of Defendants and their interpretations of the U.S. Constitution that disagree with the U.S. Supreme Court, and where lower courts may disagree with one another.

97. Dr. Purl and her clinic wish to comply with all required and permissive abuse reporting under state law, and to comply with state administrative requests authorized by state law, whether compliance with the request is required or permissive.

98. Dr. Purl fears that her clinic, its staff, or herself will be in violation of the 2024 Rule if they report such information consistent with state law.

99. The 2024 Rule imposes financial compliance costs on Dr. Purl and her clinic.

100. These include, for example, costs identified in the 2024 Rule, such as updating notices of patient privacy, developing new or modified policies and procedures, and revising training programs for staff. *See* 89 Fed. Reg. at 33,049.

101. The 2024 Rule specifies that these costs will be incurred by over 500,000 “Office[s] of Drs. & Other Professionals,” which would include Dr. Purl’s clinic. *Id.* at 33,052 tbl.4.

102. Among other compliance costs, the 2024 Rule estimates that covered entities will incur at least \$132.23 to revise notices of patient privacy and \$24.46 to post them online, \$393.70 to develop new or modified policies and procedures, and \$100.77 for workforce training. *Id.* at 33,056.

103. The 2024 Rule requires Dr. Purl and her clinic to generally comply by December 23, 2024, and to comply with the requirements of 45 C.F.R. § 164.520 by February 16, 2026.

104. As the sole owner of her clinic, Dr. Purl is responsible for ensuring such compliance and would need to spend time engaging in such compliance.

105. To comply with the 2024 Rule’s new requirements, Dr. Purl needs to spend time formulating and adopting notices, policies, and practices, and ensuring staff are trained to comply.

106. Based on the value of Dr. Purl's time, clinic staff's time, and the cost of legal services, Dr. Purl and her clinic will incur costs at least in the amount estimated by the 2024 Rule, and possibly more.

V. Legal Allegations

107. Defendants HHS and OCR are each agencies subject to the APA.

108. The 2024 Rule is final "agency action" pursuant to 5 U.S.C. § 551(13) for purposes of review under the APA, 5 U.S.C. § 702.

109. Dr. Purl and her clinic are directly regulated by the 2024 Rule and are objects of the regulation.

110. Dr. Purl and her clinic are suffering legal wrong because of the 2024 Rule and are adversely affected and aggrieved by it.

111. Dr. Purl and her clinic face imminent and irreparable harm if the Court does not issue injunctive relief.

112. Dr. Purl and her clinic have no cause of action to obtain reimbursement from Defendants for the compliance costs they must undergo because of the 2024 Rule.

113. Dr. Purl and her clinic have no adequate remedy at law.

CLAIMS FOR RELIEF

COUNT I

Violation of APA, 5 U.S.C. § 706(2)(C):

Agency Action in Excess of Statutory Jurisdiction or Authority

114. The allegations set forth in paragraphs 1–110 are realleged as if fully set forth herein.

115. Courts must “hold unlawful and set aside agency action” that is “not in accordance with law” or “in excess of statutory ... authority[] or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(A), (C).

116. The 2024 Rule is contrary to and in excess of authority granted in HIPAA, and is not authorized by any other statute.

117. Nothing in HIPAA authorizes Defendants to limit the information that Plaintiffs may provide to a government agency concerning child abuse or investigation of public health.

118. Nothing in HIPAA authorizes Defendants to create special rules targeting abortion, “gender transition,” or “reproductive health care” as distinct from other kinds of health care.

119. Nothing in HIPAA authorizes Defendants to promulgate definitions of “person” or “public health” that target state policies on these issues, or that exclude unborn children from those definitions.

120. Nothing in HIPAA or 1 U.S.C. § 8, which says that “person” shall “include” an “infant member of the species homo sapiens who is born alive,” authorizes HHS to define “person” to exclude infants prior to birth.

121. HIPAA says: “Nothing in this part [unauthorized disclosures] 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.”
42 U.S.C. § 1320d-7(b).

122. In HIPAA, Congress preserved both government law enforcement and public health protection authority and the ability of HIPAA-covered entities to comply with state officials and administrative requests.

123. Defendants may exercise only the authority conferred upon them by statute and may not legislate through regulation in order to implement policy preferences, the perceived intent of Congress, or the purported purpose behind HIPAA.

124. Defendants do not have statutory authority to promulgate or enforce the 2024 Rule.

125. The 2024 Rule, and Defendants’ promulgation and enforcement thereof, are therefore in violation of the APA, 5 U.S.C. § 706(2)(A), (C).

126. Each part of the 2024 Rule is issued in pursuit of Defendants’ lack of authority and is therefore invalid and not severable from its other parts.

127. For the same reasons, the 2024 Rule is ultra vires action by Defendants, and the U.S. Constitution and the equitable powers of the Court authorize the Court to enjoin the rule and its enforcement.

COUNT II

Violation of APA, 5 U.S.C. § 706(2)(A): Arbitrary, Capricious, Abuse of Discretion, Not in Accordance with Law

128. The allegations set forth in paragraphs 1–110 are realleged as if fully set forth herein.

129. The Court shall “hold unlawful and set aside agency action ... found to be ... arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A).

130. The APA’s arbitrary-and-capricious standard requires that agency action be “reasonable and reasonably explained.” *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

131. Defendants did not articulate a satisfactory explanation for their actions.

132. Defendants failed to reasonably explain the prohibitions on disclosure in the 2024 Rule in light of the statute’s reservation of authority to states. 45 C.F.R. § 164.502(a)(5)(iii).

133. Defendants failed to reasonably explain the presumption under which HIPAA-covered entities must conclude that an instance of “reproductive health care” is legal. 45 C.F.R. § 164.522(a)(5)(iii)(C).

134. The 2024 Rule adopts arbitrary tests and presumptions without a satisfactory or reasonable explanation for doing so.

135. Defendants failed to reasonably explain what abortions are federally protected, required, or authorized under the 2024 Rule, and how HIPAA-covered entities are to apply that provision at all, much less at their own legal risk. 45 C.F.R. § 164.502(a)(5)(iii)(B)

136. Defendants failed to adequately explain their justification for defining “person,” “public health,” and “reproductive health care.” 45 C.F.R. § 160.103.

137. Defendants failed to reasonably explain how HIPAA-covered entities are to comply with the 2024 Rule’s new attestation requirements. 45 C.F.R. § 164.509.

138. Defendants failed to consider reliance interests from covered entities operating under the HIPAA privacy rule and state laws.

139. The 2024 Rule is arbitrary and capricious and therefore violates the APA, 5 U.S.C. § 706(2)(A).

PRAYER FOR RELIEF

Plaintiffs respectfully request that this Court:

- A. Declare that the 2024 Rule violates the Administrative Procedure Act because it exceeds the agency's statutory authority;
- B. Declare that the 2024 Rule violates the Administrative Procedure Act because it is arbitrary and capricious;
- C. Issue a stay and preliminary injunctive relief preserving Plaintiffs' status and rights from the 2024 Rule while this case is pending;
- D. Hold the 2024 Rule unlawful and set it aside and permanently enjoin Defendants from enforcing the 2024 Rule;
- E. Grant Plaintiffs an award of attorneys' fees and other litigation costs reasonably incurred in this action; and
- F. Grant such other relief as justice requires.

Respectfully submitted this 21st day of October, 2024.

/s/ Natalie D. Thompson

Natalie D. Thompson

TX Bar No. 24088529

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ALLIANCE DEFENDING FREEDOM

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