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

STATE OF TENNESSEE, *et al.*, *Plaintiffs*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	Case No. 3:25-cv-00025

BRIEF OF *AMICI CURIAE* THE NATIONAL PARTNERSHIP FOR WOMEN & FAMILIES AND 23 ORGANIZATIONS IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND PRELIMINARY RELIEF

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES:

TABLE OF AUTHORITIES—Continued

Page(s)

STATUTES:

REGULATIONS:

TABLE OF AUTHORITIES—Continued

Page(s)

STATE CONSTITUTIONAL PROVISIONS:

LEGISLATIVE MATERIALS:

OTHER AUTHORITIES:

TABLE OF AUTHORITIES—Continued

Page(s)

TABLE OF AUTHORITIES—Continued

Page(s)

INTERESTS OF *AMICI* [1]

Amici are 24 nonprofit organizations that share a common commitment to ensuring the health and wellbeing of women and families. Many *amici* participated in the notice-and-comment rulemaking that resulted in the Department of Health and Human Services (HHS) issuing the final 2024 Rule at the center of this litigation. *See* HIPAA Privacy Rule to Support Reproductive Health Care Privacy, 89 Fed. Reg. 32,976 (Apr. 26, 2024). The 2024 Rule modified the Standards for Privacy of Individually Identifiable Health Information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), strengthening essential safeguards to better protect information related to reproductive health care and to bolster patient-provider confidentiality. *Amici* have a substantial interest in ensuring that these critical protections remain in effect.

The National Partnership for Women & Families is a nonprofit, nonpartisan organization with a mission to improve the lives of women and families by achieving equality for all women, especially for those that face structural barriers to opportunity and equity. Through advocacy, policy research and analysis, public education, and stakeholder engagement, the National Partnership works to advance health and economic justice, including reproductive rights and health privacy. The National Partnership is joined by 23 other nonprofit organizations as *amici* in defense of the 2024 Rule: Abortion Care Tennessee; the American Medical Women's Association; Autistic Women & Nonbinary Network; Demand Progress Education Fund; Equality California; Families USA; Guttmacher Institute; If/When/How: Lawyering for Reproductive Justice; the National Abortion Federation; the National Asian Pacific American Women's Forum; the National Association of Nurse Practitioners in Women's Health; National Council of Jewish Women;

[1] No counsel for a party authored this brief in whole or in part, and no entity or person, other than *amici*, their members, and their counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

National Council of Jewish Women – Tennessee; the National Health Law Program; National Institute for Reproductive Health; the National Network of Abortion Funds; the National Women's Law Center; Physicians for Reproductive Health; Pregnancy Justice; Reproductive Freedom for All; Rhia Ventures; SIECUS: Sex Ed for Social Change; and Tennessee Women's Political Caucus.

INTRODUCTION

HHS promulgated the 2024 Rule in response to the threats to health care privacy and patient-provider trust that emerged in the wake of the Supreme Court's decision overturning the constitutional right to abortion. The final rule prohibits regulated entities from using or disclosing protected health information (PHI) for the purposes of conducting a criminal, civil, or administrative investigation into, imposing liability on, or identifying anyone for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care. The 2024 Rule strengthens and reiterates HIPAA's statutory and regulatory promise of privacy protections, to ensure that people are not dissuaded from seeking lawful reproductive health care.

Pregnant individuals throughout the country live under the specter of surveillance and criminalization for their reproductive health decisions and pregnancy outcomes. Members of historically underserved and marginalized communities—and particularly low income, Black, and brown women—are more likely to be subjects of investigations and criminal proceedings related to reproductive health care.[2] HHS explained at length why the 2024 Rule was necessary to protect the patient trust that forms the base of the entire health care system.

[2] *See, e.g.*, Lynn M. Paltrow & Jeanne Flavin, *Arrests of and Forced Interventions on Pregnant Women in the United States, 1973–2005: Implications for Women's Legal Status and Public Health*, 38 J. Health Pol., Pol'y, & L. 299 (2013), https://tinyurl.com/38knwdep; Sandhya Dirks, *Criminalization of Pregnancy Has Already Been Happening to the Poor and Women of Color*, NPR (Aug. 3, 2022), https://tinyurl.com/yc44xh2j.

The 2024 Rule does not go as far as *amici* would have liked, as it only prohibits disclosures to law enforcement for the express purpose of criminalizing patients for lawful reproductive health care. *Amici* continue to believe that the critical importance of privacy and patient trust to the functioning of the health care system means that regulated entities should be prohibited from sharing protected health information for the purpose of criminalizing any reproductive health care. The scope of the 2024 Rule means that criminalization of pregnancy outcomes like miscarriages and stillbirths can still continue largely unabated, especially under the guise of addressing substance use during pregnancy.[3]

HHS nevertheless adopted a narrower approach, one that the agency explained was in deference to state law enforcement interests. The States' lawsuit complains that HHS's decision exceeded its statutory authority and is otherwise arbitrary and capricious. But the statutory text, history, and record demonstrate the opposite. In promulgating the 2024 Rule, HHS trod the well-worn path of defining the boundaries of permissible disclosures of individuals' health information—as HHS has done for a quarter century at Congress's explicit direction. Despite multiple opportunities to narrow HHS's authority, Congress has instead amended HIPAA without changing HHS's authority, and has even enacted new laws directing HHS to promulgate privacy regulations "at least as broad" as the regulations that HHS promulgated under HIPAA. HHS also explained at length every facet of its decision to adopt the 2024 Rule. That the States ultimately disagree with HHS's decision does not make the 2024 Rule arbitrary or capricious. The States' meritless arguments—and their extraordinary request for a preliminary injunction and vacatur of the entire rule—should be rejected.

[3] *See, e.g.*, Pregnancy Justice, *The Rise of Pregnancy Criminalization* (Sept. 2023), https://tinyurl.com/5n86bnv3; Pregnancy Justice, *Pregnancy as a Crime: A Preliminary Report on the First Year After* Dobbs (Sept. 2024), https://tinyurl.com/mrx239yz.

BACKGROUND

One of Congress's objectives in enacting HIPAA was to protect the "confidentiality of patients' individually identifiable health information" "in the midst of the rapid evolution of health information systems." *OPIS Mgmt. Res., LLC v. Sec'y, Fla. Agency for Health Care Admin*., 713 F.3d 1291, 1294-95 (11th Cir. 2013) (quoting *S.C. Med. Ass'n v. Thompson*, 327 F.3d 346, 348, 354 (4th Cir. 2003)). In pursuit of that goal, Congress prohibited the unauthorized sharing of protected health information, 42 U.S.C. §§ 1320d-5, 1320d-6, which is defined as "individually identifiable health information" transmitted or maintained in electronic form or otherwise, 45 C.F.R. § 160.103. Congress delegated to HHS the broad authority to promulgate privacy regulations addressing "at least" individuals' rights to individually identifiable health information, procedures for exercising those rights, and "[t]he uses and disclosures of such information that should be authorized or required." HIPAA, Pub. L. No. 104-191, § 264(b), (c)(1), 110 Stat. 1936, 2033 (1996). And Congress provided that HHS "shall review th[ose] standards" and "adopt modifications to the standards (including additions to the standards), as determined appropriate, but not more frequently than once every 12 months." 42 U.S.C. § 1320d-3(b)(1). HHS complied with its statutory directive, issuing final regulations known as the "Privacy Rule" in 2000, *see* Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462 (Dec. 28, 2000), and periodically revising them, *see, e.g.*, HIPAA Privacy Rule and the National Instant Criminal Background Check System, 81 Fed. Reg. 382 (Jan. 6, 2016).

To ensure that HIPAA set a national minimum privacy standard, Congress enacted a broad and explicit preemption provision dictating that HIPAA and HHS's implementing regulations "shall supersede any contrary provision of State law." 42 U.S.C. § 1320d-7(a)(1). That broad preemption authority is subject to only a few exceptions, including certain public health reporting

such as "the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." *Id.* § 1320d-7(b).

HIPAA and HHS's implementing regulations recognize that "privacy is a necessary foundation for delivery of high quality health care." 65 Fed. Reg. at 82,467. In the 2000 Privacy Rule, HHS explained that "[t]he provision of high-quality health care requires the exchange of personal, often-sensitive information between an individual and a skilled practitioner," and "[v]ital to that interaction is the patient's ability to trust that the information shared will be protected and kept confidential." *Id.* at 82,463. "More than anything else, the relationship between a patient and a clinician is based on trust," and patients that do not trust their providers are less likely to share full, accurate, and "detailed information about their personal health, behavior, and other aspects of their lives." *Id.* at 82,467. HHS has for decades recognized that privacy concerns are a central barrier to patient trust: Many patients reported that "they do not go to a physician, or do not completely share health information with their physician, because they are concerned about who will have access to that information" and "fear that their information will later be used against them." *Id.* at 82,565.

The consequences of a breakdown in trust are serious: "Health care professionals who lose the trust of their patients cannot deliver high-quality care," because incomplete medical information creates "a serious risk that the treatment plan will be inappropriate to the patient's situation." *Id.* at 82,467-68. Lack of trust between health care providers and patients has been linked to worse adherence to treatment, worse satisfaction with care, worse quality of life, and worse overall health outcomes.[4] These problems are even more acute among populations that have

[4] *See, e.g.*, Temi Adekunle, et al., *A Qualitative Analysis of Trust and Distrust Within Patient-Clinician Interactions*, 3 PEC Innov. (2023), https://tinyurl.com/czek2tk3; Pamela Sankar, et al., *Patient Perspectives on Medical Confidentiality: A Review of the Literature*, 18 J. Gen. Internal

historically experienced discrimination, including communities of color and Black women in particular. 89 Fed. Reg. at 32,985 & n.123.[5]

Twenty-five years ago, HHS recognized that "strong federal privacy protections are necessary to enhance patients' trust in the health care system." 65 Fed. Reg. at 82,565. After the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), HHS recognized that an update was necessary and appropriate to ensure continued strong privacy protections. In the wake of *Dobbs*, "the legal landscape has shifted as laws significantly restricting access to abortion have in fact become effective in some jurisdictions." 89 Fed. Reg. at 32,987. The pace of those developments and the resulting patchwork of policies across jurisdictions has resulted in significant confusion—risking the use or disclosure of reproductive health information even where that care "is lawful in the circumstances in which the health care is obtained," and thus threatening patients' "expectation of privacy of their health information." *Id.* And HHS acknowledged that this breakdown in patient trust and privacy is "likely to have a disproportionately greater effect" on "individuals from communities that have been historically underserved, marginalized, or subject to discrimination or systemic disadvantage by virtue of their race, disability, social or economic status, geographic location, or environment." *Id.* at 32,988-89.

HHS therefore promulgated the 2024 Rule to strengthen privacy protections for reproductive health care information, which "directly advances the purposes of HIPAA by setting

---

Med. 659, 659, 666 (2003), https://pmc.ncbi.nlm.nih.gov/articles/PMC1494903/ ("A significant minority of patients distrust confidentiality protections, leading some to report that they delay or forgo medical care," "or alter stories about symptoms and onset of illness, to be sure those details never emerge publicly.").

[5] *See also, e.g.*, Martha Hostetter & Sarah Klein, *Understanding and Ameliorating Medical Mistrust Among Black Americans*, Commonwealth Fund (Jan. 14, 2021), https://tinyurl.com/486kw2me (describing medical mistrust in the Black community due to historical and present-day medical abuse and discrimination).

minimum protections for PHI and providing peace of mind that is essential to individuals' ability to obtain lawful reproductive health care." *Id.* The 2024 Rule establishes that regulated entities "may not use or disclose protected health information" in order to investigate, to impose liability on, or to identify a person "for the mere act of seeking, obtaining, providing, or facilitating reproductive health care" that is lawful where provided. 45 C.F.R. § 164.502(a)(5)(iii). Reproductive health care provided by another person is "presumed lawful," unless (1) the regulated entity has "[a]ctual knowledge that the reproductive health care was not lawful," or (2) the person requesting the use or disclosure of PHI "demonstrates a substantial factual basis that the reproductive health care was not lawful." *Id.* § 164.502(a)(5)(iii)(C). And "[t]o assist in effectuating" these requirements, 89 Fed. Reg. at 32,990, the 2024 Rule provides that a regulated entity must "obtain[ ] an attestation" from the person requesting the use or disclosure that the information is not being sought for a prohibited purpose, 45 C.F.R. § 164.509.

HHS explained that the 2024 Rule "balances the privacy interests of individuals and the interests of society in an effective health care system with those of society in the use of PHI for other non-health care purposes," such as law enforcement. 89 Fed. Reg. at 32,991. The 2024 Rule "does not prohibit the use or disclosure of PHI to investigate or impose liability on persons where reproductive health care is unlawful under the circumstances in which it is provided." *Id.* at 32,994. And the 2024 Rule does not prevent States from continuing "public health surveillance, or public health investigation or intervention," 42 U.S.C. § 1320d-7(b); the 2024 Rule explains only that those terms are defined to mean "population-level activities to prevent disease in and promote the health of populations," rather than efforts to "conduct . . . investigation[s]" or "impose . . . liability" on individuals. 45 C.F.R. § 160.103.

Following the 2024 Rule's publication, a group of States brought this Administrative Procedure Act (APA) challenge, asserting that the 2024 Rule exceeds HHS's authority and is arbitrary and capricious.

ARGUMENT

I. The 2024 Rule Falls Squarely Within The Powers Delegated By Congress To HHS.

In authoring HIPAA, Congress delegated broad authority to HHS. Congress charged HHS with promulgating privacy regulations addressing "at least" individuals' rights to individually identifiable health information, procedures for exercising those rights, and "[t]he uses and disclosures of such information that should be authorized or required." HIPAA, § 264(b), (c)(1), 110 Stat. at 2033. Congress provided that HHS "shall review th[ose] standards" and "adopt modifications to the standards (including additions to the standards), as determined appropriate." 42 U.S.C. § 1320d-3(b)(1). And Congress further delegated to HHS the general authority to "make and publish such rules and regulations . . . as may be necessary to the efficient administration of the functions with which [HHS] is charged under [HIPAA]." *Id.* § 1302(a).

Those delegations of authority are broad because Congress designed and wrote them that way. The direction that HHS shall modify the standards "as determined appropriate" is exactly the kind of language reflecting Congress's decision to "leave[ ] agencies with flexibility." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 395 & n.6 (2024). Indeed, courts have long recognized that Congress conveyed to HHS "broad authority to promulgate rules and regulations protecting the privacy of patient health information," and that HHS has accordingly exercised that authority to "place strict limitations on the ability of certain health care providers to release a patient's medical records or discuss the patient's medical history." *Wade v. Vabnick-Wener*, 922 F. Supp. 2d 679, 687 (W.D. Tenn. 2010).

The 2024 Rule is consistent with that history and the statute's plain language. HHS exercised its delegated authority to modify the standards as to the permissible "uses and disclosures" of protected health information. HHS did so after determining that the Rule was "necessary to achieve Congress' directive to establish a standard for the privacy of [individually identifiable health information] for the purpose of improving the effectiveness of the health care system." 89 Fed. Reg. at 32,984. And the 2024 Rule preempts contrary state laws, as HIPAA itself makes clear. 42 U.S.C. § 1320d-7(a)(1).

The States gloss over these provisions and fixate instead on the "public health" carveout to preemption, which provides that HIPAA and HHS's regulations do not "limit the authority, power, or procedures" of States to provide "for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." *Id.* § 1320d-7(b). But HHS made clear that the 2024 Rule does not impede the public health exception: The 2024 Rule prohibits only the use or disclosure of protected health information to investigate or impose liability on a specific person for lawful reproductive health care.

The States insist that the word "limit" should be interpreted as broadly encompassing any "criteria" that might incidentally apply to a state official's request for information. States Br. 13. That approach would swallow HIPAA and render its privacy protections a nullity. For example, HHS has long regulated the operation of the public health exception, including defining which "[p]ublic health authorit[ies]" may seek the information, 45 C.F.R. § 164.501, the verification requirements that must be met before information may be released, *id.* § 164.514(h), and the "[s]tandard" for "[u]ses and disclosures for public health activities," *id.* § 164.512(b); *see generally* 89 Fed. Reg. at 33,016. On the States' logic, however, HHS could not require health care providers to "verify the identity of a person requesting protected health information" before releasing it, 45

C.F.R. § 164.514(h)(1)(i), because even that "proforma submission would amount to some 'limit' on States' authority," States Br. 15. Nothing in HIPAA supports that illogical result. "By introducing a limitation not found in the statute," the States seek "to alter, rather than to interpret," HIPAA. *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657, 677 (2020).

The history of HHS's privacy rules under HIPAA confirm that the States' interpretation is wrong. In promulgating the 2000 Privacy Rule, HHS consulted with the National Committee on Vital and Health Statistics (NCVHS)—as Congress required in HIPAA, to ensure that privacy standards would incorporate both public input and expert insight. HIPAA, § 264(d)(1), 110 Stat. at 2034; *see* 89 Fed. Reg. at 32,981. NCVHS advised that "strong substantive and procedural protections" should be imposed if health information were to be "disclosed to law enforcement," and, where identifiable health information would be made available for non-health purposes, individuals "deserve a strong assurance that the data will not be used to harm them." NCVHS, *First Annual Report*, at 20 (Feb. 1998), https://perma.cc/P699-UPBW. In the 2000 Privacy Rule, HHS accordingly adopted numerous requirements involving requests by law enforcement, including procedures designed to verify the identity of the requester. *See* 45 C.F.R. § 164.514(h)(1)(i); 65 Fed. Reg. at 82,547 ("Where the person requesting the protected health information is a public official, covered entities must verify the identity of the requester by examination of reasonable evidence, such as a written statement of identity on agency letterhead, an identification badge, or similar proof of official status.").

In its comments on the 2024 Rule, NCVHS hewed "to the principle that has been at the core of [its] work for over 25 years: medical records should not be used for purposes outside of the health care setting in ways that could harm the subject of the records, particularly for law

enforcement." NCVHS Comment Letter, at 2 (June 14, 2023), https://perma.cc/U2DH-SRTU. HHS accordingly recognized that the privacy interests associated with the provision of lawful reproductive health care outweighed interests in disclosure, and adopted procedural requirements as to the permissible circumstances for disclosure—just as it had in the 2000 Rule. This history reflects a shared understanding of regulatory authority by both the agency and the expert body charged with advising it. *See Loper Bright*, 603 U.S. at 386 ("[T]he longstanding practice of the government . . . can inform a court's determination of what the law is." (citations, quotation marks, and brackets omitted)).

Congress has also endorsed HHS's rulemaking authority. Congress has amended HIPAA without changing its delegation of authority to HHS. *See* Patient Protection and Affordable Care Act (ACA), Pub. L. 111-148, Title I, § 1104(b)(2), Title X, § 10109(a)(1), 124 Stat. 119, 147, 915 (2010); *Lamar, Archer & Cofrin, LLP v. Appling*, 584 U.S. 709, 722 (2018) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change." (citation omitted)). And Congress has repeatedly cross-referenced HHS's HIPAA regulations in other programs, directing HHS to "promulgat[e] . . . privacy protections that are *at least as broad* as those that [HHS] applies to other health data under the regulations promulgated under [HIPAA]," ACA, § 4302, 124 Stat. at 580 (emphasis added), or to "ensure the protection of individual health privacy consistent with the regulations promulgated under [HIPAA]," *id.* § 6703, 124 Stat. at 785; *see also id.* § 10411, 124 Stat. at 989. Far from contesting the scope of HHS's authority, Congress has repeatedly endorsed HHS's authority as "broad."

Resisting HIPAA's clear grant of expansive authority to HHS, the States offer a laundry list of reasons they believe it should be narrowed. None of them stand up. There is no "major

question" in HHS exercising the same core authority as to the disclosure of certain sensitive medical records that it has exercised for decades. States Br. 19; *cf. West Virginia v. EPA*, 597 U.S. 697, 724 (2022) (major questions involve an agency's "claim[ ] to discover in a long-extant statute an unheralded power representing a transformative expansion in [its] regulatory authority" (citation and quotation marks omitted)); *see also, e.g.*, 65 Fed. Reg. at 82,497, 82,514-15 (2000 Privacy Rule establishing heightened disclosure requirements for psychotherapy notes). And the cases the States cite in invoking the "federalism cannon," States Br. 19, reflect only that "Congress should make its intention 'clear and manifest' if it intends to pre-empt the historic powers of the States," *Will v. Mich. Dep't of State Police*, 491 U.S. 58, 65 (1989)—which Congress plainly did here in directing that HIPAA and HHS's implementing regulations "*shall supersede any contrary provision of State law*," 42 U.S.C. § 1320d-7(a)(1) (emphasis added).

The States also complain (at 19-20) that recognizing HHS's rulemaking authority would raise "concerns" under the nondelegation doctrine for lack of an intelligible principle. But as the Fourth Circuit explained in rejecting a nondelegation challenge to the 2000 Privacy Rule, "Congress did not abdicate its legislative responsibility in passing HIPAA"; Congress "outlined a broad set of principles to guide HHS action," and "there are at least three sources within HIPAA that provide intelligible principles outlining and limiting the Congressional conferral of authority on HHS." *S.C. Med. Ass'n*, 327 F.3d at 351-352. The States' suggestion (at 20) of a due-process problem in requiring regulated entities to render "legal judgments" is similarly meritless; the plaintiffs in *South Carolina Medical Association* likewise complained that HIPAA and the 2000 Privacy Rule required "subjective judgments on the part of health care providers" interpreting state and federal laws, but, as the Fourth Circuit explained, HIPAA and HHS's regulations may "call for covered entities to make some common sense evaluations and comparisons between state and

federal laws, but this does not mean they are either vague or constitutionally infirm." 327 F.3d at 354. The same is true here, and the States' invitation to diverge from the Fourth Circuit's well-reasoned opinion should be rejected.

II. HHS Adequately Explained Its Decision To Adopt The 2024 Rule.

The States broadly complain that the 2024 is arbitrary and capricious. States Br. 20-22. But the APA's standard of review is "deferential," and an agency's decision will be sustained so long as the agency "reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). HHS's decision easily clears that low bar. In promulgating the 2024 Rule, HHS reviewed over 25,900 public comments, in addition to consulting with NCVHS and federal and state law enforcement agencies. 89 Fed. Reg. at 32,991. HHS explained at length why the rule was a necessary response to privacy concerns engendered by the shifting legal landscape, and how HHS sought to balance individual privacy interests with state interests in public health and law enforcement. Under the APA, HHS was required to do no more. The States ultimately disagree with HHS's policy decisions, but the States "may not substitute [their] own policy judgment for that of the agency." *Prometheus Radio Project*, 592 U.S. at 423.

A. HHS Adequately Explained Its Chosen "Balance Between Ensuring Health Care Privacy And Conducting Law Enforcement Activities."

The States generally complain that HHS failed to explain how the 2024 Rule "balance[s] between ensuring health care privacy and conducting law enforcement activities." States Br. 21 (quoting 89 Fed. Reg. at 32,993). But HHS explained at length both the need for the rule and the particular balance HHS struck. *Amici* and others had urged HHS to adopt stronger privacy protections than the final rule set forth. But the APA did not compel HHS to adopt either *amici*'s

or the States' preferred rules, and HHS's explanation satisfied the APA's requirement of an explanation linking the facts found to the decision made.

As HHS explained, *Dobbs* precipitated an enormous shift in the legal rules governing routine health care. Care that was once legal nationwide has reverted to a state-by-state inquiry into the particulars of what is permitted, with widespread ripple effects. HHS collected reports of pharmacists and physicians refusing to write or fill prescriptions for methotrexate—a common drug used to treat cancer, psoriatic arthritis, and numerous autoimmune diseases—because in high doses it may cause miscarriage. 89 Fed. Reg. at 32,988 & n.156. Pregnant women diagnosed with cancer received delayed or inferior treatment, even though abortion is often the standard of care for certain patients battling cancer. *See, e.g.*, Melissa Suran, *Treating Cancer in Pregnant Patients After* Roe v. Wade *Overturned*, JAMA (Sept. 29, 2022), https://tinyurl.com/33muen4r (cited at 89 Fed. Reg. at 32,978); Jeannie Baumann, *Abortion Restrictions Weakening Cancer Care, Other Treatments*, Bloomberg Law (Aug. 14, 2023), https://tinyurl.com/49napbe4 (Kentucky hospital denied abortion to pregnant mother of five children diagnosed with advanced cervical cancer). And HHS noted reports that retail pharmacies were providing PHI directly to law enforcement in the face of "extreme pressure," even when those demands were not accompanied by a warrant or subpoena. 89 Fed. Reg. at 33,044 & nn. 398-399; *see also* Remy Tumin, *Pharmacies Shared Patient Records Without a Warrant, an Inquiry Finds*, The New York Times (Dec. 13, 2023), https://tinyurl.com/5cpka5as.

HHS recognized that changing state laws have "made information about an individual's reproductive health more likely to be sought for punitive non-health care purposes," which risks undermining the patient-provider trust on which the entire health care system is built. 89 Fed. Reg. at 33,012. HHS collected reports that shifting state laws were already engendering mistrust

between patients and providers. For example, after the Supreme Court declined to block Texas's abortion ban, a woman reported seeing a Texas doctor for abdominal pain, which turned out to be the result of a miscarriage of a pregnancy of which she had not been aware. *See* Eric Boodman, *In a Doctor's Suspicion after a Miscarriage, a Glimpse of Expanding Medical Mistrust*, STAT News (June 29, 2022), https://tinyurl.com/3kxthwmf (cited at 89 Fed. Reg. at 32,985 n.119, 32,988 n.154). She described the conversation with the physician transforming from one of sympathy to one of suspicion: a consultation that "felt like an interrogation," peppered with questions about physical activity, drug use, and abortion drugs—all prompted by the physician learning that she had undergone an abortion more than a decade earlier. *Id.*

HHS recognized that issues of medical mistrust are especially poignant for women of color and members of other marginalized communities. 89 Fed. Reg. at 32,985 & n.123. This mistrust is rooted in historic harms and past bioethical atrocities like forced sterilization, as well as health disparities that continue today, *id.*: Black women are more than three times more likely to die from a pregnancy-related cause than white women. CDC, *Working Together to Reduce Black Maternal Mortality* (Apr. 8, 2024), https://perma.cc/Z7WG-2W9A. Disproportionate effects on marginalized communities are compounded by the fact that they also face higher rates of surveillance and criminalization, 89 Fed. Reg. at 32,988-89 & nn.159-162—including prosecutions even where no crime has been committed.[6]

[6] For example, a Texas woman was charged with murder after a hospital nurse reported her complications from a self-managed abortion to law enforcement—even though Texas law specifically exempts someone who has an abortion from being prosecuted for murder. *See* Eleanor Klibanoff, *Lawyers Preparing for Abortion Prosecutions Warn About Health Care, Data Privacy*, Texas Tribune (July 25, 2022), https://tinyurl.com/4pr2k7b6; *see also Gonzalez v. Ramirez*, No. 7:24-cv-00132 (S.D. Tex. Apr. 11, 2024) (42 U.S.C. § 1983 lawsuit against Texas officials for malicious prosecution and false arrest).

HHS further recognized that widely varying state laws create the risk of law enforcement "targeting individuals for seeking lawful reproductive health care outside of their home state." 89 Fed. Reg. at 33,012.[7] The privacy implications would be felt "nationwide," "not only because of their effects on the relationship between health care providers and individuals, but also because of the potential effects on the flow of health information across state lines." *Id.* at 32,987-88. Individuals who travel out-of-state for lawful reproductive health care "may now be reluctant to have that information disclosed to a health care provider in their home state if they fear that it may then be used against them," and "[a] health care provider may be unable to provide appropriate health care if they are unaware of the individual's recent health history, which could have significant negative health consequences." *Id.*

HHS adopted the 2024 Rule against this backdrop and detailed factual findings. HHS determined that the use or disclosure of PHI for purposes of investigating, identifying, or imposing liability on people for seeking lawful reproductive health care "would erode individuals' trust in the privacy of legal reproductive health care," which would in turn "negatively affect relationships between individuals and their health care providers, result in individuals forgoing needed treatment, and make individuals less likely to share pertinent health concerns with their health care providers." *Id.* at 33,019. HHS accordingly adopted a final rule that prohibits the use or disclosure of PHI in "narrowly tailored circumstances": "where the use or disclosure is to conduct an investigation or impose liability on [or identify] a person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided." *Id.* at 32,994-95.

[7] Indeed, Plaintiff Alabama's Attorney General has "threatened prosecutions . . . intended to deter and prevent people from traveling out-of-state to receive a lawful abortion." *Yellowhammer Fund v. Att'y Gen. of Ala.*, 733 F. Supp. 3d 1167, 1188 (M.D. Ala. 2024).

HHS took care to balance privacy and law enforcement needs. *Amici* and others urged HHS to prohibit disclosures to law enforcement for the purpose of criminalizing any reproductive health care, and to broaden the scope of the rule to other forms of stigmatized, highly sensitive care. *See, e.g.*, National Partnership for Women & Families Comment Letter, at 8 (June 16, 2023), https://perma.cc/3WYQ-TKK6 ("We strongly believe that health care providers should never be in the business of policing, or facilitating the criminalization of, their patients, regardless of the type of health care they are seeking.").[8] NCVHS—the expert committee Congress tasked with advising HHS on privacy standards—agreed that such a broad proposed prohibition was important to "maintaining trust in the provider-patient relationship so that patients do not withhold information about their health from their providers out of fear of facing prosecution." NCVHS Comment Letter, *supra*, at 6. Loss of that trust and the cloud of legal liability jeopardizes "the viability of the nation's health care and public health systems," inhibiting providers from "providing necessary treatment," "fully educating patients about potential medical options," or "documenting the given care appropriately"; deterring future doctors from attending medical school and medical professionals from practicing in certain States; and ultimately reducing access to care, "leading to worse health outcomes and an increase in disparities across populations." *Id.* at 2-3. Commenters explained that extending privacy protections to cover even unlawful conduct would not be unprecedented—for instance, HHS prohibits the use or disclosure of substance use disorder treatment records "to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient," 42 C.F.R. § 2.12(a)(2)—and urged that a similar rule was necessary for reproductive health care. NCVHS Comment Letter, *supra*, at 3.

[8] *See also, e.g.*, Comment Letter of 125 Organizations in the Reproductive Rights and Justice, Civil Rights, and Consumer Health Advocacy Communities, at 4 (June 16, 2023), https://perma.cc/GZ3Q-B3AG ("The proposed rule does not go far enough to protect patients who may have self-managed an abortion or who are suspected of doing so.").

HHS nevertheless crafted a narrower rule than what *amici* and others had advocated, prohibiting only the disclosure of protected health information where the reproductive health care was lawful under the circumstances provided, in order to balance the States' law enforcement concerns. HHS recognized the States' asserted "interests of society in permitting the disclosure of PHI to support the investigation or imposition of liability for unlawful conduct," and HHS specifically designed the rule to reflect the States' asserted interests. 89 Fed. Reg. at 32,996.

HHS also explained that state laws and efforts by law enforcement to obtain PHI regarding *lawful* reproductive health care "undermine Congress' directive to develop a health information system for the purpose of improving the effectiveness of the health care system, which requires that all individuals who receive health care legally are assured a minimum level of privacy for their PHI." *Id*. at 33,061. HHS detailed how Congress established that HHS's privacy regulations preempt contrary state laws, and that HIPAA's "specific, narrow exceptions to preemption . . . did not include the use or disclosure of an individual's medical records for law enforcement purposes generally." *Id.* And HHS determined that "[b]oth the personal and public interest is served by protecting PHI so as not to undermine an individual's access to and quality of lawful health care services and their trust in the health care system." *Id.*

The States may not like the 2024 Rule. But that policy disagreement is not an APA violation. HHS responded to the States' objections and "articulate[d] a satisfactory explanation for [its] action including a rational connection between the facts found and the choice made." *Little Sisters of the Poor*, 591 U.S. at 682. That is what the law requires.

B. HHS Adequately Explained Why The Presumption Of Lawfulness Is Necessary To Ensure Compliance With Privacy Protections For Reproductive Health Care.

The States also complain that HHS arbitrarily adopted a presumption of lawfulness for reproductive health care. States Br. 21. But HHS explained at length that the presumption of

lawfulness was necessary to operationalize the 2024 Rule's prohibitions on disclosing PHI without overburdening regulated entities. The 2024 Rule requires that when a regulated entity considers a request for PHI, reproductive health care by another provider is presumed lawful unless (1) the regulated entity has actual knowledge that the care was unlawful, or (2) the request contains information demonstrating "a substantial factual basis" that the care was unlawful. 45 C.F.R. § 164.502(a)(5)(iii)(C).

The presumption of lawfulness prevents regulated entities from wasting time and resources investigating care provided by another health care provider and then trying to decide if it was lawful in response to a request for PHI. Without the presumption, regulated entities would be thrust into a logistical nightmare of trying to ascertain patient records and other necessary facts to determine if a previous provider's care was legal under the circumstances. This would be effectively impossible to accomplish and strain already scarce resources, as HHS recognized. 89 Fed. Reg. at 33,015, 33,024.

For a regulated entity to even begin investigating the legality of another provider's care, it would likely need to access the patient's private medical records and possibly other sensitive details about that care. But such records would not qualify under disclosure exceptions for "[t]reatment, payment, or health care operations" like quality-assessment reviews, as would be necessary to obtain those records absent the patient's consent. 42 U.S.C. § 164.506(b)(2). And even if the regulated entity could obtain those records, they may not illuminate whether the care was legal where provided. State abortion bans include myriad exceptions, such as terminations of molar or ectopic pregnancies or where the pregnant person's life or health is otherwise in danger;[9] many States criminalize abortion providers but not the individuals who self-manage their own

[9] *See, e.g.*, Tenn. Code Ann. § 39-15-213(a)(1), (c)(1), (d).

abortions; and many state laws on reproductive health care have shifted at such speed that the line between lawful and unlawful care would be challenging to track.[10] Indeed, commenters explained that "[d]etermining if a reproductive health care service was lawfully provided in a particular state—in a constantly changing landscape—would require up-to-the-minute legal analysis by an expert in that jurisdiction." Blue Cross Blue Shield Association Comment Letter, at 8 (June 16, 2023), https://perma.cc/UX36-RDPA. Providers frequently face difficulty in assessing the legality of their *own* actions under their *own* State's laws, as HHS and others have detailed at length.[11] 89 Fed. Reg. at 33,015, 33,024. Forcing regulated entities to Monday-morning-quarterback the legality of care provided by other entities in other States would be entirely unworkable.

Such investigations would add immense strain on already limited time and resources. With numerous requests for PHI arriving daily, adding the responsibility of determining the legality of

[10] For instance, "given the broad definitions used in Idaho's criminal abortion statute," Plaintiff Idaho "conceded that the procedure necessary to terminate an ectopic pregnancy [wa]s a criminal act" under Idaho's 2022 abortion law, *United States v. Idaho*, 623 F. Supp. 3d 1096, 1104 (D. Idaho 2022); the legislature amended the statute the following year to exclude ectopic pregnancies, *see* 2023 Idaho Laws Ch. 298 (H.B. 374) (2003); Idaho Code § 18-604(1)(c). Missouri banned abortion before Missouri voters enshrined the right to abortion in Missouri's constitution. Mo. Const. art. I, § 36(2). And Plaintiff Georgia was enjoined from enforcing its six-week abortion ban, *see* Order, *SisterSong v. Georgia*, No. 2022-cv-367796 (Ga. Sup. Ct. Sept. 30, 2024), before the state supreme court stayed the injunction and allowed the ban to resume, No. S25M0216 (Ga. Oct. 7, 2024).

[11] *See, e.g.*, Physicians for Human Rights, et al., *No One Could Say: Accessing Emergency Obstetrics Information as a Prospective Prenatal Patient in Post-*Roe *Oklahoma* (Apr. 2023), https://tinyurl.com/32exvbtc (detailing that hospitals are struggling to interpret competing abortion laws and enact clear policies that their providers can follow post-*Dobbs*); Daniel Grossman, MD, et al., *Care Post-Roe: Documenting Cases of Poor-Quality Care Since the* Dobbs *Decision*, Advancing New Standards in Reproductive Health (May 2023), https://tinyurl.com/3873ebvu ("post-*Dobbs* laws and their interpretations altered the standard of care . . . in ways that contributed to delays, worsened health outcomes, and increased the cost and logistic complexity of care"); Letter from 30 Senators to Secretary Becerra (Sept. 13, 2020), https://perma.cc/N6MW-2GCX (urging HHS to promulgate rules to address "widespread confusion among health care providers on health privacy protections, and whether they are required to turn over health information to state and local law enforcement," following the *Dobbs* decision).

prior care would overwhelm providers. Multiple health care entities submitted comments explaining that they "do not have the capacity" to investigate and make case-by-case determinations of lawfulness, and that attempting to do so "would significantly delay the response time" for information requests. Blue Cross Blue Shield Association Comment Letter, *supra*, at 8; *see also* UnitedHealth Group Comment Letter, at 3 (June 16, 2023), https://perma.cc/ZFN2-KETB.

HHS explained that it adopted the presumption of lawfulness to avoid the strain to the health care system that would result from deputizing health care providers as pseudo lawyers. 89 Fed. Reg. at 33,015, 33,024. The rule is straightforward: a regulated entity can presume that reproductive health care obtained elsewhere was lawful, unless the provider has "actual knowledge" that the care provided was illegal, or where the requester submits information demonstrating "a substantial factual basis" that the care was unlawful or that the request is unrelated to the imposition of legal liability for the care itself. 45 C.F.R. § 164.502(a)(5)(iii)(C)(1)-(2); *see, e.g.*, 89 Fed. Reg. at 33,032 (disclosure permitted where law enforcement official attests "that the PHI is necessary for an investigation into violations of specific criminal codes unrelated to the provision of reproductive health care (*e.g.*, billing fraud)").

HHS explained that these requirements adequately balance the need for privacy with legitimate law enforcement needs: Any interest in law enforcement is necessarily "reduced" when the government cannot provide a "substantial factual basis" that the care was unlawful. 89 Fed. Reg. at 32,994. HHS acknowledged the possibility that individual instances of unlawful care might "inadvertently" be shielded by the 2024 Rule, such as if the State is unable to provide a "substantial factual basis" that the care was unlawful. *Id.* HHS "[n]evertheless" concluded that "the importance of protecting individual privacy in this area" outweighed potential "benefits to societal

interests in the use or disclosure of PHI from a narrower rule," because a narrower rule would "inadvertently permit more disclosures of PHI about lawful reproductive health care" contrary to HIPAA's overarching purpose. *Id.* HHS's decision to favor privacy interests accords with both congressional intent and the agency's historical practice. *See, e.g.*, *Allen v. Highlands Hosp. Corp.*, 545 F.3d 387, 399 (6th Cir. 2008) (explaining that "patient privacy . . . is of paramount concern to healthcare providers and specifically protected by HIPAA"); *Strayhorne v. Caruso*, No. 2:11-cv-15216, 2014 WL 916814, at *4 (E.D. Mich. Mar. 10, 2014) ("In enacting HIPAA, Congress recognized a societal interest in maximizing the protections afforded in the confidential physician-patient relationship, even where a patient's medical history is at issue in a court case.").

C. HHS Adequately Explained Why The Attestation Requirement Is Necessary To Balance Privacy Protections With Law Enforcement Needs.

The States also take aim at the attestation requirement. States Br. 22. The 2024 Rule requires that individuals seeking PHI "potentially related to reproductive health care" attest that they are not seeking the information for the prohibited purposes of investigating, identifying, or imposing liability on a person merely for "seeking, obtaining, providing, or facilitating" lawful reproductive health care. 45 C.F.R. §§ 164.509, 164.502(a)(5)(iii). HHS explained at length why the attestation requirement strikes an appropriate balance between patient privacy while also considering the needs of law enforcement, because it reiterates the prohibition on disclosing reproductive PHI for a prohibited purpose, delineates the circumstances in which the information can be shared with a requester, and does not impose a significant burden on law enforcement.

HHS explained that the attestation requirement was designed to operationalize the prohibitions on disclosures of reproductive health information for prohibited purposes and to minimize the burden on regulated entities in verifying legitimate requests for PHI. 89 Fed. Reg. at 33,030. The attestation requirement is not onerous: Because the 2024 Rule prohibits disclosure

only for specific prohibited purposes, HHS explained that, for example, a simple representation from law enforcement officials tasked with investigating insurance fraud that the "purpose for the request is to investigate insurance fraud" would suffice. *Id.* at 33,037. The same is true for disclosures involving "suspected elder abuse," as "the final rule does not bar the use or disclosure of PHI for health oversight purposes, which is unrelated to the mere act of seeking, obtaining, providing, or facilitating reproductive health care." *Id.* at 32,995. And the 2024 Rule "does not prohibit the use or disclosure of PHI to investigate or impose liability on persons where reproductive health care is unlawful under the circumstances in which it is provided," *id.* at 32,994, so the State need only offer a substantial factual basis that the care actually was unlawful. That is not a heavy burden: HHS does "not requir[e] a regulated entity to investigate the veracity of the information provided in support of an attestation," in large part because of the risk of "unnecessary delays to law enforcement activities." *Id.* at 33,033.

HHS explained that it designed the attestation requirement with law enforcement in mind. For example, HHS explained that it "narrow[ed] the scope of the attestation to PHI 'potentially related to reproductive health care,' " rather than *all* PHI, out of a concern that "extending the attestation requirement to all PHI could unnecessarily delay law enforcement investigations" while the regulated entity attempted to determine whether the request in fact related to reproductive health care. *Id.* at 33,029. HHS also published a model attestation—which is barely a page long. HHS, *Model Attestation for a Requested Use or Disclosure of Protected Health Information Potentially Related to Reproductive Health Care*, https://perma.cc/L3NR-XYZ7; *see* ECF No. 64-1. Law enforcement officials need only provide a few pieces of information, including checking a box indicating that they are requesting the PHI for a law enforcement investigation and not for a prohibited purpose. *Id.* The States' complaints of immense burdens of delayed investigations are

their own inventions—because State officials have simply "declined to provide an attestation" that they are not seeking reproductive PHI for a prohibited purpose. ECF No. 26-2, Zeigler Decl. ¶ 12.

At bottom, the States' objection to the attestation requirement is not that HHS failed to explain it, but that the States do not like it. The APA does not make that policy disagreement a judicially cognizable claim.

CONCLUSION

For the foregoing reasons, the States' motion for summary judgment and preliminary relief should be denied.

Respectfully submitted,

/s/ Dana A. Raphael
Jessica L. Ellsworth* (D.C. Bar No. 484170)
Dana A. Raphael* (D.C. Bar No. 1741559)
HOGAN LOVELLS US LLP
555 Thirteenth Street N.W.
Washington, D.C. 20004
(202) 637-5886
jessica.ellsworth@hoganlovells.com
dana.raphael@hoganlovells.com

* Application for *pro hac vice* pending

Counsel for Amici Curiae

March 20, 2025

APPENDIX LIST OF *AMICI*

Abortion Care Tennessee, https://www.abortioncaretn.org/

The American Medical Women's Association, https://www.amwa-doc.org/

Autistic Women & Nonbinary Network, https://awnnetwork.org/

Demand Progress Education Fund, https://demandprogresseducationfund.org/

Equality California, https://www.eqca.org/

Families USA, https://familiesusa.org/

Guttmacher Institute, https://www.guttmacher.org/

If/When/How: Lawyering for Reproductive Justice, https://ifwhenhow.org/

The National Abortion Federation, https://prochoice.org/

The National Asian Pacific American Women's Forum, https://napawf.org/

The National Association of Nurse Practitioners in Women's Health, https://npwh.org/

National Council of Jewish Women, https://www.ncjw.org/

National Council of Jewish Women – Tennessee, https://www.ncjwnashville.org/

The National Health Law Program, https://healthlaw.org/

National Institute for Reproductive Health, https://nirhealth.org/

The National Network of Abortion Funds, https://abortionfunds.org/

The National Partnership for Women & Families, https://nationalpartnership.org/

The National Women's Law Center, https://nwlc.org/

Physicians for Reproductive Health, https://prh.org/

Pregnancy Justice, https://www.pregnancyjusticeus.org/

Reproductive Freedom For All, https://reproductivefreedomforall.org/

Rhia Ventures, https://rhiaventures.org/

SIECUS: Sex Ed for Social Change, https://siecus.org/

Tennessee Women's Political Caucus, https://www.nwpctn.org/

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with Local Rule 7.1(b) in that it does not exceed 25 pages.

/s/ Dana A. Raphael
Dana A. Raphael

CERTIFICATE OF SERVICE

I certify that on March 20, 2025, I electronically filed the foregoing using the CM/ECF system. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties of record.

/s/ Dana A. Raphael
Dana A. Raphael