

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

STATE OF TEXAS,
Plaintiff,

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;
MELANIE FONTES RAINER, in her
official capacity as Director of the
Department of Health and Human Services
Office for Civil Rights,
Defendants.

CIVIL ACTION No. _____

TEXAS'S ORIGINAL COMPLAINT

1. Texas brings this action seeking declaratory and injunctive relief against enforcement of two final rules issued by the United States Department of Health and Human Services.
2. The first is entitled “Standards for Privacy of Individually Identifiable health Information,” 65 Fed. Reg. 82,462 (December 28, 2000) (the “2000 Privacy Rule”) and became effective in 2001. This lawsuit challenges the portion of the 2000 Privacy Rule that purports to limit disclosures to State investigators (45 C.F.R. § 164.512(f)(1)(ii)(C)).
3. The second is entitled “HIPAA Privacy Rule to Support Reproductive Health Care Privacy,” 89 Fed. Reg. 32,976 (April 26, 2024) (the “2024 Privacy Rule”) and became effective on June 25, 2024.
4. Persons subject to the 2024 Privacy Rule must comply with its requirements by December 23, 2024.

5. As is relevant here, the final rules purport to limit the circumstances when a HIPAA covered entity can share information with state officials and law enforcement. HIPAA covered entities that share information with State investigators in contravention of these rules incur **criminal** liability.

6. But the HIPAA statute explicitly preserves State investigative authority, and thus, the rules are contrary to the statute.

7. Moreover, the HIPAA statute gives Defendants no authority to promulgate rules limiting how regulated entities may share information with State governments.

8. These rules significantly harm the State of Texas's investigative abilities because covered entities frequently cite the 2000 Privacy Rule as a reason they cannot comply with a valid investigative subpoena for documents, and have already begun invoking the 2024 Privacy Rule for similar purposes.

9. The rules lack statutory authority and are arbitrary and capricious. As such, the Court should vacate and set aside the rules and enjoin the enforcement of them.

I. PARTIES

10. Plaintiff the State of Texas is a sovereign state of the United States.

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

12. Defendant Xavier Becerra is the Secretary of HHS. He is sued in his official capacity.

13. Defendant Melanie Fontes Rainer is the Director of HHS's Office for Civil Rights. She is sued in her official capacity.

II. JURISDICTION AND VENUE

14. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 702 and 28 U.S.C. § 1331. This Court has authority to grant the remedy Texas seeks pursuant to 28 U.S.C. §§ 2201 and 2202 and 5 U.S.C. § 706.

15. Venue is proper in this district pursuant to 5 U.S.C. § 703 and 28 U.S.C. § 1391(e).

III. BACKGROUND

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

16. 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).

17. HIPAA criminalizes a medical provider’s act of sharing patient health information if done “without authorization.” 42 U.S.C. § 1320d-6.

18. HIPAA does not on its face affect a state law enforcement agency or a state official’s ability to obtain patient health information.

19. The HIPAA statute, in relevant part, contains fairly limited text. The 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 (emphasis added).

20. The HIPAA statute provides that, “[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. 2014); *see also Wilson v. UnitedHealthCare Ins.*, 27 F.4th 228, 245 (4th Cir. 2022) (same).

21. But the statute expressly preserves State investigative authority. Indeed, 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).

22. Congress specifically preserved State authority in the statute.

23. Moreover, nothing in the HIPAA statute authorizes defendants to construe HIPAA’s bar on disclosure “without authorization” to sweep in disclosures to a State government that are provided pursuant to compulsory process, such as a subpoena.

B. The 2000 Privacy Rule

24. In 2000, HHS adopted Standards for Privacy of Individually Identifiable Health Information (known as the “Privacy Rule” and referred to herein as the “2000 Privacy Rule”). 65 Fed. Reg. 82,462. The 2000 Privacy Rule “address[es] the use and disclosure of individuals’ health information”—called “protected health information” or PHI.¹

¹ *Summary of the HIPAA Privacy Rule*, HHS Office for Civil Rights (May 2023) at 1, <https://www.hhs.gov/sites/default/files/privacysummary.pdf>

25. The 2000 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.

26. The 2000 Privacy Rule’s self-professed “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.” Summary of the HIPAA Privacy Rule at 1.

27. The 2000 Privacy Rule sets standards for using and disclosing PHI in certain circumstances without an individual’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).

28. But the 2000 Privacy Rule purports to limit the circumstances when a HIPAA covered entity can share information with State law enforcement and State officials.

29. As relevant here, a medical provider can share information in response to a State’s administrative subpoena only if a three-part test is met.

30. 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) (emphasis added).

31. The HIPAA statute, by contrast, does not include any reference to a three-part test.

32. Nor does it allow HHS to create such a test.

33. In the rule's preamble, HHS admits it has "limited jurisdiction conferred by HIPAA." 65 Fed. Reg. 82,471. But the 2000 Privacy Rule's preamble tellingly cites no statutory authority supporting this provision of the rule.

34. Indeed, in the Final Rule's response to a comment, HHS admitted that the 2000 Privacy Rule is purely a promulgation of what HHS deems to be good policy, *not* what Congress enacted. Specifically, HHS said: "We designed the...three-part test to require proof that the government's interest in the health information was sufficiently important and sufficiently focused to the outcome of the individual's privacy interest. If the test were weakened or eliminated, the individual's privacy interest would be insufficiently protected." 65 Fed. Reg. 82,683.

35. It continues, "[a]t the same time, if the test were significantly more difficult to meet, law enforcement's ability to protect the public interest *could be unduly compromised.*" *Id.* (emphasis added).

C. The 2024 Privacy Rule

36. On April 26, 2024, HHS published the 2024 Privacy Rule.

37. HHS nakedly admitted that the 2024 Privacy 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. 32,987.

38. HHS states that “[t]his change has also led to questions about both the current and future lawfulness of other types of reproductive health care, and therefore, the ability of individuals to access such health care. Thus, this shift may interfere with the longstanding expectations of individuals, established by HIPAA and the Privacy Rule, with respect to the privacy of their PHI.”

Id.

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

40. HHS defines “reproductive health care” very broadly, including “health care...that affects the health of an individual in all matters relating to the reproductive system and to its functions and processing.” 45 C.F.R. § 160.103.

41. In the 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. 33,005.

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

43. HHS states explicitly that the 2024 Privacy Rule should not be construed to “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. 33,011.

44. In other words, the rule allows for disclosure in a request for PHI to *defend* against a claim or prosecution involving reproductive health care, but prevents disclosure in a request for PHI to *bring* a claim or enforce a law.

45. The term “Reproductive Health Care” is clearly meant to encompass abortion, hormone and drug therapy for gender dysphoria, surgical procedures related to gender dysphoria, and gender experimentation.

46. The 2024 Privacy 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).

47. In sum, the 2024 Privacy Rule restricts state officials and law enforcement from obtaining evidence of a crime or other potential violation of state law.

48. 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).

49. By these terms, the covered entity itself determines if the “reproductive health care” it furnished was lawful—and not the state officials tasked with enforcing the laws.

50. HHS goes even further and adds that if the reproductive health care is “*protected*” or “*authorized*” by Federal law, the PHI is prohibited from being disclosed.

51. Moreover, the 2024 Privacy Rule then creates a *presumption* that reproductive health care provided by another person is presumed lawful under (a)(5)(iii)(B)(1) or (2)—and so not subject to investigation by a State—unless the covered entity or business associate has either:

- (1) Actual knowledge that the reproductive health care was not lawful under the circumstances in which it was provided.
- (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)

52. So, despite Congress going out of its way to preserve State investigative authority in the HIPAA statute, HHS has sharply limited State investigative authority.

53. Further, if a covered entity does not want to disclose PHI in response to Texas’s request, they can simply “reasonably determine” that the reproductive health care was lawful and refuse to disclose the information.

54. The rule’s preamble emphasizes that determining whether reproductive health care is “lawful” rests with the covered entity receiving the request (rather than the state officials charged with enforcing state law) because “the interests of law enforcement...are outweighed by privacy interests[.]” 89 Fed. Reg. 33,014.

D. The 2024 Privacy Rule’s “Attestation” Requirement.

55. The 2024 Privacy Rule permits certain disclosures for law enforcement purposes only if the conditions in 45 C.F.R. § 164.512(f)(1) to (6) are met. Those conditions are: (1) disclosure is required by law, such as a court order, (2) disclosure in response to a law enforcement official’s request for the purpose of identifying a suspect, fugitive, material witness, or missing person, (3) disclosure in response to a law enforcement official’s request about an individual that is the victim of a crime, (4) disclosure to a law enforcement official about an individual who has died if the covered entity has suspicion that the death may have resulted from criminal conduct, (5) disclosure to a law enforcement official if the covered entity believes in good faith that criminal conduct occurred on the premises of the covered entity, and (6) disclosure to a law enforcement official if the covered entity finds it is necessary to alert law enforcement to a potential crime.

56. Throughout 45 C.F.R. § 164.512, the 2024 Privacy Rule repeatedly leaves discretion to the covered entity to decide if PHI should be disclosed to law enforcement.

57. The 2024 Privacy Rule adds § 164.509 entitled “Uses and disclosures for which an attestation is required.”

58. A covered entity or business association may not use or disclose PHI “potentially related to reproductive health care” for *any* purpose, including to comply with a State law enforcement investigation, without obtaining an attestation that is valid. 45 C.F.R. § 164.509(a).

59. A valid attestation: (1) is a document that contains the required elements (discussed *infra*) and (2) verifies that the use or disclosure is not otherwise prohibited by 164.502(a)(5)(iii). 45 C.F.R. § 164.509(b).

60. An attestation is defective if the document has any of the following defects: (1) lacks an element or statement required by paragraph (c) of this section, (2) contains an element or statement not required by paragraph (c) of this section, (3) is combined with any other document except where the other document is needed to satisfy the requirements to be valid, (4) the covered entity or business association has actual knowledge that the attestation is false, or (5) a reasonable covered entity or business associate in the same position would not believe that the attestation is true. 45 C.F.R. § 164.509(b)(2).

61. The attestation must be written in plain language and must include the following elements: (1) a description of the information requested that identifies the information in a specific fashion, including the name of any individual whose PHI is sought or a description of the class of individuals whose PHI is sought, (2) the name or other specific identification of the person, or class of persons, who are requested to make the disclosure, (3) the name or other specific identification of the person, or class of persons, to whom the covered entity is to make the requested disclosures, (4) a clear statement that the use or disclosure is not a purpose prohibited under § 164.502(a)(5)(iii), (5) a statement that a person may be subject to criminal penalties if that person knowingly and in violation of HIPAA obtains individually identifiable health information relating to an individual or discloses individually identifiable health information to another person, and (6) signature of the person requesting the PHI. 45 C.F.R. § 164.509(c).

62. In other words, covered entities cannot give State officials and law enforcement PHI in response to a request, unless they provide the covered entity with an attestation, which must contain elements that HHS arbitrarily decided are necessary.

63. A covered entity evaluates an attestation on pain of criminal penalty. If they guess wrong about the validity of an attestation, then it is HHS's view that the covered entity is subject to criminal liability.

64. And even if the State official or law enforcement official does provide an attestation, the covered entity still may not provide a response to the request for any number of reasons, discussed *supra*.

IV. LEGAL ANALYSIS

A. The Privacy Rule and the 2024 Privacy Rule violate the APA because they are contrary to statute and exceed the authority granted by Congress.

65. The Final Rules exceed HHS's statutory authority and therefore are invalid.

66. Defendant HHS is an agency subject to the Administrative Procedure Act ("APA").

67. Under the APA, 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).

68. "[A]n agency literally has no power to act ... unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986).

69. "[O]ur system does not permit agencies to act unlawfully even in pursuit of desirable ends." *Ala. Ass'n of Realtors v. Dep't of Health & Human Servs.*, 594 U.S. 758, 766 (2021).

70. "As a general rule of statutory construction, where terms of the statute are unambiguous, judicial inquiry is complete." *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 642 (1990).

71. As an agency, HHS may not impose requirements contrary to and in excess of HIPAA.

72. No text in HIPAA authorizes HHS to limit the documents that medical providers may produce to a State law enforcement agency.

73. Moreover HIPAA is clear when it comes to State authority. It 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).

74. Thus, Congress went out of its way to preserve State authority in the statute.

75. In promulgating the 2000 Privacy Rule, the preamble does not contain a statutory authority argument.

76. And in promulgating the 2024 Privacy Rule, HHS points out that HIPAA directed it to promulgate rules, but does not point to any specific authority allowing it to promulgate this rule because it cannot.

77. Because HHS has not and cannot point to any authority that allows it to promulgate the 2000 Privacy Rule or the 2024 Privacy Rule, the rules violate the APA.

B. The 2000 Privacy Rule and the 2024 Privacy Rule violate the APA because they are arbitrary and capricious.

78. Under the APA, a court must “hold unlawful and set aside agency action” that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A).

79. 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)).

80. HHS has failed to reasonably explain the three-part test in the 2000 Privacy Rule. 45 C.F.R. § 164.512(f)(1)(ii)(C).

81. HHS has failed to reasonably explain the prohibitions on disclosure in the 2024 Privacy Rule. 45 C.F.R. § 164.502(a)(5)(iii).

82. HHS has failed to reasonably explain the presumption that any reproductive health care is lawful. 45 C.F.R. § 164.522(a)(5)(iii)(C).

83. HHS has failed to reasonably explain the attestation requirements. 45 C.F.R. § 164.509.

84. Because HHS has failed to reasonably explain the 2000 Privacy Rule and the 2024 Privacy Rule, the rules are arbitrary and capricious.

V. HARM TO TEXAS

85. The 2000 Privacy Rule harms Texas's investigative abilities because covered entities in receipt of an administrative subpoena will frequently cite the rule as the reason they cannot comply with the subpoena.

86. Texas is entitled to responses to its administrative subpoenas and is therefore harmed by the 2000 Privacy Rule.

87. The 2024 Privacy Rule has already harmed Texas's investigative abilities, as well.

88. In at least one instance, a covered entity has cited the 2024 Privacy Rule as a reason it cannot comply with Texas's subpoena.

89. Texas is entitled to a response to its administrative subpoena and is therefore harmed by the 2024 Privacy Rule.

VI. CLAIMS FOR RELIEF

COUNT 1

Violation of APA, 5 U.S.C. § 706(2)(C): Agency Action In Excess of Statutory Jurisdiction or Authority

90. All foregoing allegations are repeated and realleged as if fully set forth herein.

91. The final rules challenged herein constitute “agency action” pursuant to 5 U.S.C. § 551(13) for purposes of review under the APA, 5 U.S.C. § 702.

92. The final rules exceed HHS’s statutory authority and therefore violate the APA, 5 U.S.C. § 706(2)(C).

93. Under the APA, a court shall “hold unlawful and set aside agency action, findings, and conclusions found to be ... in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(C).

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

95. The final rules are in excess of the authority Congress granted to HHS and are therefore in violation of the APA, 5 U.S.C. § 706(2)(C).

COUNT 2

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

96. All foregoing allegations are repeated and realleged as if fully set forth herein.

97. The final rules challenged herein constitute “agency action” pursuant to 5 U.S.C. § 551(13) for purposes of review under the APA, 5 U.S.C. § 702.

98. The final rules are arbitrary and capricious and therefore violate the APA, 5 U.S.C. § 706(2)(A).

99. Under the APA, a court shall “hold unlawful and set aside agency action, findings, and conclusions found to be ... arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A).

100. The final rules are neither reasonable nor reasonably explained.

101. HHS did not articulate a satisfactory explanation for its actions.

102. The final rules adopt arbitrary tests and presumptions without a satisfactory explanation for doing so.

103. The final rules conflict with the plain text of the statute it purports to interpret and implement, making them not in accordance with law.

VII. DEMAND FOR RELIEF

Texas respectfully requests that the Court:

- a. Declare that the 2000 Privacy Rule and the 2024 Privacy Rule violate the Administrative Procedure Act because they exceed statutory authority;
- b. Declare that the 2000 Privacy Rule and the 2024 Privacy Rule violate the Administrative Procedure Act because they are arbitrary and capricious;
- c. Vacate and set aside the 2000 Privacy Rule and the 2024 Privacy Rule and permanently enjoin Defendants from enforcing them;
- d. Grant Texas an award of attorneys' fees and other litigation costs reasonably incurred in this action; and
- e. Grant Texas such other relief as the Court deems just and proper and as justice so requires.

Dated: September 4, 2024.

Respectfully submitted.

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