IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI *Plaintiff*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, *Defendants.*	)	Civil Action No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. Investigating fraud, abuse, and public-health violations rests at the core of States' sovereign police power to promote their citizens' welfare and protect the public fisc. Yet under the guise of implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the U.S. Department of Health and Human Services (HHS) has imposed a novel regime that limits access to a broadly defined category of "reproductive health care" data. *See HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (April 26, 2024) (the "Final Rule") (Exhibit A). HHS's Final Rule will hamper States' ability to gather information critical to police serious misconduct like Medicaid billing fraud, child and elder abuse, and insurance-related malfeasance. That result flouts HIPAA, which specifically preserves States' longstanding authority to investigate healthcare-related issues. Because the Final Rule contravenes HIPAA's preservation of state authority, lacks a reasoned explanation, and is

inflicting here-and-now harm on the Missouri's ability to root out fraud and abuse, Missouri bring this Complaint asking this Court to enjoin, declare unlawful, and set aside the Final Rule.

PARTIES

2. Plaintiff the State of Missouri is a sovereign State of the United States of America. Missouri sues to vindicate its sovereign, quasi-sovereign, and pecuniary interests.

3. Andrew Bailey is the 44th Attorney General of the State of Missouri. Attorney General Bailey is authorized by statute to bring actions on behalf of Missouri that are "necessary to protect the rights and interests of the state, and enforce any and all rights, interests or claims against any and all persons, firms or corporations in whatever court or jurisdiction such action may be necessary." Mo. Rev. Stat. § 27.060.

4. Defendants are an official of the United States government and United States governmental agency responsible for implementing the Final Rule

5. Defendant the United States Department of Health and Human Services is the executive agency of the federal government that promulgated and now enforces the challenged Final Rule.

6. Defendant Xavier Becerra is United States Secretary of Health and Human Services. He is sued only in his official capacity.

7. This Complaint refers collectively to Defendants as HHS.

JURISDICTION & VENUE

8. This Court has jurisdiction under 28 U.S.C. § 1331 (action arising under the laws of the United States), 28 U.S.C. 1346 (United States as a defendant), and 5 U.S.C. §§ 701–706 (Administrative Procedure Act).

9. This Court may grant declaratory relief, injunctive relief, and other relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202; the Administrative Procedure Act (APA), 5 U.S.C. §§701-706; Federal Rule of Civil Procedure 57; and its inherent equitable powers.

10. Venue is proper under 28 U.S.C. § 1391(e)(1) because the State of Missouri resides in this District for purposes of the venue laws. *See Missouri v. Biden*, No. 4:24-CV-00520-JAR, 2024 WL 3104514, at *20 (E.D. Mo. June 24, 2024) ("[T]he Court finds that the State of Missouri resides everywhere in Missouri and thus resides in this district."). In addition, Defendants' challenged actions adversely affect a substantial volume of investigatory activities, state agencies, and state employees present in this District.

BACKGROUND

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

A. HIPAA protects patient data from unauthorized disclosures.

11. Congress enacted HIPAA in 1996 to "improve portability and continuity" and "simplify the administration of health insurance." Pub. L. No. 104-191, 110 Stat. 1936, 1936 (1996).

12. Under HIPAA:

> 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.

13. Thus, HIPAA prohibits health care providers from disclosing patient information "without authorization" from the patient, unless another provision applies permitting disclosure. *See United States v. Wilson*, 98 F.4th 1204, 1217 (10th Cir. 2024).

14. Violating HIPAA carries serious criminal consequences, including hefty fines and prison time. 42 U.S.C § 1320d-6(b).

B. HIPAA expressly preserves States' traditional investigatory powers.

15. The U.S. Constitution preserves States' traditional police power. *See Bond v. United States*, 572 U.S. 844, 854 (2014).

16. Since the Founding, States' police power has included the authority to pass laws protecting the public health and welfare as well as the public fisc. *See McNaughton v. Johnson,* 242 U.S. 344, 348–49 (1917); *see also L.W. by & through Williams v. Skrmetti*, 73 F.4th 408, 417 (6th Cir. 2023) (collecting cites).

17. HIPPA abides this constitutional backdrop and the States' traditional role as regulators of the medical profession and law-enforcement authorities.

18. Notwithstanding its general prohibition on unauthorized disclosure of patient health information, the statute expressly preserves States' investigatory authority. It does so by providing that "[n]othing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." 42 U.S.C. § 1320d-7(b).

19. Thus, HIPAA's bar on disclosure of patient health information "without authorization" does not include disclosures to a state governmental entity for records sought pursuant to lawful investigative authority. Nor does it override records sought pursuant to compulsory process, such as a subpoena.

II. Regulatory Background.

A. HHS adopts the Privacy Rule in 2000.

20. In 2000, HHS adopted *Standards for Privacy of Individually Identifiable Health Information*, 65 Fed. Reg. 82,462 (Dec. 28, 2000) ("Privacy Rule"). 65 Fed. Reg. at 82,462. The Privacy Rule "address[es] the use and disclosure of individuals' health information"—called "protected health information" or PHI. HHS Office of Civil Rights, *Summary of the HIPAA Privacy Rule* 1 (May 2003) ("Privacy Rule Summary"), https://www.hhs.gov/sites/default/files/privacysummary.pdf.

21. 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.

22. The Privacy Rule is meant to ensure "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." Privacy Rule Summary 1.

23. The 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).

24. Under the Privacy Rule, a HIPAA-covered entity may share information in response to a State's administrative subpoena if three conditions are met.

25. 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).

26. Despite recognizing its "limited authority" under HIPAA, HHS cited no statutory authority for this three-part test when it promulgated the Privacy Rule. 65 Fed. Reg. at 82,471. HHS instead designed the test itself, employing its own assessment of how best to balance Congress's mandates to protect patients' health information and preserve States' investigatory prerogatives:

> 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. At 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*.

65 Fed. Reg. at 82,683 (emphasis added).

B. *Dobbs* prompts HHS to propose a rule reading special protections for "reproductive healthcare data" into HIPAA.

27. In June 2022, the U.S. Supreme Court "return[ed]" abortion regulation "to the people and their elected representatives" by holding that the federal constitution does not require States to permit abortions. *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 259 (2022).

28. The *Dobbs* decision triggered state laws across the country set to take effect if the Supreme Court were to overrule *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood v. Casey*, 505 U.S. 833 (1992).

29. After *Dobbs*, HHS proposed to modify the Privacy Rule to impose new barriers against disclosure of "reproductive health care" information. *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 88 Fed. Reg. 23,506, 23,521 (Apr. 17, 2023) ("Proposed Rule").

30. HHS recognized that the Privacy Rule had "not previously conditioned uses and disclosures for certain purposes on the specific type of health care about which the disclosure relates," *id.*, but believed it was necessary to privilege "reproductive health care" data over other health records because *Dobbs* allegedly "created new concerns about the privacy of PHI related to reproductive health care," *id.* at 23,519.

31. HHS thus proposed to prohibit a regulated entity from using or disclosing an individual's PHI for the purpose of conducting a criminal, civil, or administrative investigation into or proceeding against the individual, a health care provider, or other person in connection with seeking, obtaining, providing, or facilitating reproductive health care in three instances. *Id.* at 23,552. Specifically, it would bar disclosure where the relevant "investigation" or "proceeding" concerns "reproductive health care" that is: provided "outside of the state where the investigation

or proceeding is authorized and … is lawful in the state in which it is provided"; "protected, required, or authorized by Federal law, regardless of the state in which [it] is provided"; or "provided in the state in which the investigation or proceeding is authorized and ... is permitted by the law of that state." *Id.*

32. The bar on disclosure would not be limited to investigations or proceedings involving the person who sought "reproductive health care." Rather, it would apply to investigations or proceedings involving "*any person*" in connection with such "care," even if that person's involvement was unlawful. *Id.* at 23,532 (emphasis added).

33. HHS proposed to define "reproductive health care" broadly. The term covers "care, services, or supplies related to the reproductive health of the individual[,] … includ[ing] not only reproductive health care and services furnished by a health care provider and supplies furnished in accordance with a prescription, but also care, services, or supplies furnished by other persons and non-prescription supplies purchased in connection with an individual's reproductive health." *Id.* at 23,527.

34. Put differently, HHS meant for privileged "reproductive health care" data to include "all types of health care related to an individual's reproductive system." *Id.*

35. The Proposed Rule also redefined "person" to mean "a natural person (meaning a human being who is born alive), trust or estate, partnership, corporation, professional association ... , or other entity, public or private." *Id.*

36. And the Proposed Rule defined "public health" (as in "public health surveillance," "public health investigation," and "public health intervention") to mean "population-level activities to prevent disease and promote health of populations." *Id.*

37. HHS further proposed that the recipient of a request for PHI "potentially related to reproductive health care" must obtain a valid attestation from the requesting entity before making a disclosure. *Id.* at 23,553. To be valid, the attestation must "verif[y]" that the request is not barred under the new prohibitions on disclosing PHI related to "reproductive health care." *Id.* The attestation requirement would apply to any request for PHI potentially related to "reproductive health care" for health oversight, legal proceedings, law-enforcement purposes, or disclosures to coroners and medical examiners. *Id.* (citing 45 C.F.R. § 164.512(d), (e), (f), & (g)(1)).

C. HHS's proposal generates substantial opposition.

38. The Proposed Rule received more than 25,000 comments, including many comments in opposition from key stakeholders.

39. Missouri joined a coalition of nineteen States opposing the Proposed Rule. States' Comment Letter (Exhibit B).

40. The States explained that the Proposed Rule "trespasses on and interferes" with "core state authority" by precluding "States' ability to obtain evidence that could reveal violations of their laws." *Id.* at 8. Such interference with States' traditional powers to investigate violations of their laws, the States explained, meant that the rule "cannot be reconciled with our constitutional design." *See id.* at 8–10.

41. The States also explained why the Proposed Rule was a "political[ly]"-driven arbitrary and capricious "product of implausible reasoning" without sufficient consideration of the "costs and benefits." *See id.* at 11–14.

III. HHS Promulgates the Final Rule.

42. Undeterred, HHS promulgated the Final Rule on April 26, 2024.

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

44. HHS acknowledged that the Final 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* …." 89 Fed. Reg. at 32,987.

45. According to HHS, "[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.*

46. HHS thus expressly acknowledged that the Final Rule aims to limit States' ability to enforce certain laws regulating aspects of HHS's "reproductive health care" rubric. And the Final Rule maintained the broad definition of "reproductive health care," as 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.

47. The Final Rule's preamble 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.

48. But the Final Rule's terms appear to sweep in any records request relating to the provision of care in a range of areas.

49. The Final Rule places burdens on both the entity disclosing PHI and the entity requesting PHI. States often find themselves in both roles—discloser and requestor.

A. State investigation provisions.

50. HHS's Final Rule "acknowledges" that it "may affect certain state interests in obtaining PHI to investigate potentially unlawful reproductive health care." 89 Fed. Reg. 32,995.

51. Specifically, the Final 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).

52. If the covered entity concludes that one of these two conditions, exists, it cannot disclose the information if it "reasonably determine[s]" that the "reproductive health care" at issue is either (1) "lawful under the law of the state in which such health care is provided under the circumstances in which it is provided," or (2) "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." *Id.* § 164.502(a)(5)(iii)(B).

53. The Final Rule further provides that if the reproductive health care is "*protected*" *or* "*authorized*" by Federal law, the PHI is prohibited from being disclosed.

54. This provision requires HIPAA covered entities and those requesting PHI to make predictive legal judgments about what courts might one day hold, or to accept federal agencies' view of what the Constitution and federal law require.

55. By way of example, federal officials take the position, for purposes of the Final Rule, that *Roe v. Wade* and its progeny represent the true interpretation of the U.S. Constitution,

and that *Dobbs* is incorrect. Federal officials also 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. *See* Brief of the United States, *Moyle v. United States*, Nos. 23-726 & 23-727 (Mar. 21, 2024). And federal officials take the position, for purposes of the Final 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 Final Rule. *See* Brief of the United States, *United States v. Skrmetti*, No. 23-477 (Aug. 27, 2024).

56. On top of that, the Final Rule also creates a *presumption* that reproductive health care provided by another person is lawful under 45 C.F.R. § 164.502 (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[, 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).

57. The Final Rule's regime thus both imposes an unmanageable compliance burden on state officials and seeks to preempt state laws that conflict with HHS's favored policies.

58. The Final Rule's barriers against disclosure also impede state officials and law enforcement agencies' ability to obtain evidence of a crime, other potential violations of state law, or threats to public health related to "reproductive health care."

59. The point of investigative records requests is often to obtain or uncover the "factual information" needed to confirm suspicion of fraud and other abusive and unlawful practices. HHS recognized as much in promulgating the Privacy Rule. *See* 65 Fed. Reg. at 82493 (noting that "law enforcement officials"—not regulated entities—"are empowered to prosecute cases as well as to conduct investigations" and that this authority extends to "*potential*" or "*alleged* violation[s] of law" (emphasis added)).

60. By requiring state agencies to instead come forward with specific factual information before obtaining records, the Final Rule sharply limits State investigative authority. That defies HIPPA's explicit protection of States' interests in investigating "disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." 42 U.S.C. § 1320d-7(b).

61. If a covered entity does not want to disclose PHI in response to a State's request, they can simply "reasonably determine" that the reproductive health care was lawful, or authorized by federal law, and refuse to disclose the information.

62. This scheme repeatedly leaves discretion to the covered entity to decide if PHI should be disclosed to law enforcement. At its worst, those suspected of fraud maintain the ability to thwart investigations into their misconduct. At its best, state law enforcement agencies must navigate a series of novel, resource-intensive hurdles that can complicate, chill, or block important and time-sensitive investigations.

B. Attestation requirement.

63. The Final Rule also carries forward the proposed attestation requirement. *See* 45 C.F.R. §§ 164.509, 164.512(f)(1)-(6).

64. The Final 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, as applicable. 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 is 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.

65. But 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).

66. A valid attestation: (1) is a document that contains the required elements (discussed below) 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).

67. An attestation is defective if the document has any of the following: (1) "lacks an element or statement required by [the Final Rule]," (2) "contains an element or statement not required by [the Final Rule]," (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).

68. 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) "[t]he name or other specific identification of the person(s), or class of persons, who are requested to make the disclosure," (3) "[t]he 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 [45 C.F.R.] § 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) a "signature of the person requesting" the PHI. 45 C.F.R. § 164.509(c).

69. HHS has provided a model attestation. (Exhibit C).

70. These attestation requirements are entirely absent from HIPAA.

71. Nor does the Final Rule allow state law enforcement agencies to obtain information after submitting an attestation. Instead, it places the power to assess the lawfulness or validity of any PHI request entirely with the covered entity to which the request is made. So under the Final Rule, the covered entity itself determines, among other things, if (1) the attestation is adequate, (2) if any "reproductive health care" furnished was lawful or authorized by federal law, or (3) the request is made for the "mere act" of providing such care, rather than for other purposes like

investigating billing fraud. It is not enough that state officials tasked with enforcing the laws attest to those conditions.

72. 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. And the Final Rule does not provide a mechanism by which investigators can challenge the covered entities' denial.

73. To further thwart law enforcement investigations, the Final Rule threatens criminal penalties if it is not followed to the letter. Specifically, the Final Rule requires both the HIPAA-covered entities and the requestor to sign an attestation on pain of criminal penalty.

IV. The Final Rule Inflicts Significant Irreparable Harm On Missouri.

74. HHS's Final Rule inflicts a series of irreparable harms on the State's capacity as an investigator and its HIPAA-covered entities. These harms can only be remedied by a judicial order enjoining enforcement of the Final Rule.

A. Harm to States as investigators.

75. First, the Final Rule harms Missouri's sovereign interest in pursuing investigations that promote the health and welfare of those within its border as well as root out waste, fraud, and abuse occurring within the State.

76. In Missouri, the Attorney General is authorized to investigate health care fraud and abuse under Mo. Rev. Stat. § 191.910.1. The statute provides the Missouri Attorney General with authority "all powers provided by section 407.040 to 407.090 in connection with investigation of alleged or suspected" health care fraud and abuse. *Id.* Section 407.040 authorizes the Missouri Attorney General to serve a civil investigative demand "[w]hen it appears to the attorney general that a person has engaged" in a violation of the law or even "when he believes it to be in the public

interest that an investigation should be made to ascertain whether a person in fact" has violated the law or is still violating the law. *Id*. § 407.040.1. This is consistent with the Supreme Court principle that a State "can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not." *United States v. Whispering Oaks Residential Care Facility, LLC*, 673 F.3d 813, 818 (8th Cir. 2012).

77. Under Section 191.910, health care providers are *required* to produce materials to the Missouri Attorney General investigating health care fraud and abuse "including but not limited to *any record* relating to patient care." Mo. Stat. Rev. § 191.910.2 (emphasis added). The Missouri Attorney General has routinely used his authority under Section 191.910 to seek medical records for investigations of health care fraud and abuse, and covered-entities have responded to those requests as a matter of course.

78. State agencies also maintain power under state law to investigate abuse, neglect and financial exploitation of adults in nursing homes and other healthcare facilities, as well as some cases of Medicaid recipients who are abused, neglected or financially exploited in their own homes. And these investigations also often rely on medical records obtained from HIPAA-covered entities pursuant to civil investigatory demands.

79. For example, the Missouri Board of Registration for the Healing Arts—the State oversight body for physicians and medical professionals—is authorized to investigate medical licensees for, *inter alia*, "[o]btaining or attempting to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation," Mo. Rev. Stat § 334.100.2(4)(a), "[m]isrepresenting that any disease, ailment or infirmity can be cured by a method, procedure, treatment, medicine or device," *id.* § 334.100.2(4)(e), and "[a]ny conduct or practice which is or might be harmful or dangerous to the mental or physical health of a patient or the public; or

incompetency, gross negligence or repeated negligence in the performance of the functions or duties," *id.* § 334.100.2(5). During an investigation, "*any* record relating to *any* patient of the licensee or applicant shall be discoverable by the board." *Id.* § 334.100.7 (emphasis added). Failure to comply with a request for records is grounds for the revocation or suspension of a license. *Id.* at § 334.100.2(4)(n). As such, Missouri medical providers routinely comply with requests for medical records from the Board without issue.

80. HIPAA-covered entities have historically accommodated investigators' requests so long they comply with the Privacy Rule.

81. HHS's Final Rule impedes Missouri's investigations. State investigators now must complete an attestation for the demand-recipient every time they seek PHI potentially related to "reproductive health care" through a civil investigative demand. The processing of attestations with each demand produces administrative costs and requires investigators to spend time ensuring the attestation complies with the Final Rule. Moreover, under the Final Rule, state employees now must make attestations regarding issues that are unclear upon pain of criminal liability. The result is a chilling effect on the State's ability to pursue typical investigations

82. For example, the Missouri Department of Health and Senior Services (DHSS) and Missouri Department of Social Services (DSS) have begun to receive requests for attestations from health care providers in the State, regardless of the type of records sought. As such, this requirement has significantly affected these agencies' ability to conduct their day-to-day statutory responsibilities, and have been burdensome on their operations.

83. Moreover, the Missouri Attorney General has undertaken an investigation into fraud, deception, and unfair practices in the provision of gender transition interventions by various institutions around the State. Just recently, a covered-entity raised the Final Rule as a full bar to

producing materials in response to a civil investigative demand from the Attorney General absent patient consent. Respondent/Cross-Appellant's Brief, *Bailey v. Planned Parenthood of the St. Louis Region*, No. ED112842 (Mo. App. E.D. Dec. 10, 2024). This impedes the Missouri Attorney General's ability to investigate health care fraud, abuse, deception, and unfair practices.

84. The Final Rule's vagueness and overbreadth create further compliance costs and investigatory barriers. For example, if investigators would like to investigate potential billing fraud by a urologist, they must receive PHI to compare medical records for urology care with the claims data as billed and paid. Yet the Final Rule requires both the investigators and the demand-recipient to determine that the demand complies with the Final Rule, and ultimately makes investigators' receipt of information contingent on the demand-recipient's determination that the attestation satisfies with the Final Rule.

85. The decision by Missouri health care providers to shield *all* medical records absent attestation is emblematic of the vagueness issues that permeate the Final Rule. Because these organizations are not processing requests for information that might arguably fall within the Final Rule's definition of "reproductive healthcare data" or are delaying release of such information due to uncertainty around the Final Rule's requirements, the Rule is hindering state investigations, and will continue to do so.

86. Indeed, the Final Rule forces HIPAA-covered state agencies to assess attestations from fellow state agencies, creating potential for unnecessary and burdensome conflict.

B. Harm to States as HIPAA-covered entities.

87. States' hospitals and health agencies are HIPAA-covered entities that must comply with the Final Rule. *See* 45 C.F.R. § 160.102; *see id.* § 164.500.

88. And Missouri state hospitals and health agencies regularly receive requests for PHI from law enforcement investigating fraud, abuse, neglect, and other health-related violations.

89. HHS's Final Rule is currently necessitating a system-wide overhaul of state agencies' processing systems for HIPAA requests. The financial, logistical, and personnel burdens required to come into compliance with the Rule's currently effective disclosure requirements for "reproductive health care" data are substantial. Yet on account of HHS's sovereign immunity, the Plaintiff States could not later recover these costs even should they prevail in litigation. *See Wages & White Lion Invs., L.L.C. v. United States Food & Drug Admin.*, 16 F.4th 1130, 1142 (5th Cir. 2021); *see also* 5 U.S.C. § 702 (providing for an action seeking relief "other than money damages")

CLAIMS FOR RELIEF

CLAIM I
Violation of APA, 5 U.S.C. § 706(2)(A), (C)
Agency Action in Excess of Statutory Authority

90. Missouri repeats and incorporates by reference the allegations of the preceding paragraphs.

91. The APA requires courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . (A) . . . not in accordance with law; . . . [or] (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2).

92. The Final Rule is contrary to law and exceeds the Department's statutory authority.

93. HHS is a federal agency within the meaning of the APA.

94. The Final Rule is a final agency action within the meaning of 5 U.S.C. § 704, Missouri lacks another adequate remedy in court, and no rule requires that the State appeal to a superior agency authority prior to seeking judicial review.

95. Because HHS may only exercise the authority conferred upon it by statute and may not legislate through regulation, HHS may not impose requirements under HIPAA contrary to and in excess of the authority provided in the statute by Congress.

96. The Final Rule is in excess of the authority Congress granted to HHS and is therefore in violation of the APA, 5 U.S.C. § 706(2)(C).

97. *First*, the Final Rule is inconsistent with HIPAA. Congress explicitly preserved States' "authority, power, [and] 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).

98. Congress went out of its way to preserve the States' traditional authority in HIPAA, but the Final Rule thwarts the investigative and police power authority reserved to the States.

99. "[A]n agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Reg. Grp. v. EPA*, 573 U.S. 302, 328 (2014). Because the Final Rule is inconsistent with HIPAA, it is invalid under the APA and should be "set aside," 5 U.S.C. § 706(2), meaning vacated.

100. *Second*, even if the Final Rule does not expressly contravene HIPAA's preserving States' investigatory authority, it still is unlawful.

101. "[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).

102. Yet HIPAA nowhere authorizes HHS to limit the documents that medical providers may produce to a state law enforcement agency, as evidenced by HIPPA's inability to point to an express provision conferring statutory authority to adopt the 2024 Final Rule.

103. HIPAA's general grant of rulemaking power does not provide specific authority to promulgate the Final Rule's conditions limiting States' investigatory powers.

104. HIPAA authorizes HHS to adopt regulations establishing "standards with respect to the privacy of individually identifiable health information" for certain regulated entities. Pub. L. No. 104–191 § 264(c)(1), 110 Stat. at 2033.

105. The plain meaning of "health information" cannot fairly encompass information that a State believes is evidence of a violation of state law.

106. Federal agencies may not act without authorization, particularly when federal agency action intrudes on a "traditional prerogative" of the States. *See Kentucky v. Biden*, 23 F.4th 609-10 (6th Cir. 2022). Indeed, adopting HHS's interpretation of HIPPA under the Final Rule would raise significant constitutional doubts by interfering into an area in which States "historically have been sovereign." *United States v. Lopez*, 514 U.S. 549, 564 (1995).

107. Because the Final Rule lacks statutory authority, it violates the APA and should be vacated. 5 U.S.C. § 706(2); *see also Long Island Power Auth. v. FERC*, 27 F.4th 705, 717 (D.C. Cir. 2022) ("Vacatur is the normal remedy under the APA, which provides that a reviewing court 'shall … set aside' unlawful agency action." (citation omitted)).

CLAIM II
Violation of APA, 5 U.S.C. § 706(2)(A)
Arbitrary and Capricious Agency Action

108. Missouri repeats and incorporates by reference the allegations of the preceding paragraphs.

109. The APA requires courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . (A) arbitrary, capricious, [or] an abuse of discretion" 5 U.S.C. § 706(2)(A).

110. A federal agency acts in an "arbitrary and capricious" manner when it (1) "has relied on factors which Congress has not intended it to consider"; (2) "entirely fail[s] to consider an important aspect of the [regulatory] problem"; (3) "offer[s] an explanation for" its conduct "that runs counter to the evidence before" it; or (4) reaches a determination that "is so implausible … it could not be ascribed to a difference in view or … agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). In short, agency action must be "reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

111. The Final Rule is arbitrary and capricious in multiple respects.

112. *First*, HHS has failed to reasonably explain the prohibitions on disclosure in the Final Rule; the presumption that any reproductive health care is lawful; and the attestation requirements. 45 C.F.R. § 164.509. HHS instead links these Final Rule requirements to a policy preference found nowhere within HIPPA.

113. *Second*, HHS has failed to consider the exorbitant compliance challenges and costs associated with satisfying the Final Rule in a wide range of state investigatory matters. It is also plainly arbitrary for the Final Rule to allow those who are being investigated for suspected fraud or unlawful billing practices, among other violations, to maintain veto authority over state entities' requests for relevant information.

114. *Finally*, HHS failed to adequately "consider and respond to significant comments received during the period for public comment" on the Final Rule. *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). Commenters, including the States, raised a raft of practical concerns about the constitutional defects and compliance challenges attending the Final Rule's approach. Yet the Final Rule offers only a "handful of conclusory sentences" and "unexplained

inconsistencies" about the way in which the Final Rule will impede States' ability to investigate issues unrelated to the Final Rule's policy concerns. *Gresham v. Azar*, 950 F.3d 93, 103 (D.C. Cir. 2020), *vacated as moot*, 142 S. Ct. 1665 (2022) (mem.); *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015).

115. Because HHS has failed to reasonably explain the Final Rule, it is arbitrary and capricious.

PRAYER FOR RELIEF

Plaintiff States respectfully request this Court:

a) issue an order and judgment declaring that the Final Rule violates the APA because it is in excess of HHS's statutory authority and is arbitrary and capricious.

b) permanently enjoin implementation and enforcement of the Final Rule, including by enjoining Defendants, and any other agency or employee of the United States, from enforcing or implementing the Final Rule;

c) vacate and set aside the Final Rule;

d) award Plaintiff States reasonable fees, costs, expenses, and disbursements, including attorney's fees, associated with this litigation; and

e) grant any additional and further relief as the Court may deem just and appropriate.

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