IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
KNOXVILLE DIVISION

STATES OF TENNESSEE, ALABAMA, ARKANSAS, GEORGIA, IDAHO, INDIANA, IOWA, LOUISIANA, MONTANA, NEBRASKA, NORTH DAKOTA, OHIO, SOUTH CAROLINA, SOUTH DAKOTA, and WEST VIRGINIA, *Plaintiffs*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF CIVIL RIGHTS, *Defendants.*	)	Civil Action No. _____

COMPLAINT FOR INJUNCTIVE AND DECLARATORY 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 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).

2. The Final Rule will hamper States' ability to gather information critical to policing serious misconduct like Medicaid billing fraud, child and elder abuse, and insurance-related

malfeasance. As another court has indicated, that result flouts HIPAA, which specifically preserves States' longstanding authority to investigate healthcare-related issues. *Purl v. HHS*, No. 2:24-cv-228, 2024 WL 5202497, at *6-10 (N.D. Tex. Dec. 22, 2024). Because the Final Rule contravenes HIPAA, is arbitrary and capricious, and is inflicting here-and-now harm on States' ability to root out fraud and abuse through routine investigatory functions, Plaintiffs bring this Complaint asking this Court to enjoin, declare unlawful, and set aside the Final Rule.

PARTIES

3. Plaintiff the State of Tennessee is a sovereign State of the United States of America and directly subject to the Final Rule's requirements. Tennessee sues to vindicate its sovereign, quasi-sovereign, and pecuniary interests. Jonathan Skrmetti, the Attorney General and Reporter of Tennessee, is authorized by statute to try and direct "all civil litigated matters … in which the state … may be interested." Tenn. Code Ann. § 8-6-109(b)(1).

4. Plaintiff the State of Alabama is a sovereign State of the United States of America and directly subject to the Final Rule's requirements. Alabama sues to vindicate its sovereign, quasi-sovereign, and pecuniary interests. Steve Marshall, the Attorney General of Alabama, is authorized by statute to "institute and prosecute, in the name of the state, all civil actions and other proceedings necessary to protect the rights and interests of the state." Ala. Code § 36-15-12.

5. Plaintiff the State of Arkansas is a sovereign State of the United States of America and directly subject to the Final Rule's requirements. Arkansas sues to vindicate its sovereign, quasi-sovereign, and pecuniary interests. Tim Griffin is the Attorney General of Arkansas. General Griffin is authorized to "maintain and defend the interests of the state in matters before the United States Supreme Court and all other federal courts." Ark. Code Ann. § 25-16-703.

6. Plaintiff the State of Georgia is a sovereign state of the United States of America and directly subject to the Final Rule's requirements. Georgia sues to vindicate its sovereign,

quasi-sovereign, and pecuniary interests. Georgia brings this suit through its Attorney General, Christopher Carr. He is the chief legal officer of the State of Georgia and has the authority to represent the State in federal court.

7. Plaintiff the State of Idaho is a sovereign State of the United States of America and directly subject to the Final Rule's requirements. Idaho sues to vindicate its sovereign, quasi-sovereign, and pecuniary interests. Idaho brings this suit through its Attorney General, Raúl R. Labrador. He is authorized by Idaho law to sue on the State's behalf.

8. Plaintiff the State of Indiana is a sovereign State of the United States of America and directly subject to the Final Rule's requirements. Indiana sues to vindicate its sovereign, quasi-sovereign, and pecuniary interests. Theodore E. Rokita is the Attorney General of Indiana. General Rokita is authorized to "represent the state in any matter involving the rights or interests of the state." Ind. Code § 4-6-1-6.

9. Plaintiff the State of Iowa is a sovereign State of the United States of America and directly subject to the Final Rule's requirements. Iowa sues to vindicate its sovereign, quasi-sovereign, and pecuniary interests. Brenna Bird, the Attorney General of Iowa, is authorized by Iowa law to sue on the State's behalf. Iowa Code § 13.2.

10. Plaintiff the State of Louisiana is a sovereign State of the United States of America and directly subject to the Final Rule's requirements. Louisiana sues to vindicate its sovereign, quasi-sovereign, and pecuniary interests. Liz Murrill is the Attorney General of Louisiana. She is authorized by Louisiana law to sue on the State's behalf. La. Const. art. IV, § 8.

11. Plaintiff the State of Montana is a sovereign State of the United States of America and directly subject to the Final Rule's requirements. Montana sues to vindicate its sovereign,

quasi-sovereign, and pecuniary interests. Austin Knudsen is the Attorney General of Montana. He is authorized to sue on Montana's behalf. *See* Mont. Code Ann. § 2-15-501.

12. Plaintiff the State of Nebraska is a sovereign State of the United States of America and directly subject to the Final Rule's requirements. Nebraska sues to vindicate its sovereign, quasi-sovereign, and pecuniary interests. Micheal T. Hilgers is the Attorney General of Nebraska and is authorized to bring legal actions on behalf of the State and its citizens. Neb. Rev. Stat. § 84-203.

13. Plaintiff the State of North Dakota is a sovereign State of the United States of America and directly subject to the Final Rule's requirements. North Dakota sues to vindicate its sovereign, quasi-sovereign, and pecuniary interests. Drew Wrigley is the Attorney General of North Dakota and is authorized to "[i]nstitute and prosecute all actions and proceedings in favor or for the use of the state." N.D.C.C. § 54-12-01(2).

14. Plaintiff the State of Ohio is a sovereign State of the United States of America and directly subject to the Final Rule's requirements. Ohio sues to vindicate its sovereign, quasi-sovereign, and pecuniary interests. Dave Yost, the Attorney General of Ohio, is "the chief law officer for the state and all its departments." Ohio Rev. Code § 109.02. He is authorized to represent the State of Ohio "in any court or tribunal in a cause … in which the state is directly interested." *Id.*

15. Plaintiff the State of South Carolina is a sovereign State of the United States of America and directly subject to the Final Rule's requirements. South Carolina sues to vindicate its sovereign, quasi-sovereign, and pecuniary interests. Alan Wilson is the duly elected Attorney General of South Carolina, and he has the authority to sue on behalf of the State of South Carolina. *See State ex rel. Condon v. Hodges*, 562 S.E.2d 623, 627 (S.C. 2002).

16. Plaintiff the State of South Dakota is a sovereign State of the United States of America and directly subject to the Final Rule's requirements. South Dakota sues to vindicate its sovereign, quasi-sovereign, and pecuniary interests. Marty J. Jackley is the Attorney General of South Dakota. General Jackley is authorized "to appear for the state and prosecute or defend, in any court or before any officer, any cause or matter, civil or criminal, in which the state may be a party or interested." SDCL § 1-11-1(2).

17. Plaintiff the State of West Virginia is a sovereign State of the United States of America and directly subject to the Final Rule's requirements. West Virginia sues to vindicate its sovereign, quasi-sovereign, and pecuniary interests. John B. McCuskey is the Attorney General of the State of West Virginia. The Attorney General "is the State's chief legal officer," *State ex rel. McGraw v. Burton*, 569 S.E.2d 99, 107 (W. Va. 2002), and his express statutory duties include "appear[ing] as counsel for the state in all causes pending … in any federal court[] in which the state is interested," W. Va. Code § 5-3-2.

18. Defendant the United States Department of Health and Human Services is an executive agency within the federal government of the United States.

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

20. Defendant the Office of Civil Rights for the United States Department of Health and Human Services is an executive agency within the federal government of the United States and is responsible for enforcing HIPAA and for promulgating the Final Rule.

21. This Complaint uses "HHS" to refer collectively to Defendants.

JURISDICTION & VENUE

22. 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. § 702 (Administrative Procedure Act).

23. This Court may grant declaratory relief, injunctive relief, and other relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02; the Administrative Procedure Act (APA), 5 U.S.C. §§701-706; Federal Rule of Civil Procedure 57; and its inherent equitable powers.

24. Venue is proper under 28 U.S.C. § 1391(e)(1) because the State of Tennessee resides in this District for purposes of the venue laws. 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.

25. 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).

26. Alongside HIPAA's insurance-related requirements, the statute creates rules that protect the privacy of patients' individualized health information and records.

27. Under HIPAA, a person commits a federal crime if he, "knowingly and in violation of" HIPAA, either (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" without the "authorization" mandated by the statute and implementing regulations. 42 U.S.C § 1320d-6(a).

28. Thus, HIPAA generally prohibits health care providers from disclosing patient information "without authorization" from the patient. *See United States v. Wilson*, 98 F.4th 1204, 1217 (10th Cir. 2024); *see also Wilson v. UnitedHealthCare Ins.*, 27 F.4th 228, 245 (4th Cir. 2022). It also prohibits a requesting entity or person from obtaining such health information "without authorization." 42 U.S.C § 1320d-6(a).

29. Violating HIPAA carries serious criminal consequences, including hefty fines and prison time. *Id.* § 1320d-6(b).

B. HIPAA expressly preserves States' traditional investigatory powers.

30. The U.S. Constitution's "federal system" provides the "National Government" only limited powers; the remainder, the "States and the people retain." *Bond v. United States*, 572 U.S. 844, 854 (2014). Chief among the States' reserved powers is the traditional power "to enact legislation for the public good"—i.e., the "police power." *Id.* (citation omitted).

31. 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. ex rel. Williams v. Skrmetti*, 73 F.4th 408, 417 (6th Cir. 2023) (collecting cases). This power includes "regulat[ing] the practice of medicine." *McNaughton*, 242 U.S. at 348-49. Indeed, "[t]here is perhaps no profession more properly open to … regulation" by States. *Watson v. Maryland*, 218 U.S. 173, 176 (1910).

32. States often request medical records and information covered by HIPAA while investigating allegations against medical providers suspected of fraud, unlawful billing practices, and other consumer-protection violations.

33. In addition, States implementing federally funded programs like Medicaid maintain an obligation to ensure funds are being put to proper, lawful use by qualified medical

providers. Policing those bounds likewise involves routinely assessing information subject to HIPAA.

34. As enacted, HIPAA abides the Constitution's division of federal-state power and the States' traditional role as (1) regulators of the medical profession and (2) the entities vested with primary law-enforcement authority over waste, fraud, and abuse by medical providers and others in the healthcare field.

35. In particular, notwithstanding HIPAA's general prohibition on unauthorized disclosure of patient health information, the statute expressly preserves States' investigatory authority 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) (emphasis added).

36. 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 lawful process, such as subpoenas or requests for information.

II. Regulatory Background.

A. HHS adopts the Privacy Rule in 2000.

37. In 2000, HHS adopted *Standards for Privacy of Individually Identifiable Health Information*, 65 Fed. Reg. 82,462 (Dec. 28, 2000) ("Privacy Rule"). 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.

38. 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.

39. 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.

40. 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).

41. Under the Privacy Rule, a HIPAA-covered entity may share information in response to a request for law enforcement purposes so long as:

> (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).

42. 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 overcome 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.

43. 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).

44. 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 of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992). Under those laws, and other state laws enacted after the *Dobbs* decision, many States now generally prohibit abortions unless performed to address a serious health risk to the mother. *See, e.g.*, Tenn. Code Ann. § 39-15-213; N.D.C.C. ch. 12.1-19.1.

45. After *Dobbs*, HHS proposed to modify the Privacy Rule to impose new barriers against disclosure of "reproductive health care" information. *See HIPAA Privacy Rule to Support*

Reproductive Health Care Privacy, 88 Fed. Reg. 23,506, 23,521 (Apr. 17, 2023) ("Proposed Rule").

46. HHS recognized that its approach was unprecedented: The Privacy Rule, it noted, had "not previously conditioned uses and disclosures for certain purposes on the specific type of health care about which the disclosure relates." *Id.*

47. HHS nonetheless 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.

48. HHS thus proposed new barriers to state investigators' ability to obtain "reproductive health care" records. Specifically, the Proposed Rule would prohibit a regulated entity from using or disclosing an individual's PHI to state investigators 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 when the relevant "investigation" or "proceeding" concerns "reproductive health care" that is (1) provided "outside of the state where the investigation or proceeding is authorized and ... is lawful in the state in which it is provided"; (2) "protected, required, or authorized by Federal law, regardless of the state in which [it] is provided"; or (3) "provided in the state in which the investigation or proceeding is authorized and ... is permitted by the law of that state." *Id.* at 23,552.

49. 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." *Id.* at 23,532 (emphasis added).

50. 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.

51. 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.*

52. 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.* at 23,552.

53. 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.*

54. 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.

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

56. A coalition of nineteen States, many Plaintiffs here, filed a comment opposing the Proposed Rule. *See* States' Comment Letter (Exhibit B).

57. 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.

58. 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.

59. Undeterred by the many comments submitted in opposition, HHS promulgated the Final Rule on April 26, 2024. The Final Rule became effective on June 25, 2024, but parties "subject to" the Final Rule generally were not required to comply until December 23, 2024. 89 Fed. Reg. at 32,976.

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

61. 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 32,987-88.

62. According to HHS, *Dobbs* has "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.*

63. HHS thus expressly acknowledged that the Final Rule aims to limit States' ability to enforce laws regulating aspects of HHS's "reproductive health care" rubric. The Final Rule maintained the broad definition of "reproductive health care" as including any "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.

64. 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.

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

66. The Final Rule places burdens on both the entity disclosing PHI (who must evaluate compliance with the Final Rule before releasing patient records) and the entity requesting PHI (who must attest, under penalty of criminal prosecution and other sanctions, that they are making a request permitted by the Final Rule). State entities and their employees often find themselves in both roles—discloser and requestor.

A. State investigation provisions.

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

68. 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).

69. If the covered entity in receipt of a records request concludes that either of these conditions applies, it cannot disclose the requested 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) (emphasis added).

70. Thus, the Final Rule 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.

71. Requiring that open-ended legal assessment is inherently unadministrable. By way of example, federal officials take the position that, for purposes of the Final Rule, *Roe v. Wade*

and its progeny represent the true interpretation of what the U.S. Constitution "protect[s]." 45 C.F.R. § 164.502(a)(5)(iii)(B). Federal officials have also taken 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 at 20-27, *Moyle v. United States*, Nos. 23-726 & 23-727 (U.S. Mar. 21, 2024); Dep't of Health & Human Servs., *Guidance on Nondiscrimination Protections Under the Church Amendment* (Feb. 3, 2023), https://www.hhs.gov/conscience/conscience-protections/guidance-church-amendments-protections/index.html. And federal officials have taken 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 experimental interventions constitute "reproductive health care" under the Final Rule. *See* Brief of the United States, *United States v. Skrmetti*, No. 23-477 (U.S. Aug. 27, 2024).

72. On top of that, the Final Rule creates a *presumption* that reproductive health care provided by another person is lawful under (a)(5)(iii)(B)(1) or (2)—and so not subject to an investigation request 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).

73. The Final Rule's regime thus seeks to preempt enforcement of state laws that conflict with HHS's favored policies.

74. The Final Rule also imposes an unmanageable compliance burden on state officials that must investigate a range of misconduct having nothing to do with HHS's reproductive-health-care policy concerns, like Medicaid and billing fraud, child and elder abuse, and breaches of safety regulations at healthcare facilities.

75. 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 82,493 (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)).

76. By requiring state agencies to come forward with specific factual information before obtaining the requested records, the Final Rule sharply limits state investigative authority. That defies HIPAA'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). It also contradicts longstanding practice under the Privacy Rule.

77. If a covered entity does not want to disclose PHI in response to a State's investigatory request, the Final Rule enables the covered entity to conclude unilaterally that the request was made for the mere act of providing reproductive health care that was lawful or authorized by federal law, and then refuse to disclose the information.

78. The disclosure scheme created by the Final Rule repeatedly leaves discretion to the covered entity to decide if the requested PHI should be disclosed to state law enforcement. At the Final Rule's worst, it empowers those suspected of fraud with the unilateral ability to thwart

investigations into their misconduct. At its best, state law enforcement agencies must navigate a series of novel, resource-intensive hurdles that will foreseeably complicate, chill, and otherwise hinder important and time-sensitive investigations. Those results are already playing out now that the Final Rule has taken effect. *See infra* ¶¶ 90-115.

B. Attestation requirement.

79. The Final Rule also adopts a new attestation requirement. *See* 45 C.F.R. §§ 164.509, 164.512(f)(1)-(6).

80. 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.

81. 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 the types of state law enforcement investigations listed above, without first obtaining an attestation that it determines to be valid. 45 C.F.R. § 164.509(a).

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

83. An attestation is defective if the document either: (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 associate has actual knowledge that material information in 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 with respect to the requirement at paragraph (c)(1)(iv) of this section." 45 C.F.R. § 164.509(b)(2).

84. The attestation must be written and 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 use or 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 use or disclosure," (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)(1).

85. These attestation requirements are entirely absent from the statutory text of HIPAA, and have never before existed in HHS's HIPAA-implementing regulations.

86. HHS has provided a model attestation, which contemplates that a state agency must provide detailed information about the records sought and their purpose before the covered entity can comply with a valid investigation request:

Model Attestation Regarding a Requested Use or Disclosure of Protected Health Information Potentially Related to Reproductive Health Care

The entire form must be completed for the attestation to be valid.

Name of person(s) or specific identification of the class of persons to receive the requested PHI.
e.g., name of investigator and/or agency making the request
Name or other specific identification of the person or class of persons from whom you are requesting the use or disclosure.
e.g., name of covered entity or business associate that maintains the PHI and/or name of their workforce member who handles requests for PHI
Description of specific PHI requested, including name(s) of individual(s), if practicable, or a description of the class of individuals, whose protected health information you are requesting.
e.g., visit summary for [name of individual] on [date]; list of individuals who obtained [name of prescription medication] between [date range]

I attest that the use or disclosure of PHI that I am requesting is not for a purpose prohibited by the HIPAA Privacy Rule at 45 CFR 164.502(a)(5)(iii) because of one of the following (check one box):

☐ The purpose of the use or disclosure of protected health information is **not** to investigate or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care or to identify any person for such purposes.

☐ The purpose of the use or disclosure of protected health information **is** to investigate or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care, or to identify any person for such purposes, but the reproductive health care at issue was **not lawful** under the circumstances in which it was provided.

I understand that I may be subject to criminal penalties pursuant to 42 U.S.C. 1320d-6 if I knowingly and in violation of HIPAA obtain individually identifiable health information relating to an individual or disclose individually identifiable health information to another person.

Signature of the person requesting the PHI

_____ Date _____

If you have signed as a representative of the person requesting PHI, *provide a description of your authority to act for that person.*

_____

This attestation document may be provided in electronic format, and electronically signed by the person requesting protected health information when the electronic signature is valid under applicable Federal and state law.

87. Even if a state law enforcement agency completes and submits an attestation, disclosure of the requested information does not immediately follow. Instead, the Final Rule then places the obligation and power to assess the lawfulness and validity of any PHI request entirely with the covered entity to which the request was made. Under the Final Rule, the covered entity itself determines, among other things, if (1) the attestation is adequate, (2) the attestation is true, (3) any "reproductive health care" furnished was lawful or authorized by federal law, or (4) 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.

88. Thus, even if the state official or law enforcement official provides 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 state investigators can challenge the covered entities' denial. That raises the prospect that States now must litigate each information request, which in turn will further drain resources and compromise investigations.

89. Risks of criminal penalty for covered entities and state investigators alike pervade HHS's new scheme, since releasing or obtaining records "without authorization" required is a federal crime. 42 U.S.C § 1320d-6. HIPAA-covered entities must thus evaluate every state investigative attestation on pain of criminal penalty. And the state investigator likewise must make an attestation on pain of criminal penalty.

PLAINTIFF STATES' IRREPARABLE HARM

90. HHS's Final Rule inflicts a series of irreparable harms on States in their capacity as investigators and HIPAA-covered entities. The harms can only be remedied by a judicial order enjoining enforcement of the Final Rule against entities based in Plaintiff States, state agencies, and information requested by state investigatory authorities.

A. Harm to States' traditional investigative authority.

91. The Final Rule harms Plaintiff States' sovereign interest in pursuing investigations that promote the health and welfare of those within their border as well as root out waste, fraud, and abuse occurring within the state.

92. For example, the Tennessee Attorney General's Office, along with other state agencies, are responsible for investigating Medicaid fraud. Tenn. Code Ann. § 71-5-183(a); *id.* § 71-5-2508. Other States' Attorney General's offices and state agencies have similar responsibilities. *See, e.g.*, Ala. Code § 22-1-11(a); Ohio Rev. Code §§ 109.85, 109.86.

93. To identify fraudulent schemes, Tennessee's investigators often must compare medical records against claims data billed or paid by the State's Medicaid program, TennCare. Other States likewise utilize medical-records requests to investigate fraud with respect to state healthcare programs. *See, e.g.*, N.D.C.C. ch. 50-24.8.

94. Indeed, obtaining medical records is crucial to the investigation and litigation of health care fraud. It is the most important evidence for illustrating various fraud schemes, including improper billing of care, rendering unnecessary or excessive services, billing for services that were not rendered, and other complex allegations.

95. 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 some state agencies are responsible for ensuring compliance with laws regarding certain treatments for minors. *See, e.g.*, Ohio Rev. Code § 3129.05(C).

96. These investigations also often rely on medical records obtained from HIPAA-covered entities pursuant to civil investigatory demands.

97. Medical records obtained from HIPAA-covered entities pursuant to civil investigatory demands are also necessary for state investigators tasked with policing professional misconduct and inspecting hospital facilities for evidence of patient abuse.

98. HIPAA-covered entities have historically accommodated investigators' requests that comply with the Privacy Rule. For example, providers have routinely disclosed medical records to the Tennessee Attorney General's office, the North Dakota Attorney General's office, and other Plaintiff State attorney general offices in response to civil investigative demands, as authorized by the HIPAA exception for law enforcement activities, 45 C.F.R. § 164.512(f). In such instances covered entities typically provide the requested PHI to state investigators via secure FTPs, or other secure means.

99. HHS's Final Rule impedes States' 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. 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 into things like Medicaid fraud.

100. Indeed, the Final Rule's broad definition of "reproductive health care" coupled with HIPAA's criminal penalties make it likely that both the requesting party and the producing party will undertake the burdensome attestation process in a huge swath of cases that are entirely divorced from the abortion-related concerns that ostensibly prompted the Final Rule, rendering the long-applicable Privacy Rule all but meaningless.

101. And because under the Final Rule the covered entities are in the position of determining whether an attestation is adequate or truthful, the Final Rule enables the covered entities to skirt duly authorized record requests from state investigative agencies. One of many problems with that scheme created by the Final Rule is that covered entities who are the subject of state investigations for their own suspected malfeasance or negligence will be able to deploy the Final Rule to avoid responding to valid state investigative requests by unilaterally claiming that they do not believe the state investigator's attestation is adequate or in good faith.

102. As most investigations into fraud or abuse take place before a lawsuit is filed, the requesting governmental agency's only recourse would be to petition a court of competent jurisdiction to intervene, adding months—potentially years—to an investigation and greatly increasing the administrative cost and burden for all parties.

103. Indeed, it is foreseeable that covered entities will use the Final Rule to avoid producing *any* records to state investigators without a court order either because they simply do not want to produce the records, or they want to ensure that they are insulated from criminal liability for violating the Final Rule.

104. Limiting state governments' ability to obtain medical records pursuant to valid investigations significantly impairs the states' ability to protect public funds and prosecute those who seek to abuse public programs or their patients. And protracted litigation over the enforcing agency's ability to even obtain medical records to investigate potential fraud threatens the potential scope of recovery; issues include the running of the applicable statute of limitations while records-related litigation proceeds. Thus, the Final Rule will often put state fraud and abuse regulators "on the clock" before their investigations have even meaningfully begun.

105. 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 of the lawfulness of the care provided and that the attestation satisfies with the Final Rule.

106. These concerns are not hypothetical. To the contrary, multiple state investigations have been affected by the Final Rule's novel restrictions.

107. For example, the Tennessee Attorney General's office has been thwarted seeking discovery in an ongoing consumer protection litigation concerning a physician and his fertility care clinic's business practices that harmed the clinic's patients. The State is unable to obtain relevant patient data subject to HIPAA's protections, without the attestation required by the Final Rule, which a state employee must sign under pain of criminal liability. And even if the State provides that attestation, the discovery could be denied if the covered entity determines that the relevant information would be used to impose liability for the "mere act" of providing or facilitating reproductive health care.

108. In North Dakota, since the compliance with Final Rule came into effect on December 23, 2024, healthcare providers have declined to comply with multiple law enforcement investigative requests by invoking the Final Rule and requiring state investigators to provide signed attestations about their investigations before providing requested records.

109. In Iowa, beginning in December 2024, investigators at Iowa's Department of Inspections, Appeals, and Licensing (DIAL) became frustrated in their purpose to protect the

health and safety of Iowans, as multiple institutions began withholding information requested for investigatory purposes pursuant to Iowa law. These institutions insisted on attestations as required by the Final Rule even though investigators' inquiries were made pursuant to subpoena. Thus, as of this filing, multiple health-related and health-fraud investigations have come to a halt while investigators await clarification on their obligations under the Final Rule.

110. And in Indiana, healthcare providers, citing HHS's Final Rule, have either refused to provide documents in response to subpoenas issued by the Indiana Attorney General or demanded that the Attorney General sign attestations only to then refuse to provide any documents even with an attestation. These refusals come notwithstanding the Indiana Attorney General's authority to receive, investigate, and prosecute complaints concerning consumer transactions in the State of Indiana, Ind. Code ch. 4-6-9 *et seq.*; to investigate any written complaint against a licensee and subpoena witnesses and to send for and compel the production of documents, Ind. Code § 25-1-7-5; and to request protected health information for the purpose of healthcare oversight, specifically, investigating the merits related to licensing complaints or disciplinary activities, 45 C.F.R. § 164.512(d)(1).

111. Across States, certain large state agencies and covered healthcare entities have ceased processing any 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. This is currently hindering state investigations and will continue to do so under the Final Rule.

112. The Final Rule also forces HIPAA-covered state agencies to assess attestations from fellow state agencies, creating potential for unnecessary and burdensome conflict. For example, because of uncertainty about the Final Rule's requirements, University of Iowa

Healthcare has requested DIAL investigators to sign attestations, so that it can confirm the "proper" purpose of the state-led investigation.

B. Harm to States as HIPAA-covered entities.

113. 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.

114. Plaintiffs' state hospitals and health agencies regularly receive requests for PHI from law enforcement investigating fraud, abuse, neglect, and other health-related violations.

115. HHS's Final Rule is currently necessitating a systemwide overhaul of state agencies' processing systems for requests for HIPAA-covered information. That compliance has in turn imposed financial, logistical, and personnel burdens on state agencies to ensure effective disclosure requirements. Yet on account of HHS's sovereign immunity, the Plaintiff States could not later recover these costs even should they prevail in litigation.

CLAIMS FOR RELIEF

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

116. Plaintiffs repeat and incorporate by reference the allegations of the preceding paragraphs.

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

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

119. The APA requires courts to set aside agency action that is "not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

120. 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.

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

122. *First*, the Final Rule is inconsistent with HIPAA.

123. The Supreme Court has long presumed that Congress legislates with an eye toward "preserv[ing] the constitutional balance between the National Government and the States." *Bond*, 572 U.S. at 862. To displace traditional spheres of state authority, Congress must "make its intention to do so 'unmistakably clear in the language of [a] statute.'" *Will v. Mich. Dep't of State Police*, 491 U.S. 58, 65 (1989) (quotations omitted). And that is no low hurdle: The text itself must contain "*exceedingly clear language* … to significantly alter the balance between federal and state power." *U.S. Forest Serv. v. Cowpasture River Pres. Ass'n*, 140 S. Ct. 1837, 1849–50 (2020) (emphasis added).

124. 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).

125. And Congress went out of its way to preserve the States' traditional authority in HIPAA, but the Final Rule unlawfully "limit[s]" the investigative and police power authority reserved to the States. *See Purl*, 2024 WL 5202497, at *6-10.

126. "[A]n agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regul. 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.

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

128. "[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).

129. The HIPAA statute nowhere authorizes HHS to limit the documents that medical providers may produce to a state agency for legitimate law-enforcement purposes, as evidenced by HHS's glaring inability to point to a statutory provision expressly conferring authority to adopt the Final Rule.

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

131. 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.

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

133. 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 585, 609-10 (6th Cir. 2022). Indeed, adopting HHS's interpretation of HIPAA 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).

134. Because the Final Rule lacks statutory authority, it violates the APA and should be "set aside," 5 U.S.C. § 706(2), meaning vacated. *See 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

135. Plaintiffs repeat and incorporate by reference the allegations of the preceding paragraphs.

136. The APA requires courts to 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).

137. 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).

138. Moreover, a federal agency may not adopt policies that conflict with existing regulations, or it must at least "display awareness that it is changing position." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). Agencies cannot "depart from a prior policy sub silentio or simply disregard rules that are still on the books." *Id.*

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

140. HHS has, for instance, 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 that is found nowhere within HIPAA.

141. HHS has also not explained or rationalized the Final Rule provisions placing the onus on HIPAA-covered entities, which generally specialize in health care, to determine whether an instance of "reproductive health care" was legal under federal law and the laws of various States. The Final Rule's presumption of legality creates further confusion and uncertainty for non-lawyer healthcare providers attempting to make such legal assessments.

142. HHS has also not adequately justified its broad definition of "reproductive health care," which, although aimed at counteracting *Dobbs*, sweeps in all manner of health care entirely unrelated to abortion services. 45 C.F.R. § 160.103.

143. HHS has also not adequately acknowledged or explained its departure from the Privacy Rule, which it previously determined appropriately protected patient privacy and while ensuring state investigatory interests. *See* 65 Fed. Reg. at 82,683.

144. HHS also has failed to adequately consider the significant compliance challenges and costs associated with satisfying the Final Rule in a wide range of state investigatory matters. The Final Rule is also arbitrary for failing to consider that fact that it empowers covered entities

that are themselves being investigated for suspected fraud or unlawful billing practices to use the Final Rule as a shield and refuse to respond to state investigators' valid requests for relevant information.

145. 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 Plaintiff States, raised a raft of practical concerns about the 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 (Mem.) (2022); *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015).

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

PRAYER FOR RELIEF

An actual controversy exists that entitles Plaintiff States to declaratory and injunctive relief. Plaintiffs request that this Court:

a) Declare that the Final Rule violates the APA because it exceeds HHS's statutory authority;

b) Declare that the Final Rule violates the APA because it is arbitrary and capricious;

c) Enter a stay and/or preliminary relief that preserves the State's rights against the Final Rule pending review, including by enjoining Defendants, and any other agency or employee

of the United States, from enforcing or implementing the Final Rule against the States, their state agencies, or entities within the States;

d) Hold the Final Rule unlawful and set it aside and permanently enjoin Defendants from enforcing the Final Rule;

e) Grant any and all other relief the Court deems just and proper.

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