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

STATE OF TENNESSEE, STATE OF ALABAMA, STATE OF ARKANSAS, STATE OF GEORGIA, STATE OF IDAHO, STATE OF INDIANA, STATE OF IOWA, STATE OF LOUISIANA, STATE OF MONTANA, STATE OF NEBRASKA, STATE OF NORTH DAKOTA, STATE OF OHIO, STATE OF SOUTH CAROLINA, STATE OF SOUTH DAKOTA, STATE OF WEST VIRGINIA, *Plaintiffs*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DOROTHY A. FINK, in her official capacity as Acting Secretary of the U.S. Department of Health and Human Services; and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF CIVIL RIGHTS, *Defendants*.	)	Civil Action No. 3:25-cv-00025 Judge Katherine A. Crytzer Magistrate Judge Jill E. McCook

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND PRELIMINARY RELIEF

The U.S. Department of Health and Human Services ("HHS") promulgated the *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the "Final Rule"), under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). The Final Rule became effective June 25, 2024, but parties "subject to" the Final Rule generally were not required to comply until December 23, 2024. *Id.* at 32,976. The Final Rule prohibits disclosures of protected health information related to "reproductive health care," broadly defined, for certain purposes and absent certain procedural standards. *Id.* at 33,062-66. Because Congress did not authorize HHS to

implement such disclosure requirements and the Final Rule is neither reasonable nor reasonably explained, the Plaintiff States seek summary judgment and an order "set[ting] aside" the Final Rule as "unlawful." 5 U.S.C. § 706(2)(A), (C). The Plaintiff States alternatively seek preliminary relief pending final judgment, including a preliminary injunction, Fed. R. Civ. P. 65, and stay under 5 U.S.C. § 705, which empowers courts to "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings."

SUMMARY JUDGMENT

Under Federal Rule of Civil Procedure 56, the Plaintiff States respectfully move this Court for entry of an Order granting summary judgment on their claims. The Plaintiff States contend HHS exceeded its statutory authority and acted arbitrarily and capriciously in promulgating the Final Rule.

As discussed in the supporting Memorandum, there is no genuinely disputed issue as to any material fact. The Plaintiff States are entitled to judgment as a matter of law that HHS exceeded its statutory authority, *see* 5 U.S.C. § 706(2)(C), and acted arbitrarily and capriciously, *see id.* § 706(2)(A), in promulgating the Final Rule. Accordingly, the Plaintiff States respectfully ask this Court to grant summary judgment in their favor and grant the following relief:

(A) A judgment declaring the Final Rule violates the Administrative Procedure Act ("APA") and vacating the Final Rule;

(B) Any and all other relief the Court deems just and proper.

PRELIMINARY RELIEF

Alternatively, the Plaintiff States respectfully move this Court for entry of preliminary relief under Federal Rule of Civil Procedure 65 and 5 U.S.C. § 705, postponing the effective date of the Final Rule to avert irreparable sovereign and financial injury pending judicial review of the Final Rule.

For the reasons provided in the supporting Memorandum, the Plaintiff States meet the requirements for preliminary relief under Rule 65 and 5 U.S.C. § 705:

1. The Plaintiff States' challenge to the Final Rule has a high probability of success on the merits because the Final Rule violates the APA. HIPAA does not provide HHS authority to promulgate the Final Rule. In fact, the Final Rule's infringing of state authority is contrary to HIPAA's statutory commands. And HHS promulgated the Final Rule relying on factors Congress has not intended it to consider and failing to consider important aspects of the Final Rule's problems.

2. Without preliminary relief, the Plaintiff States will suffer immediate and irreparable harm. The Final Rule is hampering important state investigations into billing fraud, unsafe medical facilities, and the like; injuring the public fisc; and forcing the Plaintiff States to expend resources on compliance costs associated with the Final Rule. In other words, the Final Rule is infringing the Plaintiff States' police powers and costing them time and money. In the absence of an Order vacating the Final Rule, the Plaintiff States can be protected from those irreparable injuries only by preliminary relief enjoining enforcement of the Final Rule against the Plaintiff States, their HIPAA-covered entities, and their investigative agencies, or postponing the effective date of the Final Rule until after this Court renders final judgment.

3. The equities favor granting preliminary relief. Absent such relief, the Final Rule is costing the Plaintiff States resources and infringing on their traditional police powers. By contrast, preliminary relief would not substantially harm Defendants.

4. Preliminary relief is also in the public interest. The public interest lies in a correct application of the law. Besides, the Final Rule's impeding state investigations of, for example, possibly dangerous medical facilities, endangers the public.

The Plaintiff States therefore respectfully request that the Court grant this Motion and enter an Order under Federal Rule of Civil Procedure 65 and 5 U.S.C. § 705 containing the following relief:

- Preliminarily enjoin Defendants from taking, endorsing, or allowing any action against the Plaintiff States, their HIPAA-covered entities, or their investigative agencies pursuant to the Final Rule; and/or
- Stay the Final Rule's current effective date of June 25, 2024, and allow the Plaintiff States to continue operating under the pre-Final Rule status quo until this Court issues Final Judgment on the Plaintiff States' claims.

ORAL ARGUMENT REQUEST

The Plaintiff States have provided courtesy copies of these filings to attorneys at the United States Department of Justice litigating similar cases. Their position on the relief sought is unknown. Plaintiff States are filing a Memorandum in Support of this Motion, along with exhibits. Plaintiff States respectfully request oral argument on this Motion.

Date: February 7, 2025

Respectfully submitted,

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*** Application for Pro Hac Vice forthcoming
**** Application for full admission pending

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served via the Court's electronic filing system on this 7th day of February, 2025 to all counsel of record. The document was further served via email on the following, who is representing the Defendants in two parallel challenges to the Final Rule in the United States District Court for the Northern District of Texas:

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IN THE UNITED STATES DISTRICT COURT
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STATE OF TENNESSEE, STATE OF ALABAMA, STATE OF ARKANSAS, STATE OF GEORGIA, STATE OF IDAHO, STATE OF INDIANA, STATE OF IOWA, STATE OF LOUISIANA, STATE OF MONTANA, STATE OF NEBRASKA, STATE OF NORTH DAKOTA, STATE OF OHIO, STATE OF SOUTH CAROLINA, STATE OF SOUTH DAKOTA, STATE OF WEST VIRGINIA, *Plaintiffs*, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DOROTHY A. FINK, in her official capacity as Acting Secretary of the U.S. Department of Health and Human Services; and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF CIVIL RIGHTS, *Defendants.*	Civil Action No. 3:25-cv-00025 Judge Katherine A. Crytzer Magistrate Judge Jill E. McCook

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND PRELIMINARY RELIEF

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INTRODUCTION

The "Law of Unintended Consequences" holds that "[w]hether or not what you do has the effect you want, it will have three at least you never expected, and one of those usually unpleasant." Robert Jordan, *The Path of Daggers* 313 (1st ed. 1998). Case in point: the U.S. Department of Health and Human Services' ("HHS") *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (April 26, 2024) (the "Final Rule"). Promulgated explicitly in reaction to the Supreme Court's decision returning abortion regulation to the States in *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022), the Final Rule is meant to pump the brakes on States' investigating and prosecuting violations of state laws protecting fetal life. That disruption to the post-*Dobbs* federal-state balance is unlawful alone, but the Final Rule does much more. Most relevant: It halts state investigations into fraud, abuse, and adverse patient outcomes unrelated to a State's limits on abortion.

The Final Rule warps the Health Insurance Portability and Accountability Act ("HIPAA") to impose barriers on the use and disclosure of protected health information ("PHI") about "reproductive health care," which it defines broadly enough to encompass almost any care conceivable. 89 Fed. Reg. at 32,978. Before using or disclosing basic, vital information for public-health and fraud investigations, HIPAA-covered entities and state investigators each must navigate a complex morass of legal judgments to ensure that the information is not sought for a prohibited purpose, including to "investigat[e]" lawfully obtained "reproductive health care." *Id.* at 33,063. This places health professionals in the position of making legal determinations that have confounded even Article III courts and requires investigators to make blind predictions under threat of criminal liability about where an investigation will lead before it has begun. Even if information is ultimately disclosed, that is only after significant delay and disruption to the investigative process.

As a district court in Texas has already suggested, Congress did not authorize HHS to use HIPAA as a roadblock to "limit" or "slow[] down" state investigations. *Purl v. HHS*, No. 2:24-CV-

228-Z, 2024 WL 5202497, at *6-10 (N.D. Tex. Dec. 22, 2024). Congress mandated the opposite: "Nothing in [HIPAA] 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). In addition to exceeding HHS's authority under HIPAA, the Final Rule is arbitrary and capricious on several fronts, including employing a new presumption of lawful care that places a thumb on the scale against complying with state records requests.

Plaintiffs—the States of Tennessee, Alabama, Arkansas, Georgia, Idaho, Indiana, Iowa, Louisiana, Montana, Nebraska, North Dakota, Ohio, South Carolina, South Dakota, and West Virginia—now seek preliminary relief prohibiting application of the Final Rule against their HIPAA-covered entities and state investigators. Preliminary relief is necessary to prevent the Plaintiff States from continuing to suffer the substantial and irreparable sovereignty and compliance harms their declarations detail. The public interest also favors the Plaintiff States' conducting effective public-health investigations and enforcing duly enacted laws and regulations prohibiting waste, fraud, and abuse. HHS, on the other hand, would suffer no harm from an order enforcing HIPAA's proper scope. In the interest of judicial economy, and because this Administrative Procedure Act ("APA") case involves pure questions of law requiring no further factual development, the Plaintiff States also seek summary judgment and request that the Court "set aside" the Final Rule as unlawful. 5 U.S.C. § 706(2).[1]

BACKGROUND

I. HIPAA and the Privacy Rule.

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

[1] Because counsel for Defendants has not yet appeared, the Plaintiff States have provided copies of their motion, this accompanying memorandum, and their supporting exhibits to counsel representing Defendants in related cases pending in the U.S. District Court for the Northern District of Texas.

Congress "encourag[ed] the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain [patient] health information." Pub. L. No. 104-191 § 261. Given the sensitivity of patients' health information, Congress made it unlawful for anyone "knowingly" to "use[]," "obtain[]," or "disclose[] individually identifiable health information" without authorization. 42 U.S.C. § 1320d-6(a). Violating HIPAA carries serious criminal consequences, including fines and jail time. *Id.* § 1320d-6(b).

Congress instructed HHS upon HIPAA's enactment to promulgate initial enforcing regulations to cover the "rights that an individual who is a subject of individually identifiable health information should have," "procedures that should be established for the exercise of such rights," and "uses and disclosures of such information that should be authorized or required." Pub. L. No. 104-191 § 264(b)(1)-(3). But HHS did not have carte blanche, and Congress was particularly concerned with the relationship between HIPAA and state laws. Thus, any regulation HHS promulgated could not preempt a contrary state law with "more stringent" requirements for protecting health information. *Id.* § 264(c)(2). Nor could HHS construe HIPAA "to invalidate or limit" States' authorities to police public-health matters. 42 U.S.C. § 1320d-7(b).

HHS thus promulgated *Standards for Privacy of Individually Identifiable Health Information*, 65 Fed. Reg. 82,462 (Dec. 28, 2000) (the "Privacy Rule"). The Privacy Rule's "major goal" "is to assure that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and well being."[2] The Privacy Rule bars the use or disclosure of PHI without the patient's approval except for specified purposes, including: for law enforcement; in response to lawful process; and for conducting public health oversight, surveillance, or investigation. *See* 45 C.F.R. § 164.512 (2023).

[2] *See* HHS Office for Civil Rights, *Summary of the HIPAA Privacy Rule* 1 (May 13, 2003), https://www.hhs.gov/sites/default/files/privacysummary.pdf.

The "law enforcement purpose[s]" encompassed by the Privacy Rule include disclosing as the law otherwise requires, identifying or locating an individual, protecting victims, investigating deaths, and reporting crime in emergencies. *Id.* § 164.512(f)(1)-(4), (6). The Privacy Rule requires that law enforcement requests for PHI pursuant to a court order, subpoena, or administrative process be for "information [that] is relevant and material to a legitimate law enforcement inquiry," "specific and limited in scope to the extent reasonably practicable," and not "reasonably" satisfied with "[d]e-identified information." *Id.* § 164.512(f)(1)(ii)(C). HHS "designed" this three-part test to preserve patient privacy without "unduly compromis[ing]" States' authorities. 65 Fed. Reg. at 82,683.

II. States Investigate Fraud, Abuse, and Adverse Patient Outcomes to Protect Public Health and Guard the Public Fisc.

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). States have "great latitude under their police powers to legislate as to the protection of lives, limbs, health, comfort, and quiet of all persons." *Gonzalez v. Oregon*, 546 U.S. 243, 270 (2006) (citation omitted).

For example, States directly "regulate the practice of medicine." *McNaughton v. Johnson*, 242 U.S. 344, 348-49 (1917). Indeed, "[t]here is perhaps no profession more properly open to … regulation" by States. *Watson v. Maryland*, 218 U.S. 173, 176 (1910). States limit *who* may deliver health services within their borders. *See, e.g.*, Tenn. Code Ann. §§ 63-6-201, -203, -213, -214. They prescribe *how* those health professionals may practice. *See, e.g.*, *id.* § 63-1-155 (authorizing telehealth); *id.* § 63-6-218 (granting good-Samaritan immunity). States also regulate *what types* of treatments or care plans health professionals may pursue. *See, e.g.*, *id.* § 33-8-315 (outlawing lobotomy); *id.* § 53-11-308(e), (f) (regulating opioid dispensing). And, more generally, States over the years have developed public-health laws and sophisticated infrastructures to protect the public from tuberculosis, *id.* §§ 68-9-101

to -116, sexually transmitted diseases, *id.* §§ 68-10-101 to -118, and all manner of public health concerns, *see generally id.*, Title 68.

States also "regulate consumer products … to promote public health and safety," which "falls neatly within [their] traditional police powers." *HW Premium CBD, LLC v. Reynolds*, No. 4:24-CV-00210-SMR-SBJ, 2024 WL 3548320, at *6 (S.D. Iowa July 25, 2024). The Consumer Protection Division of the Tennessee Attorney General's office, for its part, has pursued investigations and enforcement against health professionals who are suspected of harming patients with unfair or deceptive business practices. *See* Decl. of Kelley Groover ¶¶ 5, 12 (Exhibit A). Currently, the office is pursuing a case in which a fertility clinic shuttered overnight, and the owner is suspected of failing to properly secure or maintain cryogenic tanks that held hundreds of irreplaceable genetic specimens. *Id.* ¶ 6.

States also maintain responsibility for funding, implementing, and monitoring compliance with important federally funded programs, including Medicaid and Medicare. In that role, States often coordinate with federal partners to maintain standards of care, protect vulnerable populations, and ensure proper use of federal-program funding. For example, Tennessee's Health Facilities Commission ("Health Facilities") "conducts certification and compliance surveys of health facilities that participate in Medicare to ensure the facility maintains compliance with conditions of program participation." Decl. of Katherine Zeigler ¶ 3 (Exhibit B); *see also* 42 C.F.R., Part 482. Surveys are often conducted pursuant to a patient complaint about care or conditions at a facility. Zeigler Decl. ¶ 3. States also pursue civil and criminal investigations of Medicaid fraud. *See* Tenn. Code Ann. § 71-5-183(a); *id.* § 71-5-2508. This includes "investigat[ing] and refer[ing] for prosecution … complaints of abuse, neglect, and financial exploitation of medicaid recipients in any setting." *Id.* § 71-5-2508.

States' ability to effectively enforce these state and federal laws depends on their timely access to certain patient records. *See* Decl. of Kevin Kreutz ¶¶ 4-6 (Exhibit C); Zeigler Decl. ¶¶ 9, 15; Groover Decl. ¶¶ 9-11. For decades, States have obtained this information under the Privacy Rule

without significant hinderance. *See, e.g.*, Zeigler Decl. ¶ 5. But when targets have denied information requests, investigators have had to seek relief through "resource intensive and time consuming" court proceedings that "can delay an investigation by months or even years." Groover Decl. ¶ 13.

III. HHS Proposes New HIPAA Regulations After *Dobbs*.

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*, 597 U.S. at 259. *Dobbs* triggered state laws across the country set to take effect if *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833 (1992) were overruled. 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. Cent. Code Ann. § 12.1-19.1-02.

According to HHS, these developments "created new concerns about the privacy of PHI related to reproductive health care." *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 88 Fed. Reg. 23,506, 23,519 (Apr. 17, 2023) (the "Proposed Rule"). Thus, HHS proposed placing novel conditions on the use and disclosure of "reproductive health care" information, which HHS broadly defined as information on "all types of health care related to an individual's reproductive system." *See id.* at 23,521-27. Among other examples, HHS proposed that investigators requesting PHI from a covered entity "that is potentially related to reproductive health care" must sign an attestation under threat of criminal penalty that the "use or disclosure would not be for a purpose prohibited" by the rule. *Id.* at 23,535. HHS further proposed to require that the request recipient evaluate those attestations and determine whether the information is sought to investigate conduct that, in the recipient's judgment, was legal when rendered. *Id.* at 23,535-36.

HHS's unprecedented proposal garnered more than 25,000 comments. A coalition of nineteen States—many plaintiffs here—filed a comment letter opposing the Proposed Rule. Dkt. #1-2.

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.

IV. HHS Promulgates the Final Rule and State Investigations Grind to a Halt.

Undeterred, HHS promulgated the Final Rule in April 2024.[3] 89 Fed. Reg. at 32,976. The Final Rule built on the Proposed Rule's broad definition of "reproductive health care," "clarif[ying]" that the term encompasses the "full range of health care related to an individual's reproductive health," *id.* at 33,005, including "all matters relating to the reproductive system and to its functions and processes," *id.* at 33,063. The Final Rule also carried forward the proposed barriers to using and disclosing "reproductive health care" information even though those barriers "may affect certain state interests in obtaining PHI to investigate potentially unlawful" conduct. *Id.* at 32,995.

The Final Rule prohibits the disclosure of information about "reproductive health care" for at least three specific purposes:

> (1) [t]o conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care[;]
>
> (2) [t]o impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care[; or]
>
> (3) [t]o identify any person [for these purposes].

45 C.F.R. § 164.502(a)(5)(iii)(A). Thus, the Final Rule restricts disclosure of "reproductive health care" information if "investigation" or "liability" attaches for the "mere act" of seeking, procuring, or facilitating certain medical services.

[3] Although the Final Rule became effective in June 2024, compliance generally was not required until late December 2024. 89 Fed. Reg. at 32,976.

The Final Rule's disclosure bar applies only if state or federal law deems the medical service "lawful" under the circumstances it was provided. The Final Rule states that the bar applies only if the covered entity "reasonably determine[s] that one or more of the following conditions exists":

> (1) [t]he reproductive health care is lawful under the law of the state in which such health care is provided under the circumstances in which it is provided[;]
>
> (2) [t]he reproductive health care is protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided[; or]
>
> (3) [t]he presumption [that the "reproductive health care" at issue was lawful] applies.

Id. § 164.502(a)(5)(iii)(B). The Final Rule creates a presumption that "reproductive health care" provided by another person was lawful. *See id.* § 164.502(a)(5)(iii)(B)(3) & (C). The presumption is overcome only if (1) the covered entity has actual knowledge that the reproductive health care was not lawful or (2) the person requesting disclosure of PHI supplies "[f]actual information … that demonstrates a substantial factual basis that the reproductive health care was not lawful." *Id.* § 164.502(a)(5)(iii)(C). The Final Rule leaves the complex determination whether the information is sought for a prohibited purpose up to the covered entity—which is often the one under investigation.

Under the Final Rule, many requests for information must include an "attestation" meeting strict requirements set by HHS. 45 C.F.R. § 164.509(a)(1); *see id.* § 164.512. "The requesting agency must say the information will not be used for a prohibited purpose; must not contain any extra, non-required statements; must be believable to a reasonable covered entity; must contain a specific description of the sought information; must contain a statement that a covered entity could be subject to penalties for a HIPAA violation; must be in plain language; and must be signed." *Purl*, 2024 WL 5202497, at *9; Compl. ¶ 86 (example attestation). If the attestation is deficient, disclosure is prohibited by the Final Rule—and the HIPAA-covered entity bears the risk HHS will later determine the

attestation was deficient. *See* 45 C.F.R. § 164.509(a)(2).

At the same time, though, the Final Rule does not provide investigators with effective recourse if a covered entity deems an attestation invalid for whatever reason. Instead, the Final Rule's disclosure limits on "reproductive health care" information travel in only one direction. The Final Rule does not "prevent regulated entities from using or disclosing PHI for the purpose of defending themselves or others against allegations that they sought, obtained, provided, or facilitated reproductive health care." 89 Fed. Reg. at 33,011. So the Final Rule allows disclosure to *defend against* a claim or prosecution involving "reproductive health care," but inhibits investigators from obtaining similar information to *enforce* violations of state laws or protect public health.

Though commenters warned HHS about the Final Rule's potential impact on state enforcement authorities, *see* Dkt. #1-2 at 8-11, 14; Comment of Ethics & Pub. Pol'y Ctr. 10-18 (Exhibit D), the agency brushed off such concerns, *see, e.g.*, 89 Fed. Reg. at 33,012. And once the Final Rule's mandates took hold, the impact on state investigations became clear and immediate. To name just one, Health Facilities received complaints that substandard care at a psychiatric facility resulted in a patient's death. *See* Zeigler Decl. ¶ 8. Although the alleged misconduct had no obvious connection to reproductive health care, investigators were denied access to vital patient records without an attestation. *Id.* ¶¶ 8-11. Investigators have reasonably declined to provide that attestation given the Final Rule's vague scope and uncertain interactions with other authorities, *id.* ¶ 12, halting the investigation. Other investigations have similarly faced hurdles or outright stoppage because of the Final Rule's disclosure requirements. *See* Kreutz Decl. ¶¶ 18-21; Groover Decl. ¶¶ 7-8; Decl. of Larry Johnson, Jr. ¶¶ 9-15 (Exhibit E); Decl. of Marina Spahr ¶¶ 16-20 (Exhibit F); Decl. of Brannon Traxler ¶¶ 19-21 (Exhibit G); Decl. of Michael Targia ¶¶ 18-20 (Exhibit H); Decl. of Ashley Klenski ¶¶ 16-20 (Exhibit I); Decl. of Tonya Joiner ¶¶ 7-11 (Exhibit J); Decl. of Nicholas Dietz ¶¶ 17-22 (Exhibit K); Decl. of Charity Menefee ¶¶ 18-22 (Exhibit L); Decl. of Stephanie Azar ¶¶ 12-16 (Exhibit M); Decl. of Jordan

Stover ¶¶ 7-11, 15-18 (Exhibit N); Decl. of Amy Osborne ¶¶ 9-11 (Exhibit O).

LEGAL STANDARDS

The Plaintiff States seek both preliminary relief under Federal Rule of Civil Procedure 65 and 5 U.S.C. § 705, and, as permitted by Rule 65(a)(2), summary judgment under Rule 56. Whether to grant preliminary relief turns on four factors: "(1) whether the moving party has shown a likelihood of success on the merits; (2) whether the moving party will be irreparably injured absent an injunction; (3) whether issuing an injunction will harm other parties to the litigation; and (4) whether an injunction is in the public interest." *Vitolo v. Guzman,* 999 F.3d 353, 360 (6th Cir. 2021); *see Ohio ex rel. Celebrezze v. Nuclear Regul. Comm'n*, 812 F.2d 288, 290 (6th Cir. 1987) (same under 5 U.S.C. § 705).[4] Likelihood of success is generally "the most important factor of a preliminary injunction analysis." *Higuchi Int'l Corp. v. Autoliv ASP, Inc.*, 103 F.4th 400, 409 (6th Cir. 2024).

Typically, the lawfulness of an agency action is resolved at summary judgment because "resolution of the matter does not require fact finding." *Harkness v. Sec'y of the Navy*, 174 F. Supp. 3d 990, 1004 (W.D. Tenn. 2016) (cleaned up) (citation omitted). The APA's standard of review governs motions for summary judgment in APA cases. *See Sierra Club v. Slater*, 120 F.3d 623, 632 (6th Cir. 1997). Rather than "reviewing the record for disputed facts that would preclude summary judgment," the court is to assess the lawfulness of the agency's action based on the "evidence in the administrative record." *Ardmore Consulting Grp., Inc. v. Contreras-Sweet*, 118 F. Supp. 3d 388, 393 (D.D.C. 2015) (citation omitted). If the agency exceeded its statutory authority or acted in an arbitrary and capricious manner, the court must "hold unlawful and set aside" the challenged action. 5 U.S.C. § 706(2)(A), (C).

ARGUMENT

The issues here—HHS's statutory authority to promulgate the Final Rule and whether HHS

[4] "Courts—including the Supreme Court—routinely stay already-effective agency action under Section 705." *Texas v. Biden*, 646 F. Supp. 3d 753, 770 (N.D. Tex. 2022) (collecting cases).

acted arbitrarily and capriciously in doing so—can be resolved on the administrative record without further factual development. *See, e.g.*, *PayPal, Inc. v. CFPB*, 728 F. Supp. 3d 31, 38 (D.D.C. 2024). Rather than expend judicial resources on two rounds of near-identical briefing at the preliminary-relief and summary-judgment stages, the Plaintiff States respectfully now seek a judgment finally "set[ting] aside" the Final Rule as unlawful. Such combined motions practice is common in APA cases.[5] At a minimum, given the Plaintiff States' ongoing harm, the Court should preliminarily enjoin application of the Final Rule's disclosure requirements against the Plaintiff States, their HIPAA-covered entities and state investigators, or stay the Final Rule under § 705, pending final judgment.

I. HHS's Final Rule Is Unlawful.

A. The Plaintiff States have standing to sue.

There is "little question" that the Plaintiff States—whose health agencies and state-run health facilities are HIPAA-covered entities, and whose investigative agencies regularly request HIPAA-protected PHI—have standing to challenge the Final Rule, as they are the "object of the action … at issue." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561-62 (1992). Indeed, the Plaintiff States easily satisfy all three elements for Article III standing—injury, traceability, and redressability. *See id.* at 560-61.

The Plaintiff States' injuries are two-fold. First, States have "a recognized quasi-sovereign interest in the health … of their populaces," *Kentucky v. Biden*, 23 F.4th 585, 599 (6th Cir. 2022), and "[p]erhaps the clearest example of traditional state authority is the punishment of local criminal activity." *Bond*, 572 U.S. at 858. But the Final Rule impedes state investigations meant to enforce civil and criminal laws that protect public health and the public fisc. Such "interference with a state's sovereign 'power to create and enforce a legal code' is sufficient to establish Article III standing." *Tennessee v. U.S. Dep't of Educ.*, 104 F.4th 577, 591 n.11 (6th Cir. 2024) (citation omitted). Indeed, the Final Rule's

[5] *See, e.g.*, *1306 Lounge, LLC v. SBA*, No. 22-cv-3320-RBW, 2024 WL 4987025, *3-5 (D.D.C. Dec. 5, 2024); *Chamber of Com. of the United States v. DHS*, 504 F. Supp. 3d 1077, 1081 (N.D. Cal. 2020); *Pol'y & Rsch., LLC v. HHS*, 313 F. Supp. 3d 62, 71 (D.D.C. 2018).

explicit concern is regulating States' enforcement of laws protecting fetal life, and "when a federal regulation purports to preempt state law," States have "a sovereign interest to sue the United States." *Kentucky*, 23 F.4th at 598 (collecting cases). Second, the Final Rule's vague and overbroad disclosure conditions have required States to expend significant time and resources assessing their systems for disclosing and requesting HIPAA-protected information—particularly because improperly using or disclosing PHI carries significant criminal liability. *See, e.g.*, Traxler Decl. ¶¶ 17-18; Spahr Decl. ¶ 15-18. That's the result the Final Rule itself predicted: HHS "anticipate[d] that covered entities will need to develop new or modified policies and procedures for the new requirements." 89 Fed. Reg. 33,056. Because HHS is protected by sovereign immunity, these compliance costs are unrecoverable and constitute injury "for purposes of Article III" standing. *Kentucky v. Yellen*, 54 F.4th 325, 342-43 (6th Cir. 2022); *see Purl*, 2024 WL 5202497, at *5-6.

The Plaintiff States' sovereignty and fiscal injuries are traceable to the Final Rule. Investigators successfully obtained necessary records through requests under the Privacy Rule because it was "designed" to balance patient privacy interests against States' sovereign interests in "law enforcement." 65 Fed. Reg. at 82,683. That investigators now cannot obtain similar information without significant delay or resistance is directly attributable to the Final Rule. *See* Zeigler Decl. ¶ 11. As HHS predicted, the Final Rule's "significantly more difficult" standards "unduly compromise[]" "law enforcement's ability to protect the public interest." 65 Fed. Reg. at 82,683. And without the sea change brought by the Final Rule, States could continue to operate under their long-standing HIPAA protocols rather than update systems and trainings to account for the Final Rule's mandates. *See Tennessee*, 104 F.4th at 590; *see also Purl*, 2024 WL 5202497, at *5-6. Thus, Plaintiff States' injuries are traceable to the Final Rule and would be redressed by an order setting it aside. *See Tennessee*, 104 F.4th 590-91, 595.

B. The Final Rule exceeds HHS's statutory authority.

HHS's "power to act and how they are to act is authoritatively prescribed by Congress." *City*

of Arlington v. FCC, 569 U.S. 290, 297 (2013). So the question here is whether HHS "has stayed within the bounds of its statutory authority." *Id.* To answer that question, courts must begin with the statute's text to "determin[e] the meaning of statutory provisions." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 394 (2024). Because nothing in HIPAA permits HHS to craft special disclosure requirements for "reproductive health care" information, the Final Rule unlawfully exceeds the agency's authority.

1. Recognizing States' traditional police powers over public health and welfare, Congress explicitly mandated that "[n]othing in [HIPAA] 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). Thus, whether the Final Rule "exceeds statutory authority turns on the meaning of 'limit' in HIPAA." *Purl*, 2024 WL 5202497, at *7. HHS is not entitled to deference on what "limit[s]" are allowed by the rule of construction. Instead, this Court's interpretation of the statute's "single, best meaning" must control. *Loper Bright*, 603 U.S. at 400.

HIPAA does not define "limit," so it must be given its "ordinary, common meaning as understood by the people it governs." *Purl*, 2024 WL 5202497, at *8 (collecting cases). A "limit" is "something that bounds, restrains, or confines." *Limit*, Merriam-Webster's Collegiate Dictionary 674 (10th ed. 2001). It is a "confining or restricting agent, or influence." *Limit*, American Heritage Dictionary of the English Language 1015 (4th ed. 2000). Thus, "[a]ll agree that something is *limited* when restrictions, restraints, or curtailments are imposed." *Purl*, 2024 WL 5202497, at *8. So a "limit" need not amount to a complete bar. "[L]aws that curtail or restrain the activity—even if the activity is not completely prohibited—*limit* the activity through imposing obstructions to the relevant activity." *Id.*

So does the Final Rule restrict, restrain, or curtail States' "authority, power, or procedures … for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health"? Yes, of course. States—in both their capacity as HIPAA-covered entities and as investigative

authorities—now must navigate a "labyrinth of criteria" to police these public concerns. *See Purl*, 2024 WL 5202497, at *7 (citation omitted). The upshot is a regime that imposes several new hurdles that slow and sometimes block lawful state investigatory and public-health enforcement activities.

First, the Final Rule requires covered entities to "screen requested PHI for whether it contain[s] information potentially related to reproductive health care." 89 Fed. Reg. at 33,060. That process is no small matter: The Final Rule's definition of "reproductive health care" is intentionally broad, meaning the necessary screening will be extensive because almost any patient record could be "potentially related" to the "functions and processes" of the reproductive system. 45 C.F.R. § 160.103. The threat of criminal liability, moreover, drives covered entities to err on the side of determining that some requested information "potentially relate[s]" to "reproductive health care" as broadly defined in the Final Rule, even when the connection is far from obvious. For example, a dialysis center refused to disclose information without an attestation under the Final Rule. Zeigler Decl. ¶ 10.

Second, a determination that "reproductive health care" information is implicated necessitates a second inquiry: Whether the requesting state or local agency is (i) "conduct[ing] a criminal, civil, or administrative investigation" or seeking to "impose criminal, civil, or administrative liability" for (ii) "the mere act of seeking, obtaining, providing, or facilitating reproductive health care." 89 Fed. Reg. at 33,063. So a request recipient must evaluate the investigators' motive—apparently by using some subjective sense of whether an agency is truly targeting waste, fraud, and abuse, or instead the provision of reproductive health care that HHS favors. How that works, the Final Rule doesn't say. Rather, it leaves it, in some cases, to the target of the investigation to determine.

Third and further complicating things, the Final Rule's disclosure bar applies only if the medical service was "lawful" under the circumstances it was provided. *Id.* This legality determination is yet another impermissible "limit" that delays and frustrates investigations. *Purl*, 2024 WL 5202497, at *8-9. Indeed, HHS itself recognized that "situations may arise where a regulated entity reasonably

determines that reproductive health care was lawfully provided, while at the same time, the person requesting the PHI (*e.g.*, law enforcement) reasonably believes otherwise." 89 Fed. Reg. at 32,993. Of course, covered entities generally "are not prepared or equipped to make nuanced legal judgments." *Purl*, 2024 WL 5202497, at *8. Yet the Final Rule puts them in the position of making legal judgments in areas of the law that are unsettled and ever changing. For example, the Final Rule "would require a doctor to navigate whether an abortion was 'legal' under EMTALA … before disclosing and risking liability under HIPAA" even though "[s]uch questions [have] confounded Article III courts." *Id.* at *9 (citation omitted). And that is to say nothing of the "fluctuat[ion]" in HHS's understanding of the legality of different forms of "reproductive health care" from administration to administration. *See id.*; *compare* Compl. ¶ 71 (detailing Biden Administration's view that federal law protects abortion and gender-transition interventions in minors), *with* Tenn. Code Ann. § 39-15-213, *and* Tenn. Code Ann. § 68-33-103 (restricting same). Forcing covered entities and requesting agencies to navigate thorny legal questions under threat of criminal liability chills States' "authority, power, [and] procedures" in a way HIPAA nowhere contemplates. *See id.* at *8-9.

Fourth, the Final Rule's "attestation" requirement comprises yet another impermissible "limit." *Purl*, 2024 WL 5202497, at *9. Under it, "[a] covered entity ... may not use or disclose protected health information potentially related to reproductive health care for purposes specified in [the 2024 Rule] without obtaining an attestation[.]" 89 Fed. Reg. at 33,063. And the Final Rule imposes strict requirements for a valid "attestation." "The requesting agency must say the information will not be used for a prohibited purpose; must not contain any extra, nonrequired statements; must be believable to a reasonable covered entity; must contain a specific description of the sought information; must contain a statement that a covered entity could be subject to penalties for a HIPAA violation; must be in plain language; and must be signed." *Purl*, 2024 WL 5202497, at *9.

While even a proforma submission would amount to some "limit" on States' authority, *id.* at

*8-9, the attestation requirement is not the box-checking exercise HHS claims, *see* 89 Fed. Reg. at 33,030. The purpose of an investigation is to gather unknown information. *See* Kreutz Decl. ¶ 16. Yet the Final Rule requires investigators to complete attestations under threat of criminal liability with imperfect knowledge of the possible misconduct. That chills investigators' ability and willingness to comply with the attestation requirement, limiting their access to necessary information.

Nor is the Final Rule's attestation requirement a barrier just for the requesting party. *Purl*, 2024 WL 5202497, at *9. If any of the requirements for a valid attestation is not met, the covered entity "may not use or disclose" the requested information. 89 Fed. Reg. at 33,063. The "covered entity" is responsible for evaluating the "attestation" and if it is "defective" then they are "not in compliance" if they disclose the information. *Id.* Thus, even after an investigator provides an attestation, the covered entity (perhaps themselves subject to investigation) must scrutinize its contents and may withhold disclosure.

Fifth, on top of all that, the Final Rule directs covered entities to "*presume*" that the care provided by others was lawful "unless they know or are reasonably shown otherwise." *Purl*, 2024 WL 5202497, at *8 (emphasis in original). In this way, too, the Final Rule places a thumb on the scale for non-disclosure. The default becomes for covered entities to withhold information. And overcoming this presumption requires state investigators to proffer highly fact-specific showings about investigations they are seeking to initiate. Again, that puts the cart before the horse, since often the purpose of records requests is to gather further facts about suspected misconduct.

It may be that these "hurdles, at the end of an interpretive process," do not "outright *bar*" use or disclosure of requested information. *Id.* But the complex steps and analyses that the Final Rule requires of covered entities and requesting parties inhibits States' authority by "slow[ing] down," *id.*, "procedures … 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). These are exactly

the types of restraints and impediments that Congress expressly forbade. Thus, the Final Rule exceeds HHS's statutory authority and should be "set aside." 5 U.S.C. § 706(2)(C).

2. HHS cannot retreat to its general rulemaking authority as grounds for rewriting Congress's express prohibition against limiting States' authority. Section 1320d-7(b) nowhere "expressly delegate[s] to [HHS] the authority to give meaning to a particular statutory term," specifically "limit." *Loper Bright*, 603 U.S. at 394 (cleaned up). Indeed, that section contains no delegation of regulatory authority. Instead, HHS's authority to propose regulations governing "[t]he uses and disclosures of [health] information that should be authorized or required" is found elsewhere in HIPAA. Pub. L. No. 104-191 § 264(b)(3); *see also* 42 U.S.C. § 1320d-2. But the "statutes that *Loper Bright* cited as examples of delegations" warranting "deference don't only have broad language. They pair that language with words that expressly empower the agency to exercise judgment." *Moctezuma-Reyes v. Garland*, 124 F.4th 416, 420 (6th Cir. 2024). HIPAA's grants of rulemaking authority to HHS do not pair "broad language" with "words expressly empower[ing]" HHS to define "limit." Nor do they expressly sanction rules to restrict States' use or disclosure of health information for public health purposes. That lack of express authorization forecloses the Final Rule, since HHS "has no power to act … unless and until Congress confers power upon it." *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986).

Worse still for HHS, Congress made clear that "*[n]othing*" in HIPAA shall impose limits on States' authority with respect to policing public health and welfare. 42 U.S.C. § 1320d-7(b) (emphasis added). "Nothing" means nothing, including HHS's general authority to issue regulations and HIPAA's general preemption provision in § 1320d-7(a). So notwithstanding HHS's authority to issue certain regulations governing "[t]he uses and disclosures of [health] information that should be authorized or required," Pub. L. No. 104-191 § 264(b)(3), Congress specifically mandated that HHS's authority could not be wielded to override States' authorities recognized in § 1320d-7(b).

The novelty of HHS's disclosure limits on "reproductive health care" information reinforces

HIPAA's proper scope. "[W]hen an Executive Branch interpretation was issued roughly contemporaneously with enactment of the statute and remained consistent over time" it might be entitled to respect in interpreting the law. *Loper Bright*, 603 U.S. at 370. But the Final Rule comes well after HIPAA's enactment, and HHS admits that the rule was a direct response to the Supreme Court's decision in *Dobbs*. 89 Fed. Reg. at 32,987-88. Thus, HHS's position that the Final Rule's new limits on the disclosure and use of "reproductive health care" information do not conflict with Congress's contrary directive in 42 U.S.C. § 1320d-7(b) is not entitled to deference.

In any event, HIPAA authorizes HHS to promulgate "standards with respect to the privacy of individually identifiable *health* information." Pub. L. No. 104-191 § 264(a) (emphasis added). Nowhere does HIPAA authorize HHS to shield from authorities information that is not "health information." And the statute does not shield information that is evidence of legal wrongdoing under state law. Yet the Final Rule rests on the proposition that health information protected from disclosure to state authorities includes information that a State believes is "evidence" of a violation of state law. *See* 88 Fed. Reg. at 23,516. No fair reading of health information permits that view. And if Congress had meant to permit such a shield, it knew how. *See* Dkt #1-2 at 8 (citing Pub. L. No. 104-191 § 248(a)). But HIPAA has no express limitation for disclosures with respect to state-law investigations.

3. Bedrock interpretative cannons confirm that HHS lacks authority to specially restrict "reproductive health care" information under HIPAA. Start with the major questions doctrine. Congress is expected to "speak clearly when authorizing an agency" like HHS "to exercise powers of vast economic and political significance." *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 764 (2021) (per curiam) (internal quotation marks omitted). HHS admits that the Final Rule was a direct response to the Supreme Court's decision to return abortion regulation to the States, 89 Fed. Reg. at 32,987-88, and few issues in our nation's history match the "political significance" of abortion regulation. *See Dobbs*, 597 U.S. at 229 ("[*Roe v. Wade*] sparked a national controversy that has embittered our political culture

for a half century."). Thus, had Congress intended to empower HHS to regulate "reproductive health care" information differently than all other forms of patient health information under HIPAA it needed do so "clearly," not in a "cryptic … fashion." *West Virginia v. EPA*, 597 U.S. 697, 716, 721 (2022) (citations omitted). But HHS cannot point to *any* language—let alone clear text—conferring it with power to create heightened disclosure regimes for "reproductive health care" information.

Next, consider the federalism cannon. *See* Dkt. #1-2 at 8-11. "Congress should make its intention clear and manifest if it intends to preempt the historic powers of the States." *Will v. Mich. Dep't of State Police*, 491 U.S. 58, 65 (1989) (internal quotation marks and citation omitted). "This plain statement rule is nothing more than an acknowledgment that the States retain substantial sovereign powers under our constitutional scheme, powers with which Congress does not readily interfere." *Gregory v. Ashcroft*, 501 U.S. 452, 461 (1991). Public health, *Kentucky*, 23 F.4th at 599, and punishing "local criminal activity," *Bond*, 572 U.S. at 858, are core sovereign interests. And nothing in HIPAA provides clear notice that Congress intended to upend them. Rather, Congress expressly *preserved* States' power to obtain information from covered entities to promote these sovereign priorities. 42 U.S.C. § 1320d-7(b). Without "unmistakably clear language" in HIPAA countermanding Congress's otherwise expressed intent to preserve States' traditional authorities, HHS lacks statutory authority for the Final Rule. *See Gregory*, 501 U.S. at 460 (citation omitted).

Finally, constitutional-avoidance principles defeat any claim that the Final Rule's new disclosure limitations are lawful. "[W]here a statute is susceptible of two constructions, by one of which grave and doubtful constitutional questions arise and by the other of which such questions are avoided, [a court's] duty is to adopt the latter." *United States ex rel. Att'y Gen. v. Del. & Hudson Co.*, 213 U.S. 366, 408 (1909); *see also* Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 247 (2012). And if Congress had intended to grant HHS the power it claims under the Final Rule, significant concerns boil to the surface under the non-delegation doctrine and Due Process Clause.

Congress delegated some legislative power to HHS by directing the agency to address patients' rights under HIPAA, the "procedures that should be established for the exercise of such rights," and the "uses and disclosures" of patients' "information that should be authorized or required," Pub. L. No. 104-191 § 264(b). *See INS v. Chadha*, 462 U.S. 919, 952 (1983) ("legislative" acts have "the purpose and effect of altering the legal rights, duties and relations of persons ... outside the legislative branch."). But while Congress may "obtain[] the assistance of its coordinate Branches" by delegating legislative power, it must "lay down … an intelligible principle" to guide the delegee. *Panama Refin. Co. v. Ryan*, 293 U.S. 388, 429-300 (1935) (citation omitted). And without the constraints that Congress put in place under § 1320d-7(b), HHS's authority to set rules on the "uses and disclosures of [private] information" is essentially boundless, raising serious non-delegation concerns. *See id.*

The Final Rule also raises serious due-process questions, particularly given HIPAA's stiff criminal penalties. Most problematic, the Final Rule's "lawful"-care provision requires covered entities and state agencies to render layers of *legal* judgments on questions that are unsettled and beyond their ken. *See infra* 21-22. Given HHS's flip-flopping positions on issues like abortion and transgender-related care,[6] there is serious risk of "arbitrary and discriminatory enforcement" contrary to due process. *See Meriwether v. Hartop*, 992 F.3d 492, 518 (6th Cir. 2021). Applying the clear language of 42 U.S.C. § 1320d-7(b) and rejecting HHS's improper claim of authority under HIPAA in the Final Rule avoids these thorny constitutional questions. *See Jennings v. Rodriguez*, 583 U.S. 281, 286 (2018).

C. The Final Rule is arbitrary and capricious.

An agency action must stem from "reasoned decisionmaking," or else it is "arbitrary and capricious" and should be set aside. *See Atrium Med. Ctr. v. HHS*, 766 F.3d 560, 567 (6th Cir. 2014) (citation omitted). In promulgating a rule, an agency may not rely "on factors which Congress has

[6] *Compare*, *e.g.*, HHS, *Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37,522, 37,571-78 (May 6, 2024), *with* Executive Order 14,168, *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government* (Jan. 20, 2025), https://perma.cc/3XH2-YVYU.

not intended it to consider" or fail "to consider an important aspect of the problem." *Motor Vehicle Mfrs. Assn. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). But HHS did so here.

HHS allegedly sought to "strike an appropriate balance between ensuring health care privacy and conducting law enforcement activities." 89 Fed. Reg. at 32,993. To strike its asserted balance, HHS has imposed disclosure prohibitions related to "reproductive health care," a phrase HHS defined so as to sweep in nearly any form of health care. *See id.* at 33,063. After all, the human body's organ systems are interrelated, so nearly any healthcare "affects the health of an individual in [*some*] matters *relating to* the reproductive system and to its *functions* and *processes*." *Id.* (emphases added). That concern is not hypothetical: Health Facilities investigators, for example, have had requests for PHI related to a psychiatric facility denied. Zeigler Decl. ¶ 8-10. When commenters made HHS aware of that possibility, 89 Fed. Reg. at 33,006, HHS shrugged, *id.* at 33,007. So investigators and covered entities must sort things out among themselves without the guidance the APA requires from the agency. *See id.* at 33,063.

HHS's explanatory failures do not end there. The Final Rule requires PHI-request recipients to assess the legality of the "reproductive health care" involved in the request. *Id.* at 33,063. But, in general, request recipients will be medical, not legal, professionals, ill-suited to assessing law. *Purl*, 2024 WL 5202497, at *8. Making matters worse, the Final Rule forces request recipients to presume "reproductive health care" provided by others is lawful, unless the request recipient has "[a]ctual knowledge that the reproductive health care was not lawful" or the investigator "supplie[s]" sufficient "[f]actual information" to "demonstrate[] a substantial factual basis that the reproductive health care was not lawful." 89 Fed. Reg. at 33,063. That presumption applies even though instances of the Final Rule's "reproductive health care" are illegal in many jurisdictions, meaning health professionals making the assessment required by the Final Rule must *ignore* what they may know about the law. *See, e.g.*, Tenn. Code Ann. § 39-15-213(b). HHS officials have argued that some federal statutes preempt state

medical regulations in areas the Final Rule implicates. *E.g.*, Br. of U.S. at 20-27, *Moyle v. United States*, Nos. 23-726 & 23-727 (U.S. Mar. 21, 2024).

The upshot: Under the Final Rule, PHI-request recipients must presume some broadly defined category of "reproductive health care" is legal, even when it is not, and then do legal analysis, even though they are not lawyers, to fulfill a request. The Final Rule flunks rationality on those fronts.

Independently, the Final Rule's vesting of assessment power in PHI-request recipients has consequences HHS never considered, let alone adequately justified. The criminal liability attached to improper disclosure creates an incentive for PHI-request recipients to deny requests. *See* 42 U.S.C. § 1320d-6. Yet the Final Rule provides no recourse for a denied requestor to challenge the denial. *See* 89 Fed. Reg. at 33,063-66. HHS's choose-your-own-adventure approach perversely empowers suspected lawbreakers to hinder an investigation into themselves. Again, the Final Rule provides no justification for such a scheme, *see* 89 Fed. Reg. at 33,063-66, which thwarts the ancient maxim that "[n]o man is allowed to be a judge in his own cause." *The Federalist* No. 10, at 79 (James Madison) (Clinton Rossiter ed., 1961).

The Final Rule's paperwork gums up vital investigations without good reason. Investigators must attest that the Final Rule permits disclosure when there is a potential connection to "reproductive health care," which can encompass almost any request. *See* Zeigler Decl. ¶¶ 8-11. HHS has not explained how that scheme abides HIPAA's statutory prohibition on rules that "invalidate or limit" States' ability to regulate public health. 42 U.S.C. § 1320d-7(b). More mundane but more frequent is the Final Rule's requiring investigators to engage in difficult legal work just to get a request out the door. Spahr Decl. ¶¶ 15-20; Kreutz Decl. ¶¶ 10-14, 16-18. HHS did not adequately explain why those burdens on States' investigative authority are reasonable. And with all those burdens come costs, which HHS did not adequately account for.

II. The Entire Rule Should Be Vacated.

Section 706 of the APA instructs that reviewing courts "shall … hold unlawful and set aside agency action" that violates an agency's organic statute, the U.S. Constitution, or the APA's bar on arbitrary-and-capricious and procedurally invalid decision-making. 5 U.S.C. § 706(2). A vacatur order—unlike an injunction and other in personam relief—would act on the Final Rule itself by denying it legally operative effect and treating it as void as to all regulated parties. Vacatur is the "ordinary result" in APA cases challenging a Final Rule's statutory or constitutional authority and aligns with the APA's history and "countless decisions" from the Supreme Court that have "vacated agency actions, including agency rules." *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 829-33 (2024) (Kavanaugh, J., concurring) (collecting authorities); *see also Kiakombua v. Wolf*, 498 F. Supp. 3d 1, 52 (D.D.C. 2020) (Jackson, J.) (vacatur of a rule "for everyone" is normal APA remedy).

The Final Rule's legal flaws warrant vacatur across the board. *Cf. Ohio v. EPA*, 603 U.S. 279, 293-96 (2024); *Tennessee v. Cardona*, No. 24-5588, 2024 WL 3453880, at *4 (6th Cir. July 17, 2024). HHS's lack of statutory authority to adopt the Final Rule renders the Rule invalid and requires vacatur since an "illegitimate agency action is void *ab initio*" regardless of further agency justification. *Texas v. Cardona*, No. 4:23-cv-604-O, 2024 WL 2947022, *46 (N.D. Tex. June 11, 2024). Indeed, the core premise of HHS's Final Rule is an unlawful one: That HIPAA empowers HHS to create new categories of disclosure based upon substantive judgments about the value of particular medical procedures. So too, HHS's pervasive arbitrariness renders the Final Rule "invalid in its entirety." *Tennessee v. Cardona*, 737 F. Supp. 3d 510, 570 (E.D. Ky. 2024).

III. At a Minimum, Plaintiffs Are Entitled to Preliminary Relief.

Though this case is ripe for final judgment, this Court should at least enjoin the Final Rule's application to the Plaintiff States, their HIPAA-covered entities, and their investigative agencies. Or the Court should stay the Final Rule under 5 U.S.C. § 705. In addition to having likely merits success,

Plaintiffs satisfy the remaining preliminary-relief factors.

Irreparable Harm: The Final Rule has and will continue to inflict irreparable harms on the Plaintiff States. *First*, the Final Rule injures the Plaintiff States' sovereignty. States' sovereign police powers include powers to regulate "to promote the public health, the public morals, or the public safety," *Chicago, Burlington & Quincy Ry. Co. v. Illinois*, 200 U.S. 561, 592 (1906), and to punish "local criminal activity," *Bond*, 572 U.S. at 858. "[C]ontrol over the public fisc" is also "central to a state's sovereignty." *T.M. ex rel. H.C. v. DeWine*, 49 F.4th 1082, 1095 (6th Cir. 2022) (Readler, J., concurring). Yet the Final Rule infringes these interests. It hampers the Plaintiff States' ability to regulate to those ends by slowing or preventing state investigations, leaving patients and the public vulnerable. *See, e.g.*, Zeigler Decl. ¶¶ 8-11; Dietz Decl. ¶¶ 20-21; Joiner Decl. ¶¶ 8-9. And delays to billing-fraud investigations may impact the amount the States are ultimately able to recover. *See* Kreutz Decl. ¶ 20 (delay may push some misconduct outside the statute of limitations for recovery). Such "invasions of state sovereignty" are irreparable. *Kentucky*, 23 F.4th at 611 n.19.

Second, the Plaintiff States must expend resources to comply with the Final Rule's byzantine procedural burdens. *See, e.g.*, Kreutz Decl. ¶¶ 16-18; Spahr Decl. ¶ 15; Traxler Decl. ¶¶ 17-18; Targia Decl. ¶¶ 16-18. As HHS acknowledged, the Final Rule necessitates "new or modified policies and procedures" was well as "trainings." 89 Fed. Reg. at 33,056. And both covered entities and investigators have ongoing obligations to evaluate requests for information and attestations. Even if Plaintiff States later prevail against the Final Rule, they cannot recover money damages from the federal government. *Kentucky*, 23 F.4th at 611 n.19. Such "unrecoverable compliance costs" are irreparable harm too. *Kentucky v. Biden*, 57 F.4th 545, 555-56 (6th Cir. 2023).

Equities and Public Interest: Courts weighing the equities must consider "the competing claims of injury and ... the effect on each party of the granting or withholding of [that] requested relief." *Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 24 (2008) (citation omitted). Here, HHS would

suffer no harm from sticking to the scheme they themselves "designed" specifically to balance patients' privacy interests against State's investigatory authority. 65 Fed. Reg. at 82,683. Indeed, covered entities and State investigators have successfully operated under the Privacy Rule for a quarter century. By contrast, HHS previously warned that imposing disclosure requirements "significantly more" stringent than the Privacy Rule could "unduly compromise[]" States' "ability to protect the public interest." *Id.* That warning has proven prescient, *supra* 9-10 (collecting cites), as the Final Rule has significantly stymied the States' investigations into fraud, abuse, and other matters of public interest.

Preliminary relief also serves the public interest. The public has an interest in safe, professional medical care. Yet the Final Rule is halting investigations into fraud, abuse, and potential substandard care, preventing investigators from protecting the public fisc and ensuring the well-being of patients within their borders. HHS cannot credibly claim a countervailing public interest in promoting broader abortion access, since the Constitution leaves that choice to States. Regardless, Congress has not conferred HHS with "the power to regulate" in the challenged manner, so it is not courts' role to "weigh [the] tradeoffs" of HHS's pursuit of self-proclaimed "desirable ends." *Nat'l Fed'n of Indep. Bus. v. OSHA*, 595 U.S. 109, 120 (2022) (per curiam); *Ala. Ass'n of Realtors*, 594 U.S. at 766. By contrast, "'the public interest lies in a correct application' of the law." *Kentucky*, 57 F.4th at 556 (citation omitted). That is truer still when an agency's unlawful action "threatens state sovereign interests," *Kentucky v. Yellen*, 67 F.4th 322, 327 (6th Cir. 2023) (Bush, J., statement regarding denial of reh'g en banc)—as HHS's Final Rule does here, *supra* 11-12, 24.

CONCLUSION

For all these reasons, this Court should enter summary judgment for the Plaintiff States and set aside the Final Rule as unlawful. At a minimum, this Court should enter preliminary relief against the Final Rule pending the case's resolution.

Date: February 7, 2025

Respectfully submitted,

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*Admitted Pro Hac Vice
** Application for Pro Have Vice pending
*** Application for Pro Hac Vice forthcoming
**** Application for full admission pending

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served via the Court's electronic filing system on this 7th day of February, 2025 to all counsel of record. The document was further served via email on the following, who is representing the Defendants in two parallel challenges to the Final Rule in the United States District Court for the Northern District of Texas:

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EXHIBIT M

Declaration of Stephanie McGee Azar, Commissioner of the Alabama Medicaid Agency

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

STATES OF TENNESSEE, ALBAMA, 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. 25-cv-25

DECLARATION OF STEPHANIE MCGEE AZAR

Pursuant to 28 U.S.C. § 1746, I, Stephanie McGee Azar, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as the Commissioner of the Alabama Medicaid Agency. The Alabama Medicaid Agency is the single state agency charged with administering the Medicaid program in Alabama in accordance with Title XIX of the Social Security Act. Ala. Code §22-6-7(a). Two of the many responsibilities I oversee in administering the program are verifying whether services reimbursed were actually furnished to beneficiaries and responding to judicial demands. See 42 C.F.R. 455.1(a); 45 C.F.R. § 164.512.

3. The Program Integrity Division of the Alabama Medicaid Agency conducts investigations using methods that do not infringe on the legal rights of the persons involved. 42 C.F.R. §455.13(b)(1). One such method is requesting records from the provider to substantiate the medical necessity of services. The provider has a legal duty to maintain such records and furnish them to Medicaid. 42 C.F.R. §431.107(b)(1)-(2). These records may contain information possibly related to reproductive health care.

4. The Office of General Counsel of the Alabama Medicaid Agency responds to subpoenas issued by Courts of competent jurisdiction. Fed. R. Civ. P. 45(e)(1); Ala. R. Civ. P. 45(d). Medicaid redacts the information in subpoenas in accordance with federal and state law. *See* 42 C.F.R. §2.13(a); *See also* Ala. Code §22-11A-22. The subpoenas are often for claims data that is rife with information possibly related to reproductive health care.

5. I have reviewed the Department of Health and Human Services' *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the "Final Rule"), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024, *id.* at 32,976.

6. The Final Rule has created barriers to investigations and costs in complying with subpoenas.

7. Promulgated in response to the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), the Final Rule places limits on the disclosure and use of patient information related to "reproductive health care," which it broadly defines as "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.

8. Specifically, the Final Rule prohibits covered entities 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).

9. If the covered entity concludes that one of these two conditions exists, 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).

10. In making that assessment, 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 investigation by a State—unless the covered entity or business associate has either:

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

Id. § 164.502(a)(5)(iii)(C).

11. The covered entity that receives a request for PHI itself makes these determinations—including legal assessments of state and federal laws. And if the covered entity

determines that any of the conditions barring disclosure exist, it may deny the request. The Final Rule does not provide explicit recourse for the requesting entity.

12. Under the Final Rule, covered entities also must require attestations with a request for PHI that is potentially related to "reproductive health care" data. *Id.* § 164.509(a). Such attestations are required under the Final Rule even when regulatory conditions on disclosures for law enforcement purposes are otherwise met. *See id.*; *id.* § 164.512(f)(1)-(6)

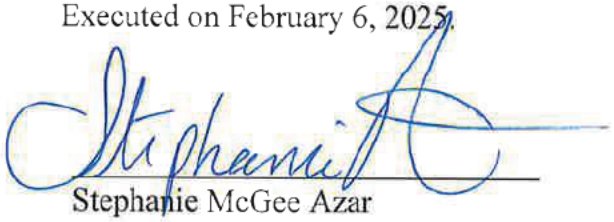
13. The Alabama Medicaid Agency has had to expend significant time and resources to determine how to comply with the Final Rule's requirements because they are vague and overbroad.

14. Through this vagueness, entities that are under investigation by the Program Integrity Division can slow the investigation by refusing to provide reproductive health care information even though it is not requested for a forbidden purpose. The only recourse the Alabama Medicaid Agency has to such a demand is to either seek an injunction in court or disenroll the provider for non-compliance with the provider agreement. *See* 42 C.F.R. §431.107(b)(1)-(2).

15. The overbroad requirements of the Final Rule now requires staff to expend much more time redacting information from lawful demands. Information potentially related to reproductive health care includes not only diagnosis such as contraception and birth, but also diagnosis such as dermatitis, cancer, or vomiting if the diagnosis is due to anything *possibly related* to reproductive organs or functions. The number of redactions required, and the time implementing those redactions, has ballooned. The sheer quantity of redactions has forced the Alabama Medicaid Agency to explore technological solutions so the limited staff can return their focus to streamlining the provision of healthcare payments for eligible Alabamians.

16. Ultimately, the Final Rule complicates the Alabama Medicaid Agency's response to judicial demands. Because of the Final Rule, responding to subpoenas will consume more resources than before the Final Rule's effective date. Because of that, the Final Rule is impacting the public health of the State of Alabama because it has added new expenses and staff resources that would otherwise be focused on health care.

Executed on February 6, 2025.



Stephanie McGee Azar

EXHIBIT K

Declaration of Nicholas J. Dietz, Louisiana Department of Health Medicaid Program Integrity Section Chief

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEEE
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. 25-cv-25

DECLARATION OF NICHOLAS J. DIEZ, ESQ.

Pursuant to 28. U.S.C. §1746, I, Nicholas J. Diez, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as the Louisiana Department of Health (LDH) Medicaid Program Integrity Section Chief. The Program Integrity Section exercises health oversight functions over persons and entities participating in the Louisiana Medicaid program, including healthcare providers enrolled with the Medicaid program and the Medicaid Managed Care Organizations (MCOs) that LDH has contracted with to administer the benefits provided to Louisiana Medicaid beneficiaries.

3. Pursuant to LSA - R.S. 36:254, LDH serves as the State Medicaid Agency (SMA) to coordinate with the federal government in the administration of the State's Medicaid program created under Title XIX of the Social Security Act.

4. Federal regulation requires LDH, as the SMA, to:

> (1) have methods and criteria for identifying suspected fraud cases and procedures for referring those cases to law enforcement officials;
> (2) to conduct preliminary investigations to determine whether a full investigation is warranted;
> (3) when warranted, conduct a full investigation until the matter is resolved through litigation or the matter is dropped because of insufficient evidence; and/or
> (4) in matters where fraud is suspected refer the case to the state Medicaid Fraud Control Unit (MFCU).

42 C.F.R. 455.12 – 455.16.

5. Program Integrity's primary function is to effectuate the aforementioned regulatory requirement to identify suspected cases of fraud, open preliminary and full investigations to ensure the benefits afforded to Louisiana Medicaid beneficiaries and paid for by the Medicaid program are provided in accordance with the law, regulations and rules governing the provision of services as required by 42 C.F.R. 455.1 *et seq,*, and when necessary, refer matters of suspected fraud to appropriate law enforcement authorities including the MFCU.

6. In addition, in Louisiana the Program Integrity Section is responsible for coordinating the Federal government's Payment Error Review Methodology to determine the error rate for which Medicaid payments are made, and conducted Medicaid Eligibility Quality Control function to identify vulnerable or error-prone areas in determining an individual's eligibility for Medicaid and the Children's Health Insurance Program.

7. In furtherance of these responsibilities, Program Integrity regularly requests information, records, and data from entities covered by the Health Insurance Portability and

Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (HIPAA), including the State's contracted MCOs and Medicaid providers. Such requests are often inclusive of Protected Health Information (PHI) protected by HIPAA.

8. For example, Program Integrity regularly requests medical records from providers, either directly or through the MCOs, when conducting its investigations and audits. This information is used to determine whether the provider complied with the specific rules governing the provision of Medicaid paid services. The records may be used to support administrative sanctions assessed on providers, or, where fraud is suspected, included with a referral to the MFCU or other appropriate law enforcement entities for possible criminal or civil investigations and litigation. Federal and Louisiana law requires Medicaid providers, MCOs, and MCO subcontractors to cooperate with these investigations and audits, and to provide Program Integrity with access to any relevant records upon request. See 42 C.F.R. §§ 438.3(h), 438.230(c)(3); LSA – R.S. 46:437.12(5); LAC (Louisiana Administrative Code) 50:I.4129, 50:I.4147(A)(21).

9. I have reviewed the Department of Health and Human Services' *HIPAA Privacy Rule to Support Reproductive Health Care Privacy,* 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the "Final Rule"), which took effect on June 25, 2024, with a compliance deadline of December 23, 2024. Specifically, the Final Rule places limits on disclosure and use of patient information "potentially related to reproductive health care," which it broadly defines as "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.

10. The Final Rule creates unnecessary barriers to Program Integrity's oversight of the MCOs and Program Integrity's investigations and audits. It impedes Program Integrity's ability to adequately conduct reviews of Medicaid paid services and coordinate with law enforcement

entities for any false or fraudulent claims submitted to the Medicaid program.

11. According to the Final Rule, it specifically applies to requests for health oversight activities and covered entities are prohibited from disclosing PHI where it will be used:

> (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; or
> (3) To identify any person for either of the above described purposes.

45 C.F.R. § 164.502(a)(5)(iii)(A).

12. If the covered entity concludes that one of these conditions exists, 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).

13. In making that assessment, 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 investigation by a State—unless the covered entity or business associate has either:

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

Id. § 164.502(a)(5)(iii)(C).

14. Pursuant to the Final Rule, the covered entity to whom the request is made makes the determination, including legal assessments of state and federal law, of whether the reproductive

healthcare provided was lawful. If the covered entity determines that any of the conditions barring disclosure exist, it may deny the request. The Final Rule does not provide recourse for the requesting entity.

15. Additionally, the Final Rule requires the covered entity to obtain an attestation with a request for PHI for health oversight purposes (among other purposes) that is potentially related to reproductive healthcare, regardless of other HIPAA provisions applicable to such disclosures. 45 C.F.R. § 164.509(a)(1). Because the Final Rule requires a new attestation for each specific request (89 FR 33030-33031) and specifically prohibits combining the attestation with any other form (45 C.F.R. § 164.509(b)(3)), we are unable to incorporate the attestation into our standard information request. The Final Rule also requires Program Integrity staff to attest, upon pain of criminal penalty, to facts that are unknowable in the beginning stages of an investigation or audit.

16. In its commentary to the Final Rule, the U.S. Department of Health and Human Services (HHS) specifically states that an attestation is required for SMA requests. In response to a request for additional examples for when an attestation is required, HHS stated that, "a regulated entity may disclose PHI to a state Medicaid agency in accordance with 45 CFR 164.512(d) where the purpose of the request is to ensure that the regulated entity is providing the reproductive health care for which the regulated entity has submitted claims for payment to Medicaid **after obtaining an attestation that meets the requirements of 45 CFR 164.509** from the state Medicaid agency." 89 FR 33041 (emphasis added).

17. Even if an attestation is provided, the covered entity is given the discretion to determine whether the attestation is not defective and whether the conditions of disclosure are met, essentially operating as a *de facto* veto on Program Integrity's audits and investigations.

18. Given the criminal liability associated with HIPAA violations, my team will have to consult extensively with LDH's legal counsel to determine whether it is possible to comply with the Final Rule's attestation requirements without triggering potential criminal liability.

19. The Final Rule also serves to abrogate various provisions within the MCO contracts and the State's Medicaid provider agreements that require the MCOs and Medicaid providers to provide direct access to documents related to services paid with Medicaid program funds. Because the covered entity makes the final determination as to whether the purpose of the request satisfies the conditions for production, any MCO or healthcare provider can cause unnecessary delay in our investigative actions.

20. At least one MCO in Louisiana has advised Program Integrity that it takes the position that, due to the breadth of the requirement that an attestation is required for any information request "potentially related to reproductive healthcare" almost all requests from Program Integrity will need to be accompanied by an attestation in the form required by HHS.

21. I am also aware of nine current investigations by Louisiana's MFCU that are being hindered by that same MCO's insistence on receiving an attestation before disclosing the requested records to the MFCU.

22. As a result, the Final Rule has complicated and hampered Program Integrity's ability to conduct its oversight responsibilities related to the State's Medicaid program.

Nicholas J. Díez

Dated: February 5, 2025

EXHIBIT D

Comment of Ethics and Public Policy Center Re: "HIPAA Privacy Rule To Support Reproductive Health Care Privacy," RIN 0945-AA20

ETHICS AND PUBLIC POLICY CENTER

June 16, 2023

Via Federal eRulemaking Portal

Xavier Becerra
Secretary
Attn: HIPAA Privacy Rulemaking
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: EPPC Scholars Comment Opposing "HIPAA Privacy Rule To Support Reproductive Health Care Privacy," RIN 0945-AA20

Dear Secretary Becerra:

We are scholars at the Ethics and Public Policy Center (EPPC), and we write in strong opposition to the Department of Health and Human Services' ("HHS") Proposed Rule "HIPAA Privacy Rule To Support Reproductive Health Care Privacy" ("Proposed Rule").[1]

Eric Kniffin is an EPPC Fellow, member of EPPC's HHS Accountability Project, and a former attorney in the U.S. Department of Justice's Civil Rights Division. For more than a decade, Eric has represented plaintiffs seeking judicial relief from the Departments' contraceptive mandate, as counsel for the Becket Fund and in private practice. Natalie Dodson is a Policy Analyst and member of EPPC's HHS Accountability Project.

We offer this public comment to make a record regarding the Proposed Rule's many and serious flaws. First, the Department has failed to establish a need for the Proposed Rule: its self-serving conjectures and its reliance on reaction pieces from last summer do not establish that the current Privacy Rule is causing "confusion." Second, even if the current rule causes "confusion," the Proposed Rule makes the Privacy Rule worse by introducing a number of critical terms that are either poorly defined or not defined at all. Third, the Proposed Rule will also create more confusion by greatly complicating the decision-making process a covered entity must undergo when deciding whether to use or disclose PHI.

But the Proposed Rule does not merely make the Privacy Rule more confusing and complicated. Covered entities must navigate this confusion knowing that HHS—the federal agency responsible for writing, finalizing, interpreting, implementing, and enforcing the Privacy Rule—is openly hostile to state efforts to protect unborn human life, protect minors from life-altering "gender transition" procedures, and other related state interests recognized by the Supreme Court in *Dobbs v. Jackson Women's Health Org.* Given the political content in the Proposed Rule, given the Department's wide-ranging authority to interpret and enforce these vague rules, and given the considerable civil, criminal, and professional consequences that come with adverse HIPAA determination under the Privacy Rule, we fear that the Privacy Rule would chill health care professionals from cooperating with legal and legitimate state

[1] 88 Fed. Reg. at 23506.

activities that stem from their traditional police powers, which include promoting the public health, morals, or safety, and the general well-being of the community.

For all these reasons, The Department should abandon and withdraw the Proposed Rule.

I. HHS has failed to establish a need for the Proposed Rule.

Federal administrative agencies are required to engage in "reasoned decision making."[2] This obligation requires a federal agency to identify the problem it intends to address.[3] To justify replacing current regulations, an agency must provide specific evidence as to how the current regulations are causing harms or burdens and how the Proposed Rule would remedy the alleged defects *without* causing equal or greater harms and burdens.[4] For this Proposed Rule, HHS has failed to meet that exacting standard in every respect. Specifically, HHS has failed to provide concrete evidence that the Privacy Rule as it currently exists has or will cause harm or burdens necessitating the need for this rulemaking and that the proposed regulations will remedy that harm.

A. The Proposed Rule asserts, but fails to establish, that the Supreme Court's *Dobbs* decision has created a need for new rulemaking.

HHS's justification for this Proposed Rule centers around the Supreme Court's June 2022 decision in *Dobbs v. Jackson Women's Health Org,*[5] which is referenced *nineteen times* in the preamble. Though the Proposed Rule was issued less than ten months after the *Dobbs* decision, HHS claims that it has already "carefully analyzed" the issue.[6] However, the Proposed Rule's preamble does not demonstrate any actual problem that needs to be solved.

Much of the Department's supposed justification for the Proposed Rule is built on other groups' short-term reactions to and unsupported claims about *Dobbs'* impact. HHS cites a Consumer Reports piece published *the same day* as *Dobbs*,[7] a JAMA Network article published *seven days* later,[8] a New Yorker piece published *eight days* after *Dobbs* decision,[9] and a blog post from the Federal Trade Commission released *twenty-one days* after *Dobbs*.[10] HHS relies on *at least eleven other reports* published in the summer of 2022.[11]

The Department also relies on a "recently filed complaint" where a plaintiff alleges that her health-care provider falsified medical records because of *Dobbs.*[12] Falsifying medical records is a felony under 18 U.S.C. § 1035 and remains such after *Dobbs*. It is not clear whether the HHS had this or other crimes in mind when the Proposed Rule states, without citation, that "[r]ecent state actions now place

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[2] *Michigan v. E.P.A.*, 576 U.S. 743, 750 (2015).
[3] EO 12866 § 1(b) (establishing the principles of regulation, including that "Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.").
[4] *Michigan*, 576 U.S. at 779 (regulation is irrational if it disregards the relationship between its costs and benefits); *Alltelcorp v. FCC*, 838 F.2d 551, 561 (D.C. Cir. 1988) ("a regulation perfectly reasonable and appropriate in the face of a given problem is highly capricious if that problem does not exist").
[5] 142 S. Ct. 2235 (2022).
[6] 88 Fed. Reg. at 23510.
[7] 88 Fed. Reg. at 23519 n.162.
[8] *Id*.
[9] 88 Fed. Reg. at 23509 n.25.
[10] 88 Fed. Reg. at 23510 n.28.
[11] *See*, for example, 88 Fed. Reg. at 23519 nn. 163, 166, and 169, *id*. at 23520 nn. 171 and 174.
[12] 88 Fed. Reg. at 23519 and n.180.

individuals and health care providers in potential civil or criminal jeopardy when PHI related to an individual's reproductive health is used and disclosed."[13] Nonetheless, it is difficult to understand how these alleged crimes justify the Proposed Rule.

The Department also relies on its own conjectures about *Dobbs'* impact. For example, HHS claims, "we ***believe it may be necessary*** to modify the Privacy Rule" to prevent people from seeking PHI "for a non-health care purpose where such use or disclosure would be detrimental to any person.[14] HHS is likewise concerned about what actions state actors "***may attempt***" in their efforts to enforce state laws, and furthermore surmises that such law enforcement efforts are "***likely to chill*** individuals' willingness to seek lawful treatment or to provide full information to their health care providers."[15] HHS claims that new laws passed after *Dobbs* "***raised the prospect*** that highly sensitive PHI would be disclosed"[16] and that such laws "***could interfere*** with individuals' longstanding expectations." It worries about what health care entities "***might be compelled***" to do.[17] The Department's guesswork does not provide an adequate basis for the proposed rulemaking.

Having relied on reaction pieces and the Department's own conjectures, HHS somehow arrives at certain conclusions. The preamble claims that the Department has "determined . . .. that information about reproductive health care . . . requires heightened protections."[18] It claims that the *Dobbs* decision makes PHI related to "reproductive health care" "is now more acute than it was before."[19] It states that because of Dobbs "effectuating the purposes of HIPPA now "require[s] regulatory provisions that restrict[] uses and disclosures of PHI related to [reproductive health care]."[20] But these bold, unsupported conclusions are not enough to meet HHS' legal obligation to justify new rulemaking. The Department's failure to justify the proposed rulemaking renders the Proposed Rule arbitrary and capricious under the Administrative Procedure Act.

II. The Proposed Rule makes the HIPAA Privacy Rule more, not less, confusing.

The Department's main argument throughout the preamble is that the Proposed Rule is needed to ameliorate alleged confusion about the HIPAA Privacy Rule in the wake of the *Dobbs* decision. HHS says *Dobbs* and subsequent legal developments have created "significant confusion for individuals, health care providers, family, friends, and caregivers regarding their ability to privately seek, obtain, provide, or facilitate health care."[21] More specifically, HHS claims "regulated agencies" have expressed "confusion and concern as to the[ir] ability . . . to use or disclose PHI for" "criminal, civil, or administrative investigations into or proceedings about that health care."[22] HHS claims that its Proposed Rule provides the "further clarification . . . needed to resolve this confusion and strengthen privacy protections."[23]

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[13] 88 Fed. Reg. at 23519.
[14] 88 Fed. Reg. at 23507 (emphasis added).
[15] *Id*. (emphases added).
[16] *Id*. at 23509 (emphasis added).
[17] *Id*. at 23519 (emphasis added).
[18] Id. at 23510.
[19] Id. at 23510.
[20] 88 Fed. Reg. at 23519.
[21] 88 Fed. Reg. 23509. *See also id.* at 23520 (claiming there is "ambiguity and confusion for individuals and health care providers . . . about when health information is protected under the HIPAA Rules"); *id*. at 23548 (alleging "significant confusion about the extent to which reproductive health care information is protected by the Privacy Rule").
[22] 88 Fed. Reg. 23528.
[23] 88 Fed. Reg. 23509.

As shown above, the Proposed Rule does not demonstrate that there is a problem that needs to be solved. But even if it had, federal agencies must also "offer[] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."[24] An agency must "articulate a satisfactory explanation for its action," including a "rational connection between the facts found and the choice made."[25]

Because this alleged "confusion" plays such a prominent role in HHS' justification for its Proposed Rule, it is important to highlight the mind-numbing confusion that the Proposed Rule *would create.* This is most easily seen through the Proposed Rule's additions to the Privacy Rule, which center on vague and undefined terms.

The byzantine complexity the Proposed Rule would create for covered entities stands in sharp contrast to the Department's own requirement that state law enforcement actions justify their requests for PHI in "plain language." The Proposed Rule's attestation requirement (§ 164.509) states that a covered entity may not comply with a "subpoena, discovery request, or other lawful process" that requests "protected health information potentially related to reproductive health care" unless the request and justification is "written in plain language." As the following examples show, the Proposed Rule fails the "plain language" test.

A. The Proposed Rule contains broadly defined and vague terms.

1. Public Health

The Department redefines "public health," as used in the terms "public health surveillance," "public health investigation," and "public health intervention," to "population-level activities to prevent disease and promote health of populations."[26] These activities, however, explicitly exclude "uses and disclosures for the criminal, civil, or administrative investigation into or proceeding against a person in connection with obtaining, providing, or facilitating reproductive health care" and "for the identification of any person in connection with a criminal, civil, or administrative investigation into or proceeding against a person in connection with obtaining, providing, or facilitating reproductive health care."[27] In short, the Proposed Rule has defined "reproductive health care" and abortion out of the definition of "public health."[28] Not only is this definitional change arbitrary and capricious on simply a surface level reading of the text, but the administration has repeatedly included "reproductive health care" and abortion as part of "public health more broadly."[29] This limitation inhibits state health departments' collection of health data and investigations and enforcement of health and safety regulations.

2. Person

The Privacy Rule defines "person" as "natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private."[30] The Proposed Rule adds to

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[24] *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Automobile Ins. Co*., 463 U.S. 29, 43 (1983).
[25] *Id*.
[26] 88 Fed. Reg. 23525.
[27] *Id*. at 23552.
[28] *Id*.
[29] Executive Order on Protecting Access to Reproductive Healthcare Services, https://www.whitehouse.gov/briefing-room/presidential-actions/2022/07/08/executive-order-on-protecting-access-to-reproductive-healthcare-services/, Executive Order on Securing Access to Reproductive and Other Healthcare Services, https://www.whitehouse.gov/briefing-room/presidential-actions/2022/08/03/executive-order-on-securing-access-to-reproductive-and-other-healthcare-services/.
[30] 88 Fed. Reg. 23523.

the definition of "person," by specifying that a "natural person" means "a human being who is born alive."[31] According to the Proposed Rule, "natural person…does not include a fertilized egg, embryo, or fetus."[32] This addition to the previously held definition is not only inconsistent with Congressional intent and federal law, but it would also create confusion and tension for state laws that define "person" to include the unborn.

In 2019, HHS, under the Trump administration, enforced HIPAA against a Florida medical center for failing to provide a mother timely access to prenatal health records for her unborn child.[33] The Proposed Rule, in contrast, will directly exclude unborn children from HIPAA protections. The Resolution Agreement, in the 2019 case, by treating the unborn as any other human person under HIPAA, established a precedent of including the unborn in the law's protections.[34] The Department is now bypassing this standard without regard to this previous action by the same Department. The Department's justification for this redefinition of "person" is not only unsubstantiated by law but is also a reversal of the 2019 HHS enforcement of HIPAA. Rather than taking into consideration this 2019 case, the Department does not mention it and instead opts to create a new definition that is discriminatory by defining away the rights of the unborn.

The Department states that it is "clarifying the definition of ''person'' to reflect longstanding statutory language defining the term," but the Department fails to cite any of this "longstanding language," other than 1 U.S.C. § 8, and instead simply asserts that such "language" exists.[35] Moreover, 1 U.S.C. § 8 does not exclude the unborn from the definition of "person."[36] To the contrary, that statute clearly states that "[n]othing in this section shall be construed to affirm, deny, expand, or contract any legal status or legal right applicable to any member of the species homo sapiens at any point prior to being 'born alive' as defined in this section."[37] The Department also justifies its definition based on another law, the Social Security Act of 1935, that *does not specify* whether unborn human beings are included in the definition of "person" that "person" under HIPAA does not include the "unborn."[38] If the Department was creating "consistent" language in federal law such a redefinition could be admirable, but instead the Department is misinterpreting or misrepresenting its cited authority.

Moreover, the Department ignores two other federal statutes that support a different definition of "person." First, the *Genetic Information Nondiscrimination Act of 2008* not only includes explicit discussion of the "fetus" and "embryo" but also specifically protects the data of unborn persons.[39] Additionally, the *National Childhood Vaccine Injury Act* covers the unborn person independently for vaccine injuries due to maternal vaccination.[40] These two examples, among others, demonstrates that Congress does consider the interests of unborn human beings when it uses the term "person" in the health care context. The better reading of HIPAA is that the law looks out for the interests of the unborn, not exclude them.

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[31] *Id*. at 23552.
[32] 88 Fed. Reg. at 23523.
[33] OCR Settles First Case in HIPAA Right of Access Initiative, Archived HHS Content, https://public3.pagefreezer.com/browse/HHS.gov/31-12-2020T08:51/https:/www.hhs.gov/about/news/2019/09/09/ocr-settles-first-case-hipaa-right-access-initiative html.
[34] Resolution Agreement, September 6, 2012, https://public3.pagefreezer.com/browse/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/sites/default/files/bayfront-st-pete-ra-cap.pdf.
[35] 88 Fed. Reg. at 23522.
[36] *Id*. at 23523.
[37] 1 U.S.C. §8(c).
[38] 88 Fed. Reg. at 23523.
[39] PUBLIC LAW 110–233, 122 Stat. 885.
[40] 42 USC 300aa-11.

Furthermore, since the Supreme Court decided *Dobbs* last summer, many states have passed or begun implanting laws that define "person" to include the unborn. One Wyoming law invokes the state's constitution to define "person" to include "the life of an unborn baby."[41] Idaho law recognizes that a "fetus" or a "preborn child" is "an individual organism of the species Homo sapiens from fertilization until live birth."[42] South Dakota has de facto included the unborn as a person by signing a law that states an "[u]nauthorized abortion [is a] felony."[43] The same law also states that "any person who intentionally kills a human fetus by causing an injury to its mother, which is not authorized by chapter 34-23A, is guilty of a Class 4 felony."[44] Another South Dakota law also defines a "human being" as "an individual living member of the species of Homo sapiens, including the unborn human being during the entire embryonic and fetal ages from fertilization to full gestation" and defines an "abortion" as "the intentional termination of the life of a human being in the uterus." [45] Texas defines "unborn child" as an "individual living member of the homo sapiens species from fertilization until birth, including the entire embryonic and fetal stages of development."[46] Finally, Arkansas defines the "unborn child" to mean "an individual organism of the species Homo sapiens from fertilization until live birth."[47] These are just a few examples of the many state laws that recognize that an unborn child is a "person," a "human being," or a member of the species "homo sapiens."[48]

Not only is the Proposed Rule's definition of "person" inconsistent with "longstanding" federal laws, but the Department's definition also conflicts with the considered judgment of at least a third of the states. This Proposed Rule creates profound conflicts with state and federal laws. This contrived and politically motivated definition of "person" lacks Congressional intent. It is, therefore, arbitrary and capricious for the Department to subsume the responsibilities of Congress to define "person." HHS should reject this unjustified and unscientific definition of "person" for purposes of the HIPAA Privacy Rule. This unjust and unjustified definition should likewise not be adopted by other agencies.

3. Reproductive Health Care

The Proposed Rule also offers broad definitions of "health care" and "reproductive health care." First, the Department defines "health care" to include "supplies purchased over the counter or furnished to the individual by a person that does not meet the definition of a health care provider."[49] Under the definition of "health care," the Department adds in the Proposed Rule, "a subcategory" called "reproductive health care."[50] The Proposed Rule's definition of "reproductive health care" includes all "care, services, or supplies related to the reproductive health of the individual."[51]

The Department admits that "reproductive health information is not easily defined or segregated."[52] Indeed, the Department's proffered definition of "reproductive health care," bolstered by

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[41] Wyoming; HB0152.
[42] Idaho Code Ann. § 18-8801.
[43] S.D. Codified Laws § 22-17-5.1.
[44] *Id*.
[45] S.D. Codified Laws § 34-23A-1.
[46] Tex. Health & Safety Code Ann. § H-2-170.A.001.
[47] Ark. Code § 5-61-303.
[48] LA. REV. STAT. ANN. § 40:1061, Wis. Stat. Ann. § 940.04, Ky. Rev. Stat. Ann. § 311.772, Tenn. Code Ann. § 39-15-213, Miss. Code Ann. § 41-41-45, ALA. Admin. Code § 26-23H 1-8, and W. Va. Code Ann. § 16-2R-1, to 16-2R-7. Some of these state laws find their definition of person and the protection of the unborn from the point of conception in their state constitutions.
[49] 88 Fed. Reg. at 23527.
[50] *Id*.
[51] *Id*.
[52] 88 Fed. Reg. at 23521.

commentary and examples throughout the preamble, subsume a wide swath of activities that few would include under this category.

The Department's definition begins with § 160.103, which states that "reproductive health care includes all "care, services, or supplies related to the reproductive health of the individual." The Department asserts that this definition, like its definition of "health care," "applies broadly."[53] Though the Department's focus on Dobbs shows it is primarily focused on abortion, this definition of "reproductive health care" would not only cover surgical and chemical abortion, it would also cover contraception, emergency contraception, IVF treatments, pregnancy, miscarriage, fertility treatments, and sterilizing treatments.

The Proposed Rule also states that "reproductive health care" can be "related to reproductive organs, regardless of whether the health care is related to an individual's pregnancy or whether the individual is of reproductive age."[54] This is a clear indication that the Proposed Rule would also cover drugs and surgeries related to "gender transition," as puberty blockers, cross-sex hormones, and the removal of reproductive organs are all "health care related to reproductive organs." Pro "gender transition" advocacy groups are already celebrating that the Proposed Rule would cover not just "abortion and reproductive health care" but also "gender affirmation."[55]

The Department also says that "reproductive health care" includes "supplies furnished by other persons and non-prescription supplies purchased in connection with an individual's reproductive health."[56] The decision to include non-prescription items as "health care" paves the way for future regulations that would allow non-health care providers to distribute abortion-inducing drugs and other drugs such as puberty blockers, which as shown below qualify under the Department's expansive definition of "reproductive health care." Lowering health care standards and encouraging "self-managed" abortions[57] puts the Department's progressive political agenda ahead of what should be the Department's focus: protecting the health of women and children.

4. Seeking, Obtaining, Providing, or Facilitating

As if its definition of "reproductive health care" was not broad enough on its own, the proposed additions to the Privacy Rule would also extend to the "seeking, obtaining, providing, or facilitating" of reproductive health care.[58] Section 164.502(a)(5)(iii)(B) defines "seeking, obtaining, providing, or facilitating" as including, but not limited to, any of the following:

> expressing interest in, inducing, using, performing, furnishing, paying for, disseminating information about, arranging, insuring, assisting, or otherwise taking action to engage in reproductive health care; or attempting any of the same.

Put together, these provisions offer fifteen verbs to extend the reach of its protections for "reproductive health care"-related PHI. Each of these terms has a broad range of meanings, and it is beyond the scope of this public policy to explore them all. But perhaps one of the most problematic terms is "inducing," which means to "succeed in persuading or influencing (someone) to do something." As such, the Proposed Rule

[53] *Id*.
[54] 88 Fed. Reg. at 23527.
[55] Comment from American Academy of Family Physicians, HHS-OCR-2023-0006, HHS-OCR-2023-0006-0001, 2023-07517, https://www.regulations.gov/comment/HHS-OCR-2023-0006-0062.
[56] *Id*.
[57] 88 Fed. Reg. at 23519 and 21.
[58] § 164.502(a)(5)(iii)(A).

would prohibit covered entities from complying with subpoenas seeking information on whether someone was coerced into getting an abortion, which is a crime in most (if not all) states.

B. These critical terms are qualified by words and phrases that are not defined at all.

Unfortunately, it gets even worse. The Proposed Rule would not only force covered entities to wrestle with these poorly defined terms: the Proposed Rule also qualifies these terms with words and phrases that are themselves not defined and susceptible to a wide range of interpretations.

Under the Proposed Rule, covered entities would have to make judgment calls about the following issues:

- When is a "use[] and disclosures" of PHI "***for*** [a] criminal, civil, or administrative investigation"? (§ 160.103)
- When is a "report of abuse, neglect, or domestic violence [] ***based primarily on*** the provision of reproductive health care"? (§ 164.512(c)(3))
- When is PHI "***potentially related to*** reproductive health care"? (§164.509(a))
- When is a request for PHI "***in connection with*** a criminal, civil, or administrative investigation"? (§ 160.103)
- When is a request for PHI **"*in connection with*** obtaining, providing, or facilitating reproductive health care"? (§ 160.103)
- When is a request for PHI "***in connection with*** seeking, obtaining, providing, or facilitating reproductive health care"? (§ 164.502(a)(5)(iii)(A))
- When is a request for PHI "***in connection with*** any person seeking, obtaining, providing, or facilitating reproductive health care" § 164.502(a)(5)(iii) (C)
- What is the legal difference between these ***three nearly-identical phrases***?
- "in connection with obtaining, providing, or facilitating reproductive health care;"
- "in connection with ***seeking***, obtaining, providing, or facilitating reproductive health care;" and
- "in connection with ***any person seeking***, obtaining, providing, or facilitating reproductive health care."
- When is a use or disclosure of PHI "***primarily*** for the purpose of investigating or imposing liability on any person"? (§ 164.502(a)(5)(iii)(D))
- When is an investigation or legal action "***for*** the ***mere act*** of seeking, obtaining, providing, or facilitating reproductive health care"? (§ 164.502(a)(5)(iii)(D))
- When is a use or disclosure of PHI "***primarily for*** the purpose of investigating or imposing liability on any person"? (§ 164.502(a)(5)(iii)(D))

It would be impossible for a covered entity to understand its new obligations under this Proposed Rule without understanding these phrases: "***for***," "***based primarily on***," "***potentially related to***," "***in connection with,***" "***mere act***" and "***primarily for***." And yet, none the Proposed Rule defines any of these critical terms.

III. The Proposed Rule complicated covered entities' decision-making process under the Privacy Rule.

The poorly defined terms and criteria described above are only part of the changes the Proposed Rule would introduce into the Privacy Rule. New substantive provisions, together with these new terms and criteria, create a new decision-tree for covered entities that is far more complicated and ill-defined than the process health care entities are accustomed to. The following is our effort to set out the questions

that covered entities would, under the Proposed Rule, have to ask and answer each time they are presented with a potential use or disclosure of PHI.

A. The Proposed Rule would make it harder for a covered entity to determine whether a proposed use or disclosure of PHI is permitted under the Privacy Rule.

HIPAA's Privacy Rule starts with the default rule that it is illegal for covered entities to use or disclose PHI except as permitted by § 164.502 or by 45 CFR Subpart C, which deals with HHS compliance and investigations.[59] Presently, a covered entity must determine if a potential use or disclosure falls under one of the categories set out in § 164.502(a)(1) or incorporated into that list by reference, especially § 164.512.

The Proposed Rule would make three important changes to § 164.512. First, the entire section is now subject to the new Reproductive Health Care Rule at § 164.502(a)(5)(iii), which is addressed separately below. Second, some *but not all* provisions in § 164.512 are subject to the new Attestation Requirement, § 164.509, which is also addressed below.

Third, the Proposed Rule would add a new Rule of Construction that *only* applies to § 164.512(c), which covers disclosures about *non-child* victims of abuse, neglect, or domestic violence. Though the first change to § 164.512 states that *all of* this section is now subject to the new Reproductive Health Care Rule, this third change says that nothing in § 164.512(c) permits disclosures prohibited by the Reproductive Health Care Rule "when the report . . . is based primarily on the provision of reproductive health care." As noted above, these terms will cause confusion. But seemingly irreconcilable additions to § 164.512 will doubtless leave covered entities befuddled:

- If *all* of "the situations covered by" § 164.512 are now subject to the Reproductive Health Care Rule, what is the point of the Rule of Construction, which says that *some* of the situations covered § 164.512(c) are subject to the Reproductive Health Care Rule?

- How should a covered entity determine whether a "report of abuse, neglect, or domestic violence" is "based primarily on the provision of reproductive health care," the standard set out in the Rule of Construction in § 164.512(c)?

- Given that the Proposed Rule defines "reproductive health care" to include "care . . . related to the reproductive health of the individual,"[60] and given that the definition of "care" includes "regard coming from desire or esteem,"[61] is not *all* sexual abuse "based primarily on the provision of reproductive health care"?

- If a covered entity decides that a "report of abuse, neglect, or domestic violence" is *not* "based primarily on the provision of reproductive health care," the standard set out in the Rule of Construction in § 164.512(c), is it possible that disclosure could still be "for a[n] investigation into . . . a person in connection with seeking, obtaining, providing, or facilitating reproductive health care," the standard set out in § 164.502(a)(5)(iii)(A)(1)?[62] If so, what is the difference between these two standards?

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[59] 45 CFR § 164.502(a).
[60] § 160.103.
[61] Care, Merriam-Webster, https://www merriam-webster.com/dictionary/care.
[62] The Surplusage Canon (*verba cum effectu sunt accipienda*) would seem to necessitate this possibility.

- If a covered entity decides that a "report of abuse, neglect, or domestic violence" is *not* "based primarily on the provision of reproductive health care," the standard set out in the Rule of Construction in § 164.512(c), is it possible that disclosure could still be "for a[n] investigation into . . . a person in connection with seeking, obtaining, providing, or facilitating reproductive health care," the standard set out in § 164.502(a)(5)(iii)(A)(1)?[63] If so, what is the difference between these two standards?

- If a covered entity decides that a "report of abuse, neglect, or domestic violence" is *not* "based primarily on the provision of reproductive health care," the standard set out in the Rule of Construction in § 164.512(c), is it possible that disclosure could still be "primarily for the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care," the standard set out in § 164.502(a)(5)(iii)(D)? [64] If so, what is the difference between these two standards?

Contrary to HHS's representation, these proposed changes to the Privacy Rule would not give covered entities "further clarification"[65] on how to determine whether a proposed use or disclosure of PHI is permitted under 45 CFR § 164.512.

B. The proposed Attestation Requirement would make it more dangerous and complicated for law enforcement to request PHI, and more dangerous and complicated for covered entities to respond to such requests.

The proposed Attestation Requirement, §264.509, likewise will make it more complicated for law enforcement entities to pursue and for covered entities to cooperate with critical public health priorities related to sexual crimes. Law enforcement would have to balance important interests related to keeping activities confidential with new obligations to explain themselves to covered entities. Covered entities will have to make difficult assessments about whether proffered attestations meet the vague standards of the proposed Reproductive Health Care Rule. Covered entities will also have to weigh the risks of being held in contempt of court for refusing a valid subpoena against the risks of HHS bringing an enforcement action for complying with the valid subpoena.

Suppose a prosecutor presents a hospital with a subpoena seeking PHI related to an alleged crime. Presuming that the subpoena is clearly for a judicial and administrative proceeding (§ 164.512(e)) or for law-enforcement purposes (§ 164.512(f)), the hospital will have to determine whether the PHI sought is "potentially related to reproductive health care." If the hospital thinks the PHI sought qualifies—or, more to the point if the covered entity is afraid that HHS might declare that the PHI qualifies—the hospital will have to refuse to comply with the court order unless the prosecutor supplies an attestation. If the prosecutor refuses to do so—because she determines that the subpoena does not seek information "potentially related to reproductive health care," or else because she finds the attestation requirement unlawful or unnecessary for other reasons—the hospital will have to choose between defying a court order and risking a HIPAA violation.

If the prosecutor agrees to provide an attestation, the prosecutor will then have to determine what constitutes a "valid" attestation, a task that begins with attempting to interpret the Reproductive Health Care Rule. Because that Rule is so complicated and ill-defined, it is difficult to understand how a

[63] *Ibid*.
[64] *Ibid*.
[65] 88 Fed. Reg. at 23509.

prosecutor could explain why she believed she had complied with the Reproductive Health Care Rule while still adhering to the Attestation Requirement's "plain language" requirement.

Once the attestation is provided, the pressure is then on the hospital to determine whether the attestation is "valid." If not, it would be illegal for the hospital to comply. To determine validity, the hospital must ask and answer the following questions:

- Does the attestation verify that the use or disclosure of PHI is not "otherwise" prohibited by the Reproductive Health Care Rule? (§164.509(b)(1)(ii))

- Does the attestation separately include a "clear statement that the use or disclosure is not for a purpose prohibited under" the Reproductive Health Care Rule? (§164.509(c)(1)(iv))

- Does the attestation identify the information requested in a specific fashion? (§164.509(c)(1)(ii))

- Does the attestation identify the name of the person whose PHI is sought? (§164.509(c)(1)(i)(A))
  - If not, would it have been "practicable" for the attestation to do so? (§164.509(c)(1)(i)(A))
  - If it was "not practicable" for the attestation to do so, does the attestation include "a description of the class of individuals whose [PHI] is sought"? (§164.509(c)(1)(i)(B))

- Does the attestation include the "name" of the "person(s)" "or class of persons" "who are requested to make the use or disclosure"? (§164.509(c)(1)(ii))
  - If not, does it include "other specific information" regarding the person or persons "who are requested to make the use or disclosure"? (§164.509(c)(1)(ii))

- Does the attestation include the "name" of the "person(s)" "or class of persons" "to whom the covered entity is to make the requested use or disclosure"? (§164.509(c)(1)(iii))
  - If not, does it include "other specific information" regarding the person or persons "to whom the covered entity is to make the requested use or disclosure"? (§164.509(c)(1)(iii))

- Is the attestation signed by the person requesting the PHI? (§164.509(c)(1)(v))
  - If not, is it signed by a representative of the person requesting the information? (§164.509(c)(1)(v))
  - If it is signed by a representative, does the attestation also include a "description of such representative's authority to act for the person"? (§164.509(c)(1)(v))

If the covered entity answers no to *any* of these questions, it *must reject* the attestation and ask the prosecutor to try again. If the prosecutor refuses, the hospital must again choose between defying a court order and defying HHS.

But even if the hospital deems the attestation valid so far, it must still continue to make a number of more nuanced and complicated judgments about the attestation.

- Does the attestation contain any "element or statement" that is "not required by [§ 164.509(c)]"? (§ 164.509(b)(2)(ii))
  - If so, the attestation is invalid, and it would be illegal for the hospital to comply.

Note that while § 164.509(b)(1)(ii) renders an attestation invalid if it contains any "element or statement" that is "not required by [§ 164.509(c)]," not every element that must be included in a valid attestation is found in § 164.509(c). For example, § 164.509(b)(1)(ii) states that a valid attestation must verify that "the use or disclosure is not otherwise prohibited by" the Reproductive Health Care Rule. ***As such, it seems impossible for a covered entity to determine that an attestation complies with both § 164.509(b)(1)(ii) and 164.509(b)(2)(ii). If this reading is correct, then the Proposed Rule would make it illegal under HIPAA for a covered entity to ever comply with a subpoena that requests "protected health information potentially related to reproductive health care."***

Is the attestation "combined with any other document"? (§ 164.509(b)(3))

- If so, the attestation is invalid, and it would be illegal for the hospital to comply.

- Does the covered entity have "actual knowledge that material information in the attestation is false"? (§ 164.509(b)(2)(iv))
  - If so, the attestation is invalid, and it would be illegal for the hospital to comply.

It is unclear from the Proposed Rule what sort of due diligence a hospital must undertake to determine whether the corporation has "actual knowledge" of this nature?

- Is the attestation "written in plain language"? (§ 164.509(c)(2))
  - If not, the attestation is invalid, and it would be illegal for the hospital to comply.

Given the complexity of the proposed Attestation Rule and given the prolix manner in which the proposed § 164.509 is written, it is difficult to imagine that a document could answer all of these complicated and poorly-worded questions and still be written in plain language.

Again, if the covered entity determines that the attestation is deficient by any of these measures, it must reject the attestation and ask the prosecutor to try again. If the prosecutor refuses, the hospital must again choose between defying a court order and defying HHS.

But even now, the covered entity is still not in the clear. Section 164.509 also creates ongoing obligations that adhere "during the course of using or disclosing protected health information in reasonable reliance on a facially valid attestation." The hospital must continue to ask itself the following questions:

- Has the covered entity "discover[ed] information reasonably showing that representations in the attestation were materially false"? (§ 164.509(d))

Note that this is a *lower bar* than what § 164.509 requires for a covered entity's *initial* determination that an attestation is valid. Under § 164.509(2)(iv), a covered entity would have to have "actual knowledge" that "material information in the attestation is false." Otherwise, the attestation is valid. But once the covered entity determines that an attestation is valid and starts complying with a subpoena, § 164.509(d) states that the entity "must cease" if it has: (1) "information reasonably showing" (a lower threshold than the "actual knowledge" standard in § 164.509(2)(iv)) that (2) *any* representation in the attestation (q lower threshold than the "material information in the attestation" standard in § 164.509(2)(iv))) is false.

Yet, in another regard, § 164.509(d) sets a *higher bar* than § 164.509. A covered entity must initially determine whether a representation is "false," but later must judge whether a representation is "materially false."[66]

- If the covered entity has discovered "information" that is "materially false," is that information "leading to uses or disclosures for a prohibited purpose"? (§ 164.509(d))
  - If the covered entity says *yes to both* questions, "the covered entity must cease such use or disclosure." (§ 164.509(d)) An affirmative answer to one or the other would not appear to authorize a covered entity to ignore a subpoena.

These differing standards create a dizzying array of complicated scenarios for covered entities to navigate. For example, what is a covered entity to do if, while it is evaluating an attestation, it determines it does not have "actual knowledge" that "material information" in the attestation is "false," but it does have "information reasonably showing" that a non-material representation in the attestation is "materially false"? It would appear that the hospital would be in contempt of court if it refused to accept the attestation, but then would be violating HIPAA if it complied with the subpoena. How does HHS expect covered entities to proceed in such situations?

C. Even if a proposed use or disclosure is permitted under § 164.502 and satisfies the Attestation Rule (if applicable), a covered entity must still judge the proposed use or disclosure under the new Reproductive Health Care Rule.

We now come to the most important and complex part of the Proposed Rule, the Reproductive Health Care Rule, located in § 164.502(a)(5)(iii). The Proposed Rule makes clear in several places that this provision is a super regulation that would override all other aspects of the HIPAA Privacy Rule that might authorize the release of PHI. For example, the Proposed Rule would add new language to the front of § 164.512 to clarify that uses permitted there are still prohibited when they conflict with the new Reproductive Health Care Rule. The Reproductive Health Care Rule also makes this unmistakably clear: "a covered entity or business may not use or disclose protected health information" when § 164.502(a)(5)(iii) applies. It is, therefore, crucial that covered entities are able to comprehend what this proposed Rule entails and what it demands of them.

1. Is the proposed disclosure "for a criminal, civil, or administrative investigation into or a proceeding against any person"?

The Reproductive Health Care Rule has several parts, and there is no obvious way for a covered entity to navigate its requirements. But it may be simplest, to begin with the general prohibition found in § 164.502(a)(5)(iii)(A). This provision may itself be divided into two inquiries. First, a covered entity must determine whether a proposed use or disclosure of PHI is "for a criminal, civil, or administrative investigation into or proceeding against any person."[67] This inquiry is also satisfied if the covered entity discerns that the proposed use or disclosure is "for the purpose of initiating" such an investigation or proceeding."[68] If no, the Reproductive Health Care Rule does not apply. But if the covered entity finds this is the case, it must proceed to the next inquiry.

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[66] To determine whether a statement is "false," one must simply uncover whether it was untrue when made. But to judge a statement "materially false," one must additionally conclude that the statements "has a natural tendency to influence, or [is] capable of influencing, the decision of the decision making body to which it was addressed." *Neder v. United States*, 527 U.S. 1, 16 (1999).
[67] § 164.502(a)(5)(iii)(A)(1).
[68] § 164.502(a)(5)(iii)(A)(2).

To understand the confusion the Proposed Rule will create, consider how it applies to a health care professional's legal duty as a mandatory reporter of child abuse and neglect. HHS states that the Proposed Rule "permits a regulated entity to use or disclose PHI to report known or suspected child abuse or neglect if the report is made to a public health authority that is authorized by law to receive such reports."[69] It claims that the Proposed Rule would not "disrupt longstanding state or Federal child abuse reporting requirements that apply to regulated entities."[70] But the Department's reassurances cannot alter the plaining meaning of the proposed regulatory text.

When a health care professional determines that she has a reasonable basis to conclude that a child has been sexually abused, the report she makes to the designated public official is made "for the purpose of initiating" "a criminal, civil, or administrative investigation into or proceeding against [a] person." The preamble reassures covered entities that their health care professionals may continue to fulfill their duties as mandatory reporters, but the proposed regulatory text appears to state otherwise.

2. Would the anticipated investigation or proceeding be "in connection with seeking, obtaining, providing, or facilitating reproductive health care?"

The second inquiry under § 164.502(a)(5)(iii)(A) requires a covered entity to determine whether the investigation or proceeding in question would be "in connection with seeking obtaining, providing, or facilitating reproductive health care." As explained above, there are three parts to this standard. The Proposed Rule offers expansive and non-exhaustive definitions of "reproductive health care" and "seeking, obtaining, providing, or facilitating." The third part of this quote, "in connection with," is not defined at all. And the preamble asserts that these phrases, individually and collectively, cover a huge swath of human activity.

The Proposed Rule would put covered entities to the daunting task of having to decide when these criteria are triggered. Some of the difficult questions covered entities will have to ask themselves would include the following:

- Would the anticipated investigation or proceeding involve, at some level, what the Proposed Rule defines as "reproductive health care"?
- If so, would the anticipated investigation or proceeding be about someone "seeking, obtaining, providing, or facilitating" reproductive health care?
- If not, would the anticipated investigation or proceeding be "in connection with" someone seeking, providing, or facilitating" reproductive health care?

[69] 88 Fed. Reg. at 23526. The Proposed Rule's allowances for child abuse reporting are much more limited than it first appears. First, HHS states that this permission is limited "to the minimum necessary to make the report." 88 Fed. Reg. at 23526. It is unclear what standards the Department will use in deciding whether a reporter has crossed this "minimum necessary" threshold. Second, this permission "does not include permission for the covered entity to respond to a request for PHI for a criminal, civil, or administrative investigation into or proceeding against a person based on suspected child abuse." *Id*. "Any disclosure of PHI in response to a request from an investigator, whether in follow up to the report made by the covered entity (other than to clarify the PHI provided in the report) or as part of an investigation initiated based on an allegation or report made by a person other than the covered entity would be required to meet the conditions of disclosures to law enforcement or for other investigations or legal proceedings." *Id*.

[70] 88 Fed. Reg. at 23527.

If the covered entity determines that the proposed use or disclosure would not be related to a government action "in connection with" any of the wide range of activities indicated above, the Reproductive Health Care Rule would not apply. Otherwise, the covered entity must continue on to the next inquiry.

Consider again how this part of the Reproductive Health Care Rule would apply to a health care professional's legal duty as a mandatory reporter of child abuse and neglect. As described above, a report about suspected child abuse is made "for the purpose of investigating or imposing liability on" the suspected abuser. Now the covered entity must decide whether the anticipated investigation the mandatory report will trigger would be "in connection with seeking, obtaining, providing, or facilitating reproductive health care." Given the broad and unbounded definition in the Proposed Rule, a covered entity could reasonably conclude (or fear) that a report about suspected child sexual abuse or a report about a suspected coerced abortion would qualify.

3. Was the reproductive health care activity in question "lawful" where it was sought, obtained, provided, or facilitated?

The Rule of Applicability in § 164.502(a)(5)(iii)(C) requires the covered entity to determine whether the reproductive health care activity in question was legal where it was sought, obtained, provided, or facilitated. The Rule of Applicability provides three scenarios to illustrate its application, covering multistate investigations, single-state investigations, and investigations into "care" protected by (HHS's interpretation of) federal law.

The Department states that the Rule of Applicability "would limit the new prohibition to certain categories of instances in which the state lacks any substantial interest in seeking the disclosure."[71] But it is far from clear that the Department has achieved this goal by making it illegal for a covered entity to use or disclose PHI "in connection with" "reproductive health care" that is "lawful."

As noted already, there are a myriad of complexities and ambiguities within the proposed Reproductive Health Care Rule. But the Rule of Applicability now adds another with the term "lawful." This term is not defined, so covered entities would have to look to the preamble for clues as to how this term will be interpreted and enforced.

The first difficulty is attempting to discern whether "lawful" applies to a drug or procedure in general or under particular circumstances. The preamble does not clearly say one way or the other. In some places, HHS seems to be focused on whether a procedure (such as an abortion) is categorically prohibited, at least under certain circumstances (for example, whether the medical professional has a good-faith belief that the unborn human being is at more than twelve weeks gestation).

In other places, the Department seems to anticipate a more granular inquiry. For example, HHS states that the Proposed Rule would address situations where law enforcement seeks PHI to determine whether or not a prescription is used "for purposes that are permissible under state law."[72] This would require a covered entity to make a judgment about the intentions of the relevant law enforcement officer or agency, the intentions of the person seeking the prescription, the intentions of the health care professional, or perhaps all of the above.

These are complicated, subjective determinations requiring expertise and judgment calls that are more in the purview of lawyers than health care professionals. Covered entities will also have to consider their potentially conflicting legal obligations under state law and federal regulations.

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[71] 88 Fed. Reg. at 23522.
[72] 88 Fed. Reg. at 23520.

If the covered entity determines that any of the reproductive health care activities in question were not legal, the Reproductive Health Care Rule does not apply. But if the activities in question were legal, the covered entity must then move on to the Reproductive Health Care Rule's Rule of Construction.

4. Would the proposed use or disclosure be "primarily" for the purpose of investigating or imposing liability on any person for "the mere act" of seeking, obtaining, providing, or facilitating reproductive health care"?

The final part of the Reproductive Health Care Rule is the Rule of Construction (§ 164.502(a)(5)(iii)(D)). This inquiry attempts to narrow the Reproductive Health Care Rule by introducing two new terms: "primarily" and "mere act."

Unfortunately, the Proposed Rule does not define either "primarily" or "mere act," and it does not provide examples that would be sufficient to help covered entities understand what they are supposed to do or how they are supposed to apply these new phrases.

If the covered entity finds that the proposed use would not be "primarily for the purpose of investigating or imposing liability" for a "mere act" related to reproductive health care, the Reproductive Health Care Rule does not apply. But if the covered entity answers this question in the affirmative, the Reproductive Health Care Rule prohibits any disclosure that is otherwise permitted under the HIPAA Privacy Rule.

IV. In light of the above, the Proposed Rule would likely intimidate covered entities into refusing to comply with longstanding professional and legal obligations to use or disclose PHI.

The Department has failed to show that the Supreme Court's *Dobbs* decision has created "confusion" that justifies the Proposed Rule. But whatever confusion there might be about how *Dobbs* and related legal developments have changed covered entities' obligations under HIPAA, the Proposed Rule would make things much worse by introducing new counter-intuitive and difficult terms, by qualifying these terms in ways that make them almost impossible to understand and apply, and by adding considerable complexity to the decision-making process health covered entities must undergo before complying with court orders.

In this final section, we offer three additional reasons why we are concerned that the Proposed Rule would have the practical effect of intimidating covered entities into refusing to comply with their longstanding professional and legal obligations to use or disclose PHI. Given the administration's aggress position on abortion and other hotly-debated issues related to "reproductive health care;" given the administration's broad authority to develop, interpret, enforce, and adjudicate matters related to the HIPAA Privacy Rule; and given the serious criminal, civil, and professional consequences that can follow from an HHS determination that the Privacy Rule has been violated, the public should be seriously concerned that the Proposed Rule will chill covered entities from complying with their moral and legal obligations to help protect vulnerable children and adults.

A. Health care professionals would be aware that the administration rejects *Dobbs* and has been a zealous advocate for radical procedures.

First, health care professionals would have to take into account that this Proposed Rule has been developed by an administration and under the authority of an HHS Secretary that have been outspoken about their opposition to *Dobbs* and that have a history of taking aggressive legal positions in the service of their pro-abortion and pro-gender-transition agendas.

The Proposed Rule makes the Department's hostility and intention plain. For example, it states that the Proposed Rule is designed to frustrate state efforts to seek PHI for what it calls "punitive non-health purposes."[73] The Proposed Rule also seeks to thwart law enforcement efforts to "request PHI from regulated entities for use against individuals."[74] To explain what sorts of uses it has in mind, HHS cites a report from a "reproductive justice" group that laments that states are using reports from "designated mandatory reporters" and "police recovery of fetal remains" to enforce laws against second and third trimester "self-managed" chemical abortions. [75]

However, as the Supreme Court affirmed in *Dobbs*, states have legitimate interests in protecting unborn human life and preventing the pain that unborn humans experience in abortions. The administration also issued statements in the wake of Dobbs that make its positions and its policy objectives clear.[76]

The administration is, of course, entitled to advocate for its policy objectives, but it is inappropriate for the Department to use the Privacy Rule to undermine states' rights, especially as Congress has not asserted a compelling interest in protecting access to abortion.

B. The administration's policy preferences are especially relevant given that HHS performs legislative, executive, and judicial functions related to the Privacy Rule.

The administration's policy preferences would not be so critical were the Proposed Rule not so vague and complicated, and if HHS did not have such an incredible and unchecked range of powers related to its development and implantation. As noted in the Proposed Rule, the HHS Secretary has granted the Office of Civil Rights ("OCR") authority to "make decisions regarding the[] implementation, interpretation, and enforcement" of the HIPAA Privacy Rule.[77]

The following chart, developed by HHS's OCR, demonstrates the Department's and more broadly the executive branch's authority related to the HIPAA Privacy Rule:[78]

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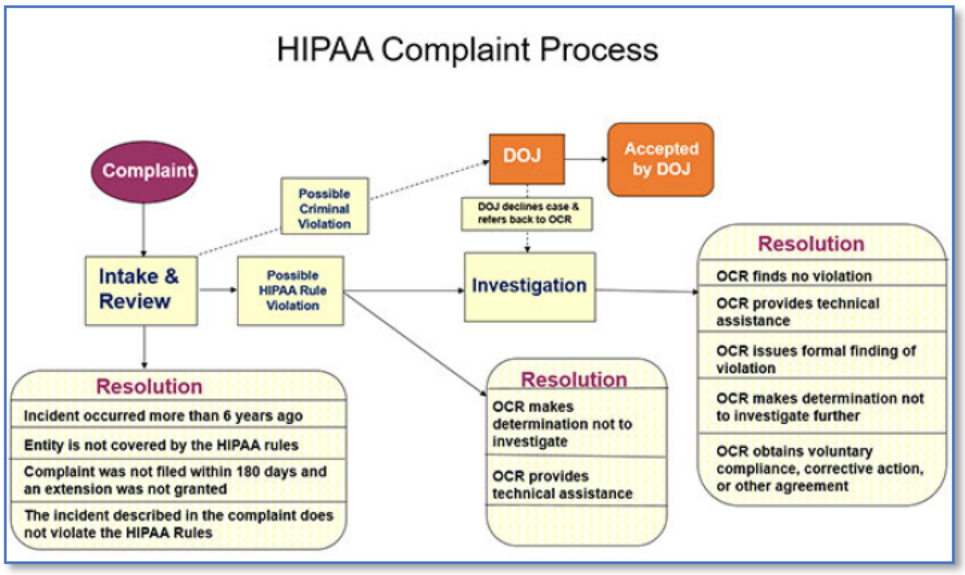
[73] 88 Fed. Reg. at 23516.
[74] 88 Fed. Reg. at 23519.
[75] Laura Huss, Farah Diaz-Tello, Colleen Samari, "Self-Care, Criminalized: August 2022 Preliminary Findings," at 2-3, https://www.ifwhenhow.org/resources/self-care-criminalized-preliminary-findings/ (cited at 88 Fed. Reg. at 23520 n.178).
[76] *See* Rachel Morrison, The Biden Administration's Post-*Dobbs*, Post-*Roe* Response, Federalist Society, July 13, 2022, https://fedsoc.org/commentary/fedsoc-blog/the-biden-administration-s-post-dobbs-post-roe-response.
[77] 88 Fed. Reg. at 23514 (citing various executive actions).
[78] Enforcement Process, https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/enforcement-process/index.html.



C. The legal and professional consequences of a HIPAA violation would color how health care professionals interpret and apply the Proposed Rule.

Finally, covered entities and health care professionals would be interpreting the Proposed Rule in light of the considerable consequences that can come from a determination that the HIPAA Privacy Rule has been violated. There are "severe penalties for violations, including prison sentences of up to 10 years and monetary fines of up to $250,000."[79] Additionally, health care professionals can suffer profound professional consequences if they are deemed to have participated in a violation of the HIPAA Privacy Rule.[80]

CONCLUSION

We urge the Departments to abandon and withdraw the Proposed Rule.

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[79] 88 Fed. Reg. at 23511 (citing 42 U.S.C. § 1320d-6(b)).

[80] See, e.g., HHS Office for Civil Rights Reaches Agreement with Health Care Provider in New Jersey That Disclosed Patient Information in Response to Negative Online Reviews, https://www.hhs.gov/about/news/2023/06/05/hhs-office-civil-rights-reaches-agreement-health-care-provider-new-jersey-disclosed-phi-response-negative-online-reviews html; HHS Office for Civil Rights Settles HIPAA Investigation with Arkansas Business Associate MedEvolve Following Unlawful Disclosure of Protected Health Information on an Unsecured Server for $350,000, https://www hhs.gov/about/news/2023/05/16/hhs-office-civil-rights-settles-hipaa-investigation-arkansas-business-associate-medevolve-following-unlawful-disclosure-phi-unsecured-server-350-000.html; OCR Settles Three Cases with Dental Practices for Patient Right of Access under HIPAA, https://www hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/september-2022-right-of-access-initiative/index.html.

Sincerely,

Eric Kniffin, J.D.
Fellow
HHS Accountability Project
Ethics & Public Policy Center

Natalie Dodson
Policy Analyst
HHS Accountability Project
Ethics & Public Policy Center

EXHIBIT A

Declaration of Kelley Groover, Senior Assistant Attorney General and Managing Attorney for the Consumer Protection Division in the Officer of the Tennessee Attorney General

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

STATES OF TENNESSEE, ALBAMA, 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. 25-cv-00025

DECLARATION OF KELLEY GROOVER

Pursuant to 28 U.S.C. § 1746, I, Kelley Groover, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as a Senior Assistant Attorney General and Managing Attorney for the Consumer Protection Division (CPD) in the Office of the Tennessee Attorney General. The CPD's responsibilities include conducting and supervising investigations to protect Tennessee consumers and businesses from those who engage in unfair or deceptive business practices in violation of the Tennessee Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, et seq.

3. As part of my responsibilities, I regularly draft and review investigative tools called Requests for Information ("RFIs") to be issued by the Attorney General, including in some instances RFIs to entities covered under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) ("HIPAA"), seeking protected health information ("PHI") to investigate consumer protection violations. The CPD is authorized to make such requests under Tenn. Code Ann. § 47-18-106.

4. I am aware of the Department of Health and Human Services' *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the "Final Rule"), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024, *id.* at 32,976.

5. In 2024, the CPD, on behalf of the State, filed suit against a Tennessee-based fertility clinic following reports of an abrupt closure. Consumers reported being unable to contact anyone at the clinic. Some were scheduled for procedures the week of closure and could not get any answers about when they might be rescheduled, how to access their medical records and genetic specimens, whether the clinic would re-open, or how to transfer care to a new provider.

6. A preliminary investigation revealed all staff other than the owner had left the clinic. Reports from the State Health Facilities Commission raised questions about the owner's ability to properly maintain the cryogenic tanks that held hundreds of irreplaceable genetic specimens. The landlord also reported the premises being left unlocked and apparently unattended, leaving the patient records and cryogenic tanks vulnerable. In addition to fearing for the ongoing preservation of patients' specimens, these findings raised concerns about potential violations of the TCPA such as misrepresentations made to consumers about the quality of services being offered by the clinic and continuity of care. Due to these concerns, we filed a consumer protection

enforcement action in Davidson County Chancery Court seeking extraordinary relief, including the appointment of a Receiver, which was granted. In the following months, the Receiver worked in cooperation with CPD to find solutions to the most immediate patient needs—finding a clinic willing to oversee the care, inventory, and transfer of patients' specimens and medical care. These most emergent issues have mostly been resolved and our team has turned its attention to discovery in our consumer protection enforcement action.

7. The Court's order appointing the Receiver directs the Receiver to preserve the records of the fertility clinic and respond to requests for documents. The order also gives the Receiver the discretion to set the time, place, and manner of document access. The Receiver has, of course, emphasized the need to be compliant with HIPAA and not wanting to violate the law in any way. When the new regulations took effect, the Receiver informed our team that someone would need to sign the attestation the Final Rule requires in order to receive productions of documents containing patient health information. Given the nature of the business at issue, practically anything we would be requesting potentially contains PHI related to the provision of reproductive care.

8. As this was the first time we had received a request to sign such an attestation, our team consulted with our superiors about this new requirement and were informed that the Office had concerns about the legality of the Final Rule and the implications of signing the attestation, including potential criminal liability. Due to those concerns, we were instructed not to sign the attestation.

9. The records we would be seeking are vital to prosecuting the State's suit against the fertility clinic for at least two reasons.

10. First, patient records help us identify consumers who may have been harmed and help us gather evidence of consumers' experiences with the clinic including affirmative representations that may have proved to be false. This helps us determine what violations of law may have occurred and identify potential witnesses.

11. Second, these records are essential for effectively identifying patients who may be entitled to consumer restitution for the deceptive and unfair practices that the clinic is alleged to have carried out. We understand from speaking with the Receiver that determining amounts patients paid to the clinic (a figure important in calculating restitution) would require reviewing records that contain PHI.

12. Although our civil enforcement authority is not specific to medical providers, this is not the only instance where we have investigated an entity covered by HIPAA providing reproductive care. For example, we have previously investigated a clinic providing treatment for erectile dysfunction and other sexual difficulties in men. We continue to receive and review complaints against similar entities which would likely be covered by the Final Rule.

13. Historically speaking, the CPD has encountered investigation targets who refuse to provide information in response to a lawfully issued RFI. *See e.g.*, *In re Wall and Associates, Inc.*, M2020-01687-COA-R3-CV, 2021 WL 5274809 (Tenn. Ct. App. Nov. 12, 2021), *In re Chicago Legal Solutions LLC*, M2020-00411-COA-R3-CV, 629 S.W.3d 124 (Tenn. Ct. App.). Enforcing an RFI through the courts is resource intensive and time consuming and can delay an investigation by months or even years. Even if the CPD seeks HIPAA covered information pursuant to an RFI and provides the requested attestation, I understand that the Final Rule empowers the recipient to decide whether ultimately to disclose the information that the CPD has requested. And, if the recipient refuses to provide the requested information notwithstanding an attestation from CPD, it

is my understanding that the Final Rule does not provide effective recourse for the CPD to challenge that decision.

14. Instead, the CPD likely would need to seek relief from a court of competent jurisdiction, delaying our ability to obtain relevant information to investigate possible violations of law and ultimately halt conduct that may be harming the public.

15. Thus, the Final Rule complicates my team's duty and ability to investigate unfair and deceptive business practices. Because of the Final Rule, investigating complaints against covered entities may require substantially more resources than was required prior to the Final Rule taking effect. For those reasons, the Final Rule is impacting the public health and safety of the State of Tennessee because it provides investigation targets an additional avenue through which to delay, impede, and deter viable investigations.

Date:

Kelley Groover
Senior Assistant Attorney General
and Managing Attorney

EXHIBIT E

Declaration of Larry Johnson, Jr., Director of the Department of Inspections, Appeals, and Licensing for the State of Iowa

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEEE
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. 25-cv-00025

DECLARATION OF LARRY JOHNSON, JR.

Pursuant to 28 U.S.C. § 1746, I, Larry Johnson, Jr., duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as the Director of the Department of Inspections, Appeals, and Licensing ("DIAL") for the state of Iowa. DIAL is a multifaceted regulatory agency charged with protecting the health, safety, and welfare of Iowans. Iowa Code § 10A.103 (2024).

3. DIAL is responsible for, among other duties, inspecting and licensing or certifying healthcare professionals and entities. In support of this portion of its responsibilities, DIAL's Professional Licensing Division and the licensing boards under its administrative authority license

health-related professionals and perform licensee investigations, licensee disciplinary proceedings, and provide oversight of professional health programs. DIAL is further responsible for the inspection, certification, and licensing of various healthcare entities in the state of Iowa. In support of this portion of its responsibilities, DIAL's Health & Safety Division routinely inspects healthcare and investigate potential statutory or regulatory violations, including those resulting in patient harm. Healthcare entities regulated by DIAL include adult day services; ambulatory surgical centers; assisted living programs; dialysis facilities ("ERSD"); elder group homes; home health agencies; hospices; hospitals; intermediate care facilities for individuals with intellectual disabilities; intermediate care facilities for persons with mental illness; nursing facilities and skilled nursing facilities; and residential care facilities.

4. Both DIAL's health professions and health facilities inspectors protect Iowans' health and safety in our largely rural state where access to healthcare is critical. Having a limited number of healthcare providers and facilities for our rural populations means the state plays a vital role in making sure Iowans are safe at their most vulnerable.

5. In the DIAL Professional Licensing Division, health professions investigators regularly draft and serve investigative subpoenas requesting patient health records or other materials.

6. Those subpoenas issued by the investigators are frequently served upon entities covered under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) ("HIPPA"), seeking protected health information ("PHI") to investigate potential violations of both practitioners and entities that provide healthcare alike. The investigators are authorized to make such requests under Iowa Code § 10A.402 (2024).

7. In the DIAL Health & Safety Division, inspectors regularly request patient health records as part of their on-site inspection of a facility. The health facilities inspectors are authorized to make such requests under Iowa Code §§ 135B.9(1) (2024), 135C.16(3) (2024), and other pertinent state statutes. DIAL's Health & Safety Division also conducts investigations and makes such requests pursuant to federal authority as the state survey agency acting on behalf of the federal Centers for Medicare and Medicaid Services.

8. I am aware of the Department of Health and Human Services' *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (Apr. 26, 2024) ("Final Rule"), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024, *id.* at 32,976.

9. In December 2024, DIAL health professions investigators and health facilities inspectors began receiving requests to execute attestation forms from covered entities in response to their investigative subpoenas. To receive the information the investigators and inspectors seek, they have been required to sign the forms. As of the date of this filing, multiple healthcare entity and professional licensing investigations have been delayed while investigators await clarification on new rules.

10. The new rules requirements are so indeterminate that the University of Iowa, also a state of Iowa entity, has required DIAL investigators and inspectors to execute attestations when seeking information from its health facilities and providers.

11. Upon receipt of the first request to sign this type of an attestation, our team consulted with the Iowa Attorney General's Office about this new requirement. We were informed that the Office had concerns about the legality of the Final Rule and the implications of signing the attestation. Due to those concerns, we were advised not to sign the attestation.

12. On January 29, 2025, however, information being sought by the health facilities division was so exigent, general counsel for DIAL executed the attached attestation and correspondence attached hereto as Exhibit A. That is despite the risk imposed on the investigators due to the indeterminate nature of the Final Rule's potential penalties.

13. The records our Health & Safety Division inspectors are seeking are vital to ensuring DIAL can discharge its statutory duties to conduct investigations relative to the standards and practices of hospitals, health care facilities, ambulatory surgical centers, and other healthcare entities.

14. The records our Professional Licensing Division investigators are seeking are vital to ensuring DIAL can discharge its statutory duties to perform licensee investigations, licensee disciplinary proceedings, and provide oversight of professional health programs.

15. Thus, the Final Rule impedes DIAL'S lawful purpose and the Iowa legislature's mandate to protect the health and safety of Iowans by frustrating our investigative processes.

I declare under penalty of perjury the foregoing is true and correct.

Executed on: 01/31/2025

By:

/s/ 

Larry Johnson, Jr.
Director
Department of Inspections, Appeals, and Licensing

EXHIBIT A

Exhibit to Declaration of Larry Johnson, Jr., Director of the Department of Inspections, Appeals, and Licensing for the State of Iowa

January 29, 2025

Unity Point Health
Iowa Methodist Medical Center
Via email to: UPH_DSM_ROI@unitypoint.org

To whom it may concern,

The Iowa Department of Inspections, Appeals, and Licensing ("DIAL") has a pending investigation initiated under its authority pursuant to Iowa Code chapter 135B and as the state survey agency for the federal Centers for Medicare and Medicaid Services. DIAL is aware of the federal Department of Health and Human Services' HIPAA Privacy Rule to Support Reproductive Health Care Privacy, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the "Final Rule"), which took effect on June 25, 2024, and under which compliance was generally required by December 23, 2024.

In the interest of expediency in obtaining records necessary to the aforementioned investigation, I have executed the attached attestation in my role as general counsel to DIAL. Please be advised that the execution of this attestation on behalf of DIAL does not indicate that the State of Iowa or DIAL concede that the Final Rule or this covered entity's attempt at implementation of the Final Rule is lawful. The State of Iowa and DIAL reserve all legal rights to challenge the Final Rule and implementation thereof.

Additionally, please consider this correspondence a litigation hold request. Please preserve all compliance policies, in their interim or final version, and any communications you have had with the federal Department of Health and Human Services related to implementation of the Final Rule.

If you have further questions regarding this correspondence, please contact Lindsey Browning, Administrative Law Section Chief of the Iowa Attorney General's Office, at lindsey.browning@ag.iowa.gov or contact me using the information provided below.

Sincerely,

Ashleigh Hackel

Digitally signed by Ashleigh Hackel
Date: 2025.01.29 12:02:27 -06'00'

Ashleigh Hackel, General Counsel
Administration Division, Legal & Policy Bureau
(515) 250-3746, Ashleigh.Hackel@dia.iowa.gov

UnityPoint Health

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***
Iowa Department of Inspections, Appeals, and Licensing, Health & Safety Division
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***
Iowa Methodist Medical Center
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]***
See "Iowa Methodist Medical Center—Records Request Addendum (1/29/25)" attached hereto.

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.

Ashleigh Hackel Digitally signed by Ashleigh Hackel Date: 2025.01.29 11:06:08 -06'00'

January 29, 2025

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.* Executed in capacity as general counsel for the Iowa Department of Inspections, Appeals, and Licensing

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.

REPRODUCTIVE HEALTH RULE ATTESTATION

Iowa Methodist Medical Center—Records Request Addendum (1/29/25)

Description of Records Requested: Complete medical record for Jeffrey Tracy, DOB 3/3/74, from January 1, 2025 to discharge.

EXHIBIT J

Declaration of Tonya Joiner, Assistant Secretary of the Office of Public Health within the Louisiana Department of Health

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. 25-cv-25

DECLARATION OF TONYA JOINER

Pursuant to 28. U.S.C. §1746, I, Tonya Joiner, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as the Assistant Secretary of the Office of Public Health (OPH) within the Louisiana Department of Health.

3. OPH's Bureau of Family Health oversees a number of public health surveillance programs which are established by state law to promote the health and wellbeing of the people of Louisiana. Three of those vitally important programs are:

(1) The Louisiana Birth Defects Monitoring Program, established by LSA - R.S. 40:31.41-31.48, which collects, analyzes, and disseminates data

regarding birth defects in Louisiana and provides information to families of affected children so that they can receive appropriate services.

(2) The Louisiana Child Death Review Panel, established by LSA - R.S. 40:2019, which collects data and conducts investigations into unexpected deaths of children below the age of fifteen with the goal of reducing the incidence of injury and death among such children.

(3) The Louisiana Pregnancy-Associated Mortality Review (PAMR), an authorized activity of the Louisiana Commission on Perinatal Care and Prevention of Infant Mortality, established by LSA - R.S. 40:2018, which collects and analyzes data for the conduct of maternal and infant mortality studies with the goal of reducing the number of teenage pregnancies, sick infants, and infant mortalities.

4. All three of these surveillance programs require the collection and abstraction of individual patient data related to maternal, infant, and child health. To that end, healthcare providers and other appropriate sources of needed information are statutorily required to provide these programs with access to relevant records upon request. See LSA - R.S.31.43(B) (Birth Defects Monitoring Program); LSA - R.S. 40:2019(F)(1) (Child Death Review Panel); LSA - R.S. 2018(I)(1) (PAMR).

5. In furtherance of their responsibilities, the data abstractors for each of these programs historically have been able to request files and records for their case abstraction activities via mail, email, fax or by direct access to the electronic health records of the healthcare provider or other data source for data abstraction following each source's HIPAA policies and confidentiality rules. These sources have worked with the abstractors to comply with the data collection requirements for each program and reduce the administrative burden on staff to ensure records could be abstracted in a timely manner to support identification, prevention efforts, and linking families to resources. The approximate numbers of individual records requested annually by each program are as follows:

- Birth Defects Monitoring Program: Over 2,000
- Child Death Review Panel: Over 450
- PAMR: Over 100

6. I am aware of the Department of Health and Human Services' *HIPAA Privacy Rule to Support Reproductive Health Care Privacy,* 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the "Final Rule"), which took effect on June 25, 2024, with a compliance deadline of December 23, 2024. Specifically, the Final Rule places limits on disclosure and use of patient information "potentially related to reproductive health care," which it broadly defines as "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.

7. The Final Rule is currently creating unnecessary barriers to the ability of these three OPH surveillance programs to access the individual records that they need in order to fulfill their statutory obligations.

8. Since the Final Rule became effective, some providers have asked the abstractors for these programs to complete attestations (as allegedly required by the Final Rule) before they provide access to records related to maternal PHI. Included among those providers is the largest birthing hospital in the state of Louisiana, which was the first to request an attestation from Birth Defects Monitoring Network staff. PAMR and Child Death Review staff have been able to continue accessing records using established remote access protocols, but have been asked to complete attestations when requesting records via email or fax.

9. Compliance with these requests for attestations, which are anticipated to increase in number as awareness of the Final Rule becomes more widespread, creates significant new administrative burdens for these programs, including time spent on completing the attestations, awaiting administrative approval before gaining access to the requested records, and consulting with legal counsel on issues related to the attestations. These burdens are increased by the Final Rule's requirement that a new attestation be provided for each specific records request.

10. Furthermore, the delays resulting from the process of complying with attestation requests and obtaining approval for data access can be anticipated to hamper the efficiency and effectiveness of the programs' data collection activities. The delays also will likely threaten their ability to meet data abstraction timeliness requirements imposed by federal funding sources for those activities.

11. These burdens, delays, and problems will only become more acute if the programs ultimately are required to provide attestations for all records that they request, including those for which they currently have remote access.

Tonya Joiner

Dated: February 5, 2025

EXHIBIT I

Declaration of Ashley A. Klenski, Director of the Medicaid Fraud Control Unit in the Criminal Law Division within the Office of the Idaho Attorney General

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEEE
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. 25-cv-25

DECLARATION OF ASHLEY A. KLENSKI

Pursuant to 28 U.S.C. § 1746, I, Ashley A Klenski, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as the Director of the Medicaid Fraud Control Unit (MFCU) in the Criminal Law Division within the Office of the Idaho Attorney General. The MFCU's responsibilities include conducting Medicaid Fraud investigations pursuant to Idaho Code § 56-226.

3. As part of my responsibilities, I regularly review requests for Medicaid provider records issued by the MFCU team to entities covered under the Health Insurance Portability and

Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (HIPAA), seeking protected health information (PHI) to investigate Medicaid fraud. MFCU is authorized to make such requests under 45 C.F.R. § 164.512.

4. For example, MFCU routinely requests billing data from health plan payers, such as health insurers or Idaho Department of Health and Welfare, Idaho's Medicaid program. This data is used to vet leads on possible violations of Idaho Code § 56-227A. I frequently must request this information with imperfect knowledge of the possible misconduct being investigated because, before receiving the data, it is impossible to know the particulars of the investigation.

5. Indeed, obtaining medical records and PHI is crucial to the investigation of health care fraud. It is a necessary component to proving various fraud schemes, including improper billing of care, rendering unnecessary or excessive services, billing for services that were not rendered, and other complex allegations.

6. Even after our office receives billing data, more investigation is generally required. To conduct investigations into healthcare fraud, it is necessary to issue written requests for records, authorized under state law, to healthcare providers in order to obtain medical records and compare billing data with services rendered, as reflected in the medical records.

7. I have reviewed the Department of Health and Human Services' *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the "Final Rule"), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024, *id.* at 32,976.

8. The Final Rule has created additional compliance costs and barriers to investigation which have the potential of impeding our investigations of healthcare fraud in Idaho.

9. Promulgated in response to the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), the Final Rule places limits on the disclosure and use of patient information related to "reproductive health care," which it broadly defines as "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.

10. Specifically, the Final Rule prohibits covered entities 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).

11. If the covered entity concludes that one of these two conditions exists, 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).

12. In making that assessment, 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 investigation by a State—unless the covered entity or business associate has either:

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

> lawful under the specific circumstances in which it was provided.

Id. § 164.502(a)(5)(iii)(C).

13. The covered entity that receives a request for PHI itself makes these determinations—including legal assessments of state and federal laws. And if the covered entity determines that any of the conditions barring disclosure exist, it may deny the request. The Final Rule does not provide explicit recourse for the requesting entity.

14. Under the Final Rule, covered entities also must require attestations with a request for PHI that is potentially related to "reproductive health care" data. *Id.* § 164.509(a). Such attestations are required under the Final Rule even when regulatory conditions on disclosures for law enforcement purposes are otherwise met. *See id.*; *id.* § 164.512(f)(1)-(6)

15. Again, the Final Rule places the power to assess the lawfulness or validity of any PHI request entirely with the covered entity to which the request is made. So, even after making an attestation it does not necessarily follow that the requesting party will receive the requested information, as discretion whether to disclose the PHI remains with the covered entity. This means that in some cases the entity under investigation for fraud will have a veto on investigators' ability to obtain records necessary for their investigation.

16. My office has had to expend time and resources to determine how to comply with the Final Rule's attestation requirements because they are vague and overbroad. The Final Rule may require me and the MFCU in some cases to attest, upon pain of criminal penalty, to facts that are difficult or impossible to know at the preliminary stages of an investigation.

17. And given the criminal liability associated with HIPAA violations, my team will have to consult extensively with other divisions within the Attorney General's office to determine

how, if possible, to comply with the Final Rule's attestation requirements without triggering potential criminal liability.

18. We have also learned from other state agencies that covered entities have refused to disclose information without an attestation required by the Final Rule even in cases that are far afield from "reproductive health care." We expect similar obstacles to our MFCU investigations.

19. Because the Final Rule itself provides no recourse to contest a demand that is denied, my office will likely need to seek relief in a court of competent jurisdiction. Such a suit has the potential to sprawl into protracted and complicated litigation, giving rise to issues such as federal preemption and removal. And such a suit may require MFCU to demonstrate in open court the theory of the case we are investigating without having adequate knowledge to do so. Any protracted litigation may impact on the amount of money the State may recoup from a viable fraud investigation because it may push some fraudulent activity outside of the relevant statute of limitations.

20. Ultimately, the Final Rule has the potential to complicate my team's duty and ability to investigate Medicaid fraud. And the Final Rule could impact our strategic investigative decisions. For those reasons, the Final Rule is impacting the public health and safety of the State of Idaho because it may delay, imped, and deter viable fraud investigations.

By: Ashley Klenski Dated: 2/4/2025

Ashley Klenski, Director
Medicaid Fraud Control Unit
Office of the Attorney General

EXHIBIT C

Declaration of Kevin M. Kreutz, Deputy Attorney General for the General Litigation Division of the State Services and Litigation Section of the Office of the Tennessee Attorney General

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEEE
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. 25-cv-00025

DECLARATION OF KEVIN M. KREUTZ

Pursuant to 28 U.S.C. § 1746, I, Kevin M. Kreutz, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as the Deputy Attorney General for the General Litigation Division (GLD) of the State Services and Litigation Section in the Office of the Tennessee Attorney General. The GLD division includes the Civil Medicaid Fraud (CMF) team. The CMF team's responsibilities include conducting and supervising investigations of Medicaid fraud pursuant to the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, *et seq.*

3. As part of my responsibilities, I regularly review civil investigative demands ("CIDs") issued by the CMF team to entities covered under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) ("HIPAA"), seeking protected health information ("PHI") to investigate Medicaid fraud. CMF is authorized pursuant to Tenn. Code Ann. § 8-6-401 to issue CIDs. Federal regulation 45 C.F.R. § 164.512 permits covered entities to disclose PHI to our office in relation to our civil investigations and CIDs issued thereon

4. For example, CMF routinely requests billing data from health plan payers, such as health insurers or TennCare, Tennessee's Medicaid program. This data is used to vet leads on possible violations of the TMFCA and other related statutes. We frequently must request this information with imperfect knowledge of the possible misconduct being investigated because, before receiving the data, it is impossible to know the particulars of the investigation.

5. Indeed, obtaining medical records and PHI is crucial to the investigation, reporting, and litigation of healthcare fraud. It is a necessary component to proving various fraud schemes, including improper billing of care, rendering unnecessary or excessive services, billing for services that were not rendered, and other complex allegations.

6. Even after our office receives billing data, more investigation is generally required. To conduct investigations into healthcare fraud, it is necessary to issue CIDs, authorized under state law, to healthcare providers in order to obtain medical records and compare billing data with services rendered, as reflected in the medical records.

7. I have reviewed the Department of Health and Human Services' *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the

"Final Rule"), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024, *id.* at 32,976.

8. The Final Rule has created compliance costs and barriers to investigation, impeding our investigation of healthcare fraud in Tennessee.

9. Promulgated in response to the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), the Final Rule places limits on the disclosure and use of patient information related to "reproductive health care," which it broadly defines as "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.

10. The Final Rule prohibits covered entities 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).

11. If the covered entity concludes that one of these two conditions exists, 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).

12. In making that assessment, 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 investigation by a State—unless the covered entity or business associate has either:

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

Id. § 164.502(a)(5)(iii)(C).

13. The covered entity that receives a request for PHI itself makes these determinations—including legal assessments of state and federal laws. And if the covered entity determines that any of the conditions barring disclosure exist, it may deny the request. The Final Rule does not provide explicit recourse for the requesting entity.

14. Under the Final Rule, covered entities also must require attestations with a request for PHI that is potentially related to "reproductive health care" data. *Id.* § 164.509(a). Such attestations are required under the Final Rule even when regulatory conditions on disclosures for law enforcement purposes are otherwise met. *See id.*; *id.* § 164.512(f)(1)-(6)

15. Again, the Final Rule places the power to assess the lawfulness or validity of any PHI request or attestation entirely with the covered entity to which the request is made. So, even after making an attestation it does not necessarily follow that the requesting party will receive the requested information, as discretion whether to disclose the PHI remains with the covered entity. This means that in some cases the entity under investigation for fraud will have a veto on investigators' ability to obtain records necessary for their investigation.

16. My office has had to expend significant time and resources to determine how to comply with the Final Rule's attestation requirements because they are vague and overbroad. The Final Rule requires me and CMF in some cases to attest, upon pain of criminal penalty, to facts that are difficult or impossible to know at the preliminary stages of an investigation. If I have imperfect knowledge of an investigation such that I am unable to attest to the facts required under the Final Rule, we cannot meaningfully begin conducting investigations.

17. And given the criminal liability associated with HIPAA violations, my team will have to consult extensively with other divisions within the Attorney General's office to determine how, if possible, to comply with the Final Rule's attestation requirements without triggering potential criminal liability.

18. In addition to these compliance costs, the Final Rule is actively making it difficult or impossible to make data requests necessary to effectively investigate Medicaid fraud. We have paused all requests for billing data and medical records from covered entities until we know how the attestation requirement impacts our team's exposure to potential criminal liability.

19. We have also learned from other state agencies that covered entities have refused to disclose information without an attestation required by the Final Rule even in cases that have no obvious connection to "reproductive health care." We expect similar obstacles to our TMFCA investigations.

20. Because the Final Rule itself provides no recourse to contest a demand that is denied, my office will likely need to seek relief in a court of competent jurisdiction. Such a suit has the potential to sprawl into protracted and complicated litigation, giving rise to issues such as federal preemption and removal. And such a suit may require me to demonstrate in open court my theory of the case I am investigating without having adequate knowledge to do so. Any protracted

litigation may impact the amount of money the State may recoup from a viable fraud investigation because it may push some fraudulent activity outside of the relevant statute of limitations.

21. Ultimately, the Final Rule is complicating my team's duty and ability to investigate Medicaid fraud. Because of the Final Rule, fraud investigations that I am undertaking are consuming more resources than they did before the Final Rule's effective date. And the Final Rule is impacting my strategic investigative decisions. For those reasons, the Final Rule is impacting the public health and safety of the State of Tennessee because it is delaying, impeding, and deterring viable fraud investigations.

Date: February 7, 2025

EXHIBIT L

Declaration of Charity Menefee, Director of the Division of Public Health for the Nebraska Department of Health and Human Services

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. 25-cv-00025

DECLARATION OF CHARITY MENEFEE

Pursuant to 28 U.S.C. § 1746, I, Charity Menefee, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as the Director of the Division of Public Health ("DPH") for the Nebraska Department of Health and Human Services ("DHHS"). DHHS's mission is "Helping People Live Better Lives," and DPH furthers that goal by protecting Nebraskans in a variety of ways. This includes licensing, inspecting, and investigating health clinics and facilities to ensure they meet federal and state standards. *See* 42 C.F.R. § 482.1 *et seq.* (federal standards); Neb. Rev. Stat. §§ 71-401 to 479, §§ 81-604.01 to 604.03 (state standards). DPH also conducts inspections and

investigations into licensed health care practitioners for licensing and disciplinary purposes. *See* Neb. Rev. Stat. § 38-103 *et seq*.

3. The investigations conducted by DPH are purely administrative investigations, resulting in disciplinary actions against licenses and fines or other penalties. While information revealed in them may be referred to county attorneys or the Nebraska Attorney General for prosecution decisions, DPH is involved in neither investigating nor prosecuting criminal cases.

4. I am aware of the U.S. Department of Health and Human Service's ("US HHS") *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the "Final Rule"), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024. *Id.* at 32,976.

5. The Final Rule is currently hindering DPH's inspection and investigation of healthcare facilities. The Final Rule's unclear applicability and wording creates confusion for DPH inspectors and investigators. The Final Rule also hinders inspections and investigations through the additional time required for DPH staff to complete the Final Rule's attestation for any information being requested, and the additional review and processing time required by the facility responding to the request for information.

6. DPH inspections and investigations are centered around safety for Nebraskans. During these actions, it is critical that DPH staff be able to review records from both clinicians and providers that contain protected health information ("PHI") as defined under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) ("HIPAA"). DPH inspections and investigations frequently involve complaints or concerns about the care provided to patients. Therefore, DPH staff must have access to full records with PHI. If a

patient complains about the care they received, a proper investigation requires detailed records of that care.

7. The Final Rule's requirements and attestation are unclear and are difficult to interpret for frontline DPH staff. They have had to spend significant time working with DHHS attorneys to determine which of the options on the attestation applies, and what information they can and cannot request based on the Final Rule.

8. The greatest source of confusion and concern is the extent to which the Final Rule limits information requested for one purpose but that after review leads investigators to require that information for another purpose. There are many instances where DPH inspections and investigations begin with a general request for information about a facility and as DPH investigates the information provided, the investigation may turn into an investigation of a credentialed provider. For example, an investigation of the general conditions of a particular clinic may lead to an investigation into an abortion that may violate Nebraska law. Neb. Const. Art. I. Sec. 31.

9. It is difficult for DPH to know at the outset of an investigation whether conduct was or was not permitted, meaning that the investigators are having to indicate on the Final Rule's model attestation form whether the information they are seeking is related to unlawful conduct before they know the answer. This causes concern and hesitation due to the potential for penalties or inability to use the information when found, and delays as staff members consider how to respond.

10. Due to the confusing wording, instructions, and rollout of the Final Rule, DPH and DHHS are also currently unaware of the extent to which they would be limited in using information obtained for investigations for which they checked the first box on the U.S. HHS provided model

attestation, but which revealed statutory or regulatory infractions that they would otherwise be able to hold a provider to.

11. This confusion is further compounded by the vague wording used, where what constitutes the "mere" act of seeking, obtaining, providing, or facilitating reproductive health is not succinctly or helpfully defined; nor does the Final Rule include an easily understood definition of what is meant by "lawful" care in the context of an administrative agency inspection or investigation and liability. *See* the Final Rule, *supra*, at 32994.

12. Additional confusion is caused by the breadth of the Final Rule, and its application to almost any facility within the State providing healthcare services of any nature. Nursing facilities within the State provide care which may be covered under the broad category of reproductive health care, but which are clearly outside of any laws the Final Rule is attempting to impact or circumvent, and yet both the facility and DHHS are required to treat their records the same as other facilities more clearly in the scope of the Final Rule.

13. DPH is one division with multiple mandates. To fulfill its mandates and the DHHS mission to protect Nebraskans, DPH staff must be able to work together effectively and efficiently. This includes the ability to use information lawfully gathered through one kind of inspection or investigation to begin another, such as when an inspection of a licensed facility leads to an investigation into and potential discipline against a licensed provider. The Final Rule's focus on the purpose of the information and the required attestations has limited this flow of information, either by siloing information based on its purpose or by creating fear and hesitation in DPH staff.

14. The final rule has thereby hindered investigations that are not related to liability for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care or to identify a person for such purposes.

15. Further, to date, covered facilities have refused to provide DPH with the requested materials without an attestation required under the Final Rule.

16. If a facility refuses to provide requested information notwithstanding an attestation from DPH, there is currently no guidance available either to DPH or DHHS legal counsel as to what grounds DPH can proceed on.

17. This raises the concern that clinics or providers which know that they may be facing administrative or regulatory liability due to their actions may attempt to hide behind the Final Rule as a smokescreen for hiding their actions. This could additionally provide time for the spoliation of evidence, using the legal fight over the confusing and imprecise Final Rule as to whether they must provide the records as an opportunity to alter or destroy them.

18. The Final Rule has also created confusion regarding the HIPAA regulations themselves as there now appear to be two competing clauses. 45 CFR § 164.512 authorizes the disclosure of PHI when said disclosure is required by law. *See* 45 CFR § 164.512(a)(1). The Final Rule, however, has been interpreted to require the use of the new attestation form if the information sought is for covered reproductive health services, even when disclosure is already authorized under 45 CFR § 164.512. Currently DPH is unaware of any federal guidance reconciling the application of the Final Rule with other pre-existing HIPAA provisions.

19. The Final Rule has also caused DPH staff to spend less time on investigations and patient safety activities in Nebraska by requiring them to spend considerable time on complying with the Final Rule. This has led to delays in investigations. These delays have both already occurred and will continue to occur going forward.

20. In the days following the enforcement date of the rule, DPH inspectors and investigators had to spend significant time working with DHHS attorneys to understand the scope

of the rule. The lack of direction provided by the US HHS meant that DPH investigators were unable to complete two hospital complaint investigations due to the hospitals' being unwilling to provide the information. Between the two complaints, this one delay cost almost 20 hours of taxpayer funded employee time.

21. Even as DPH has operationalized the US HHS-provided attestations and has become more familiar with doing so, it still adds an estimated minimum of five minutes per form to be filled out—and that 5 minutes is only in circumstances where all of the records sought can be covered under one attestation, and the inspection or investigation does not have any additional questions or concerns about the attestation that the staff will need to work with DHHS legal counsel to answer. In 2024 DPH inspectors completed a total of 1,978 onsite surveys/inspections. Even if every matter only took five minutes to review, this would represent an additional 164.83 hours added to DPH's survey and inspection time over the course of a year, assuming that each case required the release, and that number would increase if multiple attestations were required in a single inspection, or they presented legal or administrative complexities.

22. Due to all the above, the Final Rule is making DPH's duty and ability to inspect and investigate healthcare facilities and providers substantially more difficult. Because of the Final Rule, DPH staff are spending more time at the taxpayer's expense; information is being delivered more slowly, meaning all relevant DPH activities last longer and conduct which endangers Nebraskans may continue for longer; and DPH staff are forced to consider whether they will be personally responsible or liable for violations of the law, compounding delays and causing personal distress. For all of these reasons, the Final Rule is impacting the public health and safety of the State of Nebraska because it is delaying, impeding, and deterring vital inspections investigations.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 5, 2025.

Charity Menefee

EXHIBIT O

Declaration of Amy Osborne, Section Chief of Licensing Enforcement of the State of Indiana's Office of the Attorney General

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

STATES OF TENNESSEE, ALBAMA, 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. 25-cv-00025

DECLARATION OF AMY OSBORNE

Pursuant to 28 U.S.C. § 1746, I, Amy J. Osborne, in my official capacity, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as the Section Chief of Licensing Enforcement of the State of Indiana's Office of the Attorney General. The Office of the Attorney General's Consumer Protection Division (the Division) is empowered to receive, investigate, and prosecute complaints concerning regulated professional occupations in Indiana. Ind. Code § 25-1-7-2. Indiana law dictates that the Division's authority to protect consumers is to be liberally construed and applied to promote the Division's purpose and policies for protecting consumers. Ind. Code § 24-5-0.5-1.

3. The Division is responsible for investigating consumer complaints for approximately 57,642 licensees.

4. In 2024 alone, the Division investigated approximately 1,700 consumer complaints related to medical, nursing, and physician assistant licenses alone.

5. This authority includes the authority to "investigate any written complaint against a license" and "to subpoena witnesses and to send for and compel the production of books, records, papers, and documents for the furtherance of any investigation under this chapter." Ind. Code § 25-1-7-5(b)(4)–(5).

6. The Division exercises that authority by subpoenaing books, records, papers, and documents from various health organizations including hospitals, medical service centers, and individual medical professionals.

7. Because of their obligations under state and federal law, *see, e.g.*, Ind. Code § 25-1-7-5(b)(5); 42 C.F.R. § 489.53(a)(18), health care facilities in the past immediately complied with survey requirements, including by providing requested records.

8. I am aware of the Department of Health and Human Services' *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the "Final Rule"), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024, *id.* at 32,976.

9. The Final Rule is currently hindering several of the Division's investigations.

10. The Division has at least ten outstanding subpoenas against health care providers in Indiana, all of whom have declined to provide documents based on the Final Rule. The Division has filed two petitions to enforce in Indiana state court, which were removed to federal court.

Neither matter has yet been resolved. These petitions are filed under seal because the Division's investigations are confidential, pursuant to Ind. Code § 25-1-7-10(a).

11. Even in investigations where the Division does not have to file a petition to enforce, the Final Rule has still added additional steps and time to the Division's valid investigations. Health care providers now require the Division to provide a patient release before they are willing to provide a response to any consumer complaint filed against them. Neither federal nor state law requires such a response. In instances where the Division has not been able to secure this release of information from a patient, the health care provider has refused to provide a response to the consumer complaint, claiming that they cannot do so without a legal requirement to do so under the Final Rule. Thus, the Final Rule is complicating the Division's duty and ability to investigate consumer complaints against health care providers. Because of the Final Rule, the Division's investigations are consuming more resources than they did before the Final Rule's effective date. And the Final Rule is actively thwarting pressing investigations. For those reasons, the Final Rule is impacting the public health and safety of the State of Indiana because it is delaying, impeding, and deterring viable investigations.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge. Executed on this 6th day of February 2025.

Amy J. Osborne
Section Chief of Licensing Enforcement
Indiana Office of the Attorney General

EXHIBIT F

Declaration of Marina Spahr, Director of the Medicaid Fraud Unit
in the Office of the North Dakota Attorney General

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

STATES OF TENNESSEE, ALBAMA, 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. 25-cv-25

DECLARATION OF MARINA SPAHR
NORTH DAKOTA MEDICAID FRAUD CONTROL UNIT

Pursuant to 28 U.S.C. § 1746, I, Marina Spahr, affirm under penalty of perjury as follows:

1. I am over 18 years of age and am fully competent to make this declaration. The facts contained in this Declaration are based on my personal and professional knowledge and are true and correct to the best of my knowledge and belief.

2. I serve as Director of the Medicaid Fraud Control Unit (MFCU) in the Office of the North Dakota Attorney General. MFCU's responsibilities include conducting and supervising investigations of Medicaid provider billing fraud and patient abuse and neglect where there is a Medicaid nexus, pursuant to N.D.C.C. ch. 50-24.8.

3. As part of my responsibilities, I regularly review administrative subpoenas (AD SUBP) and civil investigative demands (CIDs) issued by MFCU to entities covered under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (HIPAA), seeking protected health information (PHI) to investigate Medicaid billing fraud and patient abuse or neglect. MFCU is authorized to make such requests under 45 C.F.R. § 164.512, as MFCU is both a law enforcement and health oversight agency.

4. For example, MFCU routinely requests billing data from health plan payers to vet leads on possible Medicare billing fraud. MFCU frequently must request this information with imperfect knowledge of the possible misconduct being investigated because, before receiving the data, it is impossible to know the particulars of the investigation.

5. Indeed, obtaining medical records and PHI is crucial to the investigation and litigation of health care fraud and the abuse and neglect of patients. It is a necessary component to proving various fraudulent schemes, including improper billing of care, rendering unnecessary or excessive services, billing for services that were not rendered, and other complex fraud allegations. Acquiring medical records is also essential for substantiating claims of harm to patients in facilities that receive Medicaid funding.

6. Even after our office receives billing data, more investigation is generally required. To conduct investigations into healthcare fraud or patient abuse and neglect, it is often necessary to issue AD SUBPs and CIDs, as authorized under State law, to healthcare providers in order to obtain medical records and compare billing data with services rendered.

7. I have reviewed the Department of Health and Human Services' *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, which took effect on June 25, 2024, although

compliance with the Final Rule generally was not required until December 23, 2024. 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the "Final Rule").

8. The Final Rule creates new restrictions on the disclosure and use of any patient information related to "reproductive health care," which it broadly defines as "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.

9. Specifically, the Final Rule prohibits covered entities from disclosing PHI to state investigators, like those in MFCU, 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).

10. If the covered entity concludes that either of those conditions exist, it cannot disclose the requested information if it "reasonably determine[s]" that the "reproductive health care" 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).

11. To make that assessment, the Final Rule creates a presumption that "reproductive health care" is lawful—and not subject to investigation by a State—unless the covered entity has:

> (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.

Id. § 164.502(a)(5)(iii)(C).

12. The covered entity that receives a request for PHI itself makes these determinations. And if the covered entity determines that any of the conditions barring disclosure exist, it may deny the request. The Final Rule does not expressly provide recourse for the requesting entity.

13. Under the Final Rule, covered entities also must require attestations with any request for PHI that is potentially related to "reproductive health care" data. *Id.* § 164.509(a). Such attestations are required under the Final Rule even when regulatory conditions on disclosures for law enforcement purposes are otherwise met. *See id.* § 164.512(f)(1)-(6)

14. Again, the Final Rule places the power to assess the lawfulness or validity of any PHI request with the covered entity to which the request is made. So, even after making an attestation, it does not necessarily follow they will produce the requested information, as the discretion of whether to disclose the PHI remains with the covered entity. The Final Rule thus creates the situation where entities being investigated for fraud or patient abuse and neglect will have a veto on investigators' ability to obtain records necessary for their investigation.

15. MFCU has had to expend significant time and resources to determine how to comply with the Final Rule's attestation requirements because they are vague and overbroad. The Final Rule requires MFCU investigators to attest, upon pain of criminal penalty, to facts that are difficult or impossible to know at the preliminary stages of an investigation. And if MFCU investigators have imperfect knowledge of an investigation such that they are unable to attest to the facts required under the Final Rule, they cannot meaningfully conduct investigations.

16. The Final Rule is also actively making it difficult to make data requests that are necessary to effectively investigate Medicaid fraud and patient abuse and neglect. At this point in

time, MFCU has determined that its investigators cannot truthfully fulfill the attestation requirement that is mandated by the Final Rule because it cannot predict the ways in which any information relating to potential criminal conduct may be used, especially considering the Final Rule's expansive definition of "reproductive health care." Consequently, when covered entities refuse to provide the requested health information, MFCU will be obligated to initiate an enforcement action. The necessity of bringing such enforcement actions considerably increases the time and expense for investigations, and it also threatens to permit wrongdoers to evade liability for fraud or patient abuse and neglect where there may be statute of limitations concerns.

17. MFCU has also learned from other state agencies that covered entities have refused to disclose information without an attestation required by the Final Rule even in cases that are far afield from "reproductive health care." We expect similar obstacles to MFCU investigations.

18. Because the Final Rule itself provides no recourse to contest a demand that is denied, MFCU will likely need to seek relief in court. Such lawsuits have the potential to sprawl into protracted and complicated litigation, before MFCU will have been able to conduct an initial investigation into potential fraud. Such lawsuits may also require MFCU to demonstrate in open court its theory of the case for ongoing investigations, thereby permitting entities under investigation with an opportunity to obfuscate information. Additionally, enforcement actions required to obtain records that were not provided by covered entities will result in a significant allocation of additional resources, adding excessive costs to investigations. And while MFCU anticipates that approximately seventy-five percent (75%) of those additional costs will be borne by federal funding that is provided to MFCU for its operational expenses, the other twenty-five percent (25%) of those additional costs will be borne by the State and its taxpayers.

19. The Final Rule is complicating MFCU's duty and ability to investigate Medicaid fraud. And because of the Final Rule, fraud and patient abuse and neglect investigations that MFCU is undertaking are consuming more resources than they did before the Final Rule's effective date. The Final Rule is also likely to distort MFCU's investigative decisions and priorities going forward.

20. In short, the Final Rule is impacting the public health and safety of the State of North Dakota because it is delaying, impeding, and deterring viable fraud and patient abuse and neglect investigations.

Executed in Bismarck, North Dakota, on February 3, 2025.

Marina Spahr
Director/Assistant Attorney General
North Dakota Medicaid Fraud Control Unit

EXHIBIT N

Declaration of Jordan Stover, Assistant Commissioner, Consumer Services & Health Care Regulation, Indiana Department of Health, State of Indiana

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

STATES OF TENNESSEE, ALBAMA, 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. 25-cv-00025

DECLARATION OF JORDAN STOVER

Pursuant to 28 U.S.C. § 1746, I, Jordan Stover, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as Assistant Commissioner, Consumer Services & Health Care Regulation, Indiana Department of Health, State of Indiana. IDOH's mission is to promote, protect, and improve the health and safety of all Hoosiers. To that end, we investigate complaints regarding patient safety and facility conditions to ensure compliance with federal, *see* 42 C.F.R. § 482.1, *et seq.*, and state standards, *see* Ind. Code. 16-21-1-10; 16-21-2-2; 16-21-2-13; 16-28 *et seq.;* 16-27 *et seq*.

3. For example, IDOH conducts certification and compliance surveys for hospitals that participate in Medicare to ensure the facility maintains compliance with conditions of program participation and for state licensure purposes. *See* 42 C.F.R. § 489.53(a)(18) and IC 16-21-1-10; 16-21-2-2; 16-21-2-13. These surveys are often undertaken in response to a patient complaint regarding care or conditions at a particular facility. IDOH must have "immediate access" to "provider or supplier" records and facilities "for the purpose of determining" compliance. *Id.* Failure to grant such access could result in the Centers for Medicare and Medicaid Services ("CMS") "terminat[ing]" its agreement with the provider. *Id.* at § 489.53(a).

4. In conducting surveys pursuant to state and federal law, IDOH regularly requests provider records that contain protected health information ("PHI") under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) ("HIPAA"). These requests are most often directed to the facility being surveyed, but sometimes it is necessary to request records from other providers along the patient-care chain to adequately investigate certain complaints. For example, if a patient complains that they suffered harm after being transferred to a new facility, it may be necessary to compare the patient records at prior facilities to track the diagnoses and care the patient received.

5. Because of their obligations under state and federal law, *see, e.g.*, 410 IAC § 15-1.4-1(a)(2)(B); 410 IAC § 15-2.4-1(a)(1)(B); 410 IAC § 17-10-1(k); Ind. Code § 16-28-9-3(a)(2) and (b);42 C.F.R. §§ 489.53(a)(13), 489.53(a)(18), healthcare facilities in the past immediately complied with survey requirements, including by providing requested records.

6. I am aware of the Department of Health and Human Services' *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the "Final

Rule"), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024, *id.* at 32,976.

7. The Final Rule is currently hindering IDOH's ability to conduct routine survey and certification work, including by delaying access to medical records during the course of facility surveys.

8. For example, IDOH has been asked to complete attestations for surveys being completed at hospitals and for records requests to hospitals for surveys at other Medicare certified facilities. IDOH has spent significant time trying to clarify that the attestation requirements do not apply to survey and certification activities because the records are "required by law" to be produced under state and federal law, and HIPAA permits these disclosures. 45 CFR § 164.512(a); 45 CFR § 164.103. Despite these communications, facilities have been resistant to produce records in numerous instances.

9. IDOH has not completed those attestations because such a requirement conflicts with IDOH's authority to "immediate access" to those materials as "required by law." 42 C.F.R. §§ 489.53(a)(13) and (a)(18); 45 CFR § 164.512(a); 45 CFR § 164.103.

10. IDOH sought clarification from CMS on this issue and was directed that surveyors are not required to sign attestations to receive records to complete survey and certification activities because the disclosure of these records is required by law.

11. The stalled surveys are dangerous to the safety and well-being of Indiana residents. Delay in patient safety related surveys can allow dangerous behaviors to continue, especially during facility suveys that involve abuse, neglect, or the provision of substandard care.

12. In addition to impeding IDOH's surveys, the Final Rule has imposed compliance costs, including needing to assess how, if possible, to comply with the rule's attestation requirement.

13. If a facility refuses to provide requested information without an attestation from IDOH, the potential remedies are litigation, the termination of a facility's Medicare or Medicaid certification, or state licensure revocation. The latter two remedies would, in most cases, have the effect of closing the affected health care facility.

14. Thus, the Final Rule is complicating IDOH's duty and ability to investigate healthcare facilities for violations of state and federal laws. Because of the Final Rule, surveys that IDOH is undertaking are consuming more resources than they did before the Final Rule's effective date. And the Final Rule is actively thwarting time-sensitive surveys. For those reasons, the Final Rule is impacting the public health and safety of the State of Indiana because it is delaying, impeding, and deterring viable surveys.

15. IDOH's fatality review teams have also faced investigation-limiting roadblocks because of this rule. State and local fatality review teams are tasked with studying certain deaths involving infants, children, women around the time of pregnancy, and those that have died from suicide or overdose. Ind. Code §§16-49-3-3; 16-49-3-6; 16-49-4-4; 16-49-6-4; 16-49.5-2-6; 16-50-1-7. Fatality review teams use the individual investigations to create statistical reports each year with recommendations to prevent future deaths. Ind. Code §§ 16-49-3-7; 16-49-4-11; 16-49-6-8; 16-49.5-2-14; 16-50-1-9. State law requires certain health care providers to provide medical records to the fatality review teams. Ind. Code §§ 16-49-3-5; 16-49-4-5; 16-49-6-6; 16-49.5-2-8; 16-50-1-8.

16. Fatality review teams perform public health surveillance activities pursuant to 45 C.F.R. §164.512(b), which do not require an attestation pursuant to 45 C.F.R. §164.509.

17. Facilities have asked fatality review teams to sign the attestations prior to releasing the records as required by law. IDOH had to create a general guidance document for facilities before they would provide access to the records. This has delayed access and caused confusion for the various fatality review teams throughout the state.

18. Delaying access to medical records for fatality review teams interferes with their statutory responsibilities that could limit their ability to make recommendations that could prevent future deaths.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge. Executed on this 6th day of February 2025.

_____

Jordan Stover
Assistant Commissioner, Consumer Services & Health Care Regulation
Indiana Department of Health

EXHIBIT H

Declaration of Michael Targia, Chief of the Bureau of Internal Audits and Program Integrity at the South Carolina Department of Health and Human Services

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

STATES OF TENNESSEE, ALBAMA, 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. 25-cv-25

DECLARATION OF MICHAEL TARGIA

Pursuant to 28 U.S.C. § 1746, I, Michael Targia, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as Chief of the Bureau of Internal Audits and Program Integrity ("Bureau") at the South Carolina Department of Health and Human Services ("SCDHHS"). The Bureau's responsibilities include conducting reviews of all health care provider types including, but not

limited to, hospitals (inpatient and outpatient), rural health clinics, federally- qualified health clinics, pharmacies, Ambulatory Surgical Centers (ASCs), End Stage Renal Disease (ESRD) clinics, physicians, dentists, other health care professionals, speech, PT and OT therapists, Long-Term Living (LTL) providers, durable medical equipment providers, transportation providers and behavioral and mental health care providers.

3. The Bureau conducts both announced and unannounced onsite reviews, and/or desk reviews of any current or formerly enrolled provider, agency-contracted provider, or agent thereof, at any time to determine whether the provider is complying with all applicable laws, rules, regulations and agreements. During such reviews, Bureau staff may request medical records and related documents from entities covered under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (HIPAA), seeking protected health information (PHI) to ensure compliance with all applicable laws, rules, regulations and agreements. The Bureau is authorized to make such requests under 45 C.F.R. § 164.512.

4. For example, the Bureau routinely requests medical records and other documents from Medicaid providers. These records and documents are used to ensure compliance with all applicable laws, rules, regulations and agreements. This information is frequently requested with imperfect knowledge of the possible misconduct being perpetrated because, before receiving the requested information, it is impossible to know the particulars of the conduct.

5. Indeed, obtaining medical records and PHI is crucial to the investigation and litigation of health care fraud. It is a necessary component to proving various fraud schemes, including improper billing of care, rendering unnecessary or excessive services, billing for services that were not rendered, and other complex allegations.

6. If the Bureau suspects a provider of fraud or abuse, the case must be referred to the Medicaid Fraud Control Unit at the South Carolina Attorney General's Office pursuant to 42 C.F.R. § 455.15.

7. I am aware of the Department of Health and Human Services' *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the "Final Rule"), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024, *id.* at 32,976.

8. The Final Rule has created barriers to investigation, impeding our ability to detect healthcare fraud in South Carolina.

9. Promulgated in response to the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), the Final Rule places limits on the disclosure and use of patient information related to "reproductive health care," which it broadly defines as "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.

10. Specifically, the Final Rule prohibits covered entities 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).

11. If the covered entity concludes that one of these two conditions exists, 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).

12. In making that assessment, 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 investigation by a State—unless the covered entity or business associate has either:

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

Id. § 164.502(a)(5)(iii)(C).

13. The covered entity that receives a request for PHI itself makes these determinations—including legal assessments of state and federal laws. And if the covered entity determines that any of the conditions barring disclosure exist, it may deny the request. The Final Rule does not provide explicit recourse for the requesting entity.

14. Under the Final Rule, covered entities also must require attestations with a request for PHI that is potentially related to "reproductive health care" data. *Id.* § 164.509(a). Such attestations are required under the Final Rule even when regulatory conditions on disclosures for law enforcement purposes are otherwise met. *See id.*; *id.* § 164.512(f)(1)-(6)

15. Again, the Final Rule places the power to assess the lawfulness or validity of any PHI request entirely with the covered entity to which the request is made. So, even after making an attestation it does not necessarily follow that the requesting party will receive the requested information, as discretion whether to disclose the PHI remains with the covered entity. This means

that in some cases the entity who is potentially engaging in fraud will have a veto on investigators' ability to obtain records necessary for their investigation.

16. The Final Rule requires members of the Bureau in some cases to attest, upon threat of criminal penalty, to facts that are difficult or impossible to know at the preliminary stages of an investigation. If we have imperfect knowledge of an investigation such that we are unable to attest to the facts required under the Final Rule, we cannot meaningfully begin conducting investigations.

17. And given the criminal liability associated with HIPAA violations, my team will have to consult extensively with SCDHHS counsel as well as with the South Carolina Attorney General's office to determine how, if possible, to comply with the Final Rule's attestation requirements without triggering potential criminal liability.

18. The Final Rule is actively making it difficult or impossible to make records and other information requests necessary to even detect Medicaid fraud. The Bureau received a letter on January 28, 2025 from a medical provider declining to produce records in the absence of an attestation in accordance with the Final Rule (see *Attachment A* to this Declaration). We have paused all requests for billing data and medical records from covered entities who are requiring an attestation until we know how the attestation requirement impacts our team's exposure to potential criminal liability.

19. It is my understanding that covered entities in other states have refused to disclose information without an attestation required by the Final Rule even in cases that are far afield from "reproductive health care." We expect similar obstacles in South Carolina.

20. Ultimately, the Final Rule is complicating my team's duty and ability to detect and investigate instances of Medicaid fraud. Because of the Final Rule, provider reviews that the Bureau is undertaking are consuming more resources than they did before the Final Rule's

effective date. And the Final Rule is impacting the Bureau's strategic investigative decisions. For those reasons, the Final Rule is impacting the public health and safety of the State of South Carolina because it is delaying, impeding, and deterring viable fraud investigations.

FURTHER, Declarant Sayeth Naught.

Michael Targia

January 31, 2025

Attachment A

IMPORTANT INFORMATION REGARDING YOUR REQUEST FOR MEDICAL RECORDS

01/13/2025

SCDHHS

JAN 28 2025

PI/SURS

From

Anmed Health Arrhythmia Spec
2000 E Greenville St
Anderson SC 29621-1723

To

SC DHHS
PO BOX 8206
COLUMBIA SC 29202-8206

Re:

We are unable to comply with your request at this time for the following reason(s):

Reproductive Health Attestation Required

Attestation or Authorization Required: Reproductive Health

The U.S. Department of Health and Human Services has recently imposed a requirement we believe prohibits the disclosure of HIPAA-covered protected health information that you requested (45 C.F.R. § 164.509).

To address this requirement and permit a response to your request, you will need to provide either: (1) a completed attestation or (2) an authorization from the patient (or their personal representative) to whom the records you requested pertain.

To facilitate your request and meet this new requirement, we have enclosed for your review an explanation of the new requirement from DHHS and the form of attestation they require.

Please return the completed attestation to us, or provide a patient authorization, so that we may process your request.

Sincerely,
Anmed Health Arrhythmia Spec

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. 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.)

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: _____ *Printed Name:* _____

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

_____

EXHIBIT G

Declaration of Brannon Traxler, Deputy Director of Health Promotion and Services and Chief Medical Officer at the South Carolina Department of Public Health

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEEE
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. 25-cv-25

DECLARATION OF L. BRANNON TRAXLER, MD, MPH

Pursuant to 28 U.S.C. § 1746, I, Brannon Traxler, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as the Deputy Director of Health Promotion and Services and Chief Medical Officer at the South Carolina Department of Public Health ("DPH"). The DPH is the sole advisor of the State of South Carolina in all questions involving the protection of the public health and shall investigate the causes, character, and means of preventing the epidemic and endemic diseases as the State is liable to suffer from. *See* S.C. Code Ann. § 44-1-110. Moreover, DPH has full access to any medical records and record systems maintained by physicians, hospitals, and other

health facilities to carry out its investigations. *See* S.C. Code Ann. § 44-1-110. The sharing of information on reportable conditions is necessary for the prevention of public health emergencies, and access to that information is restricted to authorized personnel only and must comply with all state and federal health information privacy laws. *See* S.C. Code Ann. § 44-1-80(B)(2), (3).

3. As part of the agency's responsibilities, staff and I regularly review requests for medical records and information issued by the DPH to entities covered under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (HIPAA), seeking protected health information (PHI) to investigate causes of epidemic or endemic diseases. DPH is considered a public health authority under 45 C.F.R. § 164.512(B)(i) and is authorized by law to collect or receive such information from covered entities without patient consent for the purpose of preventing or controlling disease, injury, or disability. Moreover, having full access to medical records is necessary to investigate the causes, character, and means of preventing the spread of infectious disease and avoiding a public health emergency. *See* S.C. Code Ann. § 44-1-80(B)(3) and § 44-1-110.

4. Additionally, DPH accesses medical records for non-communicable diseases. DPH staff regularly access medical records for the Violent Death Reporting System, the State Unintentional Drug Overdose Reporting System, as part of the Opioid Emergency Response Team, the Childhood Lead Poisoning Prevention Program, the South Carolina Cancer Registry, the Children and Youth with Special Health Care Needs Program, the Newborn Metabolic Screening Program, the Birth Defects Registry, the MD STARnet Registry, and the South Carolina Maternal Morbidity and Mortality Review Committee.

5. Furthermore, DPH routinely requests access to medical records, tumor registries, and other special disease record systems maintained by physicians, hospitals and other health

facilities. This data is used to identify the origins of communicable diseases or other public health issues in South Carolina. The agency must frequently request this information with imperfect knowledge of the possible circumstances of the disease or condition being investigated because, before receiving the data, it is impossible to know the particulars of any specific case.

6. Indeed, obtaining medical records and protected health information (PHI) is crucial to the investigation of disease and preservation of public health. It is a necessary component to ensuring that South Carolinians are safe and healthy.

7. Even after our office receives sensitive medical records, more investigation is generally required. To conduct investigations into origins of a communicable illness, it is necessary to issue additional records requests, authorized under state law, to healthcare providers.

8. I have reviewed the Department of Health and Human Services' *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32976 (Apr. 26, 2024) (the "Final Rule"), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024, *id.* at 32976.

9. The Final Rule has created compliance costs and barriers to investigation, impeding our ability to investigate origins and sources of communicable diseases in South Carolina.

10. Promulgated in response to the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), the Final Rule places limits on the disclosure and use of patient information "potentially related to reproductive health care," which it broadly defines as "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.

11. Specifically, the Final Rule prohibits covered entities 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.

(3) To identify any person for [the purpose of conducting such investigation or imposing such liability].

45 C.F.R. § 164.502(a)(5)(iii)(A).

12. If the covered entity concludes that one of these three conditions exists, it cannot disclose the requested information if it "reasonably determine[s]" that one or more of the following conditions exists: (1) the "reproductive health care" is "lawful under the law of the state in which such health care is provided under the circumstances in which it is provided;" (2)the "reproductive health care" is "protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided;" And (3) the "reproductive health care" was provided by a person other than the covered health care provider, health plan, or health care clearinghouse (or business associates) that receives the request for PHI. *Id.* § 164.502(a)(5)(iii)(B).

13. In making that assessment, the Final Rule creates a presumption that the reproductive health care provided is lawful under (a)(5)(iii)(B)(1) or (2)—and so not subject to investigation by a State—unless the covered entity or business associate has either:

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

Id. § 164.502(a)(5)(iii)(C).

14. The covered entity that receives a request for PHI itself makes these determinations—including legal assessments of state and federal laws. And if the covered entity determines that any of the conditions barring disclosure exist, it may deny the request. The Final Rule does not provide explicit recourse for the requesting entity.

15. Under the Final Rule, covered entities also must require attestations with a request for PHI that is "potentially related to reproductive health care" data. *Id.* § 164.509(a). Attestations are required prior to disclosure when the purpose of the request includes health oversight activities, judicial or administrative proceedings, law enforcement, or disclosures to coroners and medical examiners. *See* 45 C.F.R. §164.509(a)(1). Not included in this attestation requirement is section 164.512(b)(1)(i), which allows a covered entity to disclose PHI without consent to a public health authority authorized by law to collect or receive such information.

16. Again, the Final Rule places the power to assess the lawfulness or validity of any PHI request entirely with the covered entity to which the request is made. So, even after making an attestation it does not necessarily follow that the requesting party will receive the requested information, as discretion whether to disclose the PHI remains with the covered entity.

17. My agency has had to expend significant time and resources to determine how to comply with the Final Rule's attestation requirements because they are vague and broad. The Final Rule requires members of the agency's Communicable Disease Epidemiology Section, among others, to attest, upon pain of criminal penalty, to facts that are difficult or impossible to know at the preliminary stages of an investigation and which is not required due to HIPAA's public health exception.

18. And given the criminal liability associated with HIPAA violations, my team has and will continue to have to consult extensively with our legal advisors to determine how, if possible, to comply with the Final Rule's attestation requirements without triggering potential criminal liability.

19. In addition to these compliance costs, the Final Rule is actively making it difficult or impossible to make data requests necessary to promote and protect South Carolina's public health. We have received communications from hospitals and other health care providers indicating their intention to require public health epidemiologists to sign the Final Rule's attestation, despite the fact that it does not apply to our inquiries and falls within HIPAA's public health exception. Consequently, we are developing communications to share with hospitals and health care providers to educate them on the Final Rule's applicability or, in the context of public health, its lack thereof. These efforts require staff to take time away from disease investigation activities.

20. In addition, our agency provides health care services that are HIPAA-covered, and those programs receive requests for records. We must now expend time, energy, and resources, updating the forms, policies, and trainings of our health care services programs in order to comply with the Final Rule.

21. Ultimately, the Final Rule is complicating the agency's duty and ability to detect and investigate reportable illnesses or suspicious events that could evolve into a public health emergency as well as providing consistent and efficient health care services to South Carolinians. Because of the Final Rule, investigations that we are undertaking, and services that we are providing, are consuming more resources than they did before the Final Rule's effective date. And the Final Rule is impacting strategic investigative decisions. For those reasons, the Final Rule is

impacting the public health and safety of the State of South Carolina because it is delaying, impeding, and deterring time-sensitive investigations.

I declare under penalty of perjury that the foregoing is true and correct.

L. Brannon Traxler, MD, MPH
Deputy Director of Health Promotion & Services and Chief Medical Officer

Executed on 31st day of January, 2025.

EXHIBIT B

Declaration of Katherine Zeigler, Regional Administrator of the West Tennessee Office for the Health Facilities Commission

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEEE
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. 25-cv-00025

DECLARATION OF KATHERINE ZEIGLER

Pursuant to 28 U.S.C. § 1746, I, Katherine Zeigler, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as Regional Administrator of the West Tennessee Regional Office for the Health Facilities Commission ("HFC") of the State of Tennessee. HFC's mission is to protect patients and promote quality in healthcare facilities throughout Tennessee. To that end, HFC investigates complaints regarding patient safety and facility conditions to ensure compliance with federal, *see* 42 C.F.R. § 482.1, *et seq.*, and state standards, *see* Tenn. Code Ann. §§ 68-11-207, 68-11-210.

3. For example, HFC conducts certification and compliance surveys of health facilities that participate in Medicare to ensure the facility maintains compliance with conditions of program participation. *See* 42 C.F.R. § 489.53(a)(18). These surveys are often undertaken in response to a patient complaint regarding care or conditions at a particular facility. HFC must have "immediate access" to "provider or supplier" records and facilities "for the purpose of determining" compliance. *Id.* Failure to grant such access could result in the Centers for Medicare and Medicaid Services ("CMS") "teriminat[ing]" its agreement with the provider. *Id.* § 489.53(a).

4. In conducting surveys pursuant to state and federal law, HFC regularly requests provider records that contain protected health information ("PHI") under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) ("HIPAA"). These requests are most often directed to the facility under investigation, but sometimes it is necessary to request records from other providers along the patient-care chain to adequately investigate certain complaints. For example, if a patient complains that they suffered harm after being transferred to a new facility, it may be necessary to compare the patient records at prior facilities to track the diagnoses and care the patient received.

5. Because of their obligations under state and federal law, *see, e.g.*, Tenn. Code Ann. § 68-11-210 *et. seq.*; 42 C.F.R. § 489.53(a)(18), healthcare facilities in the past generally complied with survey requirements, including by providing requested records.

6. I am aware of the Department of Health and Human Services' *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the "Final Rule"), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024, *id.* at 32,976.

7. The Final Rule is currently hindering HFC's investigation of healthcare facilities.

8. For example, HFC recently received two complaints against a licensed psychiatric facility, including a complaint that one of the facility's patients received substandard care before being transferred to a regional hospital and dying shortly thereafter. HFC also received a complaint that a patient at a senior living facility suffered a fatal injury after being struck in the head by a ceiling tile. HFC commenced surveys pursuant to these complaints to determine whether the facilities were following state and federal standards to ensure the safety of other patients. As part of the surveys, HFC requested records from the hospitals who received the patients via emergency medical transport to the emergency room. Medical records are required to determine the patient's admitting diagnoses and condition.

9. These records are necessary to HFC's investigation because HFC received a complaint alleging harm to the patient within the psychiatric facility resulting in death. Without the requested records, HFC cannot know the patient's condition, diagnoses, or whether or not the complaint can even be verified or substantiated. Nor can HFC determine whether unsafe conditions led to a patient's death at the licensed senior living facility without access to her post-injury treatment records.

10. HFC has also commenced an investigation against a renal clinic pursuant to a complaint. As part of that investigation, HFC has sought medical records related to the care and treatments of the patient receiving dialysis within the facility.

11. To date, the facilities in these investigations have refused to provide HFC with the requested materials without an attestation required under the Final Rule.

12. HFC has not completed those attestations because such a requirement conflicts with HFC's authority to "immediate access" to those materials. 42 C.F.R. § 489.53(a)(18). Moreover, HFC generally does not and cannot know the ends of its investigation at the time it requests

information from a facility. Thus, HFC employees have declined to provide an attestation considering the Final Rule's vague and overbroad standards given the criminal liability attached to HIPAA.

13. The stalled investigations are dangerous to the safety and well-being of Tennessee residents. HFC's survey sof the psychiatric and senior living facilities are predicated on a complaint that resulted in a patient's death. Because HFC was denied access to the requested records, it could not intervene immediately to address possibly deadly, substandard care or dangerous conditions. With the investigation on hold, HFC has not yet been able to resolve the definite cause of the patients' deaths.

14. In the case of the renal clinic, the target of the investigation has effectively blocked HFC's survey to address the complaint against the facility.

15. Delay also creates the possibility for spoliation of evidence. In past investigations, HFC has learned of investigatory targets altering records during a survey. And without immediate access to necessary patient records, health care facilities have greater opportunity to alter records to conceal misconduct. Moreover, immediate access to the facility itself is necessary to accurately assess the conditions at the time allegedly substandard care was rendered or the allegedly dangerous condition existed.

16. HFC's stalled investigations also undermine its role in surveying healthcare facilities pursuant to our agreement with CMS. To date, CMS has provided no definitive guidance on how to navigate our obligations under that agreement considering the Final Rule's new disclosure requirements. It is my understanding that CMS is currently coordinating with HHS's Office for Civil Rights to understand the Final Rule's interaction with CMS survey regulations.

17. In addition to stopping HFC's investigations, the Final Rule has imposed compliance costs, including needing to assess how, if possible, to comply with the rule's attestation requirement.

18. Thus, the Final Rule is complicating HFC's duty and ability to investigate healthcare facilities for violations of law and noncompliance. Because of the Final Rule, investigations that HFC is undertaking are consuming more resources than they did before the Final Rule's effective date. And the Final Rule is actively thwarting pressing investigations. For those reasons, the Final Rule is impacting the public health and safety of the State of Tennessee because it is delaying, impeding, and deterring viable investigations.

Date: 2/6/25 kathy Zeigler